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Title 28--HEALTH AND SAFETY **DEPARTMENT OF HEALTH** **[28 PA. CODE CH. 9]** **Managed Care Organizations** **[31 Pa.B. 3043]**

The Department of Health (Department) hereby amends Chapter 9 (relating to managed care organizations) by repealing the existing regulations in Subchapter A (relating to health maintenance organizations), the statement of policy in Subchapter D (relating to PHOs, POs and IDs) and the statement of policy in Subchapter E (relating to quality health care accountability and protection). The Department replaces these regulations and statements of policy with the final-form regulations set forth in Annex A.

Purpose of the Amendments

The final-form regulations revise outdated regulations relating to health maintenance organizations (HMO) and implement the accountability and protection provisions of Article XXI of The Insurance Company Law of 1921 (40 P. S. §§ 991.2101--991.2193) (Article XXI), added by the Act 68 of 1998 (P. L. 464, No. 68) (40 P. S. §§ 991.2001--991.2361) (Act 68). In 1996, Governor Ridge issued Executive Order 1996-1, which required State agencies under the Governor's jurisdiction to review their existing regulations. In response to Executive Order 1996-1, the Department convened managed care policy work groups on the following seven topics: consumers; providers; special needs; behavioral health; data collection; and standards; quality assurance, utilization and credentialing; and risk assignment, fiscal and financial issues. The Department was in the process of developing amendments to the regulations relating to HMOs when Act 68 was signed into law.

The Department and the Insurance Department (Insurance) were required by Act 68 to promulgate regulations to implement the portions of Act 68 for which each is responsible. In 1998, the Department published a statement of policy concerning the implementation of Article XXI. See Subchapter E. On March 11, 2000, Insurance promulgated final-form regulations implementing its responsibilities under Article XXI. On December 18, 1999, the Department published notice of proposed rulemaking, incorporating much of its statement of policy on health care accountability and protection, as well as its statement of policy addressing issues relating to HMO contracting. See 29 Pa.B. 6409 (December 18, 1999). The Department provided a 30-day public comment period.

Discussion Of Comments

During the public comment period, the Department received nearly 1,400 individual comments from approximately 77 commentators, including members of the legislature, the public, advocacy groups and trade associations of both providers and the insurance industry. Many of these comments were not directed to any specific section of the proposed amendments, but were general comments concerning the nature of managed care and HMOs. To address these

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comments, the Department has taken the liberty of responding to them in the discussion of the sections to which they most closely relate.

Many of the comments were critical of some aspect of the Department's proposed amendments, although some commentators did express support for specific provisions of the proposed amendments. Many commentators expressed concern that the proposed amendments did not incorporate what were referred to as the "fundamental fairness" requirements for complaint and grievance reviews, originally issued by the Department as guidelines in 1991. Many of the same commentators expressed concern over what they viewed as a lack of specific and concrete quality assurance standards and definitions for adequate networks. Commentators also complained about the absence of explicit ratios for providers to enrollees.

Other commentators expressed concern over the Department's proposed application of certain requirements to managed care plans (plans) which it had proposed to apply solely to HMOs, for example, reporting requirements. Commentators also complained that the Department was proposing to omit language included in its policy statement that permitted plans to deem submissions approved should the Department fail to act on those submissions within a specific time period.

The Department received many comments on the issue of a definition for "medical necessity." Almost all commentators on this provision, including the Independent Regulatory Review Commission (IRRC), recommended that the Department either add a definition or include in the regulations the standards for the development of a definition.

Many commentators, including IRRC, commented on apparent conflicts between the Department's regulations and Insurance's regulations.

The Department has made considerable changes to its proposed amendments in an attempt to address many of these issues. The Department has revised the procedures regarding complaint and grievance reviews. The Department has added more specific credentialing requirements in Subchapter L (relating to credentialing). The Department has clarified the section on adequacy of networks, revised the section on direct access to obstetrical and gynecological services to address issues concerning perceived limitations on access, and changed language relating to enrollee rights to reflect current requirements of National Committee for Quality Assurance (NCQA). The Department has not, however, included language permitting contracts to be deemed approved if they are not reviewed by a certain date, setting provider/enrollee ratios, or defining "medical necessity."

The Department has made changes throughout the regulations when the changes were necessary to ensure consistency with the regulations promulgated by Insurance. The Administrative Code of 1929 (71 P. S. §§ 51--732) requires that "departments . . . devise a practical and working basis for cooperation and coordination of work . . ." (71 P. S. § 181). Both agencies are currently, and will continue to, work together to ensure an effective and efficient application of Article XXI and its implementing regulations.

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The Department's response to the comments received on specific provisions of its proposed amendments follow:

Subchapter F. General

Section 9.602. Definitions.

IRRC objected to the Department's reiteration of definitions contained in the statute. One commentator also recommended that the Department be consistent with Insurance's regulations and reference the statute where necessary.

To make the document more user friendly, the Department has decided to keep the statutory definitions in the regulations. In this way, the regulations are as self-contained as possible. Cross-references to the statute would be, in the Department's opinion, unwieldy. It would tend to make the regulations more difficult to read and require the reader to switch between the statute and the regulations to understand the regulations.

Several commentators requested the addition of definitions to this proposed section.

Several commentators commented that there was no definition of "adequate network" in the proposed amendments, and recommended that the Department add a definition. The Department has not added a specific definition for network adequacy to this section, since the requirements for network access in § 9.679 (relating to access requirements in service areas) define the term.

One commentator recommended that the Department add a definition of "utilization review entity." The proposed amendments did include Act 68's definition of "utilization review entity." The definition appeared under the term "certified utilization review entity" or "CRE."

One commentator recommended that the Department add the definition of "active clinical practice" from the statute. The Department agrees that the inclusion of this definition would make § 9.708 (relating to external grievance reviews by CREs) clearer, and has added that definition.

One commentator recommended that the Department include a definition of "primary care." The Department has declined to add that definition, because it is unnecessary given the definition of "primary care provider."

Two commentators recommended that the Department include a definition of "preferred provider organizations (PPOs)." The Department has declined to add that definition because the term is adequately defined in the act of June 11, 1986 (P. L. 226, No. 64) (40 P. S. § 764a) (PPO Act). Further, the Department is concerned that adding that definition here could create confusion.

Several commentators questioned the Department's clarifications of the language of Act 68, or have requested additional changes to definitions:

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One commentator recommended that the proposed definition of "ancillary service plan" be limited to plans and exclude individual or group health insurance plans, since the substance of the proposed regulations would not pertain to vision or dental services not offered by a plan.

The Department has not changed the language of the proposed definition. The definition of "ancillary service plan" in Act 68 includes vision and dental plans offered by any insurer, not just a managed care plan. See definition of "ancillary service plan" in section 2102 of Act 68 (40 P. S. § 991.2102). The definition in Act 68 excludes these single service plans from coverage under Act 68. If the language were changed as the commentator recommends, the Department would be expanding the definition of managed care plan from what the act contemplates.

Another commentator supported the Department's proposed definition, but expressed concern that there could be the potential for confusion with respect to the phrase "or an indemnity arrangement that is primarily fee for service." See section 2102 of Article XXI (managed care plan). The commentator recommended clarifying the proposed definition by stating that when a primarily fee-for-service plan requires management for the broad range of conditions treated by a particular medical specialty, for example, treatment for mental health diagnoses, that portion of the plan would be subject to Act 68 if it would have been subject to the act as a freestanding plan.

The commentator appears to be concerned that behavioral health plans could be excluded from coverage under Act 68 and these regulations. Behavioral health plans are generally licensed as risk assuming nonlicensed insurers (RANLIs) under the PPO Act. When they incorporate gatekeeping, integration of financing and delivery of services through providers selected based on specific standards and utilization of financial incentives for enrollees to obtain services from participating providers, such plans meet the definition of a managed care plan and would be subject to Act 68 and these regulations.

IRRC objected that the proposed definition of "complaint" differed from the statutory one, and asked that the Department explain the change.

The Department included two phrases in the proposed definition that were not found in the statute. It defined a complaint to be a dispute or objection "by an enrollee;" and it clarified that coverage includes contract exclusions and noncovered benefits. The Department has not changed the proposed definition since the addition of the language clarifies the statutory definition of complaint. Section 2141 of Article XXI (40 P. S. § 991.2141) requires a plan to establish and maintain a process for enrollee complaints. Section 2142 of Article XXI (40 P. S. § 991.2142) pertains to enrollee complaints and agency reviews. Inclusion of "by an enrollee" in the Department's definition adds clarity. By adding the terms "contract exclusions" and "noncovered benefits" to its definition, the Department is not only clarifying what is a complaint, but also conforming this definition to Insurance's definition of "complaint." See 31 Pa. Code § 154.17(a)(2) (relating to complaints). Further, this language aids in distinguishing complaints from grievances.

Several commentators commented that the Department's definition of "enrollee" was too narrow. Two commentators recommended that the proposed definition include representatives

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of members who are incapacitated and the parents of minors. Two commentators commented that the regulation differs from Insurance's definition. One of these commentators took issue with Insurance's definition as well, objecting that it only expanded the definition of "enrollee" for the purpose of complaint and grievance cases, but not for other parts of Insurance's regulations.

The Department agrees that the definition should be altered, and has added language to match Insurance's regulations.

Several commentators expressed support for the Department's definition of "emergency services." One commentator noted that the regulation recognized the importance of the prudent layperson standard. One commentator endorsed the clarification in the definition relating to coverage of ambulance services under the prudent layperson standard.

One commentator recommended that the Department make changes to the proposed definition, for example, changing the word "so" to "such," to conform the regulation to the language in the statute. The Department has made these changes. The commentator also pointed out that a medical condition could be of a chronic nature that could suddenly worsen, and recommended that the Department revise the proposed regulation to reflect this. The Department believes that the definition, as proposed, accounts for the sudden worsening of a chronic condition.

IRRC objected to the Department's deletion of the word "emergency" from the phrase "emergency transportation" in paragraph (3) of Act 68's definition. See definition of "emergency service" in section 2102 of Act 68. IRRC also questioned the Department's substitution of the word "care" for "service," and the addition of the phrase "if the condition is as described in subparagraph (i)" in subparagraph (ii) of the proposed amendment.

The Department has replaced the word "so" with "such" and the word "care" with the word "service." The word "emergency" was deleted as redundant in the definition, as the definition itself explains what emergency transportation is. The Department has not reintroduced "emergency" or deleted subparagraph (ii). Subparagraph (ii) clarifies that mere use of an ambulance does not qualify the event as an emergency for coverage purposes. This preserves the prudent layperson standard without creating the unintended consequence of mandating coverage for the use of ambulances in nonemergency situations. The Department's additions to the statutory language do not violate the intention of Act 68, they merely clarify that intent.

The Department received several comments on its proposed definition of "gatekeeper," all recommending revisions. One commentator raised concerns that the term would imply that physicians intentionally restrict access to needed services, and recommended that it be deleted. This commentator recommended that "gatekeeper" be replaced by the term "primary care physician," arguing that the implication of the proposed regulation is that nonphysician providers can practice independently of physicians, which is against the law.

Several commentators took issue with the Department's inclusion of health care providers and managed care plans as gatekeepers. One commentator recommended that the reference to managed care plans be removed from the definition, as it was incorrect to include plans as

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gatekeepers. Two commentators recommended that the regulations state that only a primary care provider could be a gatekeeper. One of these commentators expressed concern that the proposed definition would fail to require a gatekeeper to be a provider of services to an enrollee, but would permit it to be source of referral or approval of services.

Two commentators recommended that the Department use Insurance's definition, and two raised concerns that the Department's proposed definition conflicted with Insurance's regulation.

After reviewing these comments, the Department has determined to adopt the language promulgated by Insurance. The term "gatekeeper" must remain in the regulations because it is required to define the term "managed care plan" which, in turn, defines what entities are covered by Act 68. See section 2102 Article XXI ("Managed care plan. A health care plan that uses a gatekeeper . . . "). The Department has defined "gatekeeper" to include plans and agents of plans because plans and providers that are not primary care providers may provide gatekeeping functions (for example, social worker intake to get behavioral health referrals or nurse triage call centers). Therefore, to ensure that enrollees are protected as Act 68 intended when services cannot be obtained except by going through a gatekeeper (physician, provider, entity or plan), it is essential that such plans are included in the definition of managed care plan.

The Department received several comments on the proposed definition of "gatekeeper PPO." One commentator again recommended deleting the term "gatekeeper" as pejorative. The Department has not deleted the term. Again, the term "gatekeeper" must remain in the regulations because it is necessary to define the term "managed care plan." "Managed care plan" must be defined carefully, as previously discussed. With respect to the comment concerning the inclusion of nonphysicians as potential gatekeepers, this decision was deliberate, so that the regulation would encompass managed behavioral health plans, which may not use a physician as a gatekeeper.

One commentator recommended that the Department include in the definition a statement that a gatekeeper PPO is a managed care plan. The Department has not done so, since so long as a gatekeeper PPO meets the definition of "managed care plan" under Act 68 and the regulations, the gatekeeper PPO is a managed care plan.

IRRC recommended that the Department use Insurance's definition. The Department has used Insurance's definition of "gatekeeper." Insurance's regulations do not include a definition for the term "gatekeeper PPO."

One commentator requested that the Department either clarify how a point-of-service (POS) plan differs from a gatekeeper PPO or merge the two proposed definitions.

The Department has not merged the two definitions but has added language that a POS plan can be offered by managed care plan.

The Department received several comments on the proposed definition of "grievance." Three commentators recommended that the Department remove the word "solely" from the proposed

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definition. According to these commentators, this would eliminate the concern that enrollees who file grievances which also contain complaints or other issues would be rejected by plans because they do not solely contain issues of medical necessity. One commentator recommended that the definition affirm that any claim of medical necessity is a grievance.

The Department has not removed the word "solely" from the definition, since the proposed definition was taken from Act 68. If, however, a matter should be a complaint rather than a grievance, and it is sent to the Department or Insurance as a complaint, it will be rerouted into the appropriate process. See § 9.702(c) (relating to complaints and grievances). If a plan somehow misclassifies or ignores the real issue involved in the case, the Department and Insurance will have the ability for correction and reclassification.

One commentator recommended that the Department reference the definition of "HMO" in the Health Maintenance Organization (HMO) Act (40 P. S. §§ 1551--1568), rather than restating the definition. The Department has made no change. For reader convenience, the regulations repeat the definition rather than simply citing to it.

Several commentators, including IRRRC, raised the concern that the Department's definition of "IDS" differs from Insurance's definition. After reviewing the comments, the Department agrees to use Insurance's language.

Several commentators raised issues that need to be addressed even though the Department is adopting Insurance's language. One commentator suggested that the definition of "IDS" should be consistent with the Department's IDS statement of policy. The commentator stated that language relating to risk sharing arrangements needed to be added to the proposed definition.

This language stated that the IDS would assume, to some extent, through capitation reimbursement or other risk-sharing arrangements, the financial risk for provision of the services to HMO members. This language does not appear in either the Department's proposed regulations or Insurance's final-form regulations. The language concerning risk-sharing was deliberately excluded by both agencies as too limiting. The Department is concerned that "risk-transference" is too narrow a term to use when dealing with the wide range of financial arrangements between parties which may not be labeled risk-transference but that have the effect of limiting a plan's financial exposure. These would include, for example, fixed budgets and performance incentives.

One commentator supported the Department's proposal to apply the regulations to any IDS that subcontracted with an HMO or other managed care plan. One commentator commented that the coverage of the regulations should be limited to HMO-IDS contracts, since the Department did not have authority over contracts between any entity other than an HMO and a health care provider.

The Department's decision to include IDS arrangements with managed care plans covered by Act 68 within the scope of its regulations is consistent with Insurance's regulations. Further, the PPO Act and section 2111(1) of Act 68 (40 P. S. § 991.2111(1)), which require the Department to ensure effective and efficient provision of services and operations, and the requirements of Act 68 that the Department ensure compliance with it (40 P. S. § 991.2181(d)), provide the

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Department with the necessary authority. To the extent that an IDS is performing utilization review, credentialing, grievance reviews and managing formulary exceptions, and to the extent that there are issues relating to prohibitions against financial incentives and gag clauses, the Department has responsibility to ensure that the IDS's services comply with Act 68. The Department, therefore, has a need to review these contracts to meet its responsibility under Act 68.

Further, the IDS statement of policy (§§ 9.401--9.416) recognized that the Department had authority over gatekeeper-PPO provider contracts. The definition of "IDS" in these regulations does not broaden the Department's authority beyond its existing authority.

Several commentators raised concerns about the Department's inclusion of skilled nursing facilities within the meaning of "inpatient services." The commentators appeared to be concerned that care offered in skilled nursing facilities was different from acute care hospital inpatient care, and so reference to skilled nursing facilities should be removed from the definition of "inpatient services" and should be defined separately. According to these commentators, skilled nursing care differs from inpatient services, and could not be substituted for inpatient acute or rehabilitative care.

Although the Department understands the concerns raised by commentators, it has declined to alter the definition. The definition of inpatient services in § 9.72(a)(3) (relating to basic health services), which is being repealed, did not have a separate definition for "skilled nursing care" or "skilled nursing facilities." Skilled nursing facility care can and should be considered an inpatient benefit. The Department is not comparing a skilled nursing facility to an acute care facility. To create a separate definition of skilled nursing facility or skilled nursing facility care could be perceived as creating a new basic benefit and new coverage requirements. This could raise significant opposition among plans, and possibly result in a loss of current coverage for skilled nursing facility care.

One commentator requested that the Department add "and all diagnostic and treatment services provided by health care practitioners" after the term "diagnostic testing" in the proposed definition. Another commentator also pointed out that in the Department's Preamble to its proposed rulemaking, the Department said it was adding physicians' services to the definition of "inpatient services," but did not do so in the definition. The commentator requested clarification.

The Department has added language to its definition of "inpatient services" to clarify that coverage afforded by a plan must extend beyond fees for use of the facility to fees for related professional services which generally are not billed by the facility.

Two commentators raised the issue that the definition of "managed care plan" would neither comport with Act 68's definition, nor match the definition of Insurance. The Department has changed its definition to match the language included in Act 68. The Department will consult with Insurance prior to taking a position that an entity is a managed care plan.

Two commentators raised concerns that the proposed definition of "medical management" would include the phrase "or providing" health care services. One commentator stated that the

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use of the word "provide" would imply that any plan that performed medical management functions would also provide health care, which could create liability issues for plans. This commentator recommended the substitution of the phrase "arrange for the provision of" for "providing for" in the definition of "medical management."

The Department has not changed the proposed language of the definition. The language states that medical management is a function that includes "other activities for the purpose of determining, arranging, monitoring or providing effective and efficient health care services." This language makes "providing" one of the types of activity that qualifies as medical management. Providing services is not the sole component of medical management, nor does the language imply that every plan that provides medical management functions also directly provides health care services.

One commentator recommended that the patient's home be included in the definition of "outpatient setting." The commentator noted that providers do make house calls and home visits, and therapeutic care is often provided in the patient's home. The Department agrees with this comment, and has made the necessary change to the regulations.

One commentator supported the proposed definition of "primary care provider." Several commentators raised concerns with it.

Two commentators commented that the proposed definition would describe only duties and not medical credentials of the primary care provider. One commented that the proposed definition would conflict with Act 68 and with Insurance's proposed regulation. The other commented that enrollees should know the medical background and experience of primary care providers, and there should be uniform requirements across plans for who can be considered to be a primary care provider.

Another commentator strongly objected to the proposed amendments not using the term "primary care physician" that was included in the regulations being repealed, and the replacement of that term with the term "primary care provider." The commentator stated that there were significant and substantial differences between an appropriately trained and experienced primary care physician and a primary care provider as defined by Act 68. The commentator stated that these two terms were not interchangeable, and to treat them as such could dilute health care in this Commonwealth. The commentator recommended that the Department retain the term "primary care physician" even though the proposed definition of "primary care provider" would track the statutory definition.

The commentator stated that Act 68 did not alter requirements under the HMO Act, and the Department's regulations promulgated under the HMO Act required primary care physicians to be made available. Therefore, it contended that the Department's final-from regulations must be changed to state that a primary care physician should supervise and coordinate care. The commentator argued that certified registered nurse practitioners (CRNP) and physician's assistants should not expressly or by implication be permitted to possess supervisory and coordination authority because Act 68 did not expand their scope of practice. Therefore, the commentator urged, they could not practice independently of a physician. The commentator

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stated that neither a CRNP nor a physician's assistant should be permitted to be a primary care provider, and recommended that the regulations be revised to prohibit that from occurring.

One commentator pointed out that § 9.77(a)(2) (relating to subscriber rights) of the regulations that are being repealed requires a primary care provider to spend half the provider's time as a primary care provider, or to have limited the provider's practice for at least 2 years to general practice, family medicine, internal medicine or pediatrics. The commentator strongly suggested that, at minimum, the Department's final-form regulations maintain these standards. The commentator stated that the Department should require minimum levels of experience and schooling for primary care providers, and claimed that without guidance or credentials, enrollees could not tell whether a plan's primary care provider network consists of appropriately qualified providers.

The Department has considered these comments and has decided not to change the definition of "primary care provider." The definition matches the language in Act 68 and in Insurance's regulations.

With respect to the comments concerning use of the word "provider" rather than "physician," Act 68 did not alter the HMO Act, but it does broaden the scope of permissible primary care providers by defining a primary care provider as a health care provider. This definition encompasses practitioners other than physicians. See definition of "primary care provider" in section 2102 of Act 68. However, the provider is still limited by the scope of practice defined by the provider's license. Licensing boards and statutes determine the scope of practice, education and training requirements. The Department cannot set Statewide standards for minimum primary care provider credentials. Further, Act 68 did not make disclosure of a provider's credentials automatic or available upon request.

Also, because Act 68 expanded the definition of "primary care provider" to include specialists in certain situations (see section 2111(6) of Act 68), a requirement that a primary care provider must practice a minimum number of hours per week or have a certain number of years of practice as a primary care provider would serve to disqualify most specialists from serving as a primary care provider. This may indirectly prevent an enrollee from having a specialist serve as the enrollee's primary care provider.

One commentator recommended adding the sentence, "a POS plan is a managed care plan," to the end of the definition of "POS." This language is not definitional, and the Department has not made the change.

The Department has changed the definition and added language to clarify that a POS plan is offered by a plan and may require an enrollee to choose and use a gatekeeper to obtain the highest level of benefits with the least out-of-pocket expense. Further, a POS plan may allow enrollees to use providers either inside or outside the network without the referral of a gatekeeper.

Three commentators, including IRRC, objected to the proposed definition of "service area" as differing from the definition of "service area" included in Act 68.

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The Department has not changed the proposed definition. The Department does not agree that the language conflicts with Act 68. The Department expanded the Act 68 definition to further define the requirements for service areas under the HMO Act because the Department certifies an HMO initially on a limited geographic basis. The Department then approves expansions of the service area on a county-by-county basis, following a determination by the Department that the HMO has an adequate provider network in that proposed county. The initial certificate of authority is granted based on the original proposed service area. As HMOs expand, a new certification is not required, but the new network must be approved by the service area expansion request process. The Department's additions to the Act 68 definition reflect this.

Two commentators commented that the Department's proposed definition of "UR" would go beyond Act 68's definition, because it would allow utilization review (UR) to be performed by any health care plan, and not just a CRE. One of these commentators recommended deleting the term "health care plan" from the definition. The commentator recommended that the Department reference CREs, since they were defined earlier in the proposed amendments, and add the word "certified" before the word "utilization review entity."

The Department included the term "health care plan" in the proposed definition of UR deliberately because section 2151(e) of Article XXI (40 P. S. § 991.2151(e)) states that managed care plans with certificates of authority need not be certified to conduct UR. Therefore, Act 68 clearly contemplated certain managed care plans would be performing UR. The Department has not deleted the term "health care plan" from the definition, but has changed the term to "managed care plan" to more accurately reflect the statutory language.

One commentator recommended that the Department add time frames for reviews and standards for how a plan should test for reviewer reliability, and include in the definition what a CRE should include in its written complaint and grievance review decisions.

The Department agrees that the issues of timeliness and the content of complaint and grievance review decisions should be addressed, and has done so in other sections of the regulations. Time frames are addressed in the operational standards section, § 9.751 (relating to time frames for UR) and the content of complaint and grievance review decisions are addressed in §§ 9.703 and 9.705 (relating to internal complaint process; and internal grievance process), as well as § 9.750 (relating to UR system standards).

Section 9.603. Technical advisories.

The Department received eight comments on this proposed section. One commentator supported this section as an advantageous undertaking because it would foster the working relationship of plans and the Department.

Several commentators commented that the Department had not provided for public review and comment of technical advisories. IRRC commented that the proposed regulation would not address how the Department would notify interested parties that a technical advisory was being issued. Several commentators, including IRRC, recommended that the advisories be published in the *Pennsylvania Bulletin* with information on how to obtain copies. One commentator commented that the technical advisories should be available in advance, to

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permit public comment. Several commentators stated that the Department should specify in regulation that purchasers, the public, and providers have access to its advisories.

The Department uses technical advisories to provide guidance. They are not binding. They represent the Department's interpretation of a regulation or of a statute. Since these are not binding statements, the Department sees no need to provide a time period for public comment. However, to notify all interested parties, the Department will publish notice of the availability of a technical advisory in the *Pennsylvania Bulletin*.

One commentator commented that the Department's explanation of the effect of a technical advisory as nonbinding was appropriate. The commentator commented that a technical advisory could not be used as a waiver mechanism, as the Department had done in the past to permit plans to use CRNPs as primary care providers. The commentator stated that a technical advisory could not be used to secure waiver of statutory and regulatory requirements.

With respect to the comment regarding CRNPs, the Department may choose to waive enforcement of a regulation, so long as that regulation is not also a statutory requirement. The Department's issuance of a technical advisory to explain that it would grant a waiver of its then current regulation requiring plans to make primary care physicians available, and, instead, allow the use of CRNPs, was appropriate.

Section 9.604. Plan reporting requirements.

The Department received approximately 30 comments regarding this proposed section. Two commentators commended the Department for establishing reporting requirements that would help ensure effective oversight as well as provide the public with data on plan practices. Another commentator commented that the reporting requirements that would be imposed by the proposed amendments were insufficient to demonstrate to the Department that a plan was in compliance with Act 68.

Two commentators provided the Department with a list of elements that should be included as reportable information. One of these commentators suggested that the Department add UR time lines, explanations of how a plan will test for reviewer reliability, and a summary of the content of complaints and grievances, to the reporting requirements.

The Department has not added these recommended data elements. The Department will consider adding them in future reporting years, but at the present time it prefers to verify this data through onsite reviews and auditing, rather than plan self-reporting.

The other commentator recommended that the Department add the following data elements: quality improvement reports; changes in utilization data since the last report; formularies and process to obtain prior authorization or an exception; a report on monitoring activities for IDS and medical management contracts; the number, type and reason for payment procedures to out of network providers; a report on activities to accommodate access needs for persons with disabilities to provide services to persons with limited English and to accommodate persons with sensory disabilities; a report on the provider complaint process, including the number of complaints filed by type of provider and outcome; if applicable, a report on utilization for

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persons seeking drug and alcohol abuse treatment services, by type of service provided; and a copy of the annual financial report given to the Insurance Commissioner.

The Department reviewed these suggestions, but has determined not to add any additional reporting requirements. The Department believes the reporting requirements are sufficient for its purposes, and notes that the reports are not the only way in which the Department will verify and ensure compliance with Act 68.

The Department has the following response to the data elements recommended. The quality assurance report is already required as part of a plan's annual report. A change in utilization data can be calculated by the Department from the data requested, and does not need to be self-reported. Formularies are extremely large and too subject to change to require that they be reported, particularly as the Department does not need this information to ensure compliance with the regulations or with Act 68. Requirements related to the formulary exceptions process are included in § 9.673 (relating to plan provision of prescription drug benefits to enrollees) and need not be reported here. Out-of-network information could be useful to the Department in monitoring network adequacy but is a difficult element to accurately capture and analyze given the proliferation of open access plans that allow enrollees to obtain services from a nonparticipating provider. The Department will, however, consider this for future reporting requirements. The Department will also consider adding a report on accommodations for disabilities and non-English accommodations in the future. Act 68 did not create a provider complaint process other than for timely payment, which is a matter addressed by Insurance. Drug and alcohol abuse treatment requests and services provided will more likely be addressed through external quality assurance reviews of managed behavioral health plans, but the Department will consider requiring plan reporting on this in the future. The Department has access to financial statements from Insurance. The Department will review them as it finds a review necessary to ensure compliance under the regulations and statutes. Additionally, a copy of the financial annual report to Insurance is currently included in the annual report submission to the Department.

One commentator also commented that the Department lacked the statutory authority to require all plans to report as HMOs are required to do. The commentator stated that the Department should limit plan reporting to what is required in section 2111 of Article XXI.

The Department has the authority to require plan reporting. Section 2111 of Article XXI requires that plans report to the Department what is necessary for the Department to determine compliance with Act 68, including information relating to complaints and grievances. See section 2111(13) of Article XXI. The section leaves it to the Department's discretion to determine what information the Department needs to be reported to enable it to ensure a plan's compliance with Act 68. The Department has included in § 9.604 (relating to plan reporting requirements) a listing of reportable items. The reporting of these items will allow the Department to monitor compliance with the various parts of Act 68, for example: timely access and availability to health care providers, section 2111(1) of Article XXI; institution of appropriate complaint and grievance processes, section 2111(8) and (9) of Article XXI; and direct access requirements, section 2111 of Article XXI. The commentator in question has not pointed to any required reporting element that is inappropriate under Act 68.

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IRRC commented that the proposed requirement that key utilization, enrollment, and complaint and grievance system data should be reported was vague and should be clarified. IRRC recommended that the Department specify what data would be required. The Department agrees, and has done so.

IRRC also commented that the proposed section did not specifically reference penalties if reporting requirements were not met. Two other commentators also commented on the lack of a specific penalty for late reports. One of these commentators recommended adding subsection (c), to establish penalties for late filing of reports.

The Department has the authority under Act 68 and the HMO Act to impose certain fines. That authority is included in the regulations in § 9.606 (relating to penalties and sanctions). These fines may be charged against plans which fail to report in a timely fashion. That language need not be repeated in this section to be applicable. The Department cannot, however, create penalties that are not provided for in statute.

IRRC also recommended cross-referencing § 9.606 for the purposes of clarity. The Department considered making a cross-reference, however, it has determined not to reference the section because if the Department were to do so here, it would be necessary to cross-reference § 9.606 in every instance where a penalty could be applied. Since a violation of nearly every section could result in a penalty, this could become excessive.

Several commentators noted that there was no requirement in this proposed regulation for use of the Health Plan Employer Data and Information Set (HEDIS) data collection elements. One commentator noted that the section would not require plans to provide information as to outcomes in any manner. The commentator stated that such information was a crucial set of data needed by consumers to choose health plans. The commentator also recommended the establishment of an advisory panel on data; and that quarterly and annual data be made available in user friendly reports to purchasers, providers and the public to allow comparisons of different managed care plans and providers in terms of costs, quality and outcomes. Several other commentators commented that the proposed regulation would fail to require that annual data about the plan to be made available in a user-friendly format for public review.

The Department's objective in requiring plan reporting is for regulatory oversight and compliance. The Department is aware of the public interest in obtaining information for public review, and is looking into whether the reported data can be used to generate the user-friendly information in question. Outcome criteria is currently not recorded, tracked or analyzed in the same manner by all health plans. HEDIS data is expensive to collect, validate and report. While most health plans in this Commonwealth currently collect, validate and report HEDIS data to the National Committee on Quality Assurance (NCQA), not all health plans do. Mandated collection of HEDIS data could be an extensive undertaking, expensive and potentially burdensome on the managed care industry. Additionally the Department does not want to limit itself to HEDIS data should alternate data elements be determined to more accurately reflect outcomes and performance. At the moment, the data requested by the Department is sufficient for its regulatory purposes; however, the Department is considering ways in which it can in the future provide information which would be useful to consumers in evaluating health plans.

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Several commentators had comments regarding specific data elements required by the Department in proposed subsection (a). One commentator recommended deletion of the reference to county disenrollment data from proposed subsection (a), which would set requirements for plan annual reports, since it was not reportable by plans, and since its usefulness to the Department, according to the commentator, was questionable.

The Department believes that if plans are able to report enrollment by county, they should be able to report disenrollment by county. Because, however, the Department can calculate this information from comparisons with previously reported enrollment data by county, the Department will delete the reference disenrollment data by county from subsection (a)(1).

IRRC and several other commentators commented that the requirement in proposed subsection (a)(2) that plans report health utilization data was vague, since it did not list specific types of data required.

The Department agrees that the language should be clarified, and has included language from the Department's regulations that are being repealed to specify what information is required.

IRRC and several other commentators raised concerns that the reference to data relating to complaints and grievances in proposed subsection (a)(3) was vague, and could result in the reporting of substantially less information than the Department would desire. One commentator commented that reporting of this data was missing altogether.

Proposed subsection (a)(3) would have required reporting of complaint and grievance data. Complaint and grievance data would have also been required to be reported quarterly in proposed subsection (b). The Department has, however, added language from Insurance's regulation to provide more detail. See 31 Pa. Code § 154.13 (relating to managed care plan reporting of complaints and grievances).

One commentator also recommended reporting by categories of complaints and grievances, for example, quality of care, days to appointment, specialists referrals, requests for interpreter services and denials of emergency room claims. The commentator also recommended reporting by medical/nonmedical categories, as well as by total provider appeals.

The Department currently categorizes all third-level complaints and grievances, but has not required that plans do so. The Department is exploring standard reporting categories (for example, quality of care, access, noncovered benefit, cosmetic procedure) for use by all plans in future reports to be consistent with the Department's own reporting categories.

The Department has also added language to the proposed paragraph to make it clear that plans must obtain and report activity by subcontractors. This is necessary since Act 68 allows grievances to be delegated to CREs.

Two commentators recommended that the Department change proposed subsection (a)(6) to require a plan to report the number of primary care providers, specialists and pharmacists joining and leaving the plan. The proposal would require only the reporting of physicians joining or leaving a plan.

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Any potential exodus of a hospital or primary care provider that serves large numbers of enrollees must be reported to the Department under § 9.679 as an early warning system which the Department feels is preferable to retroactive reporting. The number of physicians in the network provides a quick and useful indicator of the status of a network; however, the Department currently reviews network adequacy through the entire provider directory and investigations of complaints made to the Department. The Department cannot necessarily take action against a plan because of the migration of providers into and out of the network. Therefore, the usefulness of the information is questionable. Because listing every type of provider and the totals of providers moving in and out of the network would be burdensome for the plan, and would not alleviate the need for the Department to validate the information through the network, the Department has not added this requirement to the regulation.

Two commentators took issue with the Department's proposed requirement in subsection (a)(8) that plans provide reimbursement methodologies to the Department for the Department's review. There is a concern on the part of plans that the information, which they consider to be proprietary and confidential, would become public. Further, one of the commentators stated that it would become difficult for plans to negotiate appropriate contractual modifications with providers with this requirement in place.

The Department is aware of the plans' concern regarding their proprietary and confidential information. However, Act 68 requires that no managed care plan use any financial incentive that compensates a health care provider for providing less than medically necessary and appropriate care to an enrollee. See section 2112 of Article XXI. To ensure compliance with this requirement, the Department must review reimbursement methodologies, as well as any changes to those methodologies. The Department is sensitive to the plans' concerns, however, and will take every step possible to ensure the confidentiality of the information in question. The Department is adding language to this provision, and to several other sections of the regulations, on which it intends to rely for protection of the confidentiality of the information if requests are made for the information's release. The Department will provide the plan with notice of the request and allow it to either consent to the release, or to take action to prevent the release. The Department will support the plan's action.

IRRC and another commentator raised concerns about the catch-all provision in proposed subsection (a)(11) intended to allow the Department flexibility to request additional information in the annual report upon advance notice. IRRC recommended that the Department either clarify the subsection to specify the type of information it might request, and the length of the advance notice period, or delete it.

The Department understands the commentators' concerns, and has deleted subsection (a)(11).

One commentator has requested changes to subsection (b) similar to those the Department has made to subsection (a)(2) to clarify the data elements. The Department has revised this proposed subsection, but has chosen not to reiterate the language in subsection (a)(2). The Department has, instead, referenced that provision, requiring the data as specified in that paragraph be reported on a quarterly basis. The Department has also referenced subsection

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(a)(6) to make it clear that the Department must also receive network information on a quarterly basis.

Section 9.605. Department investigations.

Three commentators, including IRRC, commented concerning inconsistencies in the wording in this section. All three noted that proposed subsection (a) would apply to all plans, while proposed subsections (b)--(e) would apply only to HMOs. All three commentators requested that the Department reconcile this inconsistency, although one commentator stated that this should not be done by extending the Department's investigatory powers to all plans. The commentator further stated that the Department had no need for or authority to investigate and review plan information generally.

The Department agrees the section should be applied consistently to all plans, not only HMOs. The Department has the authority to enforce Act 68 (see section 2181 of Article XXI (40 P. S. § 991.2181)), as well as the HMO Act.

Two commentators requested that the Department add language to proposed subsection (a) allowing the Department to investigate provider complaints regarding quality of care, and provider grievances. The commentator noted that the proposed subsection would only reference enrollee grievances and complaints.

The Department agrees that language referencing enrollee and provider grievances should be included in this subsection, and has made the change. The Department will investigate alleged violations of Act 68, but has no general authority with respect to provider complaints, nor does it have the authority to become involved generally in disputes between providers and plans so long as there are no Act 68 or HMO issues in question. The Department has also changed the language of subsection (a) to clarify that its authority to investigate whether a plan is complying with Act 68, the HMO Act, the PPO Act and the regulations is not limited to annual, quarterly and special reports, grievances and enrollee complaints.

One commentator commented that the investigations referenced in this proposed subsection (b) should include all subcontractors regardless of whether they take risk.

The Department has made no change to proposed subsection (b). The Department has the authority to investigate issues regardless of which entity performs the actual function. The plan retains ultimate authority and responsibility for compliance under Act 68, and should the Department need to investigate a subcontractor, it has the authority to do so by virtue of its authority over the plan. Further, since the definition of "IDS" does not contain any reference to risk, this is no longer an issue.

Two commentators expressed concern that the Department exempted financial business from review in proposed subsection (c), which would provide the Department and its agents to all books, records, papers and documents that would relate to the business of the HMO other than financial business. One commentator was concerned that this information could be directly related to quality of care or services, or deficiencies found in those areas. The commentator stated that business practices and solvency could have an impact on the

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provision of services and benefits, provider contracting and credentialing. The commentator did not believe that the Department could monitor without this information.

The Department has made no change to the proposed subsection. The Department is aware of the linkages between solvency and plan operations as it affects quality of care and service. However, Insurance has jurisdiction over the financial aspects of managed care plans and the documents related to those issues. If the Department needs the information, the Department will be able to obtain the information from Insurance.

Two commentators have recommended that proposed subsection (d), which would provide the Department with access to medical records for certain purposes, be modified. One commentator recommended the addition of the language "to the extent permitted by law" after the phrase "The Department will have access to medical records of HMO enrollees" The other commented that not all HMOs have medical records available, only staff model HMOs do. This commentator recommended altering the language to provide the Department with access to medical records "only to the extent available."

The Department has made no change to the proposed subsection. Section 2131(c)(2)(ii) of Article XXI (40 P. S. § 991.2131(c)(2)(ii)) provides the Department with access to records for certain purposes, despite the general confidentiality provisions in section 2131(a) of Article XXI. Subsection (d) tracks the language of section 2131(c)(2)(ii) of Article XXI.

Section 9.606. Penalties and sanctions.

Several commentators have requested additions to this proposed section. Although one commentator commented that the section had been substantially revised and had improved draft regulations the Department circulated in May of 1999, it recommended that the Department add language that would permit it to recoup its costs upon obtaining injunctive relief. Another commentator noted that the experience of other State regulators has demonstrated that regulators need to have available to them strong administrative penalties taken in conjunction with injunctive relief to ensure that plans comply with regulations.

Although the Department agrees that these recommendations would be helpful in enforcing the statutes and regulations, the Department is unable to create penalties that do not exist in either the HMO Act or Act 68. Therefore, the Department has not changed the regulation.

One commentator commented that any penalties or sanctions should be governed by the appeals processes in 2 Pa.C.S. Chapter 5, Subchapter A (relating to practice and procedure of Commonwealth agencies). The Department has changed subsection (e) of the regulation to clarify that, with respect to penalties and sanctions under Act 68, the requirements of 2 Pa.C.S. Chapter 5, Subchapter A apply. The language of subsection (c) reflects the language of the HMO Act, and has not been changed.

One commentator recommended that the Department publish annually a list of plans, by area served, which had no deficiencies and were not required to file plans of correction for the year.

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The Department decided against making this change to the regulations. Under the regulations, plans are required to be reviewed by an external review organization and to maintain a continuous quality improvement program that reports on its activities annually to the plan board of directors and to the Department. Quality improvement is the continuous and systematic advancement toward goals designed in pursuit of the very best that can be achieved. No plan, even the very best performer, achieves a perfect score on the external review or a perfect outcome on every quality improvement initiative undertaken. The Department makes available to the public the annual quality improvement work plan and those portions of external reviews that result in Department-requested plans of correction, along with those plans of correction. No plan has received perfect scores or achieved 100% on every quality initiative undertaken. Therefore, the Department questions the usefulness of a listing of virtually every plan as a "nonperfect" plan. The Department prefers to make available to the public those reports where the Department is requiring corrective action. They provide more meaningful information.

Two commentators requested that the Department clarify the proposed subsection (a)(1) by adding a reference to Article XXI in paragraphs (1) and (2). The Department has not done so, since Article XXI is referenced in subsection (a), and it is clear that all the penalties and sanctions in subsection (a) are for violations of Article XXI.

One commentator recommended that the Department add to proposed subsection (a)(3) language that a ban on enrollment shall continue "until the plan comes into compliance with law and regulations."

The Department has not added this language to proposed paragraph (3). The Department reserves the right to determine what the timeframe for such a ban should be. Depending upon the nature of the violation, it may be possible to lift the ban when the violation has been substantially corrected. For example, if a plan failed to have a medical director, and the Department banned enrollment to the plan, the Department might lift the ban if the plan obtained a medical director on a temporary basis until one could be located and hired. Technically, the problem would not be resolved since the plan would not have hired a medical director, but the potential harm to the enrollees would have been alleviated.

One commentator recommended that the Department add language to subsection (a)(4), which would require a plan to notify enrollees of the existence of a plan of correction within 60 days of its approval by the Department. Further, the commentator recommended the addition of language stating that the Department will monitor the plan of correction.

The Department has not changed the substance of proposed paragraph (4) to reflect this comment. The Department has the responsibility to monitor the plan of correction, without including any additional language in the regulations. The Department will not require notice to enrollees of a corrective action plan. This is burdensome financially for plans, given the number of enrollees in a plan, and the questionable utility of the knowledge. For example, the Department may determine that a plan with 500,000 enrollees, which processed 250 first level complaints in a year, had in 5% or 13 cases failed to issue its decision letters within the statutory time limits of Act 68. In those 13 cases, the plan was 1 day late. The Department then required a plan of correction to address the problem. To require the plan to provide notice of this plan of correction to 200,000 households for an issue that affected 13 households would

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be hugely expensive. The information would be essentially useless to the vast majority of enrollees, most of whom will never file a complaint. (These numbers represent the actual volume of first level complaints for a plan with this size enrollment, as based on data from the 1999 annual reports).

The Department has moved the substance of proposed paragraph (4) to subsection (d), and has added language to clarify that the Department may request a plan of correction for violations of the HMO and PPO Acts, Act 68 and the regulations. The Department has also added language to clarify that failure to comply with a plan of correction could result in the Department's taking action under subsection (a) or (b), as appropriate.

IRRC recommended that the Department clarify the proposed section by defining a plan of correction, and explaining what must be in it.

The Department has not added a definition for "plan of correction." The Department believes that the concept of a plan of correction is self-explanatory. The Department provides the plan with the list of issues to which the plan must respond, or face other action, and the plan either responds with sufficient explanations and actions, or does not. No definition for this term exists in the Department's other licensing regulations, although it is used extensively in the regulations for both long term care facilities and hospitals.

One commentator commented that, since HMOs do not provide services, proposed subsection (b)(1) should be revised to include the words "arranging for" services rather than the words "providing inadequate services" in proposed paragraph (1). The Department agrees that the word "arranging" should be added to the paragraph, to clarify that HMOs can provide for or arrange for services. It has included that word to state that an HMO may be fined if the Department finds that the HMO is providing or arranging for inadequate or poor quality care. See subsection (b)(1).

The Department has deleted subsection (b)(3), since Insurance is the agency with authority over fraudulent insurance practices. See generally the Unfair Insurance Practices Act (40 P. S. §§ 1171.1--1171.15).

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Subchapter G. HMOs

The Department received over 200 comments on this proposed subchapter.

Several commentators made general comments not addressed to any particular section. One commentator commenting on the overall subchapter, raised concerns that the Department would have little oversight in establishing criteria and review of HMO licensing.

The Department sets the standards for obtaining a certificate of authority, and will conduct a readiness review, as well as a review of the application to determine whether the applicant meets those standards. Use of a private entity to perform reviews is not unheard of, and does not eliminate the Department's responsibility for ensuring that an HMO complies with the HMO Act and the regulations.

One commentator raised concerns that the Department's proposed revisions to the HMO regulations would be disadvantageous to consumers, and that Act 68 did not provide the statutory authority to make these changes.

The Department is revising its HMO regulations to comply with Executive Order 1996-1, which requires all agencies to review all regulations for necessary changes. The Department was in the process of making these changes when Act 68 was passed. Because the two sets of regulations are highly interdependent, the Department chose to combine the two processes. The Department has the authority to accomplish the revisions and deletions it proposed through both Act 68 and the HMO Act. The Department disagrees that the regulations in any way harm consumers. The Department has gone to considerable lengths to include consumer protections in the final-form regulations adopted under both Act 68 and the HMO Act.

Two commentators commented that the proposed regulations did not include minimum standards for education, training, experience and record keeping, among other things. One commentator stated its concern that the proposed regulations would also fail to require Department review of information about practitioners, including substance abuse history, board certification and malpractice history.

This comment pertains to credentialing of providers, which the Department addresses in an entirely separate subchapter. See Subchapter L. This comment is addressed in that section. Again, that is a credentialing issue for the HMO.

Section 9.621. Applicability.

The Department received one comment on this proposed section. The commentator recommended that the Department identify specific types of plans covered by Act 68 and make this list available to consumers and providers.

The Department does not intend to develop a list of all types of plans subject to Act 68. Also, this subchapter applies exclusively to HMOs. Although all HMOs are subject to Act 68, not all plans subject to Act 68 are also subject to the HMO Act. Section 2102 of Article XXI contains a definition of what plans are subject to Act 68. To the extent that this comment was made in an

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effort to help consumers and health care providers understand their rights under Act 68, the Department believes that a list could be misleading to enrollees. An enrollee may in fact be covered by a plan administered by an HMO or other plan that is preempted by the Federal Employee Retirement Income Security Act (ERISA) from Act 68's jurisdiction. Through the disclosure requirements issued by Insurance and those contained in this section, a plan is responsible for providing Act 68 information to enrollees and health care providers.

Section 9.622 Prohibition against uncertified HMOs.

The Department received one comment on proposed subsection (a). That proposal would prohibit a corporation from operating an HMO within this Commonwealth without a certificate of authority. The commentator noted that the proposed subsection prohibited only corporations from engaging in HMO activity. The commentator recommended that the Department delete the first four words, and replace them with, "no person, partnership, corporation, or limited liability company or other entity shall"

The language in the proposed subsection would track the HMO Act. The Department has not changed the proposed subsection. It is written in this manner because under the HMO Act, only a corporation may apply for a certificate of authority to operate as an HMO.

The Department received comments from one commentator on proposed subsection (b). The proposal would prohibit a foreign HMO from operating within this Commonwealth without a certificate of authority from the Commonwealth. The commentator recommended that the Department specifically exclude out-of-State HMOs that enroll Pennsylvania residents employed in another state under group contracts issued and delivered in that other state, if the HMO has a valid certificate of authority in that state.

The Department is not empowered to regulate contracts between non-Pennsylvania plans and non-Pennsylvania employers, even though they may affect residents of this Commonwealth who happen to work out-of-State. The HMO Act and Act 68 regulate the corporation, not the enrollee. HMOs licensed and regulated in other states, which issue contracts in this Commonwealth, are considered foreign HMOs under the section 6.1 of the HMO Act (40 P. S. § 1556.1) and the statute specifically requires foreign HMOs to obtain a certificate of authority from the Commonwealth.

The commentator also recommended that rather than requiring a separate certificate of authority for potentially small amount of business by foreign HMO, the Department should rely on and exercise its regulatory oversight in areas of access to quality of care and quality of care issues.

The statute requires a foreign HMO to obtain a certificate of authority to do business in the Commonwealth. The foreign HMO may always make an argument to the Secretary of the Department and the Commissioner of Insurance under section 6.1(b) of the HMO Act that specific requirements of the regulations or the HMO Act should be waived. The Department, however, is not prepared to make the sweeping declaration that only portions of the regulations apply to foreign HMOs.

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Section 9.631. Content of an application for an HMO certificate of authority.

The Department received several comments on this proposed section.

One commentator recommended that the Department's and Insurance's requirements be the same for what is to be included in an HMO certificate of authority application. The Department disagrees. Each agency requires different information for its particular purposes, since each has different responsibilities under the HMO Act. Although both agencies require different information, there is a joint application.

Several commentators, including IRRC, commented on the Department's proposed deletions from the application which had been required by the regulations the Department was proposing to repeal. IRRC commented on the Department's proposed elimination of a job description for the medical director, of the procedure for referral of subscribers to nonparticipating specialists and of procedures for payment of emergency medical services. IRRC noted that in its Preamble to the proposed rulemaking, the Department stated that these requirements were either unnecessary or superseded by Act 68. IRRC disagreed, and stated that these requirements needed to be present for the Department to determine an applicant's ability to operate in accordance with Act 68 and the HMO Act. IRRC asked the Department to either reinsert these items, or explain why they were no longer necessary and what portions of Act 68 superseded them.

Another commentator also raised concerns that the Department was proposing to eliminate the regulatory requirement that an HMO provide a detailed description of position of the medical director. The commentator also raised concerns that the Department was proposing to eliminate the requirement for review and approval of the HMO's procedure for referral of subscribers to nonparticipating specialists. This commentator stated that the Department could not determine whether the person in medical director's position had authority to oversee UR and quality assurance without reviewing the job description. The commentator recommended that the Department require that the medical director: (1) be qualified or have experience in performing these functions; (2) presently live in this Commonwealth or have lived here in recent memory; (3) have a job description requiring the medical director to perform these activities; (4) utilize appropriate review criteria for this purpose; (5) be employed for more than 1 hour per year; (6) not have incentives based on decreased utilization; and (7) report directly to the HMO's board. In the commentator's opinion, Act 68 did not require that these requirements be repealed.

The same commentator raised concerns that the Department was proposing to repeal the regulatory requirement that the applicant provide a copy of its financial information and proposed subscriber literature. The commentator stated that the Department had expertise in reviewing subscriber literature to determine whether it complied with Department policies. Secondly, the commentator stated that the Department could not determine if there was consistency between what the plan stated it would do to gain a certificate of authority and what it had done without seeing the subscriber literature. Thirdly, the commentator raised concerns that the Department would not have available needed financial statements to determine what the plan had in place regarding personnel, equipment and offices as opposed to what it would need to put in place if the requirement was deleted.

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After reviewing these comments, the Department has decided to keep language requiring that an applicant provide the Department with information concerning the job description for the medical director. See paragraph (16). The Department has not addressed the issue of what qualifications the person holding the position of medical director must have in this section. The Department addresses this issue in the discussion of comments on proposed § 9.633 (relating to HMO board requirements).

The Department has also decided to keep language requiring applicants to submit a procedure for referrals to nonparticipating providers, see paragraph (17), and copies of member literature. See paragraph (18). Copies of general member literature are required in the agencies' joint application for a certificate of authority, which both agencies receive and review. Although the Department will receive the member literature, it is Insurance that has the authority to review and make certain the application contains this particular information.

The Department has decided against including language requiring the submission procedures for payment of emergency services in the HMO certificate of authority application. The regulatory requirement the Department is repealing was meant to ensure that plans were not summarily rejecting emergency room claims, regardless of the medical condition, on the technicality that the primary care provider had not given prior authorization. Under the prudent layperson standard, the condition must be considered and the lack of a prior authorization cannot be used to summarily reject the claim. Act 68 not only requires plans to utilize the prudent layperson standard when processing claims, it also delineates those services that must be included for payment. See section 2116 of Article XXI. Section 9.672 (relating to emergency services) addresses emergency services including payment requirements and nonparticipating requirements.

One commentator also raised concerns that the Department was proposing to eliminate the regulatory requirement that an HMO provide a description of the process of board selection. The commentator stated that this change was not required by Act 68. The commentator commented that the board of directors is ultimately responsible for policies that guide plan selection, and without the Department's review of the selection process or without a requirement that boards be balanced and diverse, HMOs could "stack" the board. The commentator stated that the Department could not regulate the outcome without regulating the process.

The Department has not changed the proposed section to address this concern. The Department does ask for the bylaws of the corporation, which include the process by which the board is selected. The Department also asks for a list of senior officials in paragraph (2). Matters related to the board of directors and the background of senior officials are handled by Insurance.

One commentator recommended that the Department include a requirement that the HMO notify the Department of any significant changes in operations or structure that would differ from the HMO's original application.

The Department has not changed the proposed section to address this concern. Plans do report changes in structure through the annual report. Changes in operations do not require

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prior approval under the HMO Act; however, the Department does monitor operational changes through annual site reviews, the external quality review process and complaint investigation.

IRRC and another commentator noted that the Department had stated that it was proposing to remove this subject matter addressed in proposed paragraph (1) from its regulations, but in fact it appeared in the proposed amendments. Proposed paragraph (1) would require the application to include information explaining the applicant's organizational structure.

The Department has reconsidered eliminating the subject matter addressed in the proposed paragraph, and has decided to retain the proposal in the final-form regulations.

IRRC commented that the Department had stated that it was proposing to remove the subject matter addressed in proposed paragraph (4) from the regulation, but paragraph (4) also appeared in the proposed regulations. Proposed paragraph (4) proposed to require the applicant to include a copy of each proposed standard form health care services contract and each IDS contract including a detailed description of the types of financial incentives that the HMO may utilize.

Another commentator commented that the proposed regulation lacked a requirement that an HMO provide the Department with a detailed description of the financial incentives that it will use. The commentator stated that the Department's proposed regulation would only require the HMO to tell what types of incentives it might use. The commentator expressed concern that bonus payments to reward low utilization could constitute up to half of a provider's compensation. This could expose members with high medical needs to an enormous risk of reduced levels of care. The commentator stated that a Health Care Financing Administration (HCFA) study had shown that when rewards for low utilization reach 25% of total potential payments, the provider reaches a threshold that can color treatment decisions and result in inadequate care for the patient.

The Department inadvertently included in the proposed regulations both proposed paragraphs (4) and (16), which proposed to require the applicant's submission of a detailed description of the applicant's incentives and mechanisms for cost-control within the structure and function of the HMO. In this context, cost-control is was a broad concept involving utilization review, case management and other administrative mechanisms employed to control health care costs. As these administrative mechanisms are well-established and well-known within the industry, the Department will only be requiring financial methodologies. The Department has changed the language in paragraph (4) to require that HMOs include a detailed description of reimbursement methodologies along with the standard IDS-provider contract. The Department has, therefore, deleted from the regulation proposed paragraph (16), which contained the requirement relating to cost control. The Department will continue to receive the necessary information to evaluate potential impact of reimbursement methodologies on the provision of health care services.

Since the Department has included a requirement for reimbursement methodologies in paragraph (4), the Department is also including language that states that the Department will maintain the confidentiality of this information unless ordered to release it by a court of law.

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The Department will notify the HMO of any request for the information to either obtain consent to release the information from the HMO, or to allow the HMO to take action to prevent the release of the information.

With respect to the comment relating to the HCFA standard, that standard refers to 25% of total potential payments. The Department's regulation requires that whatever the bonus or incentive program is, the bonus program cannot weigh utilization factors more highly than a combination of all other factors. The Departments' standard addresses incentive plans separate from payment for services, whether fee-for-service or capitation. Regardless of the amount of the bonus, it cannot be paid out or earned based solely on utilization. This issue is more fully discussed in the Department's response to comments on § 9.722 (relating to plan and health care provider contracts).

Section 9.632. HMO certificate of authority review by the Department.

The Department received several comments on this proposed section.

One commentator raised a general concern that the proposal included no standards for quality assurance and no requirement to use generally accepted medical standards for UR.

The Department has changed the regulations to link the requirement that an HMO have and provide a detailed description of its proposed system for on-going quality assurance to § 9.674 (relating to quality assurance standards). See § 9.631(8) (relating to content of an application for an HMO certificate of authority). The Department has also changed the regulations to link the requirement that the HMO have and provide a detailed description of its proposed UR system to §§ 9.749--9.751 (relating to UR system description; UR system standards; and time frames for UR).

In subsection (b), the Department proposed that it publish notification of receipt of a complete application for a certificate of authority in the *Pennsylvania Bulletin*, and that a public meeting on the application might be held if the Department chose to do so. One commentator recommended that the discretionary public meeting on new HMO applications should be mandatory to better serve the public interest.

The Department has not changed the proposed subsection. The Department is providing for public comment, even though it does not intend to hold public hearings in all instances. This should be sufficient to protect the public interest.

One commentator supported the requirement in proposed subsection (c) that would give the Department additional time to determine what additional information is needed from a plan, since the regulations that are being repealed only gave the Department 10 days for this purpose.

One commentator supported the proposed elimination of the practice of deeming applications complete even though the Department might not have all the necessary relevant information relating to provider networks. See subsection (d). The commentator stated that the

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Department needed all information required by the regulations before providing a certificate of authority.

Several commentators raised concerns that proposed subsection (e) would not require the Department to conduct a visit to an HMO applicant, and that the Department could rely solely on external review by firm hired and paid for by the HMO.

The Department does conduct a readiness review of an HMO applicant before granting a certificate of authority; that may not in all instances entail a site visit. After consideration of the comments, the Department has included language in subsection (e) stating that it will conduct a site visit as part of its readiness review.

With respect to the comment concerning external review organizations, these organizations are selected and approved by the Department, and they do not review the plan until after the first year of enrollment activity. The Department does not and is not proposing to use them to conduct readiness reviews.

Section 9.633. Location of HMO activities, staff and materials.

The Department received several comments on this proposed section. Three commentators noted that the Department was proposing to repeal requirements for the position of medical director, and recommended the inclusion of these requirements in the final-form regulations.

The Department agrees that the regulations should contain qualifications for the position of medical director. The Department has included language in § 9.633(2) (relating to location of HMO activities, staff and materials) of the final-form regulations similar to that which is included in the regulations it is repealing. See repealed § 9.76(b) (relating to professional staffing of health maintenance organizations). Section 9.633 requires the HMO to identify a physician to serve as its medical director. Section 9.633(2) also requires the medical director to be licensed in this Commonwealth, and qualified to oversee the delivery of health care services in this Commonwealth. As did the regulation the Department is repealing, § 9.633(2) makes the medical director responsible for overseeing UR and quality assurance activities regarding coverage and services provided to enrollees, general coordination of the medical care of the HMO on behalf of the HMO and appropriate professional staffing of the HMO. Section 9.633(2) also requires the medical director to design protocols for quality assurance and makes the medical director responsible for the evaluation of quality assurance programs and continuing education requirements. This was also required by the regulation the Department is repealing.

One commentator recommended including qualifying requirements for quality assurance (QA) committee members.

Two commentators also raised concerns that the proposed amendments would have no standards for ownership of HMOs, and that owners and operators do not have to demonstrate prior experience in health care management.

Another commentator recommended that the Department reinstate the language it had included in 1999 draft regulations, a version of the regulations that the Department circulated

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before promulgating proposed rulemaking. That draft section related to the character and competency of owners and officials. The commentator also recommended that any HMO that employs an officer, director or other management person who has been convicted of a Federal offense as defined by Medicare regulations should be disapproved until the official is removed. It noted that the Federal Office of Inspector General could automatically exclude that entity from participation in Medicare.

The Department received several comments on proposed subsection (a), which would require an HMO to establish a board of directors, at least 1/3 of whom were enrollees of the HMO, within 1-year of the award of the certificate. Comments were divided into three separate topics: (1) the requirement for enrollees to be members of the board in 1 year or in 18 months; (2) the prohibition against undue influence and the requirement for diverse representation; and (3) the need to prohibit HMO employees from being enrollee members.

Four commentators remarked on the Department's failure to remove the requirement that an HMO have enrollee board members within 1 year of the certificate of authority from the proposed amendments, and replace it with an 18-month time period, as it stated it intended to do in the Preamble to the proposed rulemaking. One commentator supported the change, since the 1-year period was onerous for HMOs, three recommended the Department retain the 1-year time period. These commentators commented that the 1-year period would ensure that there were sufficient qualified individuals to serve as members of the board, and it was critical that plan be held accountable for actions from initial date of operation.

One commentator commented that proposed subsection (a) would exceed the Department's statutory authority. The commentator noted that the HMO Act only states that the board must be 1/3 subscribers and follow HMO's charter and guidelines. Therefore, the Department's addition of language requiring the selection process to be structured to secure "diverse representation of broad segments of the enrollees" and prevent "undue influence in the selection process by non-enrollee members of the board" would go beyond the HMO Act.

IRRC commented that the phrases "undue influence" and "diverse representation of broad segments" needed to be clarified. Another commentator commented that they should be deleted, as they were editorial in nature and invited litigation.

One commentator also recommended that the Department clarify in proposed subsection (a) that employees of the plan or board members could not qualify as enrollee board members.

After reviewing these comments, the Department has decided to delete this section. Since Insurance is the agency responsible for reviewing the organizational and business structure of the HMO, and has mechanisms in place to do so, there is no need for the Department to duplicate that function. The review of officers and directors of the HMO board is routinely addressed by Insurance, which, together with the Department, has authority over the certification of HMOs. The decision on this particular part of the application is within the jurisdiction of Insurance.

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One commentator recommended that the Department add language allowing the medical director or quality assurance committee to report quality or access problems to the board as soon as they were identified.

While the Department does not object to the QA committee going directly to the board if need be, the Department believes that the decisions on how reports of this nature are to flow within the corporation should be left to the corporation.

One commentator commented that decisions relating to medical necessity and coverage of emergency services should be made by emergency physicians licensed in this Commonwealth, actively practicing emergency medicine at least 20 hours per week. This commentator stated that there were no medical specialties similar to emergency medicine.

This comment is more appropriately addressed to § 9.672 (relating to emergency services). The Department has not changed either § 9.672 or this section. Now that the prudent layperson standard must be applied by plans, there is no need for a specialist to review emergency services. The standard is no longer what is a true emergency, but rather whether a prudent layperson would believe that an emergency existed.

Section 9.634. Delegation of HMO operations.

The Department received several comments on this proposed section, which has been renumbered as § 9.633 in the final-form regulations.

Seven commentators objected to the Department's elimination of specific enrollee/provider ratios from the regulations the Department is repealing. See repealed § 9.76. The commentators recommended that the final-form regulations contain specific requirements for plans to maintain sufficient staff to carry out functions required by Act 68, and that the Department impose these requirements on all plans, not just on HMOs.

One commentator disputed the Department's rationale for repealing several of these ratios included in the Preamble to the Department's proposed rulemaking in the commentator's general discussion on Subchapter G (relating to HMOs). The commentator stated that these standards were not obsolete, the requirements were not sufficiently dealt with at the individual HMO level through credentialing, and that the requirements of §§ 9.678 and 9.681 (relating to primary care providers; and health care providers) were not sufficient. The commentator stated that the same objective criteria were not present in these proposed regulations, and that there was a need to establish network enrollee ratios and standards for all HMO models.

This commentator further stated that failure to include a primary care provider/enrollee ratio, which must be used to determine network adequacy, would eliminate the Department's basis for disapproval of network adequacy.

The Department has decided against including specific provider to patient ratios in the regulations. Staffing levels at an HMO are reviewed through the certificate of authority application, (see § 9.631(11) and (14)), with on-going requirements that do apply to all plans in quality assurance and utilization review. See §§ 9.678 and 9.681. HMO staffing levels can and

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should vary significantly based on the technology available, the population served and the corporate structure. For example, the number of member services calls, and, consequently the staff required to answer the calls is much larger for Medicare+Choice and Health Choices enrollees who have more questions and concerns and issues than the general population. The technology used to route calls and assist member services staff can also significantly impact the number of calls a representative can take per day. The Department does not wish to dictate business operations at this level. The Department monitors effectiveness of operations through site reviews, audits and complaint investigations.

Further, the HMO regulations that the Department is repealing are not applicable to the current managed care environment in this Commonwealth. Those regulations require a primary care physician to enrollee ratio of 1:1,600, and overall physicians to enrollees of 1:1,200. These standards are relevant to staff model HMOs, a model in which physicians are employees of the HMO, and service only the HMO's enrollees. The ratios are not and would not be applicable to contracts with independent physicians who see patients with all types of insurance and are not able or willing to dedicate room in their practices for 1,600 patients of any particular HMO. To apply this standard today would mean that an HMO with less than 1,000 enrollees in one county need only have one primary care provider in that county. This also presupposes that the single primary care provider is willing and able to take 1,000 enrollees of one HMO. This is highly unlikely. This ratio does not support development of an adequate network promoting access and availability. Therefore, the Department declines to reinsert it, as it pertains to an HMO model no longer prevalent in the industry.

Further, the Department does not use physician/enrollee ratios for network review. The standards for network review are included in § 9.679.

One commentator also stated that plans should be required to maintain adequate numbers of staff in this Commonwealth. The commentator stated that plans do not want to spend time and money on tasks such as utilization review by appropriate specialists, answering requests for information, providing documents to which enrollees are entitled to have access and responding to complaints and grievances. Plans will assign people whose primary responsibilities are elsewhere, and these tasks will be delayed. This commentator stated that the regulations must include requirements for adequate staff, and that the proposed regulations allowed the plans to decide whether or not to maintain adequate staff. The commentator stated that the proposed regulations would probably result in State oversight only after a serious problem developed and complaints about inaccessibility had grown loud enough.

The Department has made no change to the proposed amendments to address these concerns. For reasons stated earlier, technology and innovation make it difficult to set minimum staffing standards in regulations. These standards may serve to stifle improvements in productivity and service by requiring outmoded, unproductive and inefficient standards.

Further, with respect to the fact that the comment addresses all plans, and not just HMOs, this section only addresses the Department's responsibilities in granting certificates of authority to HMOs. The Department only has certification authority over HMOs, and not other managed care plans. Assurance of adequate resources is required in the on-going quality assurance

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program (§ 9.674 (relating to quality assurance standards)), and in UR (see Subchapter K) both of which apply to all plans.

With respect to the concern that an HMO shall maintain adequate staff numbers in this Commonwealth, the Department has no authority to require that activities be done only within this Commonwealth. A plan is obligated to adhere to the requirements of the law and regulations with respect to services provided within this Commonwealth, regardless of where support activities take place. The Department's authority and oversight is not diminished by a plan's out-of-State activities.

One commentator raised concerns that the Department was proposing to eliminate qualifications for primary care physicians, contained in the regulations the Department is repealing (see repealed § 9.76). These include a requirement that a primary care physician must practice 50% of time as a primary care physician, and have practiced as a primary care physician for the previous 2 years.

The Department has decided not to change the proposed section to include qualifications for an HMO's primary care physician. Act 68 now defines the term "primary care provider." See definition of "primary care provider" in section 2102 of Article XXI. The Department has included Act 68's definition in its regulations, as well as additional requirements for primary care providers in § 9.678. The Department sees no need to retain standards for primary care physicians. The 50% practice requirement was to ensure patient access, and that the provider would be able to address primary care concerns. For example, a board certified internal medicine physician also has a subspecialty in cardiology. If this physician dedicates all patient hours to cardiology, the physician will not have sufficient access for general primary care concerns, and may not be keeping current with general primary care issues. Act 68, however, contemplates that a patient with a heart condition would receive approval for the patient's cardiologist to serve as the primary care provider. Rather than set an arbitrary standard in regulation which could prevent specialists from serving as primary care providers, the Department is requiring plans to adopt credentialing standards for who can and should serve as primary care providers, and what patient access protections should be in place, whether they pertain to a specialist or a primary care provider.

One commentator recommended that the Department keep the language in its 1999 draft regulations that would have required an HMO to have a place of business accessible to enrollees and providers, and personnel sufficient to respond to complaints, grievances, and urgent and emergent requests for assistance concerning the provision of health care services.

The Department has decided against including this language in its final-form regulations. The Department does review staffing and operations to ensure there are resources in place to respond to enrollee inquiries from the first day of operation.

One commentator recommended that the Department change the proposed time frame included in proposed paragraph (1) within which documents are to be made available from 48 hours, to 20 days, consistent with timing in civil suits. IRRC also commented on this proposed paragraph and asked the Department to explain how it decided upon 48 hours. IRRC also asked whether the Department considered using business days rather than hours. The

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Department has changed the language to require that documents be made available within 30 days, unless the Department determines that the matter relates to patient safety. In that case, the HMO shall provide the records within 2-business days.

With respect to the other comments, the Department is requiring that it be afforded access to the documents, not as part of discovery in a civil suit, but as the regulator responsible for the welfare of the citizens of this Commonwealth. If a serious problem arises which requires the Department to have access to the information quickly, 2-business days would permit the plan to have the documents either sent by some type of express mail, or brought by courier to the State, while still allowing the Department quick access.

The Department received two comments on proposed paragraph (2), which would require the medical director to be licensed in this Commonwealth, and qualified to perform the duties of a medical director in this Commonwealth.

One commentator recommended that the medical director not be required to be licensed in this Commonwealth, but merely be required to have a license in good standing.

The other commentator, IRRC, stated that there was no statutory requirement that a medical director be licensed in the Commonwealth. IRRC noted that some HMOs may have operations in other states and may employ physicians licensed in other states. IRRC asked what other factors qualified a physician to oversee delivery of health care services, and why Pennsylvania licensure should be required.

It is correct that there is no specific statutory requirement that an HMO with a certificate of authority in this Commonwealth have a medical director licensed in this Commonwealth. However, the Department has the responsibility for the oversight of quality of care provided or arranged for by an HMO, and to that end the Department has determined that a medical director licensed in this Commonwealth would be more aware of the rules and regulations of this Commonwealth. A medical director licensed in this Commonwealth would also be more familiar with the practice of medicine and delivery systems issues within this Commonwealth, as well as more in touch with the needs of Pennsylvania enrollees.

The Department also notes that the HMO regulations it is repealing required an HMO to have a physician as its medical director. Since 1 Pa.C.S. Part V (relating to Statutory Construction Act of 1972) defines a "physician" as a person licensed in this Commonwealth to practice medicine or osteopathic medicine (see 2 Pa.C.S. § 1991 (relating to definitions)), the regulations could have been read to require the medical director to be licensed in this Commonwealth.

IRRC also asked whether it was the Department's intention to require a separate medical director with separate license requirements to oversee those enrollees who work in this Commonwealth but reside in a neighboring state. If this was not the case, IRRC questioned the necessity of the reference to enrollees who are residents of this Commonwealth.

Another commentator also requested that the Department delete the phrase "residents of this Commonwealth," since not all enrollees are residents of this Commonwealth.

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The Department has deleted this language as unnecessary.

IRRC commented that it was not clear from proposed paragraph (3) how many health care providers on the HMO's quality assurance/improvement committee had to be licensed in this Commonwealth, and requested clarification. Proposed paragraph (3) would require the HMO's quality assurance/improvement committee to include health care providers licensed in this Commonwealth.

The Department has not changed the proposed amendments to specify an absolute number or percentage. The number of providers on the committee licensed in this Commonwealth is not as important as the undertakings and results of the committee with regard to assuring and improving quality. The Department does not wish to create an artificial ratio not related to the caliber of the committee and the results achieved. The Department has added language to clarify that at least one health care provider on the committee must be licensed in this Commonwealth.

Another commentator commented that the QA committee should only include Pennsylvania-licensed health care providers.

The Department has not changed the proposed paragraph to impose this as a requirement. Multistate plans frequently have National QA committees that determine policy based on National standards. This creates convergence and sharing of techniques, technologies and practice that are at the forefront of medical evolution. The Department cannot require plans to have only physicians licensed in this Commonwealth on a National committee. The Department is, however, requiring the medical director responsible for oversight of services in this Commonwealth to be licensed in this Commonwealth as that position involves daily oversight of and responsibilities for medical management activities, including utilization review of health care services. The person occupying that position must be aware of and familiar with the practice of medicine in this Commonwealth.

Section 9.635. Issuance of a certificate of authority to a foreign HMO.

This section has been renumbered as § 9.634 in the final-form regulations. The Department received six comments on proposed subsection (a), which would recognize that HMOs may delegate by contract HMO operations and that the Department has the ability to monitor quality of care and require corrective action of the HMO regardless of the contracted delegation.

The Department received one comment in support of the Department's authority to require renegotiation of contracts between an HMO and its contractors for delegated duties.

Several commentators commented on the lack of a definition for "HMO operations," which is a term used in the proposed amendments. One commentator noted that a broad interpretation of the term would result in HMOs having to file with the Commissioner every vendor or outsource contract, whether for printing, or advertising, or for any similar type of arrangement. This would be burdensome for plans, and for the Department.

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One commentator recommended that the Department use the following language: "An HMO may contract with any individual, partnership, association, corporation, or organization. A contract for the delegation of HMO operations does not diminish the authority or responsibility of the board of directors of the HMO, or the ability of the Department to monitor the quality of care and require prompt corrective action of the HMO when necessary."

One commentator stated that this proposed section appeared to be duplicative of the Pennsylvania Holding Company Act (40 P. S. §§ 991.1401--991.1413), under which HMOs must file management agreements with Insurance.

This commentator, as well as IRRC, recommended that if the Department did not delete the proposed provision, it should add several things. First, the Department should clarify what constituted a delegation of HMO operations subject to this provision. Secondly, the Department should limit the requirement that delegation agreements be submitted to areas specific to the Department's jurisdiction, for example, delivery systems, quality of care or access to care. Thirdly, the Department should clarify what agreements were likely to be produced, relative to other current regulatory requirements, under the Department, Insurance and Department of Public Welfare. IRRC also recommended that if the Department retained the provision, it define what contracts it will review under the HMO Act.

The Department has made changes to proposed subsection (a) for clarity and to cite to section 8(b) of the HMO Act (40 P. S. § 1558(b)), which defines by example the types of matters that are considered to be HMO operations. The Department will not attempt to define every arrangement considered to be a contract for the delegation of HMO operations, or seek to assume jurisdiction over every arrangement. The Department is simply saying that whatever delegation arrangements an HMO may make, those arrangements do not relieve the HMO from meeting its responsibilities to enrollees or its duty to correct deficiencies, and will not prevent the Department from regulating HMOs under the HMO Act and under these regulations with respect to work they seek to delegate. The Department has not said that it must review and approve every type of delegation of HMO operations, it has specifically stated, under subsection (b), that it will review contracts for the delegation of medical management. The Department has the authority over these medical management agreements because, among other reasons, they involve utilization review, and because of the need for these subcontractors to be certified by the Department.

One commentator noted that Insurance has traditionally been responsible for oversight of management contracts. The commentator requested clarification concerning how the Department and Insurance will coordinate regulatory oversight in regard to the delegation of HMO operations. The commentator asked whether the requirements of this section impacted current IDS arrangements and filing requirements, and recommended that, if this were the case, the changes should be specifically stated.

Another commentator commented that delegations should be listed with the Department rather than filed with Insurance, and should be limited to delegation of performance of covered services that relate to quality of care rather than administrative functions, which are corporate operational concerns.

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It is extremely unlikely that an IDS will contract to provide services without also requiring some autonomy or control over its own operations, over how resources are allocated to provide health care services, and how money is spent. To the extent this includes UR, this is a contract that must be reviewed by the Department under Subchapter J (relating to health care provider contracts), and will most likely not fall under this section, since it does not deal solely with operations, but involves the provision of services. If a contract, which would otherwise fall under this section, deals strictly with utilization review services and does not involve an arrangement with health care providers it is a medical management contract, and would be subject to the Department's review under § 9.675. Insurance, as co-regulator, will continue to carry out its duties and responsibilities by focusing on areas under its expertise and purview.

Section 9.636. Issuance of a certificate of authority to a foreign HMO.

The Department received several comments on this proposed section, which has been renumbered as § 9.635 in the final-form regulations.

IRRC commented that the HMO Act states that the Department may develop reciprocal licensing agreements with other states which permit audits, inspections and reviews of agencies from other states to determine whether the HMO meets Commonwealth requirements. IRRC recommended that the Department include in the final-form regulations standards related to this provision.

The Department has included in the regulations language which states that in the event or to the extent the Department and Insurance are able to arrive at reciprocal licensing agreements with other states, the requirements of the section may be waived or modified. See subsection (e).

One commentator stated that the Department should not require certificates of authority for foreign HMOs.

The HMO Act requires that foreign HMOs doing business in the Commonwealth must have a certificate of authority in this Commonwealth. See section 6.1 of the HMO Act (40 P. S. § 1556.1). The Department cannot alter a statutory requirement. However, an HMO licensed and operating solely outside of this Commonwealth, including issuing coverage to non-Pennsylvania employers, does not constitute a foreign HMO operating in this Commonwealth, even though some residents of this Commonwealth may have coverage through this out-of-State arrangement.

IRRC noted that although the proposed amendments would allow the Department to grant a certificate of authority to a foreign HMO if the Department is satisfied that it is fully and legally organized and approved and regulated under laws of another state and complies with requirements of this Commonwealth, proposed subsection (a) does not specify what documentation the Department needs to have to be satisfied. IRRC recommended that the Department include this information in the final-form regulations.

The Department rejects the recommendation. The Department will accept the application currently on file with the regulatory agency of the "home" state of the foreign HMO. The

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Department will contact that regulatory agency and verify whether the standards in that state match the standards set out in this Commonwealth. The Department has added language to this subsection that requires the foreign HMO to provide the Department with a copy of its application for licensure or certification on file with its state of domicile. This will allow the Department to review official documentation as it considers the applicant.

Several commentators, including IRRC, raised concerns with proposed subsection (c), which would permit the Department to waive or modify its requirements under the HMO Act and the proposed regulations. One commentator commented that the Department was proposing to allow secret waivers of statutory requirements by foreign HMOs without comment or public hearing.

Three commentators stated that the proposed amendments failed to ensure quality of care, since the Department would be allowed to waive requirements for out-of-State HMOs.

IRRC requested that the Department clarify how it would determine to grant a waiver of State requirements with respect to foreign HMOs.

The HMO Act specifically permits the Department and Insurance to waive the requirements of that act so long as the waiver or modification is consistent with the purposes of the HMO Act, and the waiver or modification does not unfairly discriminate on behalf of the foreign HMO. See section 6.1(b) of the HMO Act. The language in subsection (c) is taken directly from the HMO Act, with the exception that the Department's proposed regulation made reference to the HMO Act and to this chapter. The language has been revised to reference those chapters that deal with matters relating solely to HMOs under the HMO Act. It excludes the requirements of Act 68 from the waiver provision because the Department is not empowered by Act 68 to waive any of its requirements.

Further, because the Department accepts public comment on applications for certificates of authority for HMOs, the Department agrees that it would be useful to accept public comment on applications for foreign HMOs as well. The Department has included language in subsection (f) to allow for public comment concerning the application, including any potential waiver, so that the Department has the opportunity to consider those comments before the Department and Insurance grant a waiver.

Section 9.651. HMO provision and coverage of basic health care services to enrollees.

The Department received several comments on this proposed section.

Several commentators commented that the proposed section would fail to require HMOs to provide access to providers within 24 hours for urgent care.

Subsection (c)(1) does require access to providers within 24 hours for urgent care by requiring primary care providers to be available 24 hours-per-day, 7 days-per-week to provide services or to refer enrollees for services when necessary. Additionally, enrollees have the prudent layperson standard to protect them when they access care through the emergency room directly even when the ultimate diagnosis was less than a true clinical emergency.

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One commentator recommended that the Department delete the inclusion of skilled nursing care from inpatient services, since the two are entirely different. The Department rejected the recommendation, as it explains in its discussion on the comments on the definition of "inpatient services."

Another commentator commented that the proposed regulations would eliminate inpatient physician care and ambulatory physician care as a defined required basic health care service. This was unintentional. The definitions of "inpatient services" and "outpatient services" in § 9.602 have been revised to include professional services.

The same commentator raised concerns that the Department would allow an HMO to refuse to cover services prescribed by a licensed health care provider based on medical necessity. The commentator also raised concerns that the Department would not require that the denial be based on accepted medical practice, unlike the draft regulations it circulated in 1999. The commentator stated that the proposed section would allow HMOs to have unfettered discretion in defining medical necessity criteria and in applying it.

The Department has addressed the issue of definitions of medical necessity in § 9.677 (relating to requirements of definitions of medical necessity). Plans have the responsibility to define "medical necessity" under Act 68. This section addresses the types of services that must be covered as basic benefits.

IRRC commented that the terms "adequate," "appropriate" and "unreasonable" used in proposed subsection (a) were vague. Proposed subsection (a) would require an HMO to maintain an adequate network of health care providers through which it would provide coverage for basic health services as medically necessary and appropriate without unreasonable limitations as to frequency and cost. IRRC asked how the Department would enforce this provision and require compliance with Act 68 without more specific standards.

The Department has not made a change to the proposed subsection. The word "appropriate" is part of the term "medically necessary and appropriate," and the Department has declined to set a definition for that term for reasons that are discussed in commentary on § 9.677. Plans, however, are required to set a definition for this term under section 2111(1) of Act 68. The term, therefore, does not go undefined, although the definition may alter from HMO to HMO. Further, an enrollee who has an issue concerning the manner in which the term is applied may file a grievance.

Further, the Department's use of the terms "appropriate," "adequate" and "unreasonable" with respect to networks and network services are also sufficient, given the complicated nature of the task of determining the adequacy of networks. In any case, because the Department also sets out specific standards for what constitutes an adequate network in § 9.679, these terms are not vague. The difficulty with setting standards such as these in regulation is that the context of necessity is always unique to the enrollee, and for the provision of health care services, must remain so. Definition of the terms in regulations run the risk of setting standards that could serve to limit an enrollee's access to the care required more swiftly than other enrollees' typically need. (See *Pennsylvania Association of Township Supervisors v. Commonwealth, Department of Insurance*, 412 A.2d 675 (Pa.Cmwlt. 1980) (statute which

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used the terms, "equitable," "impartial," "inadequate" and "discriminatory" had adequate standards to guide the Commissioner in considering rate proposals, given the complicated nature of that task).

Another commentator requested that the Department clarify that services are provided according to a contractual relationship. The commentator recommended language stating that: "An HMO shall maintain an adequate network of health care providers through which coverage for medically necessary and appropriate basic health services is provided to enrollees in accordance with the benefits included in the enrollee's contract or benefit category."

The Department has rejected the recommendation. By statute, the HMO is required to provide at least the basic health services listed in the HMO Act and in these regulations. That cannot be further limited by contract.

Four commentators, including IRRC, raised issues concerning the language "customarily excluded by indemnity insurers" in proposed subsection (b). Two requested clarification of the language, including what it meant, who would evaluate whether the term applied, and how it would be evaluated now that commercial group products are not filed.

One commentator commented that the proposed subsection, which would permit an HMO to exclude coverage for services that was customarily excluded by indemnity insurers, appeared to suggest that HMOs must wait for indemnity insurers to add an exclusion before the exclusion becomes customary.

One commentator suggested that the subsection be deleted altogether.

One commentator commented that the proposed subsection was unsupported by Act 68, since consumers give up access to providers available under indemnity insurance to obtain more comprehensive and preventative services provided by managed care.

The Department has reviewed the language in proposed subsection (b) in light of the comments. The Department has deleted references to customary exclusions by indemnity insurers, and has simply stated that an HMO may exclude coverage for a service, except to the extent that a service is required to be covered by State or Federal law.

IRRC commented that there were no parameters defining the term "medically necessary" in proposed subsection (c). IRRC recommended that the Department consider identifying basic components required in the definition of "medical necessity" to ensure that the HMO's definition met requirements of Act 68. Another commentator recommended that the Department approve definitions of "medical necessity."

This has been more fully addressed in the discussion of comments on § 9.677 (relating to requirements of definitions of "medical necessity").

One commentator suggested that the first sentence of the proposed subsection (b), "An HMO may exclude coverage for the services as are customarily excluded by indemnity insurers, except to the extent that a service is required to be covered by State or Federal law,"

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be amended to read that HMOs must either provide or arrange for the provision of basic health care services, to clarify that most HMOs do not provide services through its employees.

The Department has added the language "or arrange for the provision of" after the words "shall provide" for the purposes of clarification.

One commentator commended the Department for including language in proposed subsection (c)(1) that would prohibit an HMO from requiring an enrollee to use a participating service, including an ambulance service, in an emergency.

The same commentator recommended the inclusion in the final-form regulations of a requirement for disclosure, and a clarification of the extent of coverage, as described in the statute. The commentator stated that to be consistent with the statute, an HMO shall disclose to enrollees and health care providers financial and other responsibilities regarding emergency services. The plan must also provide reasonable payment or reimbursement for emergency services. The Department has not made the recommended change. The Department has addressed the issue of payment in § 9.672 (relating to emergency services). Insurance has addressed the issue of disclosure in its regulations. See 31 Pa. Code § 154.16(h).

The commentator also recommended that the Department add two sentences to clarify that the prudent layperson standard should be used as the definition of medical necessity for the provision and coverage of emergency services, without prior authorization: "In considering emergency services, the plan shall provide coverage according to the prudent layperson standard;" and "Coverage of emergency services is not subject to prior approval."

The Department has not added the recommended language here. This language already exists in § 9.672. Further, emergency services are determined by application of the prudent layperson standard. See definition of "emergency services" in § 9.602. The Department has, however, added in subsection (c)(1) a cross-reference to § 9.672 to eliminate the possibility of confusion.

The commentator also recommended substitution of the word "shall" for "may" in subsection (c)(1) to strengthen the language of the proposed subsection as it was in the draft 1999 regulation. The proposed subsection would read "The plan shall not require an enrollee . . ."

The Department has not made the change. The phrase, "may not" is a stronger negative than the phrase "shall not."

IRRC commented that the regulations the Department was proposing to repeal had a standard for general acute care inpatient hospitalization services of 90 days per contract or calendar year, and asked why that standard had not been included in subsection (c)(3), which would list inpatient services as a basic health service. Another commentator stated that there was no statutory justification for this repeal.

After considering the comments and the language in repealed § 9.72(a)(3) (relating to basic health services), the Department has decided to retain the 90-day minimum requirement for covered general acute care inpatient hospital days since the Department believes this would

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be beneficial to enrollees to retain. For purposes of this section of the regulations, inpatient general acute care does not include behavioral health services.

One commentator commented, with respect to proposed subsection (d), that benefits could be defined to include the right to be evaluated and stabilized in an emergency department as required by the Emergency Medical Transportation and Action Labor Act (EMTALA). Proposed subsection (d) would state that "An HMO shall provide other benefits as may be mandated by State and Federal law." The commentator recommended adding the language "reimbursement for" directly after the opening phrase: "An HMO shall provide"

The Department has not made any change to the proposed subsection. The Department does not intend to require plans to pay what is charged. Plans are free to negotiate reimbursement terms with providers. The Department is concerned with the integrity of the coverage. Further, the Department will not list all currently mandated benefits, as this list is subject to change more frequently than the Department wishes to revise the regulations. The HMO shall provide whatever benefit a law requires it to provide.

Section 9.652. HMO provision of other than basic health care services to enrollees.

One commentator requested that the Department clarify the extent to which an HMO may offer other product lines independently of the provision of basic health care services. For example, may an HMO offer its dental program/product to a member of an enrolled group who does not select enrollment in the basic HMO benefits package? May an HMO offer its dental plan to a group which does not offer its HMO benefits package as an option to employees? May an HMO offer a PPO product?

This proposed section was intended to apply to benefit packages offered by HMOs and those services, than can be offered in addition to basic health services not instead of basic health services. The other questions raised by the commentator are more appropriately addressed to Insurance.

One commentator commented that this proposed section failed to require the disclosure of basic services to potential enrollees.

This proposed section was intended to implement provisions of the HMO Act that discuss what services are to be provided to the enrollee, not what disclosures were to be made to potential enrollees. See section 4 of the HMO Act (40 P. S. § 1554). Section 2136(a) of Article XXI (40 P. S. § 991.2136(a)) does require managed care plans to make disclosure of benefits, limitations, and exclusions and other information to enrollees and potential enrollees upon written request. This is further addressed by Insurance in 31 Pa. Code § 154.16. The Department has made no change to the proposed section based on this comment.

Two commentators commented on the lack of access norms for appointments in the proposed section. One of these commentators commented that the definition of "network" would be inadequate. The commentator stated that the proposed section would not specify what providers and specialists would be required to be available, whether networks would be required to include adult and pediatric providers for each specialty, what appointment access

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standards would apply and how far an enrollee would have travel for a referral. Another provider also commented on the lack of access norms for appointments.

IRRC recommended that the Department define what would constitute reasonable access to a network as required by paragraph (1).

Another commentator commented that the proposed amendments should include sufficient standards for primary care provider training and for an adequate network.

The Department requires plans to develop access and availability standards, which are highly dependent on the individual patient's condition and not suitable for government regulation. Reasonable patient access to a magnetic resonance imagining or MRI scan could range from same day to within 2 weeks depending on the nature of the suspected illness or condition. An arbitrary standard such as 3 days could be much too long for some patients and much too aggressive for others.

With respect to access to pediatric and adult specialty providers, the proliferation of pediatric subspecialties is a relatively recent development that has not fully evolved. There are times when the patient's condition absolutely warrants a pediatric subspecialty, but that is not always the case. For example, there are very few, if any, otolaryngologists, (commonly known as ear, nose and throat specialists or ENTs) who have not provided care to children with otitis media. The fact that there is now a subspecialty called pediatric otolaryngology does not mean that a general ENT is no longer qualified to continue treating pediatric patients. The Department's focus is on requiring the plan to have adequate and accessible health care services, not on dictating treatment terms or appropriate providers.

Further, the Department's network access standards are included in § 9.679. The Department has cross-referenced that section in paragraph (1) for clarity. The Department is requiring the plans to set standards for provider training and specialists as primary care providers that they must audit against. See § 9.683 (relating to standing referrals or specialists as primary care providers).

One commentator requested clarification concerning what entity would be responsible for offering and conducting the complaint and grievance process with respect to nonbasic health services offered by the HMO through contracts with ancillary service plans, such as vision or dental, which would not be subject to the proposed regulations. See proposed paragraph (3).

If an HMO chooses to offer a nonbasic, or supplemental, health service as part of its benefits package, the HMO is responsible for providing the Act 68 grievance and complaint process, regardless of whether or not it subcontracts with an ancillary service plan to provide the network, benefits or administration. The Department has made no change to the proposed paragraph based on this comment.

Section 9.653. Use of copayments and coinsurances in HMOs.

The Department received several comments on this proposed section. Two commentators supported the Department's proposed repeal of the copayment language in § 9.72(b), now

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repealed. One of these commentators noted, however, that the proposed section would deal with copayment as well as coinsurance. The commentator stated that approval of coinsurance was not authorized by statute.

The commentator also recommended that the Department add language which would state that the Department's consideration of whether the request to charge copayments would detract from the availability, accessibility, or continuity of services would be from the economic position of the lowest wage enrollee in the plan.

One commentator commented that an HMO should have the freedom to meet the expectations of the market place in terms of the levels of copayment and coinsurance available as part of a benefits package.

Seven commentators raised concerns that the proposed section would not set standards for the review of copayments and coinsurances.

One recommended that language establishing standard or a maximum threshold be added to the regulation.

One stated its concern that the proposed section would fail to limit copayments.

One commented that the proposed amendments would not list criteria the Department would use to determine impact on availability, accessibility or continuity of services or how it would ensure that the request constructively would advance the purposes of quality assurance, cost effectiveness and access. If the Department intended to review these matters, it should alert the regulated community to standards it would use to make these decisions.

One stated that the proposed amendments would fail to provide for the review and monitor of copayments, set maximum limits, and provide for the HMO to periodically update and disclose copayments to potential enrollees and enrollees.

One stated that the proposed section would be too vague, and needed to be clarified to ensure patient access to care.

One commented that the proposed section would be weaker than the language of the regulations the Department is repealing because the proposed amendments would not include the percentages in repealed § 9.72(b), and because the Department would only review these matters if Insurance requested the Department to do so.

One commentator recommended that copayments and coinsurances should be the same for patients seeking emergency medical care at participating and nonparticipating facilities. The commentator recommended that the standards should not be set so high as to dissuade prudent laypersons from using emergency medical services.

Several commentators commented that the Department should review coinsurances and copayments for their impact on access to care, and the regulations should state specifically that the Department is doing so. These commentators stated that any potential negative effect

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of excessive copayments and coinsurance amounts would impact quality of care concerns, which are fully within the jurisdiction of the Department. These commentators recommended the removal of language, which would only permit the Department to review these matters at the request of Insurance. One commentator recommended that the Department retain the right to establish maximum coinsurance and copayment amounts.

One commentator stated that the proposed section should contain a much stronger statement that there was a need to limit copayment to avoid undertreatment. This commentator noted that the PPO regulations state that copays of over 20% can result in undertreatment. The commentator stated that if percentages were a problem in the Department's previous regulations, other methods should be used to accomplish the same result.

Two commentators questioned whether the proposed section was superfluous. One recommended deleting the copay section since Insurance may ask for the Department's opinion without it, and language to that effect should be in Insurance's regulations, and not the Department's. The other commented that since Insurance already reviews rates, this proposed section could impose two levels of review as part of the regulatory approval process, causing unnecessary delays and extra costs.

IRRC asked whether the Department had approval authority over an HMO's request to use copayments and coinsurances in its benefit structure. IRRC also asked why it was necessary for the Department to state in its proposed amendments that it could perform an interagency review on this particular issue. IRRC asked whether there were other aspects of HMO operations that the Department have reviewed at Insurance's request, what they were and how they were carried out.

The Department has decided to delete this section. The authority for the review of these matters rests with Insurance since approval of copayments and coinsurances is directly related to the approval of rates and benefits.

Section 9.654. HMO provision of limited networks to enrollees.

The Department received several comments on this proposed section, which has been renumbered as § 9.653.

IRRC recommended that the Department define the term "limited subnetwork" in the definition section. Several other commentators also requested a definition of the term.

One commentator requested clarification of the term "limited subnetworks." The commentator commented that it was subject to many interpretations, and asked whether it meant closed panel products only.

IRRC also noted that the Department used both the term "limited network" and the term "limited subnetwork" in proposed subsections (a) and (b). IRRC recommended that the Department use one term.

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The Department does not need to add a definition of "limited subnetwork" to § 9.602, as the definition is included in the language of subsection (a). It is a network that includes only selected participating health care providers. The Department has added language to the subsection to clarify the definition.

The Department agrees that it should be consistent with terms, and has chosen to use the term "limited subnetwork." The Department has made the necessary changes to proposed subsections (a) and (b).

With respect to the question concerning closed panel products, the term "limited subnetworks" applies to both open and closed panel products. The limited subnetwork must still meet the minimum standards regardless of product line or model type.

One commentator raised concerns that the proposed section would have a negative impact on children with disabilities. The commentator criticized the proposed section for not imposing limits on how far an enrollee might have to travel to a provider, or how long the enrollee might have to wait to get an appointment. The commentator stated that failure to regulate these matters could result in burdensome travel and paperwork requirements on children with disabilities and their families, especially if they do not have a choice of plan.

Again, the limited subnetworks described in the proposed section would still be required to meet the minimum access requirements in § 9.679, which do limit travel for frequently utilized services. The Department has added paragraph (5) to clarify that a limited subnetwork shall meet standards for adequate networks and accessibility.

One commentator stated that there was no statutory basis for allowing HMOs to provide a limited network. The commentator stated that the process included in proposed subsection (b) was inadequate to protect consumers.

The statute neither mandates nor prohibits limited subnetworks, so that the Department can neither require an HMO to have them, nor prohibit it from using them. The Department can attempt to place some limitations on limited subnetworks, for example, requiring an HMO to notify enrollees of coverage so that they do not suffer out-of-pocket losses from failing to understand the terms of the plan and the network limitations.

One commentator commented that the proposed section would sanction discrimination on the basis of race or payment source. The commentator noted that plans can bid on Medicaid contracts, shield mainstream providers from serving the Medicaid population, provide lower capitations for higher risk enrollees and so on.

The Department's regulation does not allow discrimination. Any limited network must continue to meet the minimum access standards in § 9.679. Limited subnetworks are generally offered in cases when the employer wants to concentrate services in a smaller number of providers than the overall larger plan network. This could be to decrease costs and premiums, to keep benefits affordable or it could be because the employer believes the subnetwork represents the best performing, highest quality providers in the area. In all cases, the limited subnetwork must meet the minimum network standards, there must be clear notice to

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enrollees and enrollees cannot be financially penalized with lesser coverage when services are not available through the limited subnetwork.

One commentator recommended that proposed paragraph (3) could be strengthened by replacing the proposed language with language that states that the HMO is required to have "an adequate number and distribution of network providers with the training and experience to provide care. . . ." The commentator noted that the proposed paragraph would require an adequate number and distribution of providers, but expressed concern that HMOs often fail to include an adequate number or distribution of providers who have training and experiences to meet needs of enrollees. The commentator stated that the addition of this language would address that issue.

Adequate training and expertise must be determined by the plan in conjunction with the individual enrollee's circumstances and needs. The Department can not set into regulation standards for training and expertise sufficient to cover all possible and potential enrollee needs. In the event an enrollee has a concern regarding adequacy of the plan's providers, the Department will investigate.

One commentator raised concerns that the requirement in proposed subsection (a) that an HMO obtain prior approval of a limited network before offering it would negatively affect future development and implementation of the options. The commentator noted that these networks were a result of purchaser preference and demand. At a minimum, the commentator asked the Department to define "limited subnetworks" and give direction on when prior approval is necessary.

The Department must review the adequacy of the network for the population to be served. If the Department did not do so, HMOs could offer products with less than minimally adequate networks.

The Department received several comments on proposed subsection (b)(1), which would require the HMO to ensure adequate disclosure to potential enrollees of the limitations in the number of the provider's participating.

IRRC commented that the term "adequate," which the Department used to describe disclosure of participating provider information to enrollees, is vague, and that the Department should provide more specific parameters. IRRC also commented that disclosure must be consistent with disclosure requirements in Insurance's final-form regulations. Four other commentators noted that the Department had failed to set disclosure standards. One of these noted that the standards should include requiring the inclusion of disclosure language in a provider directory, or marketing and enrollment materials.

Several commentators noted that the proposed amendments would not require disclosure to current as well as new enrollees. One of these commentators expressed concern that because of this, the regulations were not protective of older persons. By allowing plans to limit networks beyond the amount needed for certification, the commentator stated that the Department was taking a step backward from the legislative intent of the General Assembly.

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One commentator commented that the disclosure to enrollees of limited networks would mean little since many employees have no choice.

The Department's regulations do not permit a plan to limit the network below the minimally acceptable threshold in a service area and retain the ability to operate in that area. The Department's prior approval process is intended to prevent this from occurring. Further, if the Department receives complaints of access problems, the Department has the ability to, and does, investigate and take action against the plan when warranted.

The Department did not intend to provide a notice requirement in this section that would allow enrollees to avoid limited networks. The Department is aware that is the employer's choice to offer these networks. The Department has no authority to forbid the networks from existing, but can ensure that HMOs provide adequate access and availability of services. The disclosure requirement is intended to protect enrollees from out-of-pocket costs by ensuring they are notified of the network's limitations, and the possible economic impact to them if they obtain services outside of the network. Therefore, the Department has changed the proposed amendments to require notice of coverage limitations in marketing and membership material that must be issued in advance of the effective date of coverage. This notice must also be contained in membership material to current enrollees, for example, in handbooks, newsletters and announcements. See subsection (b)(1).

The Department agrees that this disclosure should go to current as well as potential members, and has revised the proposed subsection (b)(1) to require this.

Further, these limited networks must meet the access standards in § 9.679. The Department has added language to clarify that fact, and to clarify that disclosure must be consistent with Act 68, and with Insurance's regulations. The Department has added a reference to 31 Pa. Code § 154.16. See subsection (b)(1).

Four commentators stated that the wording of proposed subsection (b)(2) made it clear that the Department would approve networks without a single provider in them, if the HMO could otherwise provide the service. They stated that proposed subsection (b)(2) would require an HMO to provide or arrange for the provision of services to an enrollee at no cost other than a routine copayment if a covered service were not available within the limited network. One of these commentators stated that this would permit an HMO to restrict enrollees to inadequate networks.

One commented that this would give an enrollee no choice in the matter of choosing a provider. One also commented that proposed subsection (b)(1) would allow an HMO to restrict access by limiting some enrollees to a potentially inadequate network.

One commentator also commented that the proposed subsection (b) would allow a plan to arrange for the service out-of-network without giving the enrollee a choice of provider. The commentator stated that the HMO could get the lowest price from a noncredentialed provider and force the consumer to receive services there.

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The comments made by the commentators on this proposed subsection (b)(1) are incorrect. The Department cannot and would not permit a limited network without a single provider. Limited network products must meet the minimum network requirements. As the Department has stated, limited subnetworks are generally developed at the request of employers as discussed above to either reduce premiums and retain benefits or to develop a network of those providers viewed as most highly qualified. HMOs do not place enrollees in these limited network plans; the employer or the enrollee must select the plan. More importantly, the Department requires the limited network to meet minimum access standards. The Department has added subsection (b)(5) to clarify that the standards in § 9.679 apply.

With respect to out-of-network usage, it is not the intention of the Department to allow an HMO to force enrollees to obtain services from uncredentialed providers. In a basic 2-tier limited subnetwork arrangement, enrollees obtain their highest level of coverage when accessing care within the subnetwork. There may be no coverage available when the enrollee obtains care outside of the subnetwork, or there may be reduced coverage. There can be a multiple-tier plan that would provide the highest level of coverage when services are obtained through the subnetwork, reduced coverage when an enrollee goes to providers in the overall network who are not part of the subnetwork, and further reduced or no coverage when the enrollee goes to providers who do not participate at all with the HMO.

In any of these scenarios, the Department's position is that the enrollee cannot be penalized economically when the plan has no provider on the panel from whom the enrollee can receive care and the highest level of coverage. In other words, it is not the enrollee's fault if the enrollee needs something for which there is no network provider. The plan has the option to recruit a provider into the network or provide the benefit at a network rate when a nonnetwork provider is used. Having no provider option to offer, the plan is not in a position to force the enrollee to use any one nonnetwork provider over another. It was not the intention of the Department to allow this to occur. The Department has added language to subsection (b)(2) stating that the HMO is to provide for the service at no additional out-of-pocket cost to the enrollee.

IRRC commented that the Department used the term "adequate" to describe number and distribution of network providers in subsection (b)(3), and that the term was vague. Proposed subsection (b)(3) would require a limited subnetwork to have an adequate number and distribution of network providers to provide care that is available and accessible to enrollees within the service area.

Again, for reasons already discussed, the Department must consider adequacy based on the individual needs and circumstances of the patient. The Department has minimum standards for adequate networks set out in § 9.679. The Department has added language to subsection (b)(3) referencing § 9.679 to clarify that these requirements apply.

IRRC and four other commentators commented that the Department failed to define "reasonable traveling distance" in proposed subsection (b)(4). The proposed subsection would state that enrollment would be limited to enrollees within a reasonable traveling distance to limited participating network providers. The commentators stated that this would permit limited networks.

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The Department requires the limited network to meet minimum access standards. As stated previously, the Department is adding subsection (b)(5) to clarify that the standards in § 9.679 apply to the provisions of this section.

Section 9.655. HMO external quality assurance assessment.

The Department received several comments on this proposed section, which has been renumbered as § 9.654 in the final-form regulations.

Four commentators raised concerns about the Department's proposed repeal of repealed § 9.93(c)(5), particularly the provision which required a statistically significant sample of medical records be done during the external review. These commentators commented that the proposed section reduced the scope of the external review by dropping this requirement.

The Department has not changed the regulation to reinsert a requirement that statistically significant sampling be done. These reviews are done to monitor recordkeeping in the physician office. Statistical sampling is not necessary for this; rather, the random review of records will provide enough information to be able to assess the provider's adherence to the record keeping standards of the plan.

Seven commentators also raised concerns that the proposed section contained no requirement for corrective action when violations are detected.

The regulations in § 9.606 do include mechanisms for corrective action if problems are found during external reviews. There is no need to reiterate this at every step of the regulations where corrective action might be needed. Section 9.606 provides several options for how to compel correction, including the ability for the Department to require a corrective action plan from an HMO. How and when the Department chooses to use these options, however, is within the Department's discretion.

The Department received over 20 comments on proposed subsection (a). Proposed subsection (a) would require an HMO to have an external quality assessment conducted by an external quality review organization acceptable to the Department within 18 months of receipt of a certificate of authority, and every 3 years thereafter, unless otherwise required by the Department. These comments fell into three categories: (1) whether the review was an independent review; (2) the change from 1 year to 18 months; and (3) questions concerning the use of an independent review organization.

Independent External Quality Assurance Assessment

Several commentators raised concerns that the proposed subsection (a) would provide for an external review to be done by a reviewing organization hired and paid for by the HMO, and that the HMO, rather than the Department, would determine the scope of review. They averred that the review process was therefore flawed in that it was not an independent review.

The Department disagrees with the comments that the process is not independent, and is driven by the HMO. Although an HMO is required to pay for the review, the Department sets

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the standards for the review by approving the review organization performing the review and the standards used by that organization. The Department participates in the reviews to ensure compliance with the standards included in the HMO Act, Act 68 and these regulations. Also, the Department must review the findings of the independent organization, and decide whether to accept or reject those findings.

18-Month Review Period and 3-Year Review Period

Several commentators raised concerns that the proposed subsection would change the time frame for the initial quality assurance review from 12 months, under the regulations proposed for repeal, to 18 months. The commentators stated that this would leave consumers in new untested plans that had not been subjected to any scrutiny. They also stated that enrollees would not be protected from unacceptable practices, since there would be no readiness review and the Department might or might not perform a site visit.

Several commentators also raised concerns that proposed subsection (a) would not require ongoing reviews even if there were serious problems, and that the second external review required of a plan would not be until a period of 3 years after the first.

IRRC noted that the Preamble to the proposed rulemaking stated that the Department had chosen these time frames to be more consistent with Nationally recognized accrediting bodies. IRRC asked for the Department to identify these bodies.

One commentator recommended that the requirement for external quality review be at 18 months after enrollment of the first subscriber, rather than 18 months after receipt of a certificate of authority. The commentator stated that this would ensure sufficient data for a meaningful review.

The Department agrees that the first external review should occur within a certain time frame after the first enrollment has taken place, and has changed the language of proposed subsection (a) accordingly. The Department has not changed the proposed time frame, however. Subsection (a) requires an HMO to have an external review 18 months after enrollment begins. This reflects the NCQA requirements as the Department stated in the Preamble to its proposed rulemaking. The NCQA is currently the only organization approved by the Department to perform external quality assurance reviews. For the NCQA to do a valid review, it must base its review on 12 months of utilization data, which can only be gathered from the time enrollment begins.

Further, the Department does perform readiness reviews, and has added language stating that it will perform readiness reviews prior to approving a certificate of authority. See § 9.632(e). The Department has also added language to the regulation stating that it will conduct a site review 12 months following the approval of a certificate of authority even if there are no enrollees. See subsection (a)(1). The Department has also added language to allow it to perform site visits in instances where more than 18 months from the issuance of a certificate of authority the plan continues to have no enrollment. See subsection (a)(2). Lastly, the Department has added language to make certain that if more than 24 months go by without enrollment, the HMO cannot enroll members until the Department has conducted a site visit.

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See subsection (a)(3). Because of these additional Department reviews, the impact of this 6-month change on enrollees should be negligible.

Further, the requirement of a site visit in the nature of a licensing visit every 3 years is not unusual in the area of health licensure. The Public Welfare Code (62 P. S. §§ 101--1553) limits the term of a license of a drug and alcohol abuse treatment facility to 1 year. See section 1009 of the Public Welfare Code (62 P. S. § 1009). The Health Care Facilities Act (35 P. S. §§ 448.101--448.904b) limits the length of a license to a 1-year period with respect to health care facilities other than hospitals and a 2-year period for hospitals, or to the dates of licensure which coincide with Nationally recognized accrediting agency accreditation (3 years for hospitals). See sections 804(d) and 809(a)(i) (35 P. S. §§ 448.804(d) and 448.809(a)(i)). The Department makes a licensure visit, or expects an accrediting body to make a licensure visit of a health care facility at 1, 2 or 3-year intervals, depending upon the type of facility. This does not mean that the Department never visits those facilities at any other time, nor does it mean that the Department does not have the authority to do so.

With respect to the comments that the proposed section does not require a review to be done, even if a serious problem arises, the language of subsection (a) would give the Department the ability to require formal external reviews whenever it finds them necessary. The subsection specifically states that these formal external reviews will occur every 3 years, unless otherwise required by the Department. The Department may always, under the regulations, conduct an investigation, including a site visit, whenever that visit is necessary. As in the regulation of health care facilities, the Department has the ability to investigate any complaint (whether or not it is filed under Act 68) made against an HMO by conducting a site visit, as it has stated in § 9.605 (relating to Department investigations). The Department has the ability to investigate and conduct site visits as it sees fit, including to investigate problems uncovered during the external review or upon review of the quarterly or annual reports. The Department does not need to set in regulation what events will trigger such an investigation. In fact, for purposes of monitoring and investigation, it is more effective not to set these triggering events in regulations. It provides the Department with greater flexibility.

Review organizations approved by Department

Several commentators, including IRRC, recommended that the Department make the list of acceptable quality review organizations available to the public. Several commentators, including IRRC, recommended that the Department publish a list of these organizations in the *Pennsylvania Bulletin* or the instructions for obtaining the list.

One commentator asked that, if the Department expanded its list of review organizations, the Department include a provision in the regulations permitting plans to request review by an alternative organization if the plan can demonstrate good cause, such as a conflict of interest.

Another commentator asked whether the Department would make available criteria used to evaluate and identify acceptable external quality review organizations.

The Department agrees that the list of approved external quality review organizations (EQRO) should be published in the *Pennsylvania Bulletin*. It has added language to this

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section stating that the list will be published annually. At the present time, NCQA is the only approved EQRO. See subsection (g). The Department will consider making the criteria it uses to approve EQROs available, most likely through a request for qualifications (RFQ) process. The Department is currently considering issuing an RFQ.

When the Department has more than one EQRO approved, plans will be able to choose from those that are approved to the extent the EQRO and the plan do not have conflicts of interest. Any limitations or requirements will be published at the time the list is published.

The Department received three comments on proposed subsection (c), which would allow an HMO to combine the external quality assurance assessment with an accreditation review offered by an external quality review organization acceptable to the Department, if certain conditions are satisfied.

One commentator requested clarification on the latitude the Department would grant regarding external reviews conducted by National accrediting agencies. The commentator stated that the proposed provision seemed to imply that where the requirements of National agencies differed from the regulations, the Department could request the entity to incorporate areas specific to the regulations or assist Department staff in the review. This could occur, for example, with the processing of enrollee complaints and grievances as defined by the regulations.

IRRC and another commentator asked what the assessment factors required by the Department would be. IRRC also recommended that the Department list these specific factors that must be considered, for example, review of a statistically significant sample of medical records.

Although a plan is required to pay for the review, the Department sets the standards for the review by approving the review organization performing the review and the standards used by that organization. The Department has clarified this subsection by adding language that states acceptable reviews must include information that enables the Department to determine compliance with the HMO Act, the PPO Act, Act 68 and the regulations. The Department will supplement the standards of the reviewing organization as necessary by jointly performing reviews against the standards included in Act 68 and these regulations to ensure compliance with that act. The Department has added language to subsection (d) to clarify that the reviews are to assess the quality of care and effectiveness of the quality assurance program developed by the plan under § 9.674 (relating to quality assurance standards), and to assess compliance with Act 68, the HMO Act and these regulations.

As already stated, the only EQRO currently approved by the Department for performing external quality assurance assessments is NCQA. The Department's regulations contain much of what is required by NCQA. Its standards are well known and they are available to the regulated community and to any interested person. There are areas in which the NCQA process is not sufficient for the Department to gauge compliance with Act 68, the HMO Act and these regulations. Therefore, to the extent necessary, the Department will be supplementing the external review with agency audits as appropriate. With respect to the specific comment concerning statistically significant samples, the Department does not intend to include this

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requirement in the regulations for the reasons discussed in the general commentary on this section.

The Department received several comments on proposed subsection (d), which would state that the assessment would study the quality of care being provided to enrollees and the effectiveness of the quality assurance program established by the HMO.

One commentator recommended that the Department add the language "as measured by patient outcomes" to the end of the proposed subsection.

Several commentators complained that proposed subsection (d) does not include any standards other than that the external assessment would be conducted on the quality of care being provided to enrollees and the effectiveness of a quality assurance program. The commentator noted that no mention was made of regulatory compliance under Act 68. The commentators recommended that the proposed subsection should include the scope of the review in detail.

The Department will perform reviews along with the external review organization to ensure that the plan is in compliance with the requirements set out in Act 68, the HMO Act and these regulations. As stated previously, the Department has added language to the proposed subsection to stress that the assessment is being done for these reasons. The Department has explained its decision not to include patient outcomes more fully in the discussion on comments on proposed § 9.674 (relating to quality assurance standards). While the Department is concerned with the question of patient outcomes, the state-of-the-art concerning measuring, quantifying and analyzing outcomes is less well developed than would be prudent to address in these regulations.

The Department received several comments on proposed subsection (e), which would set requirements for who is to receive a copy of the external quality review assessment.

Several commentators commented that proposed subsection (e) would not provide for public access to the external review report.

One of these commentators noted that other health care providers were required to post deficiencies in public places, and that outcomes were available to the public on the Department's website. The commentator suggested that the Department was permitting private reviewers to do the review instead of the State and keeping the outcome private.

One commentator commented that the public should have access to reviews in a format that is understandable and provides a basis for consumers to compare plans.

The Department's requests for plans of correction, correspondence between the Department and the plan relating to the plan of correction and follow-up documentation from the plan are available to the public. See subsection (f). The external review organization will always provide feedback to the plan. It is important to note that the reviews are not structured as pass or fail.

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Subsection (f) also provides that the Department will not make the review containing proprietary information available, unless authorized by the HMO or directed to do so by a court of law. To take advantage of this provision, the HMO must, however, request that the Department maintain specific information as confidential and proprietary, since the Department cannot determine on its own what information the HMO may consider to be proprietary. Those areas of commendation or positive performance recognized in the report, such as patient outreach programs that improve birth outcomes, generally reflect plan innovations that are proprietary trade secrets, the details of which HMOs do not want made available to their competitors. While the public may benefit from selecting plans with such initiatives, enrollees are generally made aware of such programs and offerings in the marketing literature without the detailed information on the program operations and performance benchmarks.

The Department is attempting to coordinate the resources to develop information that would be useful to the public in this way. The Department hopes to be able to achieve this goal within the next 2 years. There does not need to be language in regulation for this to occur.

IRRC recommended that the Department either add a subsection regarding penalties to this section, or cross reference § 9.606, since proposed subsection (e) would not include a penalty if the HMO would fail to file a copy of all interim and final reports on the assessment with the Department.

Another commentator commented that although proposed subsection (e) would require that a copy of the external review report go to the Department within 15 days, the subsection would not require the HMO to provide a corrective action plan.

The Department has not added language referencing a penalty to this proposed subsection. The regulations and statute have sufficient language to permit the taking of corrective action as necessary by the Department should the HMO fail to comply with this section. With respect to the comment regarding corrective action plans, the Department has added language to proposed § 9.606 to acknowledge that HMOs may be required to provide corrective action plans with respect to violations of the HMO Act or the regulations implementing that act. There is no need to repeat that language here.

One commentator commented that proposed subsection (e) would not require that a copy of the assessment report go directly to the board, but rather, the proposed regulation would require it to go to the plan's senior management. Since the board is responsible for policy, the commentator stated that the board should be given the report.

As the senior managers are often responsible for day-to-day HMO operations, including correcting problems, they should also have a copy of the report. The Department has added language to the proposed subsection requiring senior management to provide a copy to the board.

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Subchapter H. Access and Availability

The Department received more than 400 comments on this proposed subchapter.

Section 9.672. Emergency services.

The Department received several comments on this proposed section. One commentator found the regulation to be generally positive. Two commentators commented that the proposed regulation should be consistent with Insurance's regulation on the same topic.

The Department's regulation is consistent with Insurance's. The Department and Insurance have different responsibilities, based upon their different functions, expertise and authority. Consequently, the regulations are not and should not be exactly the same. Plans covered by the regulations are required to comply with both Insurance's and the Department's regulations.

One commentator commented that the proposed section would limit access to emergency services; however, it did not explain how or why this was so. The Department believes that this regulation implements Act 68, and ensures that plans afford coverage for emergency services.

One commentator recommended that the Department include language stating that providers may advocate for patients and that they may obtain written consent to do so at the time of treatment.

The Department has not changed the regulation to incorporate the recommended addition. Providers may always advocate for patients. The Department has included language that would permit providers to obtain consent to file a grievance on the enrollee's behalf at the time of treatment, in § 9.706 (relating to health care provider initiated grievances).

One commentator raised general issues with respect to coverage and payment for emergency services not necessarily tied to the wording of the proposed section. The commentator requested that the Department state in the regulations that providers of ambulance services are to be paid directly for services rendered. The commentator stated that direct payment should be made to both participating and nonparticipating providers. The commentator noted that, since 911 responders are often nonparticipating, payment is made to the patient. Further, the commentator commented that it, by law, was unable to directly bill city residents. The commentator asked what recourse a nonparticipating provider has to pursue when an HMO denies the claim and the bill is uncollectable.

The Department does not have the authority to address the issue of whether the provider or patient should receive payment from the plan. A contracted provider can bill patients but only when the service or amount is not covered by the plan. The Department does not prohibit, either by regulations or through statute, the billing of city residents.

The commentator also asked whether a 911 call precipitating an ambulance transport could be considered a binding unwritten contract between the enrollee and the ambulance service so that an ambulance service could appeal plan referrals to pay for ambulance trips. The commentator asked whether the proposed regulations would require all 911 calls to be

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considered emergencies, and who would determine what an emergency was. The commentator stated that it was having a difficult time obtaining enrollee consent to allow it to appeal grievances.

The Department has no authority to compel enrollees to cooperate with collection activities or consent to allow a provider to initiate a grievance. Act 68 requires that consent be obtained from an enrollee before a provider may file an appeal. See section 2161(a) of Article XXI. The enrollee must have the opportunity to consider whether or not the enrollee wishes to cede appeal rights to another party. The Department would not support the concept of a 911 call creating a binding contract allowing the provider to appeal without enrollee consent. This would violate the terms of Act 68, which requires a written consent.

Further, since Act 68 defines "emergency services" by using the prudent layperson standard, and not all 911 calls may meet that standard, neither 911 ambulance transport or 911 calls can automatically be considered to be emergencies under Act 68. The plan is required, under Act 68 and the regulations, to apply the prudent layperson standard in determining whether or not an emergency existed. If the plan fails to do so, the plan is liable for sanctions under Act 68.

The commentator also expressed concern with the denial of ambulance transport bills. It noted that it must respond to emergency calls regardless of whether the call is later determined to be an emergency. The commentator stated that if it is denied payment, it has no recourse.

An ambulance transport that meets the prudent layperson standard for an emergency service is a covered service under Act 68, without more regulation on the Department's part. If the plan fails to apply this standard, the plan may be sanctioned under Act 68.

Two commentators commented that the proposed amendments should include language concerning notification from the emergency provider to the enrollee's plan that an emergency service was provided, as Insurance did in its regulations. Notification requirements are a part of section 2116 of Article XXI, and were included by Insurance in 31 Pa. Code § 154.14(e).

Because Insurance was issuing language on the issue relating to plan notification by providers, the Department did not want to inadvertently contradict or undermine it. Upon reviewing the comments, however, because hospital notice is a utilization review issue over which the Department does have responsibility, and for clarity, the Department has added to this regulation language regarding hospital notice from 31 Pa. Code § 154.14(e). See subsections (f)--(h).

IRRC also commented that the proposed section should include the language of 31 Pa. Code § 154.14(f) in its section on emergency services. Because this section requires disclosures to enrollees and providers, the Department has not added the language from 31 Pa. Code § 154.14(f) to its regulation on emergency services.

One commentator commented that although section 2116 of Article XXI states that a plan shall pay all reasonable and necessary costs, the proposed amendments did not propose criteria for determining what constitutes a reasonable and necessary cost. The commentator

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recommended that the regulation states how the Department will monitor reasonable and necessary costs.

The Department has made no change to the regulation to address this concern. The plan must honor coverage for the enrollee at the covered level of benefit and must exercise judgement in determining what claims for services reasonably relate to the emergency situation regardless of whether the provider is a participating provider, or a nonparticipating provider. Plans may retrospectively deny payment for services provided that the services were not medically necessary or appropriate. The provider or enrollee may then file a complaint or grievance.

One commentator recommended that the regulation include a limited set of signs and symptoms that could reasonably precipitate a visit to the emergency room, and suggested that these could be limited to those that occur most commonly but might or might not be an "emergency," for example, dizziness. The commentator stated that this would allow for the consistent application of the prudent layperson standard by providers and payers.

The Department has not made this change to the regulation. It is impossible to specify each and every symptom that would justify an emergency room visit under the prudent layperson standard. This type of clinical information, which may change from time to time, is not the type of information that lends itself to regulation. Further, the Department would have to list every symptom for every condition as related to the individual enrollee, and those that were not on the list, even if they should have been, would not need to be considered emergencies. That would serve to inadvertently deny coverage in situations where it is warranted.

Secondly, the prudent layperson standard is to benefit the enrollee, not the plan or provider. The enrollee should not have to memorize a list of symptoms and conditions that could permit him to go to the emergency room and be covered by his insurer. The whole purpose of the prudent layperson standard was to avoid this type of categorization, and to enable the enrollee to go to the emergency room when the enrollee reasonably felt seriously threatened by illness.

One commentator recommended that the Department add language to proposed subsection (a) requiring plans to respond in a timely fashion for the authorization of post-stabilization care. The Department has made no change to this subsection, since the topic of preauthorization or concurrent authorization requests is addressed in § 9.751 (relating to timeframes for UR).

One commentator recommended that proposed subsection (a) be revised to address access to emergency services by requiring all insurance plans, not just managed care plans, to adopt the prudent layperson standard, and include the definition of that standard in all marketing materials, policies, and consumer and provider communications.

The Department has not made this change to the regulation, since Act 68 does not give the Department the authority to mandate that all insurance companies utilize the prudent layperson standard.

One commentator supported proposed subsection (b), which proposed to prohibit denial of claims for lack of prior authorization for emergency services.

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One commentator suggested that plan coverage of services in the emergency department should be required without preauthorization by the primary care provider. The commentator stated that to require otherwise would be burdensome for the hospital and would interfere with the efficient delivery of care in the emergency department. The commentator stated that preauthorization should be unnecessary given the suspicious nature of signs and symptoms with which the patient presented.

It was not the Department's intention to imply that conditioning plan coverage for emergency services on preauthorization from a primary care provider was permissible. The Department has deleted the language "from a gatekeeper or the plan itself" from the proposed subsection to clarify that a plan may not require prior authorization from a primary care provider in this situation.

Three commentators stated that proposed subsection (c) should have used the words "a plan shall" use the prudent layperson standard, rather than "a plan may use" the standard. The Department has made no change to the regulation, since the word "may" in this subsection was a misprint, and was corrected by a publication in the *Pennsylvania Bulletin* the week following the publication of the proposed rulemaking. One commentator made mention of the correction.

Several commentators, including IRRC, commented on the phrase "adjudicating related claims . . ." in subsection (c). One commentator claimed the reference was unnecessary. IRRC and another commentator stated that the term "related" was unclear and should either be eliminated or clarified. Other commentators recommended that the Department use the word "adjudicating" rather than "adjudication."

One commentator recommended that the Department use language in section 2(c) of the act of July 11, 1996 (P. L. 655, No. 112) (40 P. S. § 3042(c)) (Act 112) for clarity, since the language in the proposed subsection could be misconstrued. Section 2(c) of Act 112 states in pertinent part that "an insurer shall consider both the presenting symptoms and the services provided in processing a claim for reimbursement of medical services."

The Department has changed the regulation to use the word "adjudicating" rather than "adjudication," found in the December 25 correction. (See 29 Pa.B. 6470). The Department has not deleted the word, however. "Adjudication" or "adjudicating" is the process of evaluating a claim for payment in terms of the enrollee benefit contract and applicable provider contract (if any). It is important for the regulation to convey that a plan must provide for the prudent layperson standard in such a decision-making process. Without it, the prevailing contract could require an exclusion that would violate Act 68. Related claims are those claims from ambulance, facility and professional services that were reasonable and necessary for treatment during the emergency.

Further, payment for services that were not medically necessary may be denied and the provider or enrollee may then file a complaint or grievance to contest the determination and obtain coverage. To require coverage of all services would bind a plan to cover services that were extreme, unnecessary, unrelated or dramatically different from the emergency event. For

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example, a patient could go to the emergency room for a possible heart attack, and while there receive services for the removal of a mole, which is an unrelated condition.

One commentator also commented that it was essential that a plan review documentation including presenting symptoms and services provided. The commentator recommended that this be done through the use of a universal form on which symptoms and services could be documented.

Although the Department acknowledges that a universal form would be sensible, the Department has no authority under Act 68 to develop and require use of a form.

One commentator supported proposed subsection (d) for including emergency transportation and related emergency care provided by ambulance services as emergency services.

Several commentators raised issues concerning lack of language in the proposed subsection referencing stabilization, evaluation, and testing. IRRC and another commentator noted that these services had been defined differently by Insurance. Insurance's regulation states that a plan must pay all necessary costs, including evaluation, testing, and, if necessary, the stabilization of the enrollee. IRRC commented that the Department's proposed regulations were less comprehensive than Insurance's. IRRC recommended that the Department reference section 2116 of Article XXI to ensure payment for all services properly classified as "emergency services."

The Department agrees that language referencing stabilization, evaluation and testing from section 2116 of Article XXI should be included in this section. The Department has revised subsection (d) to include language from Insurance's regulations which states that coverage for emergency services, provided during the period of the emergency, will include evaluation, testing, and if necessary, stabilization of the condition of the enrollee.

One commentator also stated that Act 68 and the regulations could create problems with respect to the EMTALA. First, it commented that language in Act 68 which states that "if an enrollee's condition has stabilized and the enrollee can be transported without suffering detrimental consequences or aggravating the condition . . ." requires more than stabilization before transfer can occur. See section 2116 of Article XXI. The commentator recommended adopting EMTALA, which states that stabilized means that no material deterioration of the condition is likely, within reasonable medical probability, to result from or occur during the transfer of the individual from a facility. The commentator stated that the physician treating the patient must decide whether and when the patient is considered to be stabilized for purposes of transfer or discharge, and that decision must be binding on plan.

Further, the commentator stated that Act 68 may give the provider the option not to treat, since it states that "if an enrollee seeks emergency services and the emergency health care provider determines that emergency services are necessary, the emergency health care provider shall initiate necessary intervention to evaluate and, if necessary, stabilize the condition of the enrollee . . ." See section 2116 of Article XXI. The commentator stated that Federal law requires a medical screening examination for all persons that present to an

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emergency room. It recommended that the Department make it clear that Federal law must be followed.

The Department has not changed the regulation. All Federal and Commonwealth laws must be satisfied, with or without the statement in the regulations. Presumably, the initial screening required by EMTALA is how the provider will "determine" if emergency services are necessary as required by Act 68. There is no conflict between EMTALA and Act 68, and the provider is charged with complying with both statutes.

The Department received one comment in support of proposed subsection (e). Another commentator commented that the word "may" in this subsection should be replaced with the word "shall." The Department has not changed the regulation, since use of the words "may not" is appropriate. For statutory construction purposes, the phrase "may not" is more prohibitive than the phrase "shall not."

One commentator took exception to the Department's use of "rate" in the preamble and "benefit" in the regulations which would suggest that the Department was requiring noncontracted hospitals to accept the "rate" paid by the health plan as payment in full. One commentator supported the proposed amendment for requiring payment at the same benefit level for services provided regardless of whether the provider is contracted with the plan or not.

Several commentators suggested that the Department should clarify that enrollees receive the same benefit level for either emergency services provided by a nonparticipating provider, or for services for which there are no participating providers capable of performing the service.

One commentator recommended the addition to proposed subsection (f) of language regarding what services are covered under emergency services and what the plan's payment obligations are for those services. The commentator raised concerns that because plans must cover services provided by nonparticipating providers at the same level of benefit as services provided by participating providers, there would be no incentive for organizations to become participating providers, and costs would increase. The commentator recommended that the Department add language requiring nonparticipating providers refusing to contract with plans to accept plan rates for services.

Based upon reexamination of the language in the statute and Insurance's regulations, along with consideration of the comments, the Department is deleting section (f) and modifying section (d) to more accurately reflect the statute and Insurance's regulations. The Department does not have sufficient authority under Act 68 to require noncontracted providers to accept plan reimbursement rates as payment in full nor can the Department require plans to pay the full amount charged if the provider does not have a contract with the plan. This would be tantamount to a benefit mandate and could easily lead to facilities refusing to contract with plans for emergency department services in an effort to force plans to pay full billed charges for emergency services. The Department is not prepared to issue a benefit mandate.

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Section 9.673. Plan provision of prescription drug benefits to enrollees.

The Department received numerous comments on this proposed section. One commentator supported the provisions of this proposed section that would require the plan to disclose to an enrollee or prospective enrollee within a specified time limit from when the inquiry is made, as to whether a particular drug is on its formulary and the recognition that disputes about exceptions to the formulary should be treated as grievances.

One commentator commented that the proposed section was not protective of older persons, since it permitted plans to impose drug formularies without requiring them to tell prospective members whether their medications would be covered.

The Department appreciates the concern expressed by this comment, however, the Department believes it has done what could be done within the constraints of the language of Act 68 to ensure that information is provided to all enrollees albeit by enrollee or prospective enrollee request. Subsection (a) of the regulation requires a plan to disclose to an enrollee that it uses a formulary and that limitations may result. Subsection (b) requires the plan to tell an enrollee, prospective enrollee or health care provider, upon request, if a particular drug is or is not on the formulary and if not, what other drugs in the class are covered or how to access the formulary. The Department has added language to the proposed section to allow for a verbal as well as a written enrollee or prospective enrollee request, to provide greater access to necessary information for enrollees to make informed decisions.

Several commentators stated that proposed subsection (a) should require plans to inform prospective enrollees if the list of available drugs is to be strictly limited. One commentator commented that it was insufficient for the proposed subsection to require notice of potential limitations in the formulary. The commentator urged that information on all drug exclusions should be provided to current and potential enrollees. One commentator stated that the marketing material should also include the procedure for obtaining an exception to the drug formulary.

The Department has made no change to proposed subsection (a). Disclosure of the existence of a formulary and what the requirement to use a formulary entails in the marketing material does make the information available to prospective enrollees. Disclosure of a list of all drugs excluded by the formulary would be a prohibitively large amount of information of questionable usefulness to the vast majority of enrollees, and extremely expensive to provide. Disclosure of the procedure for requesting an exception to the formulary is not included in Act 68 as an automatic disclosure, but must be made available to the enrollee upon written request.

Further, subsection (b) requires a plan to answer a prospective enrollee's inquiry about a specific drug. The Department has also added the requirement that the plans provide a list of those drugs in the same class that are on the formulary in any negative response, or instruct the enrollee how to obtain access to formulary alternatives, for example, through use of a website. This serves to give the enrollee and prospective enrollee useful information about what alternate drugs are covered by the plan rather than a simple answer that the requested

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drug is not on the formulary. Enrollees may then discuss the formulary options with their prescribing physicians and make informed decisions.

Several of the comments on subsection (b), including one from IRRC, related to the Department's proposed requirement that a plan respond in writing, within 30 days of its receipt, to an enrollee's or prospective enrollee's request concerning whether a specific drug is on the formulary. All of these commentators commented that the time period was too long, and some suggested time frames of from 1 day to 5 days.

Two commentators commented that potential enrollees should be able to obtain classes of disease specific drugs included on the formulary immediately upon a verbal or written request.

The Department recognizes that most inquiries and responses are verbal. In fact, it has been suggested that a written response should not be required. Plans are able to satisfy the enrollee by a verbal response at the time of the call, therefore, the enrollee has the necessary information. However, written notification is the only way to confirm that the activity did occur, and within the required time frame. The Department recognizes that some plans do have formularies on the Internet and can respond more quickly, however, the Department has decided to adhere to a maximum of a 30-day written response time. Further, the Department agrees that plans should be able to accept a verbal request. The Department will continue to require the plan to provide a response in writing, even if the information is provided at the time of the verbal inquiry. Although health care providers are generally provided with the formulary, the Department also agrees that a health care provider should be able to make the request for a patient. The Department has made changes to the proposed subsection to implement its decision on these matters.

One commentator commended the Department's formulary exception process. The commentator also recommended that the Department require that a formulary exception be granted by the plan when an enrollee has a chronic condition that is difficult to manage and has been finally stabilized on another medication.

Several other commentators recommended changes to the exception process including: that the Department specify conditions when a plan must approve an exception; that Department approval of the exception process be required; that the exception process be separate from the grievance process; that coverage must be provided if the drug is medically necessary; that plans consider information from other persons, including family, when reviewing for medical necessity; that plans be prohibited from forcing providers to use the formulary; that plans be prohibited from denying coverage for a drug because it is not on the formulary; that specific time frames for processing an exception request be set, ranging from 1-business day to 48 hours; that all denials of requests for an exception to the drug formulary be processed as expedited grievances; and that providers be given notice of proposed formulary changes along with the opportunity to comment. Additional comments included: recommending requirements that the plan's formulary committee include a primary care physician in active practice and licensed in this Commonwealth; that the enrollee be provided coverage for the excluded drug throughout the exception request and appeal processes; that an enrollee getting drugs later excluded through changes to the formulary receive continued coverage under a

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"grandfathering" provision, and, that a consistent and uniform policy regarding amounts of drugs to be dispensed be required across all plans.

One commentator also recommended changing the language to state that a provider "may request" to prescribe and obtain coverage rather than "may prescribe and obtain coverage."

The Department reviewed the comments, and agrees that a time limit should be set on the exception request process. The Department has added language to proposed subsection (c) requiring that exception requests be processed within 2 business days of receipt, consistent with a prospective utilization review request (see section 2152(a)(4)(I) of Article XXI (40 P. S. § 991.2152(a)(4)(I)), and that a denial must include the basis and clinical rationale for the decision. See section 2152(a)(6) of Article XXI. The Department will not amend the regulation to provide that coverage will be required during the review period just as it will not require coverage for any other health care service under prospective review. The Department has added language, however, to clarify that if the exception to the formulary is granted, the plan must provide coverage for the exception to the extent that it has disclosed it would in the description of coverage, benefits, and benefit maximums required by section 2136(a)(1) of Article XXI (40 P. S. § 991.2136(a)(1)).

The Department is also requiring plans to provide at least 30 days notice to health care providers of formulary changes that remove drugs from the formulary, unless the Food and Drug Administration (FDA) either approves a new drug or withdraws approval of a drug. This will serve as notice to providers that patients should be transitioned to alternate medications on the formulary or that formulary exceptions must be requested. See subsection (e).

With respect to the comment that the regulations should require plans to provide a comment period before making changes to the drug formulary, and require plans to include a physician on the formulary review committee, the Department's authority is limited to the requiring that a plan set up an exception procedure to seek coverage of nonformulary drugs. The Department cannot require plans to allow a comment period or require the plans to include a primary care physician licensed in this Commonwealth and in active clinical practice on the review committee. Further, once a plan deletes drugs from the formulary, the Department cannot require the coverage to extend beyond the effective date of the change, but the Department can require 30 days advance notice in instances when drugs are removed from the formulary, and it has done so.

With respect to the comment concerning prohibiting plans from requiring physicians to prescribe from the formulary, physicians are not limited to prescribing only those drugs on a formulary. Further, the Department is unaware of any instance in which a provider contract requires or "forces" the provider to prescribe only formulary drugs. The Department, however, is unable to require coverage for any drug a physician prescribes. This would have the effect of mandating a benefit, which the Department has no authority to do. The Department has, however, included in the regulations the conditions under which a plan must consider an exception to provide coverage for a drug not included.

Commentators, including IRRC, recommended that the Department add language to proposed subsection (d) requiring that the plan provide its policy and process for obtaining an

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exception to enrollees and prospective enrollees upon request. One commentator recommended that the policy and process also be sent to nonparticipating providers.

The Department has added language to implement the first recommendation. As to the second comment, the Department's original intent was to require automatic distribution to participating health care providers of the plan's policy and process for obtaining an exception to its drug formulary even though Act 68 only makes this item required upon request. The language in this subsection was limited to providers because the exception process is to be a process by which a provider may prescribe and obtain coverage for certain drugs and types of drugs enumerated in subsection (c).

Seven commentators, including IRRC, questioned the proposal that all refusals to grant exceptions should be treated as grievances. Several commentators commented that if a drug is not covered as result of an exclusion the member should be directed to file a complaint. Others commented that the denial of an exception should always be considered a complaint.

After reconsideration of this issue, the Department agrees that challenge to a plan's refusal to grant a formulary exception may not always be a grievance, however, it may not always be a complaint. If a drug, class of drugs or drugs used to treat a specific condition are specifically excluded from coverage in the enrollee contract, appeals for coverage of specific exclusions would be considered complaints, as the issue is a contractual limitation regardless of medical necessity and appropriateness. If the appeal involves the medical necessity and appropriateness of one drug versus another, the appeal is a grievance and must be processed as a grievance. The Department intends to categorize as grievances all requests for formulary exceptions that were based upon medical necessity and appropriateness. The Department has changed the language of this subsection to clarify whether an appeal is a complaint or grievance.

One commentator requested clarification of whether this provision would apply to closed formularies. This subsection applies whether or not the formulary is closed.

Section 9.674. Quality assurance standards.

The Department received many comments on this proposed section. One commentator was pleased that the proposed regulations required quality assurance programs. Several commentators, including IRRC, commented on the lack of specific standards or outcome measurements in the proposed regulations. Several of these commentators stated that the requirement that plans have a quality assurance process in place and follow that process was insufficient for quality assurance purposes. These commentators stated that the Department should be involved in the determination of quality standards and the evaluation of quality. One commentator recommended that the Department require plans to have a quality improvement plan when quality assurance standards are not met.

For over 10 years, all health plans in this Commonwealth have been reviewed and assessed by the NCQA according to its quality assurance/quality improvement (QA/QI) standards. The NCQA is the only entity currently approved by the Department to conduct external quality assurance assessments. The NCQA's review includes evaluation of a plan's quality

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management and improvement program, including the structure, operations, provider contracting, access and availability of providers, member satisfaction, health management systems, clinical practice guidelines, continuity of care and coordination, clinical measurement activities, intervention and follow-up for clinical issues, effectiveness of that program and oversight and performance of any subcontractors. The NCQA's quality assurance standards also include standards for utilization management, credentialing and recredentialing, member rights and responsibilities, preventive health services and medical records. These NCQA standards do not set quality goals, but rather focus on meaningful structure, process and systems that must be present, documented and verifiable in a legitimate, thorough, committed, integrated and responsible QA/QI effort.

The Department believes that QA/QI is, and must be, a cyclical and constant process of evaluation, goal setting, development and implementation of interventions, performance measures and reevaluation of goals. The QA/QI is the continuous and progressive advancement toward goals designed in pursuit of the very best that can be achieved. The focus of a continuous quality improvement program is the relentless drive to attain 100% perfection. Regulatory standards will serve to define minimally acceptable quality to the degree that quality can be defined at this point in time given current knowledge of healthcare and healthcare delivery. Due to rapid advances in medical technology and treatment, such standards may serve to chain plans to outmoded or possibly unsafe practices simply because regulations require it. For example, to require that all children be fully immunized by the age of 2 represents the best thinking and current state of medicine at the present time. This thinking may be revised to raise the age at which full immunization should occur or to lower it, based on scientific advances. Plans would be forced to choose between regulatory compliance or the dictates of Nationally recognized standards of care. And while it is true that regulations can be amended, the rapid advances in medicine would likely make this an annual if not semi-annual occurrence should the Department start setting performance standards in regulation.

Additionally, the state-of-the-art of measuring and defining quality is by most accounts in its infancy. Quality is most always defined on a highly individual and therefore subjective level. As an illustration, a surgeon may have successfully reattached a severed hand, which results in moderate mobility for the patient. The surgeon believes this to be a quality outcome. The patient may not be able to retain employment unless able to grasp objects, and the patient, therefore, believes the outcome to be poor quality because the patient has less than full mobility. A prosthesis which would have allowed the patient to grasp objects would have allowed continued employment and could have been a more preferable and therefore a more quality outcome from the patient's perspective.

The Department believes that the approach it has taken in the regulations, imposing requirements for a meaningful, sustainable and dynamic quality program accountable to the board of directors and the agency for results as well as process, is a more realistic approach to achieving continuous quality improvement than attempting to define a set of quality standards in regulation.

Several commentators commented on the lack of a consumer satisfaction survey in this section. All plans currently are required to undergo an external quality assurance assessment by an agency approved by the Department. The NCQA is, and has been, the only agency

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approved to perform these reviews for the last 10 years. Therefore, all plans are reviewed consistently and equally against NCQA requirements. One of these requirements is to conduct a member satisfaction survey using the Consumer Assessment of Health Plans Survey (CAHPS) survey instrument and standardized methodology, developed independently by a consortium of Harvard Medical School, RAND, Research Triangle Institute, Westat and the Agency for Healthcare Research and Quality. In addition to requiring periodic assessment of consumer satisfaction through the external quality assurance assessment review, the Department will be conducting its own survey of member satisfaction using this standardized survey tool in fiscal year 2000--2001 and intends to make the results available to the public.

One commentator raised concerns about the fact that the Department relies upon external reviews by the NCQA, or another approved accrediting body. The commentator commented that this external review was being done by an accrediting body hired by the plan and paid for by the plan. The commentator also stated that the plan determines the scope of review.

A plan does not determine the scope of review. Rather, the Department determines the scope of review when it evaluates and approves accrediting bodies to perform external reviews. By evaluating the NCQA standards and requirements and by approving the NCQA to conduct external quality reviews, the Department has defined the scope of the review not the plans. See § 9.654 (relating to HMO external quality assurance assessment).

Several commentators recommended the addition of specific language concerning the quality assurance plan, including standards for health promotion, detection of disease, injury prevention, and early identification of special chronic and acute care needs. A few commentators also recommended including in this section maximum appointment waiting times for all types of health care services. One commentator recommended that the QA plan require fair utilization standards that would be applied consistently and equitably, but with attention to the individual. This same commentator recommended that the Department add three clinical improvement study activities and a minimum of ten quality improvement initiatives to the regulation. The commentator also recommended that the Department add a requirement that plans include a "medical necessity" definition that complies with Act 68, and provides quality health care for enrollees of all ages, including those with chronic health care conditions.

The Department agrees that health promotion, detection of disease, injury prevention, clinical improvement activities, quality improvement initiatives and early identification of special chronic and acute care needs should be included in the regulation as components of a quality assurance program. It has added this requirement as subsection (c), but has not specified the number of initiatives in each category that a plan must undertake each year. The Department does not want to set a minimum number in regulation that could rapidly prove insufficient or substandard for the purpose of improving healthcare services. The Department has also added the requirement that the plan notify health care providers and enrollees of these standards, and that the plan involve health care providers and enrollees in updating the QA plan.

Concerns about development and application of fair and consistent utilization review standards are addressed in subsection (c)(1)(v). That regulation requires a plan to set access and availability standards, approved by the plan's quality assurance committee comprised of health care providers, and to conduct an annual study of access and availability to be included

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in the plan's annual report of quality assurance activities. See subsection (b)(10). The Department will continue to closely monitor the access and availability standards, studies and audits. The Department has not, however, set appointment times in standards. Plans are not solely in control of this dynamic which is extremely variable and highly dependent on the existing delivery system in a community, the overall demographics and health care purchasing habits of a community, seasonality stressors, introduction and proliferation of technology, and provider motivation.

One commentator recommended that the Department delete the language in proposed subsection (b)(1) that states a description of the plan's quality assurance program must be provided upon request, and replace it with language requiring the information to be submitted at the time of the application for a certificate of authority, or when changes to the QA program are made. This would allow the Department and interested parties to review the information.

After reviewing the language of the proposed paragraph, the Department has decided to revise the regulations to address the commentator's recommendation. Information relating to studies, evaluation of results, actions recommended and implemented, and aggregate data are more appropriately included in subsection (b)(10), which requires that the plan annually provide a report of the annual quality assurance activities to the plan's board and to the Department. The Department has, therefore, moved that language from subsection (b)(1) to subsection (b)(10). The Department has also revised § 9.604 (relating to plan reporting requirements), to make it clear that the description of the quality assurance program (subsection (b)(1)), the description of the annual quality assurance work plan (subsection (b)(9)) and the annual report of quality assurance activities (subsection (b)(10)) are submitted to the Department as part of the annual report. See § 9.604(a)(9). Two commentators supported the proposal in subsection (b)(3) that the activities of the plan's quality assurance program be overseen by a quality assurance committee that includes plan participating physicians in active clinical practice.

Two other commentators recommended that the Department change the proposed regulation to require health care providers or professionals other than physicians to be a part of the committee. One of these commentators also recommended that participating physicians not employed by the plan should also be included on the committee.

The Department reviewed these comments, and agrees that the quality assurance committee would benefit from a broader array of health care providers participating on the committee. The Department has changed the language of the regulation to require the committee to include plan participating health care providers instead of just physicians. This will allow for greater involvement by all providers participating in the plan. Further, if plans choose to use a treatment team approach and involve nonphysicians on the committee, the Department would not object.

With respect to the comment that participating physicians not employed by the plan be included in the committee, the Department has made no change. The prohibition against plan employment for members of the committee is not necessary, as the function of the committee is to review clinical issues and not business practice. Further, if this suggestion was made in an attempt to avoid conflict of interest, it would not be enough to prohibit physicians employed

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by the plan from serving on the committee. The Department would also have to prohibit a participating provider since participating providers can and do draw significant income from reimbursement for health care services provided. The Department has reinforced the purpose of and charge to the committee in the regulations; it believes this will reinforce the duty of those on the committee to serve as practicing physicians first and foremost.

Two commentators recommended that the Department define "active clinical practice," since it is used in subsection (b)(3) and in other parts of the regulations. The Department agrees that it would be useful to include this definition, and has included the definition from Act 68 in § 9.602.

IRRC commented on proposed subsection (b)(4), stating that the Department needed to define the appropriate individuals and their responsibilities regarding quality assurance structures and processes. The Department has not changed this proposed paragraph. The Department cannot define the organizational structure of the corporation and has no desire to get to this level of detail. It is up to the plan to define the appropriate individuals to participate in the QA process, the relationships within the organization and how their responsibilities are to be defined and assigned.

IRRC commented that proposed subsection (b)(9) and (10) were similar, and recommended that they be combined. Paragraph (9) pertains to the plan's duty to report to the Department its quality assurance work plan, while paragraph (10) pertains to the plan's duty to report on its quality assurance activities to the plan's board of directors and the Department.

The Department has reviewed proposed paragraphs (9) and (10). The Department has decided against combining these paragraphs. The Department requires the details of what QA activities are to be undertaken, and how the plan proposes to carry out these activities. The board of directors should be reviewing the results of the activities in addition to the Department. The plan may, if it chooses to do so, combine these reports, if the plan notifies the Department that it is combining the documents. Other revisions to paragraph (10) previously discussed further warrant the separation of the two paragraphs.

Several commentators had general comments relating to the proposed subsection. One commentator commented that the 3-year review period for external reviews was too long, and that annual reporting was necessary. Another commentator recommended that the Department evaluate each plan's quality improvement efforts for effectiveness on an annual basis and make the results of that evaluation public.

The Department does require annual reporting. The annual report by the QA committee to the board of directors is part of the annual report sent to the Department by the plan, and is available to the public. See § 9.604(a)(9) (relating to annual reports). Further, the Department will review the plan's annual quality assurance work plan, or schedule of activities, including objectives, scope, and planned projects or activities for the upcoming year. See § 9.674(b)(9) (relating to quality assurance standards.)

One commentator recommended that the Department reconcile proposed subsection (b)(10) with proposed § 9.604. The commentator commented that the section made sense in fulfilling

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responsibilities under section 2111 of Article XXI; however, the combined reporting requirements in proposed § 9.604 and this proposed section go beyond what was envisioned by Act 68. The commentator stated that the reports were not needed by the Department to ensure compliance with that act.

The Department has reviewed both sections, and finds no inconsistencies. The sections may be read together, and together require that the Department be provided with sufficient information to carry out its responsibilities under the HMO Act, the PPO Act and Act 68.

Section 9.675. Delegation of medical management.

The Department received several comments on this proposed section. One commentator supported the proposed section as making a substantial contribution to the Department's goals. Another commentator supported the Department's language in proposed subsection (c) prohibiting compensation to contractors performing medical management from including incentives to deny payment for services.

One commentator requested clarification from the Department concerning the applicability of this proposed section to ancillary service plans for any functions other than UR. The commentator stated that current NCQA standards do not require any oversight of vision or dental subcontractors.

If ancillary service plans subcontract with an HMO to provide benefits and services that are sold and billed by the HMO, and part of that service involves medical management as defined by the Department's regulations, rather than simple benefits administration, then this section would apply.

The commentator also asked what latitude the Department would grant regarding a National accrediting organization's requirements for subcontractor oversight. For example, if a subcontractor is approved by the NCQA as a credentialed verification organization (CVO), then the commentator stated that the plan should be relieved of oversight functions for credentialing delegation, consistent with the NCQA's accrediting standards.

A plan is never relieved of oversight completely even under the NCQA standards. The degree of oversight and vigilance that a plan must exercise over a subcontractor may be relaxed to some degree by the plan's confidence in the subcontractor's accreditation from the NCQA. However, the Department takes the position that the plan is always responsible for plan activities whether performed by the plan or a subcontractor, and the terms of the medical management contract must make that clear. The contract must also enable the plan to monitor and take corrective action on a timely basis.

Two commentators raised issues concerning the concept of subcontracting medical management functions. One commentator commented that the absence of controls on

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subcontracting was troublesome. The commentator was concerned by delegation of medical management if the Department approves the medical management agreement without explicit standards for UR in an integrated delivery system. The commentator also raised concerns that an HMO would be at risk for plan obligations and responsibilities with minimal protections for important functions such as credentialing and quality assurance performed by subcontractors.

Another commentator found it disturbing that plans are permitted to subcontract functions to unlicensed entities.

There is no provision in statute for the Department to certify or license all types of contractors; however, the entity over which the Department has regulatory authority, that is, the managed care plan, remains responsible for the subcontracted functions, regardless of whether the subcontractor is licensed or not. Contractors undertaking utilization review as an aspect of medical management must be certified and therefore must meet the standards in Subchapter K before they can perform UR functions. This means that the Department will take action against a plan if its contractor is not performing in accordance with the law. The action may take the form of a fine, a ban on admissions, or a revocation or suspension of certification in the case of an HMO.

Further, there is nothing in Act 68 or the HMO Act that would prohibit a plan from contracting for these functions. The Department is taking steps to oversee these arrangements by including standards that plans must meet before the contracting can take place, and by requiring more reporting to the plan by these entities to ensure more plan oversight than has previously been occurring.

One commentator commented that plans should be required to disclose medical management delegation to enrollees and health care providers. Since the regulated entity is responsible for the provision or arrangement of the provision of services to the enrollee, the fact that certain functions are delegated should make no difference to that enrollee. The Department has made no changes to this proposed section based upon this commentator. If there is a breakdown in services caused by the delegation, it is the plan that will answer to the Department. Further, disclosure of medical management contracts to enrollees is not required by section 2136 of Article XXI.

The Department received several comments on proposed subsection (a). One commentator supported the requirement that a plan obtain approval from the Department for any contract that would delegate medical management functions to another entity.

IRRC and another commentator both commented on the lack of a timeline for the Department's review of a medical management contract in the proposed subsection. The commentator recommended that the Department include language in the regulation permitting a plan to deem the contract approved if the Department does not approve it or request further information within a specific time period.

The Department specifically removed all reference to what are referred to as "deemer provisions" from the proposed regulations, and does not intend to reintroduce them. The Department has a responsibility under the law to ensure that certain actions by plans meet the

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standards of Act 68 and the HMO Act. As medical management almost invariably involves UR, much more scrutiny of contract terms is now required given the requirements and prohibitions in Act 68. To deem something approved without actually reviewing and approving it is to abdicate responsibility under those statutes, since contracts that do not meet the standards of the regulations may be approved by this mechanism. The Department must, therefore, review these contracts.

The Department is aware, however, of the concerns of plans that delay on the Department's part could create difficulties for plan operations. The Department has, therefore, included language that will require a plan to submit a contract prior to its use, but if the Department fails to review the contract within that time frame, the plan may use the contract. The contract will be presumed to meet the requirements of all applicable laws. If the contract is in violation of law, the plan must correct that violation. The plan is responsible for ensuring that the contract meets the requirements of Act 68, and any other applicable law. The Department may, within that 45-day period, request further information or changes from the plan; such a request would toll the 45-day review period.

One commentator also raised concerns that plans have contracts in place without previously being required to obtain Department approval. The commentator asked whether the Department intended to "grandfather-in" existing contracts, and strongly urged that this proposed section should only apply to contracts coming into existence or renewed after the effective date of the final-form regulations. The commentator also raised concerns that plans that have contracts in effect at the time of the effective date of the final-form regulations could face sanctions if language changes were not made to the proposed regulations. The Department will not require refile of contracts already approved.

One commentator requested that the Department clarify its statutory authority to require submission and prior review of medical management contracts between a plan and a contractor. The commentator stated that plans should be free to contract with vendors without prior review and approval by the Department, and that it was the Department's responsibility to review the results of the medical management, and not the vendor relationships. The commentator also raised concerns regarding confidential and proprietary nature of the information contained in the contracts.

The Department has authority to promulgate regulations relating to contractual relationships between the managed care plan and providers, including medical management arrangements, under Act 68, the PPO Act and the HMO Act. The Department has the authority to require HMOs to renegotiate provider contracts when they provide for excessive payments, fail to include reasonable incentives for cost control, or otherwise substantially and unreasonably contribute to the escalation of costs of providing health care services, or they are otherwise inconsistent with the purposes of the HMO Act. See section 8(a) of the HMO Act (40 P. S. § 1558(a)). If the Department has already determined that a certain contractual provision will always be disapproved, or that certain language must be included in a contract to obtain approval, the Department has the ability to prohibit or require that information in a contract, or to require renegotiation. The Department can, therefore, pre-approve contracts under the HMO Act, given this renegotiation authority.

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The PPO Act requires that Insurance consult with the Department in determining whether arrangements and provisions for a PPO which assumes financial risk, which may lead to under-treatment or poor quality care, are adequately addressed by quality and utilization controls. See section 630 of the PPO Act (40 P. S. § 764a(e)). These provider contracts are mechanisms by which the managed care plan can address quality and utilization.

Finally, section 2111(1) of Article XXI requires a managed care plan to assure availability and access of adequate health care providers to enable enrollees to have access to quality and continuity of care. Unless the Department reviews these medical management arrangements before their initiation, the Department could be permitting an arrangement that would impact the health and safety of the enrollee, and would be abdicating responsibility under the Article XXI.

The Department certifies the original medical management operations of the plan through the application process and readiness review. The Department monitors changes in structure, process and outcomes through the annual and quarterly reports. Delegation of medical management as a critical function to an unknown entity requires the same level of review by the Department as that of a start-up plan, that is, the Department must verify that the operations will be sufficient before allowing the plan to provide coverage to a single enrollee who would be placed in jeopardy if the subcontractor is not ready to perform medical management functions. All these provisions, taken together, permit the Department to review and approve medical management contracts.

One commentator has suggested that the results of the medical management contract, and not the contract itself, should be the focus of the Department's review, and that, therefore, the Department need not review contracts prior to their use. The Department disagrees with this reasoning. The consequences or results of a medical management contract could be an inappropriate denial of coverage for medically necessary and appropriate services, which, once done, cannot be undone for the affected enrollee in a way which would restore lost health or safety. The Department's focus under Act 68 is access and availability to health care providers that allows an enrollee to receive quality care. See section 2111(1) of Article XXI. If an enrollee is harmed due to a failure of a plan to meet the standards of the act and regulations on these matters, fining the plan does not serve to make that enrollee whole, although other enrollees may be prevented from harm in the future. The Department will enforce the act by reviewing these contracts to prevent this type of harm from occurring in the first instance.

The Department understands the plans' concerns with regard to proprietary and confidential information. It will consider requests to list information as proprietary and confidential. The Department is adding language to subsection (a) which states its intent to keep confidential reimbursement methodologies confidential, unless ordered to do so by a court of law; however, if other information submitted in a filing is neither proprietary, nor is protected by any other law or regulation, the Department most likely cannot keep such information from the public record.

One commentator questioned whether the Department was requiring filing of each medical management contract, or whether the Department was requiring filing of generic contracts. The

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commentator also asked whether the Department would deem approved those medical delegation plans approved by a National accrediting organization.

The Department is requiring submission of specific contracts, since the Department's intention is to ensure that the contractor will perform its functions as would the plan, and that the plan will be maintaining oversight, and, if necessary, can take remedial action if a problem arises.

Although the Department has permitted contractors involved in arrangements with HMOs to obtain a separate review of its operations by an external quality review organization approved by the Department, the Department does not intend to deem this review as dispositive of whether the arrangement meets its approval. The Department will consider that review (see subsection (c)), but the final decision rests with the Department.

Two commentators recommended that the Department include in proposed subsection (d)(3) a requirement for random sampling to be performed by a plan annually, or to include enough persons to have validity. One of these commentators also recommended that contractors be required to report to a plan on a monthly basis.

The Department's regulation does require random sampling, and the Department has added the requirement that the sampling occur annually. Plans should not be required to obtain statistically significant evidence to have proof of the contractor's failure to perform, evidence produced by random sampling is sufficient to show a contractor's breach. Monthly reporting is very costly to both parties; a plan may choose to require monthly reports if it wishes, however, the Department will not require it. The Department believes quarterly reporting is sufficient for responsible oversight and provides the plan with sufficient data for the plan's required quarterly report to the Department.

One commentator commented that proposed subsection (d)(2), which would require quarterly reporting by the plan regarding the delegated activities, and proposed subsection (d)(5), which would require the contractor to submit written reports of activities to the plan's quality assurance committee on a quarterly basis, seemed to be the same. Since this was not the Department's intention, and since the proposed paragraphs did sound similar, the Department has added language to clarify the differences.

In paragraph (2), the contractor will now be required to report concerning the arrangement or provision of health care services and the impact of the delegated activities on the quality and delivery of health care services. Paragraph (5) will now require the contractor to cooperate and participate in any quality assurance activities and studies undertaken by the plan that pertain to the enrollee population served by the contractor, including submitting written reports of activities and accomplishments on plan-directed and any contractor initiated activities.

One commentator requested that the Department ensure that the requirements for independent review of delegated subcontractors do not conflict with the requirements of any National accrediting body.

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There is no need for the Department to make any change to the regulation to address this concern. The Department will keep this comment in mind as additional accrediting bodies are approved to ensure that no conflicting standards are inadvertently set. The Department reserves the right to disagree with any standard of an accrediting body.

Section 9.676. Standards for enrollee rights and responsibilities.

The Department received several comments on this proposed section. Most of the comments expressed concern over the Department's revisions of an earlier set of draft regulations. One commentator provided the Department with comments upon that draft, rather than on the Department's proposed regulations.

After review of the many comments received on this proposed section, some of which argued that the Department did have authority to promulgate a list of enrollee rights and plan responsibilities, and others which argued that the Department did not, the Department has decided to replace the proposed language with language from the NCQA standards regarding a health plan's commitment to enrollee rights and responsibilities. This eliminates any concern that the Department is attempting to require additional disclosure of plans beyond those required by Act 68 and, which is predominantly the purview of Insurance. The Department has substantially retained subsections (b) and (c) of repealed § 9.77 (relating to subscriber rights), since these requirements are unique to this Commonwealth, and would not appear in the NCQA standards.

Several commentators raised concerns that the proposed section did not include Act 68 rights, and requirements that enrollees and other persons be given notice of rights. The Department is not, however, the agency with responsibility for requiring full and accurate disclosure by managed care plans to enrollees. Those responsibilities devolve to Insurance, which is the agency given statutory oversight over subscriber agreements and marketing literature, and which enforces the Unfair Insurance Practices Act. Section 2136(b)(10) of Article XXI, cited by one commentator as proof of the Department's authority to set out these rights, only states that the Department may, along with Insurance, require that plans provide other information those agencies specify to the enrollee or prospective enrollee if they specifically request it. This is not a clear charge to the Department to develop and require plans to provide notice to enrollees, prospective enrollees or providers with a list of rights.

Two commentators recommended that the Department more fully address the needs of non-English speaking enrollees. The Department believes Act 68 is clear that a plan has a responsibility to disclose how it will address the needs of non-English speaking enrollees. See section 2136(a)(5) of Article XXI, and, further, that Insurance is the agency with responsibility for disclosure issues.

Several commentators recommended that the Department address the issue of disclosure to enrollees concerning a plan's complaint and grievance system. These commentators raised concerns that enrollees will overlook information provided on an annual basis and which does not come contemporaneously with a denial letter.

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With respect to specific concerns surrounding notice of the complaint and grievance system requirements, the Department's regulations require that a plan notify the enrollee in writing that the enrollee has the right to be present at the review. Further, the regulations require that the decision letters of the plan include language notifying the enrollee that the enrollee has a right to appeal, and how to do so. See §§ 9.704 and 9.706. Issues concerning the complaint and grievance procedures are addressed in Subchapter I (relating to complaints and grievances).

Subsection 9.677. Requirements of definitions of medical necessity.

The Department received several comments on this proposed section. Several commentators stated that the Department had the authority to establish either a definition of medical necessity, or standards of reasonableness that a plan would need to satisfy in developing a definition. Five commentators recommended specific definitions for inclusion in the regulation.

Section 2111(3) of Article XXI makes it the responsibility of the plan to adopt and maintain a definition of medical necessity to be used by the plan in determining health care services. Act 68 does not make it the responsibility of the Department to develop such a definition, nor does it require plans to adopt the Department's definition. The definition is inextricably tied to benefits covered and excluded and the corresponding premiums charged. There is no way to predict what impact a regulatory definition of "medical necessity" would have on premiums and coverage throughout this Commonwealth.

This regulation requires that a plan's definition of medical necessity be consistent throughout the plan's documents. Eight commentators expressed support for this requirement. If a plan has failed to carry out this requirement, the Department will investigate, and take appropriate action under the regulations and Act 68. The Department has clarified this intention by requiring the definition to comply with the HMO and PPO Acts, Act 68 and the regulations.

One commentator did express concern over the requirement that definitions of "medical necessity" be consistent throughout a plan's documents. The commentator recommended that the Department limit this requirement to the plan contract and any other material covered by Act 68. It was the Department's intention, however, to include any document used by an entity defined as a managed care plan under Act 68 to determine coverage. The Department has decided against revising the proposed section.

More than 15 commentators recommended that the Department reinsert language from a draft which predated the proposed regulations. Several commentators raised issues concerning the deletion of language from the draft, which required the CRE performing the external grievance review to examine whether the plan's definition of "medical necessity" was unduly restrictive, or whether it deviates from the usual and customary language concerning medical necessity.

The Department reviewed the language in its earlier draft and decided against making any change based on that language. In fact, the earlier draft was faulty in that the term "usual and customary" was used, and is an inapplicable standard. Further, if the language were added, CREs would have been able, through external grievance review decisions, to alter the terms of

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coverage under the contract. This would essentially cede regulatory oversight to the CRE. The statute does not give CREs the authority to dictate the terms of coverage.

These commentators also recommended that the Department reinsert language which would have required the plan to adopt a definition that was consistent with industry standards, was not unduly restrictive and did not rely solely upon the interpretation of the medical director.

Again, the Department has decided to make no change to the proposed section based on the recommended language. Requiring plans to set a community standard could lower one person's access to care, while raising another's, so that there is no real uniformity. Further, as with the term "usual and customary," the Department decided that the original draft was faulty in that there is no real National or industry standard for definitions of medical necessity, and that the requirement would be too subjective. The standard would have been unenforceable as too vague.

Four commentators commented that the Department should add language to the proposed section requiring the plan to consider information provided by the enrollee, the enrollee's family, the enrollee's primary care provider and other providers and agencies that have evaluated the enrollee in making a determination of the medical necessity.

The Department acknowledges that, to the extent the information offered is offered by someone who has clinically evaluated the individual, it could be useful in determining medical necessity. Information from sources other than those of a clinical nature are of less probative value in determining whether there is a medical reason for the service. Since, however, the Department does not intend to define the term, it has not added this language to the regulation.

One commentator commented that any definition included in the regulations must reference the Health Choices definition of medical necessity. Again, the Department has declined to include a definition. Therefore, this comment is moot. The Department of Public Welfare is acting as a purchaser, not a regulator, and is acting in conformance with Federal statute. Commercial plans have different considerations.

Section 9.678. Primary care providers.

The Department received several comments on this proposed section.

One commentator raised concerns that the proposed section contained no maximum doctor to patient ratio. The commentator noted that in the absence of a ratio, 1 doctor could treat 5,000 patients.

The Department has decided against including ratios in the regulations, because, except for a staff model HMO, they are no longer useful. Ratios are useful and necessary when a provider and all of the patients are in only one health plan. The plan can then hire additional providers when the ratio requires it. This is what repealed § 9.76(a)(1) was intended to address. It pertained to staff model HMOs in which the provider was an employee of the plan and called for a ratio of 1 physician to 1,600 patients.

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In today's environment, however, providers are rarely employees of the health plan and each plan represents only a fraction of a physician's overall patient population. The physician, to a certain extent, can control this percentage by favoring one plan over another so that not all of the physician's patients are enrolled in any one health plan. Therefore, a physician could meet the ratio requirement for the enrollees of a given health plan, for example, the Department's current ratio of 1 to 1,600, and still be seeing 5,000 patients, 3,400 of whom are covered by other health plans or possibly have no insurance and pay directly for care. Further, unless the provider is an employee of the plan, the plan cannot control the staffing of a physician's office, which may have a different mix of advance practice nurses and other professionals.

The Department is including in subsection (a) a requirement that each enrollee have access to a primary care provider. The Department is requiring elsewhere in these regulations that a plan maintain a QA plan that sets standards for access, requires provider audits against those standards and develops initiatives or expands the network to address improving access and availability of care. See § 9.674(b)(7) (relating to quality assurance standards). These requirements are more relevant to availability and accessibility to care, given the changing nature of plans, than provider to patient ratios.

One commentator raised the same issues regarding subsection (a) as it did concerning the definition of "primary care provider." It objected to replacement of "physicians" with "providers," and stated that, since Act 68 did not alter requirements under the HMO Act, and the Department's previous regulations promulgated under the HMO Act specifically required the use of physicians, the change to providers could not be made. The commentator also stated that neither a CRNP nor a physician's assistant should be permitted to be a primary care provider, and recommended that the proposed section be revised to reflect that fact.

The Department has made no change to the proposed section based upon these comments. As the Department stated earlier, Act 68 created the term "primary care provider" and did not limit it to physicians. The fact that the Department's earlier regulations promulgated under the HMO Act, used the term "physician" does not require a different outcome. The HMO Act does not state that only physicians can be primary care providers. Further, enrollees have the ability to choose a primary care provider from the network.

Two commentators commented on the lack of training requirements in subsection (b). One of these commentators raised concerns that the proposed section did not require a primary care provider to be trained and experienced in primary care medicine. The commentator commented that persons with HIV are highly susceptible to a variety of opportunistic infections, many of which are life threatening if not treated properly. The commentator contended that if a provider, not trained in primary care medicine, fails to diagnose or properly treat these infections, the consequences could be deadly.

IRRC commented that this proposed subsection would allow a health care provider to operate as a primary care provider. IRRC noted that a health care provider under Act 68 included a wide variety of persons, and requested that the Department clarify which health care providers could operate as primary care providers.

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Another commentator provided the Department with a list of criteria that it believed the Department should require physicians to meet before they could be considered to be primary care providers.

The Department's response to these commentators is the same. Act 68 defines a primary care provider as a health care provider who, within the scope of practice, supervises, coordinates, prescribes or otherwise provides or proposes to provide health care services; initiates referral for specialty care; and maintains continuity of care. So long as a health care provider, as defined under Act 68, meets this definition and the Department's additional requirements, that provider may be considered to be a primary care provider by the plan. The plan may set the training requirements it believes to be necessary for a provider to be considered a primary care provider through its credentialing requirements. Patients with any life-threatening, degenerative, or disabling disease or condition, including HIV/AIDS, may seek a standing referral to a specialist or the designation of the specialist to serve as a primary care provider, if they are concerned that the primary care provider they have chosen is not sufficiently expert in the disease to provide the necessary care.

One commentator commented that the proposed subsection should be revised to clarify that certain enrollees are entitled to have a specialist as their primary care provider. In fact, the subsection did provide for this as proposed, and does provide for this as adopted.

One commentator requested that the Department clarify whether a group of physicians practicing from the same location may combine their office hours to reach the number of hours required by subsection (b)(1). The commentator recommended that the proposed paragraph be revised to state: "Each primary care physician or group of primary care physicians in a medical office must have a provider network physician available for scheduled visits a minimum of 20 hours per week, either individually or in the aggregate."

The Department has not changed the proposed paragraph to include this recommendation. Each primary care provider must provide office hours (in that office) either directly or through other providers in the group to meet the hour requirement. The intent is for the enrollee to have access to primary care services from a single primary care provider or group of providers for no less than 20 hours per week. The language of paragraph (1) does not preclude the 20 hours-per-week requirement being satisfied by a group of primary care providers.

One commentator commented that the proposed subsection (b)(2) standard could be too restrictive if on-call arrangements could be made only with plan participating providers. The commentator further commented that plans should have the flexibility to review and approve alternative coverage arrangements, so long as enrollees are properly protected.

The Department has changed the language in paragraph (2) to clarify that all on-call arrangements must be with other primary care providers. The Department does not agree that arrangements may automatically be made with nonparticipating providers. Arrangements with nonparticipating primary care providers may be made, but only if the plan approves the arrangement, agrees to cover the services provided by the nonparticipating provider, and agrees to hold the enrollee harmless financially if plan policies and procedures which could result in noncovered services for enrollees are not met by the nonparticipating provider, or if

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the nonparticipating provider misleads the enrollee into believing a noncovered service will be covered.

One commentator supported the alternate arrangement language of proposed subsection (b)(4) for admitting an enrollee in a hospital, but requested that the Department provide protections to prevent plans from discriminating against providers by refusing to approve alternate arrangements.

The Department has not changed the proposed subsection. Discrimination complaints may be made to the Department, but Act 68's standard is accessibility of adequate providers. See section 2111(1) of Article XXI. This allows plans to determine what types of providers they will choose to use as primary care providers and what alternate arrangements will promote effective and efficient delivery of quality health care services.

One commentator recommended deleting from subsection (b)(4) the term "admitting privileges," and replacing it with the term "staffing privileges." The Department agrees that this change should be made, and has deleted the word "admitting" from the regulation. The Department has chosen to delete the word altogether, rather than to replace it with the word "staffing," since the term "staffing" may not be used in all hospital bylaws that categorize the various types of privileges at each facility.

One commentator commented that proposed subsection (c) was unclear, since it did not state that under Act 68 plans are required to allow specialists to serve as primary care providers. The commentator requested clarification.

The proposed subsection would not have eliminated the requirement that plans provide an evaluation for a specialist as a primary care provider and, if the standards of the plan are met, permit that specialist to serve as a primary care provider. For clarity, however, the Department has added a cross-reference to § 9.683 (relating to standing referrals or specialists as primary care providers) to the language in the proposed subsection.

One commentator recommended that the Department consider including doctors of chiropractic as primary care providers.

The Department is requiring the plan, through the quality assurance committee, to develop criteria for credentialing providers. The Department is not defining in regulations what healthcare providers, by specialty type, may or may not provide primary care or serve as a primary care provider. As discussed further in response to comments on § 9.683, the plan must consider the needs of all enrollees and those with chronic conditions when evaluating the appropriateness of a type of provider who proposes to serve as a primary care provider.

The Department received about ten comments on proposed subsection (d), which pertains to a CRNP serving as a primary care provider. Two were in support of it, and one was adamantly opposed to it, claiming that it had no statutory basis in Act 68. The remainder of the comments requested clarification on some aspect of the regulation.

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One commentator recommended that the Department clarify that plans need not accept a CRNP as a primary care provider.

The Department has not changed the proposed subsection with respect to these comments. The language in proposed subsection (d) states that a plan "may consider a CRNP. . . as a primary care provider, if the CRNP meets the plan's credentialing criteria. . . ." The use of the word "may" is sufficient to indicate that plans are permitted to use discretion in making this decision.

Another commentator asked whether plans would be required to file and receive approval of a waiver to use CRNPs as primary care providers.

Plans are no longer required to request a waiver in order to use a CRNP as a primary care provider. The definition of health care provider in section 2102 of Article XXI specifically lists CRNPs as health care providers, and, depending upon the scope of a CRNP's practice, a CRNP could fit within the Act 68's definition of the term "primary care provider." Therefore, there is no need to make provision for a waiver of regulatory requirements, since use of a CRNP as a primary care provider would be consistent with the regulations.

One commentator commented that if plans are permitted to use CRNPs, they should be permitted to allow enrollees to choose physicians as primary care providers rather than CRNPs. This commentator, along with IRRC, recommended that the Department consider requiring a written notice to alert an enrollee that the enrollee's primary care provider is a CRNP, and not a physician. IRRC recommended that the notice include name of the physician with whom the CRNP has a written agreement to provide services.

The Department has not changed the proposed subsection based on these comments. Enrollees are permitted to choose from a variety of provider types approved and credentialed by a plan as a primary care provider in such areas as pediatrics, family practice and general internal medicine. Any enrollee who has a choice of a CRNP also has a choice of all other types of primary care providers. Provider directories, which are reviewed by Insurance, list providers by practice area (specialty) and provider name, including credentials, address and telephone number. Practitioners are identified with their proper credentials as an M.D., D.O., CRNP and so on. Therefore, enrollees will know who and what they are selecting for their primary care provider.

IRRC has recommended that the Department either cross-reference to the State law and regulations which list the scope of licensure for a CRNP, or specifically state that CRNPs are only permitted to perform certain functions in collaboration with and under the direction of a licensed physician.

The Department is aware of the practice requirements attached to the practice of a CRNP in this Commonwealth. The Department has stated in this regulation that a CRNP must practice in accordance with State law, which, as IRRC commented, requires collaboration and direction of a physician for certain purposes. The Department intended to reference the scope of practice of a CRNP by including in the proposed section the language: "practices in accordance with state law." To clarify this, the Department will replace the language which

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IRRC has suggested is unnecessary and should be deleted, with the specific citations to the Medical Practice Act (63 P. S. §§ 422.1--422.45) and the Nurse Practice Act (63 P. S. §§ 211--225) and the relevant regulations.

One commentator commented that in community-based nurse managed health centers, nurses practice as primary care providers independently in collaboration with a physician. Physician supervision is not consistent with current practice. It has requested that the Department's comments in its Preamble to this section concerning supervision be clarified.

The language to which the commentator refers regarding supervision was taken out of context from the Preamble. It was meant to refer to the supervision and coordination of the care of the individual patient's needs by a primary care provider. This is the role of the primary care provider in managed care.

One commentator recommended the revision of language in proposed subsection (e) to take into account concerns that it could be interpreted as requiring directories to advise members of the implications of any referral changes on a provider by provider basis. The commentator recommended using the following language: "A plan shall include in its provider directory a clear and adequate notice of the possibility of limitations caused by the choice of a given provider as a primary care provider."

The Department agrees with the recommendation, and has changed the language to clarify the subsection.

One commentator also recommended that the provider directory indicate which primary care providers refuse to allow, perform, participate, or refer for certain health care services on moral or religious grounds.

The Department has not made this change, since plans do not survey religious or moral opinions of their primary care providers. If the primary care provider does not intend to provide the full range of primary care services in the contract, for example, birth control, the provider is required to refer out for services the primary care provider does not provide. Additionally, an enrollee may transfer to another primary care provider if the enrollee chooses to do so.

IRRC commented that the language in proposed subsection (f) was vague, and that the Department should provide a specific time frame in which an enrollee must give a plan notice of the enrollee's intention to transfer.

The Department has not made the recommended change to the proposed subsection. The Department does not believe that setting a timeframe in this context would be useful. Plans set timeframes based on operational concerns, which can and are waived in unusual circumstances warranting an enrollee's immediate transfer. A Department standard could lock an enrollee into a relationship with a primary care provider beyond that which is prudent. This could be disadvantageous to the enrollee and would eliminate plan flexibility.

Section 9.679. Access requirements in service areas.

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The Department received several comments on this proposed section. After reviewing all the comments on the proposed section, many of which raised issues with the Department's use of minute and mileage standards, the Department has determined to revise the proposed subsection to address those concerns. The Department has deleted proposed subsections (c) and (e), and added new language to proposed subsection (d). The changes are more fully explained.

Several commentators raised concerns with proposed subsection (a), stating that the provision would fail to take into account enrollees who live outside the service area but receive care within the service area.

The Department recognizes this concern, and has changed the language in the proposed subsection to take into account those enrollees who both work and reside in the approved service area.

One commentator suggested that the criteria the Department intended to use in proposed subsection (c) to determine adequacy of services, healthcare providers, access and availability were not specifically identified.

One commentator recommended that the Department modify subsection (c) to reflect the longstanding practice of only requiring contractual arrangements with primary care providers and frequently utilized specialties. The commentator stated that if nonfrequently utilized specialists are either not available within the geographic criteria or refuse to contract with the plan, it assumed that the Department would still approve the network on the condition that the plan has adequate provisions to address those specialties.

After reviewing the comments on this proposed subsection, the Department has decided to replace the proposed text with the more specific network requirements of subsections (d) and (e).

To the extent these comments still apply to the final-form regulations, the Department has always taken the position that if infrastructure did not exist in a service area, the Department would not require it to be built. The Department is, however, requiring a plan that cannot immediately meet the requirements in subsections (d) and (e) to explain to the Department why this problem is occurring, and what other alternate arrangements the plan intends to undertake to meet the standards. See subsection (d)(3). An acceptable arrangement would be to allow enrollee access to nonparticipating providers; however, this is suboptimal for frequently utilized specialties as the plan is disadvantaged not only financially but also in terms of credentialing and compliance with plan policies, procedures, and quality assurance initiatives and activities. The Department would not want this to be a permanent alternative.

One commentator commented on the propensity of plans to shut out optometrists from their networks because an ophthalmologist is in the service area, or because the plan does not cover routine eye examinations or glasses. The commentator stated that optometrists provide other medically related eye care services, and most primary eye care in medically underserved areas is provided by optometrists.

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The Department has not included language to its regulations to require plans to take one of every type of provider who can provide a particular health care service. The act requires plans to assure the availability and accessibility of adequate health care providers in a timely manner which enables enrollees to have access to quality care and continuity of care. See section 2111(1) of Article XXI. Act 68 does not require a plan to have one of each type of provider, and the Department will not promulgate a regulation to the contrary.

One commentator, although recognizing the need for the Department to be aware of potential service disruptions, raised concerns that the immediate notification requirement in proposed subsection (d) would be burdensome. The commentator recommended that the Department require a report within a reasonable time.

The Department agrees with the comment, and has deleted the word "immediately" from the proposed subsection, which is now subsection (c). The Department has also changed the word "potential" to "probable" to reflect the Department's intention to only require notice of those threatened terminations that are likely to become actual terminations.

The commentator also commented that it was unclear how the proposed requirement to report a serious change in the plan's ability to provide services affecting 10% or more of the enrollees in a service area would be applied to plans with service areas that cover more than one county and different geographic regions.

The Department, after reviewing this comment, agrees that the 10% requirement could be broadly interpreted, and, therefore, difficult to apply. The Department has also decided that a service area is too broad an area that needs to be updated to trigger a reporting duty, and may allow plans to avoid providing notice when a provider in a small community with many enrollees terminates and the community and the plan are without alternatives. The remaining providers in the area might not be able to handle the influx, although the number of enrollees affected would not trigger the necessary 10% threshold for the entire service area. To address these concerns, the Department has deleted the proposed language, and has added language that requires a plan to notify the Department of a loss from the network of any acute care hospital and any primary care provider in either an individual practice or group practice with 2000 or more assigned members. See subsection (c). The Department recognizes that the loss of other types of providers in a network is always disruptive to the patient affected; however, access to primary care as the entre to all other services, and hospitals as the source of most urgently and severely needed services, are the main concerns of the Department.

Proposed subsection (e) generated several comments from a variety of commentators--plans, advocacy groups, legislators, and provider associations, as well as IRRC. One commentator commented that the subsection was too vague. Some commentators commented that the subsection contained no specific standards for frequently utilized specialists. Other commentators commented that the subsection lacked standards for infrequently utilized specialists. One commentator stated that criteria for less frequently utilized specialists should be based on need, and not on use. IRRC stated that the subsection should contain criteria used to determine network adequacy, or should reference § 9.653(b) (relating to HMO provision of limited networks to select enrollees). IRRC recommended that for some specialty areas, network adequacy be based on a case-by-case basis.

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Several commentators took issue with the proposed mileage and time requirements. IRRRC and others questioned these requirements in light of the Department of Public Welfare's different contractual requirements for Health Choices contractors.

Two commentators recommended clarifying the term "access" since it implied a use of motor vehicles, but did not take into account inaccessible or unaffordable transportation.

After having reviewed all the comments it received on this subsection, the Department has substantially revised the proposed section and subsection to address these concerns. First, to address concerns raised by commentators with respect to the Department of Public Welfare's Health Choices contractors, the Department has decided to use metropolitan statistical areas (MSA) to designate counties as rural or urban. The Department has altered its mileage and distance accessibility requirements to 20 miles/30 minutes in an MSA county otherwise considered urban, and 45 miles or 60 minutes in a nonMSA county otherwise considered rural. Further, the Department has required that services be accessible to 90% of the enrollees in that area. MSAs are Nationally designated based on census data, population density and the percentage of workers who commute to adjacent MSA counties.

The Department is continuing to require plans that cannot immediately meet the accessibility requirements to report that they cannot do so, explain why, and explain how they intend to provide access to covered health care services through alternate means. The Department has also provided examples of alternative arrangements in the regulation. See subsection (f)(3). The Department cannot and does not require plans to create providers where none exist. Additionally, the Department does not want to inadvertently create a situation that would allow one provider to block entry into a county by refusing to contract with the plan despite the desires of other providers to participate, employers to offer, and enrollees to join managed care plans. The Department can, however, require plans to consider alternative means of providing covered services and inform the Department as to how it intends to fulfill its obligations under section 2111(1) of Article XXI.

In response to comments that the Department failed to define frequently or infrequently utilized health care services, the Department has added subsections (e)--(h). In subsection (e), the Department has listed the services that it considers to be frequently utilized health care services which must be provided in accordance with subsection (d). It has taken this list from the commonly accessed major specialty areas as designated by the American Board of Medical Specialties (ABMS). This does not mean the Department regards other ABMS specialties or subspecialties as unnecessary, but, rather, addresses the majority of a population's needs by assuring a network of at least the main specialty categories.

The Department has also addressed less frequently utilized health care services in subsection (h). That subsection states that less frequently utilized health care services may be provided by a nonparticipating health care provider or under a contract with a health care provider outside the approved service area. Those services, of which the Department uses a transplant for an example, are basic health care services other than those listed in subsection (e). Subsection (g) discusses health care services that can reliably be provided in the home, and exempts them from the travel requirements of subsections (d) and (f) as the services are provided in the home, and the location of the provider's administrative office is not an issue.

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One commentator recommended that the Department include providers of assistive technology and services in its final-form regulations. The commentator stated that access to these services should be addressed the same as a frequently used specialist. The Department has declined to specifically include assistive technology and services in the regulation. Generally speaking, these are services of benefit to a small sub-set of the population; however, to the extent that they can be defined as nonbasic health care services, the plan would need to meet the standards in subsection (d) in providing them. The Department has included standards for nonbasic health care services, for example, prescription drugs, vision, dental and durable medical equipment, in subsection (i). Since these types of services are not defined as basic health care services, the Department does not see them as either frequently or less frequently used health care services, but, rather, as a third and separate category. The Department has, however, required that the plan meet the standards in subsections (d), (f) and (g) in providing nonbasic health care services for the reason that these benefits are generally offered as optional and supplemental, but limited to a single benefit category (such as vision or durable medical equipment) which is viewed as a stand alone network which must meet the minimum requirements to be of any benefit to enrollees.

In subsection (j), the Department has allowed plans to arrange for services at a distance greater than the travel times in subsections (d) or (c), if the plan does so for therapeutic reasons to provide access to quality health care services.

Act 68 changes how the Department must review and verify networks in several ways. Plans must have an adequate network of health care providers, and the term "health care providers" now includes everything from doctors to pharmacies to durable medical equipment suppliers. The Department does not want to discourage plans from contracting out-of-the-service area with centers of excellence for transplants and other specialized services. The Department's standards in this section are intended to permit this.

One commentator commented that the proposed section contained no access norms for appointments. Another commentator commented that access should not be limited to geographic access. The commentator cited, as an example, that if an ophthalmological office within 30 miles in a rural area was only open once a week, the standard should not be considered to be met.

As previously discussed, the Department will not set access norms for appointments. This issue is best handled by the plan's quality assurance committee and access auditing. Should an appointment not be available to an enrollee in what the enrollee considers to be a timely fashion, the enrollee has the option of filing a complaint against the plan or reporting the concern to the Department. The Department believes that plans should have flexibility to manage this operational issue within their limited ability to control it.

The Department has added subsection (k), which requires a plan to provide coverage for services provided by nonparticipating health care providers at no less than the in-network level of benefit for services provided when the plan has no available network provider. The Department is attempting to clarify that a plan is not required to have network providers available outside of the approved service area for the purposes of enrollees seeking basic health care services while outside of the service area. Further, a plan is not required to pay a

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noncontracted provider at the same level of benefit as a network provider for basic health care services sought by and provided for an enrollee outside the service area.

Finally, in subsection (j), the Department has added language setting out standards for a plan to follow to obtain a service area expansion.

Section 9.680. Access for persons with disabilities.

The Department received several comments on this proposed section. The proposed section was intended to reiterate requirements in Act 68 that plans comply with Title III of the Americans with Disabilities Act of 1990 (42 U.S.C.A. §§ 12181--12188) (ADA). Proposed subsection (a) would require plans to have in network providers who are physically accessible to persons with disabilities in accordance with Title III of the ADA. Proposed subsection (b) would require plans to have in network providers who could communicate with persons with sensory disabilities in accordance with the ADA.

Several commentators complained that the proposed section would not include minimum requirements to assure that HMOs provide access to persons with sensory and physical disabilities. Commentators also stated that the proposed section would not ensure ADA monitoring and enforcement.

One commentator commented that the proposed regulations would not address the problem of providers refusing to serve persons because of their disabilities, and noted that it receives weekly calls concerning dentists who refuse to serve persons with retardation.

One commentator commented that the Department should include in the regulation minimum standards and a monitoring process governing not only access for persons with wheelchairs, but also assuring communication between providers and members who have hearing and visual problems. The commentator recommended that the Department take notice of a lawsuit on these issues against the Department of Public Welfare.

One commentator also mentioned the possibility of legal action against the Department and HMOs. According to this commentator, the Department is required to comply with the ADA, and is failing to do so by not promulgating specific regulations.

Although the Department is sensitive to concerns of persons with disabilities and their advocates concerning physical and sensory access to health care providers, the Department cannot set standards for how plans are to comply with a Federal statute. Act 68 specifically references the ADA in setting requirements for plans to ensure that they have providers that are physically accessible to persons with disabilities and who are able to communicate with persons with sensory disabilities. The ADA calls for reasonable accommodation for persons with disabilities; that is a standard interpreted by the Department of Justice and the courts, not the Department. No standard set by the Department purporting to ensure that a plan or provider would be in compliance with the ADA would be binding on the Federal government if it decided to the contrary.

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With respect to issues concerning the ADA and Health Choices contracts, the Department of Public Welfare, unlike the Department in this instance, is a purchaser, and not a regulator. The question of whether the Department of Public Welfare would have been required to set standards for its contractors is different from whether a state regulator is required to set standards for compliance with a Federal statute. There is even a question as to whether the Department can, legally, undertake such regulations due to preemption issues.

Three commentators recommended that the Department add language to the proposed section requiring it to review a plan's policies and procedures to ensure compliance. One of these commentators commented that the proposed regulations should be amended to ensure that HMOs do not use fiscal disincentives to underserve persons with disabilities. The commentator recommended that actual reimbursement methods should be provided to the Department, and these methods should be monitored and reviewed for their impact on persons with disabilities.

Act 68 contains a clear directive that plans may not use incentives to provide less than medically necessary and appropriate care to an enrollee. See section 2113 of Article XXI (relating to prohibition on financial incentives). The Department will enforce this for all enrollees, including those with disabilities.

Further, section 2111(1) of Article XXI does require that all enrollees have access to adequate health care providers in a timely fashion. The Department does investigate allegations that access is being denied. Again, however, the Department cannot hold anyone responsible under the ADA. That would require a referral to the Department of Justice.

One commentator requested that the Department clarify that providers not plans must comply with the ADA.

Because the Department does not enforce the ADA, it cannot speak to whether a plan must comply with the ADA or not. That is a matter for the Department of Justice and the courts. Act 68 requires plans to have procedures in place that comply with the ADA.

Section 9.681. Health care providers.

The Department received several comments on this proposed section.

Several commentators recommended language changes to this proposed subsection. IRRC recommended the addition of the language "updated annually" to proposed subsection (a), and stated that the Department should explain whether a plan was required to distribute an entire provider directory annually, or just updates, or whether a plan could make updates available upon request.

Another commentator also commented concerning publication times, and stated that the provider directory should be published annually and updated quarterly, that there should be telephone responses or 24-hour verification, or both, and that the directory should include the identity of all associated health care providers, their hospital privileges, and CRNPs' collaborating physicians.

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One commentator recommended that the Department add the language: "or area of practice concentration substantiated by clinical training and experience," to the end of subsection (a).

One commentator recommended deleting the proposed requirement that providers be listed by specialty. The commentator noted that provider directories are arranged by different methods, some by specialty, others by other methods. The commentator stated that this was a specific problem for plans that enroll Medical Assistance (MA) recipients because such directories often list providers by zip code for ease of enrollment. Eliminating this requirement would have no effect on consumers being provided with appropriate information, as required under Act 68, but would allow for flexibility on plan's behalf.

One commentator recommended deleting the proposed subsection on the basis that the subject matter is already covered in Insurance's regulations.

After considering these comments, the Department agrees that the information is covered in Insurance's regulations, and is including Insurance's language here. Section 154.16 of 31 Pa. Code handles this topic, including timing of publication. The Department has adopted the language in 31 Pa. Code § 154.16(c)(2).

Three commentators commented on proposed subsection (b). One commentator commented on the proposed language, which would require a plan to provide access to an alternative provider if the participating provider ceases participation. The commentator stated that the standard could not always be met, and recommended the addition of language stating that the plan would make every effort to provide access.

The Department has not changed the proposed subsection. A plan is obligated to arrange for covered services. Whether it does this through contracted providers or noncontracted providers, the coverage must be provided. A plan that is unable to meet this standard through its provider network must allow enrollees to access covered services through nonparticipating providers with no penalty, as the network is inadequate for the service required.

The commentator also commented that the term "alternative provider," in proposed subsection (b) could be misconstrued as allowing the enrollee access to practitioners of alternative medicine. Although the intention was not to reference alternative forms of medicine, to ensure that there is no confusion, the Department has replaced the word "alternative" with "other."

Two commentators noted that disclaimers were typically the responsibility of Insurance. One commentator recommended that the agencies ensure their regulations are consistent, and the other recommended deleting proposed subsection (b) in its entirety as already being covered by Insurance.

The Department sees no reason to delete this provision, as it is not inconsistent with Insurance's regulations. Further, as stated earlier, plans must be in compliance with both sets of regulations.

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Although the Preamble discussion relating to proposed subsection (c) stated that the plan must cover nonnetwork services under the same terms and conditions as it would a participating provider, the proposed subsection requires coverage at the same level of benefit. Three commentators raised concerns about the language in the Preamble being inconsistent with language in the proposed subsection. These commentators all commented that the language could create serious problems for plans and providers.

The language in the Preamble was incorrect, and the language of the proposed subsection was accurate. Plans shall cover nonnetwork services at the same level of benefit as if a network provider had been available. The enrollee shall have access to covered services and cannot be penalized by lesser coverage when the network is inadequate.

Two commentators commented that the proposed subsection provided for going out-of-network when there were no providers available. They recommended that the final regulation define the circumstances under which the plan must pay for out-of-network care, and the procedure for doing so.

To address these comments, the Department has added language to clarify that a plan is required to provide access to services within the approved service area and is also required to set standards for availability approved by the physicians of the quality assurance committee. When the network has a deficiency, a plan must extend nonnetwork benefit levels to the out-of-network event because the plan had no network alternative. It is not possible for the Department to define every circumstance of network failure that would allow enrollees to obtain services from nonnetwork providers without financial penalty. The Department and plans can only address access from the standpoint of objective need and not subjective personal tolerances, preferences and perceptions. The Department has added language to clarify that covered services and availability is reviewed based on the approved service area. Plans are not expected to have every specialty under contract everywhere in the world to take into account enrollee travel or location outside of the approved service area. IRRC commented that the criteria for determining whether a health care provider exists, is available, or is participating were not clear. IRRC recommended that the Department further define "no available participating health care providers" or provide the criteria for determining whether a health care provider is available or participating.

The Department added language to clarify the network expectations pertaining to the approved service area, but has not changed the regulation with respect to this concern. As long as the plan has one provider in the network who can perform the health care service within the time frame recommended, the plan has an available participating provider. Enrollees who do not want to go to the participating provider may file a grievance if the basis of the grievance would be the medical necessity and appropriateness of the provider, or a complaint if the basis is personal preference.

Three commentators commented that proposed subsection (d) would not include standards for less frequently used specialists, or for providers who are not hospitals, primary care providers, or specialists, for example, drug stores, home health agencies, and durable medical equipment providers.

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This subsection is intended to only address access to those services which are commonly used, and to which access is necessary as the first step in obtaining additional services. The Department has addressed access for pharmacy and durable medical equipment in § 9.679. The Department has not changed the proposed subsection with respect to this concern because standards for infrequently utilized services are difficult to set in regulation for several reasons. First, by definition, they are infrequent and may not occur for more than one patient. Appropriate access is directly related to the patient's medical situation. For example, reasonable and necessary access to a transplant could range from a time period of 24 hours to several months dependent upon the patient's diagnosis and health status. Secondly, while travel distance is a concern, in unusual circumstances such as transplant, the qualification of the provider generally override travel considerations. The Department does not wish to set a standard for access for infrequently utilized services that inadvertently limits the number of available providers or unduly restricts a plan in contracting with specialized centers of excellence with Nationally recognized expertise.

One commentator commented that the requirement for written procedures should reflect the definition of "emergency services," specifically serious injury, impairment or dysfunction. The Department has not changed the proposed subsection to address this comment because the term "emergency services" has already been defined in the regulations.

One commentator commented that if proposed subsection (d) was intended to imply that plans may impose some limits on the availability and accessibility of these services, it was troubling. It recommended that the Department clarify the proposed subsection, and state that availability and access to these services must be assured.

The Department has added language to state that the procedures must ensure the availability and accessibility of these services. The Department has also included routine appointments in subsection (d)(5) as a frequently utilized health care service. This is necessary to ensure plans address enrollee's ability to obtain timely appointments.

Section 9.682. Direct access for obstetrical and gynecological care.

The Department received several comments on this proposed section. One commentator commented that it did not understand why the Department had issued proposed amendments on this topic.

The Department issued the proposed amendment because the Department has the responsibility to ensure direct access to, and availability of, obstetrical and gynecological services. It is the Department's intention to carry out this responsibility by this regulation.

Five commentators commented that the Department's standards should be consistent with Insurance's standards. One commentator stated that the standards were consistent with Insurance's standards. One commentator commented that although Insurance's regulations do specifically state that no time frames will apply, the Department's do not. One commentator commented that obstetrical and gynecological services should be regulated by the

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Department, and not Insurance, since the Department has the expertise to determine what services are outside a health care provider's scope of practice.

Even though the Department's proposed standards would be consistent with the regulations promulgated by Insurance, these comments indicate that the Department's intentions are not clear. The Department has, therefore, adopted the language of Insurance in subsections (b) and (c) of the final-form regulations, including language prohibiting time limitations on the direct access of these services. See § 9.682(b). With respect to the other subsections, both agencies have responsibilities in regulating direct access to these services. Since each department has different responsibilities based upon its different expertise, the regulations of both agencies should not be exactly the same.

One commentator commented that the proposed section should be expanded to provide for direct access to chiropractic services. The commentator noted that because chiropractic care is most beneficial immediately after the onset of an injury or trauma, patients should be able to have immediate access to chiropractic care. The commentator recommended allowing direct access subject to regulatory or monitoring oversight by the HMO, its gatekeeper or its delegated medical management team.

Act 68 requires direct access only to obstetrical and gynecological health care services. See section 2111(7) of Article XXI. The Department may not require direct access to chiropractic services in its regulation. Legislation would be required to accomplish this.

One commentator recommended that the Department add language stating that providers may advocate for patients, and may obtain written consent to do so at the time of treatment.

The Department has not changed the proposed section to add the requested language. Providers may always advocate for patients and do not need regulations from the Department to allow them to do so. The issue of consent to file a grievance is addressed in § 9.706 (relating to health care provider initiated grievances). The Department has revised that section to specifically permit providers to obtain consent to file a grievance on the enrollee's behalf at the time of treatment, as long as the provider does not condition treatment on the enrollee's consent.

One commentator commented that Insurance's regulations prohibit a plan from paying less for directly accessed obstetrical and gynecological services than for authorized services, but that the Department's proposed regulations would not. It is not, however, a conflict for one agency to make a requirement, which the other agency does not. Plans shall comply with both sets of regulations, and not one in lieu of the other. The Department has decided against adding this language to the regulation.

One commentator also commented that both Insurance's and the Department's regulations contradict Act 68 because they seek to limit direct access to obstetrical and gynecological services, whether for routine or other care. The commentator stated that this was not what the General Assembly intended.

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Insurance's regulations were approved and are final. The Department did not intend to place any restriction on access to care not contemplated by the statute, and does not believe that this regulation does so.

The Department received several comments on proposed subsections (b) and (c). Commentators included legislators, advocacy groups, trade associations and IRRC. All recommended revision of the proposed subsections. Most comments involved the Department's use of the terms "routine" and "nonroutine." The commentators questioned what these terms meant, and commented that to create the concept of routine services, and then require prior authorization for nonroutine services, would limit an enrollee's direct access in violation of the Act 68.

One commentator commented that the proposed subsections (b) and (c) were inconsistent with the regulations promulgated by Insurance.

One commentator commented that it recognized that Act 68's intent was not to include direct access for gynecologic subspecialty care, including, for example, reproductive endocrinology, oncologic gynecology, and maternal and fetal medicine. It recommended that the Department add language stating that these subspecialty services were the only restrictions for direct access.

One commentator commented that inclusion of related laboratory or diagnostic procedures exceeded the scope of Act 68.

After review of these comments, the Department has decided to delete the proposed texts in subsections (a), (b) and (c) of its proposed regulations, and replace them with language contained in 31 Pa. Code § 154.12(a) and (b) (relating to direct enrollee access to obstetrical and gynecological services) of Insurance's regulations. It was not the Department's intention to limit access to services. Act 68 prohibits prior authorization in certain circumstances, but does not prohibit prior authorization for any services other than those specified services. It was the Department's intention to attempt to interpret and explain for what services prior authorization may be required by a plan. Adoption of Insurance's language will ensure consistency between the agencies on these issues, and eliminate the confusion over the terms "routine" and "nonroutine." Further, subsection (b) will permit a plan to require prior authorization of certain diagnostic testing and subspecialty care, for example, reproductive endocrinology, oncologic gynecology, and maternal and fetal medicine, as was recommended by one commentator. This was the Department's original intent. The subsection now defines by example for what types of services a plan may require preauthorization.

Two issues were raised with respect to proposed subsection (a), which still remain despite the Department's deletion of that proposed subsection. One commentator recommended that the term "health care provider" be replaced with term "obstetrical and gynecological provider" to ensure that practitioners with the appropriate training and scope of practice are providing these services.

Another commentator recommended that language be added to the proposed subsection to state that the plan cannot penalize a family physician economically, or in any other manner,

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which includes refusing to credential that provider, since an enrollee is required to be afforded direct access to obstetrical and gynecological services. The commentator also commented that plans refuse to recognize that family physicians can provide these services, and are taking the position that Act 68 requires plans to credential providers for the provision of obstetrical and gynecological services where they have requisite experience. The commentator stated that this position operated to the detriment of the enrollee, and recommended that the Department expressly require plans to credential family physicians for these services, and that plans inform enrollees of their availability.

Even though subsection (a) has been deleted, the Department believes that these comments need to be addressed. Act 68 already states that the health care services must be within the scope of practice of the provider to which the enrollee has access. See section 2111(7) of Article XXI. Plans are free to determine who may be directly accessed for these services, since it is direct access to the service that is required by the statute, and not direct access to a particular type of provider. *Id.* Nothing in Act 68 requires that the plan credential every health care provider capable of providing the service as a provider who may be directly accessed for these services. A plan is required to maintain an adequate and accessible network and to credential the providers in that network. The Department is not in a position to review the training and expertise of every specialty and subspecialty area and issue judgements about what health care services certain providers can and cannot be allowed to perform. The Department will not regulate to that level of detail.

The Department is redesignating proposed subsection (d) as subsection (c). The proposed subsection would require a plan to develop policies and procedures that describe the terms and conditions under which a directly accessed health care provider may provide and refer for health care services with and without obtaining prior plan approval. The proposed subsection would have also required the plan to have these policies and procedures approved by its quality assurance committee, and to provide the terms and conditions to all health care providers who may be directly accessed for maternity and gynecological care.

Two commentators raised issues with this proposed subsection. One commentator stated that there is no statutory authority for requiring plans to have policies and procedures addressing when referrals are necessary, no statutory authority to require the plan to have these policies and procedures approved by the plan's QA committee, and no statutory authority to require the plan to provide the policies and procedures to providers.

With respect to direct access, the Department has the statutory authority to require plans to submit policies and procedures to a quality assurance committee. Act 68 need not specifically include language authorizing the Department to take an action for the Department to have the authority to do so. The Department has the ability to interpret the statute to enforce the statute's requirements, as required by the legislature. To implement the direct access requirements of section 2111(7) of Article XXI, the Department is requiring plans to develop policies and procedures (credentialing and quality assurance) for the provision of direct access. Further, the Department is requiring that these policies be reviewed by the quality assurance committee to ensure that the most up-to-date medical and clinical information is considered in determining when and how prior authorization will be required. All this is

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necessary to ensure that enrollees obtain direct access to services which is meaningful and clinically appropriate. These requirements are well within the parameters of the statute.

IRRC commented that the Department had required no other policies and procedures to be approved by a plan's QA committee, and asked why the Department had singled out obstetrical and gynecological care. The Department did not single out obstetrical and gynecological care for review by a plan's QA committee. The QA committee is concerned with the UR function, among other things. The Department has required QA committee approval of a specialist as a primary care provider or standing referral policies and procedures. See § 9.683(c) (relating to standing referrals or specialists as primary care providers). The Department has included this requirement in the regulation because the Department believes clinical determinations, for example, the identification of those services for which prior approval may be obtained, which may, in fact, change rapidly as the course of medicine changes, are inappropriate for definition by the Department, or for inclusion in regulation. Therefore, the Department determined that review by the plan's quality assurance committee was the most appropriate way to allow for clinical review and for flexibility, including the addition of new services, without the need for regulatory amendment.

Section 9.683. Standing referrals or specialists as primary care providers.

The Department received several comments on this proposed section. One commentator noted general concerns with the regulation, but did not specify them. Two commentators supported the regulation. One commentator commented that the Department's proposed amendments were far more detailed than Insurance's regulations concerning the process for deciding whether an enrollee could have a standing referral or specialist. The commentator stated that this was one more example of why the regulations should have been considered at the same time. Another commentator stated that Insurance should not regulate standing referrals, rather the Department should since they involved issues of medical necessity.

The issue of whether Insurance's regulations should have been reviewed with the Department's proposed amendments is now moot. Insurance's regulations are already final. In any case, the regulations do not contradict each other, they complement each other and contain what is necessary for both agencies to carry out their responsibilities under Act 68.

One commentator commented that the proposed amendments were inadequate and would fail to assure compliance with Act 68. The commentator specified the problems with the proposed regulations as follows: (1) they would fail to set criteria for when plans should grant standing referral requests; (2) they would fail to set time frames for plans to decide on such requests; and (3) they would fail to require disclosure to consumers and providers of the criteria for approving these requests.

In response to the first point, the criteria would involve different standards for each and every possible disease or condition and the provider combinations that could or would be appropriate for a standing referral. These determinations are complex, clinical and can change over time. The Department believes that this information is improper for regulation, which does not allow for the necessary flexibility required to match individuals with the most appropriate provider.

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Further, Act 68 requires the plan to set these criteria and develop procedures for, first, an evaluation of the patient, and then for the provision of the standing referral. The threshold standard for a standing referral is already in Act 68. Act 68 states that the enrollee must have a life-threatening, degenerative or disabling disease or condition to make a request and obtain an evaluation. See section 2111(6) of Article XXI. Secondly, the Department did set time frames for the plan to act on the request--a reasonable amount of time given the individual's disease or condition, but within 45 days. Lastly, Act 68 already requires disclosure of procedures. Section 2136(a)(13) of Article XXI.

One commentator recommended that the Department use its criteria as the standards for evaluating whether physicians in nonprimary care specialties can serve as primary care physicians.

The Department has declined to adopt those criteria. Act 68 leaves the determination of whether or when to request an evaluation for a standing referral to a specialist for care or to have a specialist function as a primary care provider up to the enrollee. The plan is required to set standards for these evaluations and for determining whether or not to grant the enrollee's request, but it is the enrollee who initiates the request. The plan may include the primary care provider (Act 68 provides for a primary care provider, not necessarily a physician) in this evaluation; that is up to the plan to determine, in accordance with the Department's regulations. The Department does not intend to place additional restrictions on the plan or the enrollee by requiring the plan to defer to the primary care physician in making its determination of whether to allow a standing referral, or designate a specialist as a primary care provider.

One commentator complained that the proposed regulations would not require the plan to notify or seek Department approval of policies, procedures, clinical criteria or any amendments for referral.

The Department has not changed the proposed regulations with respect to this concern. The Department believes the setting of clinical standards, such as those that shall govern a determination under this section, are more properly reviewed by the plan's quality assurance committee.

The Department received one comment on this proposed subsection (a). The commentator recommended that the Department clarify that plan was not obligated to offer eligible members a choice between a specialist as a primary care provider or a standing referral to a specialist. The commentator stated that the plan should be permitted to determine which of the two approaches that would be most consistent with its program, and pointed out that either approach would achieve the same goal.

The Department sees no need to clarify the subsection. The Department takes the position that Act 68 permits either approach. The Department also believes that the plan must establish standards for evaluating, issuing or denying a request for either approach. Which approach is provided by the plan should depend upon which is appropriate given the particulars of the patient and the nature of the request. A plan must develop policies for providing either approach as is appropriate. A plan will not meet the terms of Act 68 or the Department's regulations by only setting out standards for one or the other. The enrollee may request one

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approach, although the plan, under its standards, directs a different approach because it determines it is preferable given the circumstances of the enrollee's condition. The plan may want to approve a standing referral rather than designate a specialist as a primary care provider if the specialist in question does not have adequate office hours or on-call arrangements to ensure that the enrollee has access to primary care. Granting approval of one approach over another is permissible under Act 68, although the enrollee may choose to file a complaint or a grievance if the approach approved is not acceptable to the enrollee.

The one comment that the Department received on proposed subsection (b)(1) recommended that the Department delete the phrase "including a process for reviewing the clinical expertise of the requested specialist." The commentator stated that this was the purpose of the existing credentialing process.

The Department has not deleted the language. The requirement of the proposed paragraph would be beyond the scope of the regular credentialing process. A plan cannot anticipate every type of request that may be made to it in advance and cannot be expected to determine the extent to which every specialist can or should serve as a primary care provider. The regular credentialing process will not tell a plan whether a cardiologist should serve as a primary care provider for a patient with rheumatoid arthritis, whether an obstetrician/gynecologist should serve as a primary care provider for a patient with a heart condition or whether a chiropractor should serve as a primary care provider for a diabetic. A provider may be credentialed through the credentialing process as a specialist, but the provider's training may not be appropriate for the needs of the individual patient making the request. This is what the plan's procedures should address.

The Department received several comments on proposed subsection (b)(3), three of which noted that the Department had failed to include the statutory language in the proposed paragraph which requires the treatment plan to be approved in consultation with the primary care provider, the enrollee and as appropriate, the specialist. Section 2111(6) of Article XXI. The Department acknowledges the oversight, and has included the language "in consultation with the primary care provider, the enrollee, and as appropriate, the specialist" in the regulation.

One commentator also requested that the Department specify who would develop the treatment plan, and what it would include. The commentator recommended that if the plan is a clinical plan of care, the member's physician, primary care provider or specialist should develop the treatment plan. The commentator recommended that the Department add the following language to the proposed paragraph: "The specialist physician will develop a treatment plan in coordination with the member's primary care physician as applicable. This treatment plan will be presented to the managed care plan for approval."

The Department has made no change to the proposed paragraph to address this concern. Who develops the treatment plan is not as significant as who participates in the development and who approves the treatment plan. The Department does not feel the need to dictate this level of detail on what is essentially a plan of action agreed to by the enrollee, the specialist and the plan arrive at an acceptable arrangement. The primary care provider is not the controlling factor, but should be included in the process so that the provider is able to

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coordinate care of the patient when the specialist is no longer acting as the primary care provider, or more importantly, during the course of the standing referral so that each provider and the enrollee understand who to contact for what services.

One commentator recommended that the Department include language in subsection (b)(4) stating that subjecting the procedures to the utilization management requirements and quality assurance criteria would in no way eliminate the right of the enrollee to an evaluation for a standing referral to a specialist or designation of a specialist as the enrollee's primary care provider. The commentator was concerned that without this language, there would be ambiguity as to the enrollee's right to request an evaluation.

The Department has not added the language. This paragraph does not impact the enrollee's right to request an evaluation. Rather, it refers to the operational guidelines, terms and conditions a provider must follow once the arrangement is approved. Regardless of the absence or presence of plan procedures, the enrollee always has the right to request an evaluation to determine specialist involvement.

Two commentators requested alterations to subsection (b)(5). One commented that since a primary care provider could be designated as a specialist, the language was not quite correct. The commentator recommended changing the word "specialist" to "provider." Both commentators also recommended changing the last sentence of the proposed subsection to take into account the plan's need to keep the services in network. One suggested replacing "as appropriate" with "if no participating provider is available." The other recommended "When possible, the specialist must be a health care provider participating in the plan."

The Department agrees with the comments. It has changed the word "specialist" to "provider." It has also added to the regulation the following language: "when possible, the specialist must be a health care provider participating in the plan."

Two other commentators suggested that the proposed paragraph should contain language requiring an expedited review when the decision to disallow the request could impact the life, health or maximum function of the enrollee. The Department has not made this change. Subsection (b)(7) designates the denial of the request for a specialist as a grievance and requires the plan to provide individual information on how to appeal a denial through the grievance process. The regulations already provide an expedited review for certain grievances, see § 9.709 and there is no need for a special expedited review process in this section.

It is important to underscore the fact that an enrollee making this type of request is not being denied care or services. Services are available through the enrollee's designated primary care provider; however, the enrollee wishes to have them provided by a specialist. The Department is requiring a plan to review the enrollee request in a time frame that takes into consideration the enrollee's situation, but on no account to exceed 45 days. Even if the plan takes the full 45 days to conduct the evaluation and reach a decision, the enrollee is able to receive care through the primary care provider and traditional referrals during that time period.

One commentator supported the time limits on responding to requests in subsection (b)(6).

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Several commentators commented on this time period. IIRC requested that the Department explain why 45 days would be an appropriate time period in which to respond to the request for a standing referral to a specialist, or designation of a specialist as the enrollee's primary care provider. Another commentator recommended that the Department reduce the 45-day time limit for final decision to 30 days. The commentator noted early intervention promotes timely recovery.

One commentator stated that the Department had failed to ensure timely access to specialists for both acute and long-term disease management of brain diseases. This commentator noted that best practice standards require access to array of medically necessary medical and rehabilitation treatments.

The Department has not changed the proposed paragraph to address these issues. A plan review of an enrollee request generally requires consideration of the requested specialty provider's suitability given the enrollee's condition, availability to serve 24 hours, 7-days-per-week, the scope of the proposed treatment and a determination as to whether a standing referral or primary care provider designation is most appropriate in the circumstances. This review will generally include the medical records of the requesting enrollee and a specific treatment plan. As stated previously, a review of this type of request does not mean that services are not being provided. Services are not denied during the review period but are made available by the participating care provider or "by referral," arrangements less preferred by the enrollee. Further, the Department requires the plan to take no more than 45 days and to take into consideration the nature of the enrollee's condition in arriving at its decision. Plans could and should take less than 45 days to review the request if the enrollee's condition warrants it.

One commentator commented that proposed subsection (b)(6) contradicted Insurance's regulations, since Insurance did not address these issues.

The Department's regulation regarding time frames contradicts nothing in Insurance's regulations. The fact that one agency issues a regulation on which the other agency chooses to be silent does not create a contradictory regulation. To be in compliance for the purposes of Act 68, a plan must be in compliance with both sets of regulations.

One commentator supported the proposal in subsection (b)(7) that a denial of the request would give rise to a grievance. Another commentator disagreed with this, and stated that since these decisions would be based on plan policies, which are operations and management decisions, they should be complaints. This commentator also noted that the Department's current statement of policy and Insurance/Department grid of complaints and grievances treats them as complaints.

The Department has reviewed its proposal to designate these denials as grievances in its policy statement. The statement of policy is repealed by these regulations. The grid remains a tool for guidance, and is not dispositive of these issues. The grid has long since been acknowledged by the Department as inaccurate and obsolete in many cases. The nature of the request and the underlying decision in these matters focus on medical necessity; that is, whether the enrollee's request for a specialist to serve as a primary care provider or a standing

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referral is medically necessary or appropriate. In considering such a request, the plan shall weigh the clinical appropriateness of the alternate arrangement, whether the specialist is appropriate for the condition, and whether the enrollee's condition is such that care can be better delivered or managed by a specialist. In rejecting such a request, a request that a specialist must have agreed with and supported, the plan is either disagreeing with the appropriateness of the specialist in favor of the primary care provider, or making a determination that the enrollee's condition does not warrant such an arrangement. These matters should be grievances. Therefore, the Department has not changed the proposed paragraph to address the concern.

One commentator recommended that the enrollee be required to get the consent of a specialist to be the enrollee's primary care provider so that the plan could avoid reviewing cases when a particular specialist does not want to be the primary care provider.

The Department acknowledges that there is some merit in this suggestion, because the arrangement cannot and should not take place without the consent and support of the specialist. However, the Department believes that the burden placed on the enrollee to articulate the request, negotiate the terms and gain the consent of a specialist would be too great for the Department to make this a condition for requesting such an arrangement. Additionally, the enrollee need not request a specific specialist by name in making a request for a standing referral or designation of a specialist. It is conceivable, in fact, that an enrollee may not have a particular specialist in mind when the request is made. The Department would expect the plan not to approve such an arrangement without first ascertaining the willingness of a specialist to agree to such an arrangement.

If an enrollee has a specialist the enrollee intends to suggest in making the request, and with whom the enrollee has a prior relationship, it would be useful to both the enrollee and the plan to determine that the specialist is willing to operate in this capacity. It is not required that the enrollee do so, however.

A commentator again raised the issue that Insurance has no regulation concerning the need to include information concerning appeal rights in the plan's decision. The Department reiterates its position: the fact that one agency issues a regulation on which the other agency chooses to be silent does not create a contradictory regulation. The Department's regulation regarding appeal rights information contradicts nothing in Insurance's regulations. To be in compliance with Act 68, a plan must comply with both sets of regulations.

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Section 9.684. Continuity of care.

The Department received several comments on this proposed section. Six commentators stated that the proposed section should be consistent with Insurance's regulations. One commentator commented that since continuity of care was already covered by Insurance, reference to it should be deleted from the Department's regulations.

The Department and Insurance regulations are consistent. Each agency has different responsibilities, based upon its different expertise. Therefore, the regulations cannot and should not be exactly the same.

One commentator recommended that the Department address requirements for continuity of care to make sure a patient's change of health plans or employment status does not inappropriately impact upon the patient's access to healthcare.

The Department cannot address this concern. Act 68 does not provide authority for the continuation of coverage lost due to a person's change of plan or job. Section 2117(a) of Article XXI only provides for continuity of care "if a managed care plan initiates termination of its contract with a participating health care provider." See section 2117(a) of Article XXI. These are the only circumstances under which Act 68 provides for continuity of care. To extend this benefit to other situations, the statute would have to be amended.

One commentator recommended adding language to subsection (a)(1) to clarify that this proposed paragraph would apply, except in the case of noncovered benefits addressed in subsection (j), now subsection (i), and termination for cause addressed in subsection (k), now subsection (j). The Department has added the suggested language for clarity.

The same commentator recommended changing the language of the proposed paragraph to read that enrollees may continue an ongoing course of treatment for up to 60 days. The commentator stated that "up to" is a direct reflection of Act 68, and would not lead enrollees to assume that the continuity of care period will automatically be 60 days. The Department has added the suggested language for clarity.

Another commentator requested clarification concerning when the 60-day time period would begin. The commentator noted that it is impractical and contrary to the intent of Act 68 to start the continuity of care period from the notice of termination.

While the Department understands the concern raised by the commentator, the clear language of the statute requires that the period of continuity of care run from notice to the enrollee of termination or pending termination of the provider. This period of up to 60 days, even if it will run from the notice of pending termination, will allow sufficient time for the enrollee to transition from one provider to another, which is an important aspect of continuity of care.

One commentator objected to the proposed requirement in subsection (a)(2) that plans provide written notice to enrollees of primary care provider terminations, and asked for that language to be deleted. The commentator commented that many member plans make contact

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with enrollees by telephone to begin work as expeditiously as possible with enrollees on selecting another primary care physician. The commentator requested that the Department allow the plans to maintain flexibility.

The Department has not changed the proposed paragraph. Since the continuity of care period runs from the date of notice of termination or pending termination, and is at the enrollee's request, the enrollee shall have written evidence of that date of notice to begin the process for requesting continuity of care. The written notice shall also tell enrollees how to exercise this option, along with clear notice of the continuity of care period's start and end date for enrollees. While the Department does not dispute the practicality of contacting enrollees by phone to initiate transfer, the Department needs to ensure that there is a reliable means of ensuring an enrollee is provided with consistent, accurate and unambiguous notice of the continuity options and instructions for initiating the process. Member services staff responsible for verbal notification are expected to make every effort to provide clear information and direction; however, the ability of the enrollee, plan and Department to effectuate and verify compliance requires written notification.

One commentator commented that the proposed paragraph is in conflict with Insurance's regulations since it requires the plan to notify patients of the right to continuity of care, or termination, and Insurance's regulations do not. The commentator credited the Department for recognizing the importance of notifying enrollees when their providers are being terminated.

One commentator requested that the Department clarify proposed subsection (b) by adding the phrase "including fee schedules," after the phrase "terms and conditions." The commentator interpreted the proposed subsection to mean that the plan would not be responsible for paying a nonparticipating provider charges, but only the fee on its fee schedule that would have been paid to a participating provider for the same services.

The Department has not made the requested change. If a plan chooses to make fees part of the terms and conditions, it may do so. The Department is not requiring that fees be included, nor is the Department regulating the subject of fees and payment between providers and plans.

One commentator has commented that the proposed subsection, particularly the phrase "with the exception that a plan may not require nonparticipating health care providers to undergo full credentialing," is problematic. The commentator raised the concern that a shortened credentialing process, which requires the collection of only a limited amount of information, could have serious quality of care implications for members who are using nonnetwork, noncredentialed providers. If the Department included this language in the final regulation, the commentator requested that the following language be included as well: "Managed care plans shall have no liability to enrollees who elect to receive care from nonparticipating noncredentialed providers."

The Department cannot waive tort liability for managed care plans by adding this language to a regulation. Only a statutory provision enacted by the General Assembly can grant immunity to a group in a particular situation. The Department will not delete the proposed requirement prohibiting full credentialing, since it is necessary to ensure that enrollees are able to access

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providers to realize the continuity of care benefit provided by Act 68. If the plan chose to require full credentialing, which in all probability would take at least 90 days, and given that the continuity of care period extends for only 60 days, the process would operate to prevent the enrollee from exercising this benefit. The Department notes that if plans are concerned with liability for failing to fully credential nonparticipating providers under this subsection, despite the Department's regulation prohibiting full credentialing, they could require a waiver from an enrollee.

Further an enrollee who is just joining a managed care plan would most likely be accessing nonparticipating and, therefore, uncredentialed providers. As discussed previously, the Department cannot permit plans to require full credentialing as a term or condition, as that alone would vitiate the chances of an enrollee ever realizing this benefit. However, in the event that plans wish to ascertain at least licensure in good standing and current malpractice coverage as minimal credentialing requirements, the Department is not adverse to this basic health and safety precautions, and subsection (f) does not prohibit it.

One commentator recommended that, although Act 68 permits a plan to require a nonparticipating provider to accept the same terms and conditions as participating providers, the Department should affirmatively prohibit that requirement.

The Department cannot prohibit something that Act 68 permits, and so has made no change to this proposed subsection.

One commentator recommended that the Department add language requiring a provider to accept the plan's reimbursement as full payment for short continuity of care period.

The Department is not able to require providers to accept the plan's reimbursement as payment in full as was recommended. The nonparticipating health care provider and plan shall come to mutually acceptable terms on their own.

One commentator stated that it appreciated the Department's exclusion from the section of a requirement that nonparticipating provider accept the plan's reimbursement as payment in full.

IRRC commented that the term "best efforts" in proposed subsection (h) is vague, and proposed that the Department provide samples of what would constitute best efforts in the final-form regulations.

The Department agrees with the comments, and taking into consideration the changes it has made to proposed subsection (i), it has deleted the subsection. The Department has also added the term "terminated" to subsection (g), since that subsection is meant to apply to both nonparticipating and terminated providers.

The Department received two comments on proposed subsection (i), both requesting revisions.

One commentator requested clarification of the duration of the "period of negotiation," commenting that it was confusing as written, and impractical in application. Another

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commentator stated that the proposed subsection presented quality-of-care and liability concerns. The commentator recommended eliminating this proposed subsection and replacing it with language from Insurance's regulations.

The Department does agree, after reviewing the comments, that the proposed subsection should be rewritten for clarity, and has renumbered it as subsection (h). The Department has decided to adopt Insurance's language and to require providers to notify affected enrollees that the provider has not agreed to the plan's terms and conditions prior to providing the service. This is the same as informing new patients prior to providing services that the provider does not accept the enrollee's insurance.

IRRC recommended that the Department cross-reference in subsection (k), (now subsection (j)), section 2117(b) of Article XXI, since the term "cause" is unclear. Section 2117(b) of Article XXI lists reasons providers can be terminated for cause under Article XXI. The Department agrees that referencing this section would clarify the term "cause." The Department has made the change to the proposed subsection.

Section 9.685. Standards for approval or point-of-service options by HMOs.

The Department received several comments on proposed § 9.656, which has been renumbered as § 9.685 and moved to Subchapter H (relating to access and availability). The Department has removed the section from Subchapter G, since the revisions the Department has made to the section now address all plans, rather than simply HMOs.

One commentator commented that this proposed section would allow an HMO to offer a point-of-service (POS) without doing so through a licensed insurer, and that that arrangement is currently not allowed in statute.

One commentator noted that since this proposed section would apply specifically to HMOs, PPOs offering POS options would not be required to follow the approval standards in the proposed section.

These comments are correct. POS plans are offered by HMOs. The definition of "POS" has been changed to reflect the fact that PPOs may also offer POS products. The title of the section has been changed accordingly, and references to "HMO" throughout the section have been replaced with references to "plan."

One commentator recommended that the Department ensure that plans have in place effective quality assurance programs.

The Department has not added the recommended language. Out-of-network use of providers can reflect enrollee preference; however, this section requires a plan to investigate instances, not of enrollee preference, but of network adequacy.

One commentator commented that the proposed section would not establish a monitoring mechanism to determine if access problems existed, or if HMOs were complying with required procedures, and taking corrective action if there appeared to be problems.

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The Department does not need to establish a separate monitoring mechanism for a POS product. Since Act 68 and the HMO Act apply to HMOs, they also apply to the POS product offered by an HMO. POS products shall also meet the minimum network access standards in § 9.679. Additionally, the Department has the same access to the books and records, and the ability to investigate complaints with respect to a POS product as it does with any plan. An POS is a type of benefit plan or product line offered by a plan.

The Department does not need a specific provision requiring corrective action in every section of the regulations. The requirements in § 9.606 apply to every section of the regulations. There is no need to repeat those provisions or cross reference that section in every other section of the regulations.

IRRC commented that proposed subsection (a) would require an HMO to submit a formal product filing for a POS product to the Department and Insurance. IRRC recommended that, for clarity, the Department cross reference Insurance's regulations. Language has been added to clarify that filings are only required if a plan proposes to offer a POS product. See subsection (a). The Department has already stated that plans must comply with Insurance's regulations as well as the Department's regulations.

Three commentators, including IRRC, raised concerns that informing an enrollee's primary care provider of care provided by another provider without referral from the primary care provider would breach confidentiality. IRRC questioned why the provision was necessary. Proposed subsection (b)(1)(i) would have permitted an HMO to offer a POS option to groups and enrollees if the HMO has a system for tracking, monitoring and reporting enrollee self-referrals for the purpose of periodically informing an enrollee's primary care provider of enrollee self-referred services.

One of these commentators stated that it was the enrollee's responsibility and privacy right to decide whether the specific nature of those services provided without a referral by a primary care provider should be communicated to the primary care provider. The commentator stated that the proposed amendments would provide ample quality safeguards to ensure that patient self-referrals were not a reflection of access or quality problems on the part of the primary care provider practice.

Another commentator objected to proposed subsection (b)(1)(i) as being administratively burdensome for the HMO, as well as possibly violating patient confidentiality, and recommended that it be removed.

IRRC also questioned what the time frame required by the word "periodically" was intended to be.

The Department has deleted this language because of the privacy concerns expressed by commentators, and because of the promulgation of Federal regulations on the privacy issue. The Department has replaced proposed subsection (b)(1)(i) with a requirement that a plan develop an alternate method of monitoring to ensure that self-referral activity is not a byproduct of an access problem, a deliberate attempt to keep some or all enrollees out of the

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office of the primary care provider for nonmedical reasons, or reflective of overrestrictive or burdensome plan requirements.

One commentator commented that POS options were created in response to consumer demand for the ability to self-refer outside the HMO's contracted network. Therefore, it contended higher than average usage would not necessarily reflect consumer dissatisfaction, but rather enrollee preference for a nonnetwork provider. The commentator stated that it was unclear as to how the Department would quantify and enforce higher than average usage of out-of-network care. The commentator recommended that the Department revise proposed subsection (b)(1)(ii).

Another commentator disagreed with the proposed subsection's requirement that HMOs monitor a practice when enrollee self-referrals to care are higher than average to ensure that self-referrals are not a reflection of access or quality problems on the part of the primary care provider practice. The commentator stated that in its experience, patients use nonreferred care due to the HMO's lack of approval of referrals, lack of adequate specialists in the network, lack of coverage for particular care or services offered through the more tightly managed care products. The commentator recommended that the section be revised to require investigations for the real reasons.

The Department understands that the reasons for self-referral can vary from being beyond provider access problems to general personal preference to administrative difficulties. The Department has revised the proposed subsection (b)(1)(ii) to require that the plan have the ability to review any primary care provider practice in which self-referrals are substantially higher than average, and to ensure that this is not reflective of access problems, inappropriate patient direction or burdensome plan requirements.

IRRC also asked the Department to define the word "promptly" in subsection (b)(1)(ii). The Department has not defined the word in the regulations, since it intends "promptly" to be given its common usage, that is, ready and quick to act as the occasion demands. See *Webster's Ninth New Collegiate Dictionary*, (1984) pg. 942. The Department believes that plans should investigate these situations quickly as on the patient's individual circumstances demand.

One commentator recommended that the Department add the following language to the end of proposed subsection (b)(2): "such expenses shall be reasonable and not designed to unfairly restrict access to such services." The proposed subsection would state an HMO could offer POS options to groups and enrollees, if the HMO would provide clear disclosure to the enrollee of the enrollee's of out-of-pocket expenses.

Two commentators noted that Insurance was the lead agency on disclosure. One of these commentators recommended that the disclosure requirements should be coordinated with the requirements of Insurance's final-form regulations. The other expressed concern that further delineation of regulatory authority between the agencies will prove confusing and duplicative for regulated agencies, and recommended that the Insurance handle this issue.

The Department will defer to Insurance on matters relating to disclosure.

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Subchapter I. Complaints And Grievances

The Department received over 450 comments on this proposed subchapter.

Some commentators commented generally on the proposed subchapter unrelated to specific sections, and recommended certain actions to the Department. These general comments are as follows:

Regarding UR, one commentator recommended that the Department strengthen its standards regarding UR and UR decisions so that the Department could effectively monitor UR practices. This comment is addressed in discussions on §§ 9.749 and 9.750 (relating to UR system description; and UR system standards). The Department does include requirements for more and detailed information to be included in UR decision letters.

Regarding coordination with Insurance, one commentator noted that both Insurance and the Department have the authority to address complaints and grievances and that some plans have been informed that the Department will handle grievances only and Insurance will handle complaints only. This commentator recommended that this confusion be resolved by the agencies. In response, both agencies have the authority to address complaints under Act 68. The Department has the authority to assign grievances to a CRE for an external review.

Regarding retrospective UR denials, several commentators raised general concerns about plan's retrospectively denying coverage for inpatient days previously approved, suggesting the Department prohibit retrospective denials unless the provider was derelict in providing information to the plan needed by the plan to make an appropriate decision. The commentators further stated that to do otherwise would discourage providers from exercising due process rights to appeal decisions. One of these commentators expressed concern that the enrollee has no motivation to provide consent since the enrollee is not financially responsible for paying for the denied inpatient days. The commentator recommended that the Department adopt one of three options: (1) prohibit health plans from retrospectively denying coverage for services that were prospectively or concurrently approved unless the provider was derelict in providing information to the health plan which was needed to make a decision; (2) allow providers to obtain the patient's consent when treatment is initiated; or (3) remove the requirement for a patient's consent on retrospective denials.

In response to these comments, the Department disagrees with the concept that plans should not be permitted to retroactively deny reimbursement for services after preapproving them. In defining "retrospective utilization review" in Act 68, it is clear by statute that retrospective review that "results in a decision to approve or deny payment for the health care service" is permissible. The Department does allow providers to obtain consent at the time of treatment, and has specified in § 9.706 (relating to health care provider grievances) that such consent may be obtained at the time of service, if it is not a condition of the enrollee's obtaining treatment.

In another general comment, one commentator believed that the proposed regulations would eliminate the requirement that plans routinely tell dissatisfied members of their rights, and how to file a complaint or grievance. This was not the Department's intention. The Department has

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required that plans include in the initial UR decision letter and the subsequent complaint and grievance review decision letters an explanation of how to file a complaint or grievance. See §§ 9.703(c)(1)(v)(D) and (2)(vi)(D), 9.705(c)(1)(v)(D) and (2)(vi)(D), 9.708(a) and 9.750(f).

One commentator complained generally that the proposed amendments contained no penalty for plans that miss deadlines, or otherwise fail to adhere to the complaint and grievance process. Another raised concerns that there would be no verification of adherence to timelines in the regulations. The Department proposes to conduct regular audits to ascertain timeliness and will investigate complaints of this nature brought before it. Penalties are permissible under § 9.606.

Regarding overall fundamental fairness issues, several commentators expressed concern that the Department did not include its 1991 Guidelines and Technical Advice to HMO Applicants Regarding Member Grievance Procedure (1991 guidelines) for the conduct of complaint and grievance hearings in its proposed regulations.

One commentator complained that there would be no process for the Department's intervention in cases in which a member's rights were being ignored, noting the proposed amendments did not provide for Department assistance to enrollees in identifying and gathering information needed to proceed with the appeal at the agency level. This commentator stated that the absence of fundamental fairness guidelines in the proposed regulations was of particular concern.

IRRC asked the Department to explain whether complaint and grievance procedures established in the 1991 guidelines would change upon implementation of the proposed regulations, and whether the changes in the complaint and grievance procedures would diminish the rights of enrollees. IRRC also asked why the provisions of the 1991 guidelines that were consistent with Act 68 and the HMO Act were not codified, and how areas in the 1991 guidelines that were not included in regulation would be enforced by the Department.

Upon publication of final rulemaking, the 1991 guidelines that the Department has decided to retain will become part of its regulations. The 1991 guidelines never had the force of law, not having been promulgated as regulations. The 1991 guidelines were an expression of the Department's views of how a fair complaint or grievance proceeding should be conducted and have since been referred to as the Department's "fundamental fairness" rules. The Department believes that certain basic requirements are necessary to create a problem resolution process, for complaints and for grievances, in which both sides can participate and feel that their interests are fully presented and fully considered.

With the passage of Act 68 in 1998, a statute that detailed specific requirements of grievance and complaint procedures, the Department was under the impression that the General Assembly intentionally did not include the Department's fundamental fairness guidelines in Act 68. This was a mistake on the part of the Department. The Department is in agreement with numerous commentators that it would be beneficial to enrollees and plans to establish specific requirements for fairness. The Department has, therefore, incorporated portions of the 1991 guidelines in these regulations for the purpose of ensuring that fairness exists in the review process.

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In response to IRRC's specific question, the regulations will supersede any other guidance document in existence, and those provisions in the guidelines that are not included in the regulations will not be enforced. The Department will discuss the specific changes made in discussions on comments to §§ 9.703 and 9.705 (relating to internal complaint process; and internal grievance process).

Four commentators raised general issues relating to access to the complaint and grievance process for enrollees with disabilities, non-English speakers, families of enrollees and public and nonprofit groups, presumably to advocate for enrollees. The Department will address these comments in specific sections later in the Preamble.

Section 9.701. Applicability.

One commentator requested that the Department clarify what entities were covered by this proposed section. The commentator asked whether PPOs were required to maintain grievance systems under these regulations or other regulations.

Any entity that meets the definition of "managed care plan" under Act 68 is required to have a complaint and grievance procedure in place. See section 2111(8) and (9) of Article XXI. Therefore, PPOs that use a gatekeeper, and are therefore plans under section 2102 of Act 68, are required to have a complaint and grievance system which complies with Act 68. PPOs are also required to have a grievance resolution system approved by the Commissioner in consultation with the Secretary under section 4.1(e) of the PPO Act (40 P. S. § 764a(e)).

Section 9.702. Complaints and grievances.

The Department received over 40 comments on this proposed section.

IRRC commented that the Department had failed to include a requirement of Act 68 that an enrollee may designate a representative to participate in the process. It recommended that since this requirement is for the entire complaint and grievance process, it should be mentioned here even though it is mentioned elsewhere. IRRC also expressed concern that the proposed regulations would not include Act 68's requirement that a plan have a toll-free number that enrollees could use to obtain information regarding the filing and status of complaints and grievances.

The Department agrees that both of these requirements are important, and has included them in subsection (a)(3) and (5). The Department has also added in subsection (a)(5) a requirement that the plan make reasonable accommodation to enable persons with disabilities and non-English speaking enrollees to secure the same information.

The Department also agrees with other comments it has received with regard to including language in the regulations from its 1991 guidelines requiring the plan to make available a plan employee who did not participate in any previous plan decisions to deny coverage for the issue in dispute to aid in the preparation of the complaint or grievance. The Department believes that this is the most appropriate section in which to include that requirement, and has done so in subsection (a)(4). This requirement is not intended to require a plan to provide an employee to

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advocate for the enrollee, but, rather, to provide the enrollee with access to an individual who can explain the procedure involved in the plan's complaint or grievance process. An advocate is not necessary, since the enrollee has the ability to appoint someone to represent the enrollee during the complaint or grievance process.

Another commentator requested that the Department clarify how to treat an enrollee's cancellations or failures to participate in a meeting scheduled for a second level review. The commentator asked how an enrollee's failure to participate affected the compliance time frames.

The Department believes that an enrollee must be given ample opportunity to participate in the process, and that if the enrollee requests that a hearing be rescheduled, the plan should reschedule the hearing at least once as a courtesy to the enrollee. The plan should also reschedule the hearing after that if the enrollee has an unforeseen complication preventing the enrollee's attendance such as illness or transportation breakdowns. Since the plan sets the hearing date, often times without consulting the enrollee, the plan must make reasonable efforts to reschedule to accommodate the enrollee. If the enrollee fails to appear at the hearing after the plan has rescheduled the hearing for the convenience of the enrollee, the plan could put its case on the record, and may provide the enrollee with the ability to add information to the record prior to the review committee's decision. As the plan faces statutory deadlines, it must render a decision based on the record at the time of the deadline. As the deadline is for the benefit of the enrollee, the enrollee may agree to allow the plan to exceed this deadline to submit additional information or to facilitate enrollee participation at the review. Both parties must consent in order to extend the time. The Department will not impose a penalty if the plan refuses to agree to an extension of time and completes the review within the time period permitted in the statute.

One commentator suggested that proposed subsection (a) ignored Act 68's clear instructions that complaints were the responsibility of Insurance and not the Department, and stated generally that the other proposed provisions were unduly vague.

It is incorrect to say that Act 68 clearly requires complaints to be exclusively under the jurisdiction of Insurance. Act 68 specifically gives the authority over complaints to the appropriate agency, either the Department or Insurance. See section 2142(a) of Act 68. Act 68 also gives both agencies the authority to investigate violations of Act 68, including the sections relating to complaints. See section 2181(d) of Act 68. The Department disagrees that the remainder of the provisions are vague.

IRRC commented that Department should either explain what additional requirements the Secretary may impose on the complaint and grievance procedure, or delete the phrase: "and is satisfactory to the Secretary" from subsection (a)(1). IRRC also recommended that for clarity the Department should use the plural word "procedures" rather than the singular word "procedure" to emphasize that complaints and grievances are separate procedures.

The Department's intention in including the phrase "and is satisfactory to the Secretary" was to provide notice of its authority over complaint and grievance processes under section 10(e) of the HMO Act (40 P. S. § 1560(e)) and section 630(e) of the PPO Act (40 P. S. § 764a(e)) in

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addition to Act 68. Because, however, by definition, the regulations are what is acceptable to the Secretary, the Department has removed the language from subsection (a)(1). The Department has also changed the regulation to clarify that the two review procedures are separate procedures.

IRRC recommended that proposed subsection (b) be revised to include health care providers as well as enrollees among the persons plans cannot discourage through their administrative procedures from filing complaints and grievances since providers are able to file grievances.

The Department agrees and has made this change.

One commentator recommended that the Department include in the proposed subsection a mechanism for addressing the fairness of a plan's procedures as applied to an individual specific complaint or grievance in real time. The commentator noted that enrollees have no process for addressing the problem in a timely fashion.

The proposed subsection would prohibit a plan from incorporating administrative requirements, time frames, or tactics to discourage the enrollee from, or disadvantage the enrollee in utilizing, complaint and grievance procedures. The Department agrees that there should be a mechanism by which enrollees, and health care providers who file grievances, can make the claim that the plan is acting inappropriately. The Department is requiring plans to notify an enrollee through the denial letters that, in addition to the procedures and deadlines for continuing through the complaint and grievance procedures, the enrollee may contact the Department directly if the enrollee feels the plan is handling the review procedure inappropriately. The Department has the discretion to investigate the matter and take whatever appropriate action is required regardless of the level of the appeal. The Department has added language to this effect in subsection (a)(2)(i) and (ii).

Further, these investigations should not prevent the grievance or complaint process from going forward. The Department has added subsection (a)(2)(iii) to clarify this. If the enrollee believes that the plan's action adversely impacts the decision in the matter, the enrollee may raise that issue to the next level of review.

Two commentators recommended revising proposed subsection (a) to provide an enrollee access to records and other information necessary to adequately prepare for an appeal. One of these commentators recommended including the following: (1) the opportunity for timely advance review of his or her plan file, and copies of plan records whether or not they were relied upon by the plan in reaching its decision; (2) the identity and credentials of whomever participated in a decision to reduce or deny services; (3) and the opportunity to question plan employees or contractors whose action or inactions are at issue at the second level review.

The Department agrees that plans should make documents used in making the decision available to the enrollee. The plan may choose to charge a reasonable copying fee for these documents. Because these issues are specific to procedure, the Department has chosen to address them specifically in the sections dealing with review processes. See §§ 9.703(c)(1)(iii) and 9.705(c)(1)(iii). The Department received 6 comments on proposed subsection (a)(3)

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(moved to subsection (a)(6)), which would require a plan to provide copies of its complaint and grievance procedures to the Department for review and approval.

One commentator supported the Department's advance review of complaint and grievance systems. Several others took issue with this proposed requirement.

One commentator requested that the Department clarify its authority to require prior review and approval.

The Department has addressed this issue in its discussion of comments on § 9.710 (relating to approval of plan enrollee complaint and enrollee and provider grievance systems).

All plans should currently be operating under policies and procedures that are in compliance with Act 68. The Department will review any new policies and procedures due to requirements in the regulations; the Department will provide for a period of transition to allow plans to implement any necessary changes once the regulations are final.

One commentator raised concerns that this proposed requirement for prior approval would create problems for managed care plans enrolling Medical Assistance (MA) recipients. The commentator noted that plans currently submit copies of grievance and complaint procedures to the DPW for review and approval. The commentator was concerned not only about the cost of duplicative requirements, but also that different agencies might have different determinations regarding the adequacy of the complaint and grievance procedures, placing the plan in precarious position in terms of regulatory compliance. The commentator recommended that the Department work with the DPW to eliminate duplicative reviews and clarify regulatory authority.

There should be no confusion as to regulatory authority. The DPW is in the role of purchaser, and buys certain products from HMOs with certificate of authority for its MA population. To the extent that a plan has contracted with DPW to provide services, it is required to meet DPW's contractual requirements. It is the Department, however, along with Insurance, that has regulatory oversight over HMOs in this Commonwealth. Therefore, an HMO must have a certificate of authority from the Department and Insurance to be eligible to contract with DPW. In other words, the HMO bidding on DPW's request for proposal must meet the Department's and Insurance's standards for a certificate of authority, and must comply with the Department's and Insurance's regulations to maintain compliance with Act 68 and the HMO Act and to retain its certificate of authority to operate. The DPW communicates with the Department concerning the Department's regulatory requirements and, to the fullest extent possible, coordinates both agencies coordinate activities.

It should also be noted that a plan serving an MA population must not only offer procedures and processes that comply with the terms of Act 68, but also a fair hearing process, in accordance with Federal law and regulations. The enrollee has a choice of pursuing either procedure, or both, in challenging a plan decision. The Department and DPW treat these as separate procedures; the Department has no authority over the DPW fair hearing process and DPW has no jurisdiction over the Act 68 process.

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One commentator stated that the proposed subsection ignored Act 68's clear instructions that complaints are the responsibility of Insurance, and not the Department, and that the other provisions were unduly vague.

Another commentator commented that since the Department has the authority to approve complaint and grievance procedures as part of its Act 68 compliance and review activities, and the authority to review and approve forms, Insurance should not. The contention was that both agencies should not have approval over complaint and grievance procedures.

Act 68 gives authority over complaints to both agencies. See section 2142(a) of Act 68. Which one is appropriate depends upon the subject matter of the complaint. Act 68 also gives both agencies the authority to investigate violations of Act 68. See section 2181(d) of Act 68. The Department and Insurance will work together to ensure that the documents approved are in compliance with Act 68 requirements, and the standards for grievances as developed by the Department.

IRRC commented that this proposed subsection was unclear because it would not provide any specific requirements for the approval of procedures. IRRC recommended that the Department add a reference in this subsection to § 9.710 (relating to approval of plan enrollee complaint and enrollee and provider grievance systems). The Department has added the reference.

One commentator supported proposed subsection (b) since it would require a plan to immediately correct procedures found to be noncompliant or creating unacceptable administrative burdens on the enrollee.

IRRC commented that since the Department has the authority to require a plan of correction, this proposed subsection should be revised to specifically require a plan to develop and adhere to a plan of correction.

IRRC also asked for an explanation of the difference between a noncompliant plan and a plan that would create an unacceptable administrative burden on an enrollee. IRRC recommended that the Department delete the phrase "or to create unacceptable administrative burdens on the enrollee."

The Department agrees that the phrase "create unacceptable administrative burdens on the enrollee" is redundant, and should be deleted. The Department has replaced that phrase with the phrase "with the act or this chapter."

The Department has not included language in the proposed subsection specifically stating that the plan must develop and adhere to a plan of correction, since that language already appears in § 9.606. The Department may choose to use a plan of correction in this instance, or it may choose to prosecute violations in other ways permitted by § 9.606.

IRRC commented that the use of the term "appeal" in proposed subsection (c) was vague and would conflict with the use of the term in proposed § 9.705. IRRC recommended that the Department use another term in the proposed subsection.

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The Department agrees, and has replaced the word "appeal" with the phrase "request for an internal review" as a more descriptive term.

IRRC and another commentator commented that proposed subsection (c) would not provide guidance on how to distinguish between complaints and grievances. IRRC noted that Insurance included examples in its final-form regulations, and recommended that the Department consider adding language that explains the difference between a complaint and a grievance, along with examples. The other commentator suggested that the Department could state that it would provide updates on its interpretation in its website or in technical advisories. The commentator urged that this was necessary in addition to providing the opportunity for individual plan consultations as described in the proposed regulations.

The Insurance regulation referred to by IRRC (31 Pa. Code § 154.17(a)(3)) includes types of complaints the Insurance would review upon appeal, and not examples of complaints versus grievances. The Department agrees that further guidance should be given to plans, enrollees and providers. It believes that it will be more appropriate to provide such guidance and examples through a technical advisory, which will allow it more flexibility in terms of the narrative explanations and examples. The Department will also include this information on its website.

IRRC recommended that the Department review Insurance's regulations to ensure there are no conflicts in the classification of complaints and grievances. The Department has reviewed the regulations and is satisfied that no conflict exists.

IRRC commented that, to be consistent with subsections (a) and (b), the Department should change the word "process" in proposed subsection (c)(1) to "procedure."

The Department has made the change.

One commentator recommended that the Department change the language in proposed subsection (c)(1) to permit the Department to correct situations where there may not have been deliberate action by the plan to deny or affect the enrollee's access to the complaint or grievance process, but the classification nevertheless resulted in access being affected or denied.

The Department has the ability under the regulations to change a complaint to a grievance when it finds that classification is more appropriate. That decision, however, is not predicated upon whether or not the plan intended to harm the enrollee by its classification of the request for review. The Department has not changed the regulation.

IRRC commented that proposed subsection (c)(2) would only require the plan to consult with the Department or Insurance concerning whether the case was a complaint or grievance, and that it was unclear whether the Department's decision is binding. IRRC recommended that the regulation should state whether determination is binding or not.

The Department agrees, and has added language to the regulation that states that the decision is final and binding.

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One commentator welcomed the Department's recognition that its intervention would be necessary when the enrollee believes that the plan has improperly classified the request for an internal review. Three commentators recommended that language be added to the proposed regulations to provide for the disclosure of this right.

The Department agrees that the enrollees should be informed of their ability to question the classification of the request for an internal review. Therefore, the Department will require plans to add language in their letter acknowledging receipt of the matter from the enrollee that the enrollee can contact the Department to question the classification of the case. This is addressed in §§ 9.703(c)(1)(i)(A) and 9.705(c)(1)(i)(A).

One commentator commented that rather than orienting the regulations to establish the enrollee's choice of classification as a complaint or grievance, the final-form regulations should at least guard against enrollee ignorance, plan's perverse incentives and passive oversight. The commentator recommended two changes: establishment of affirmative enrollee rights to information, and a disincentive against misclassifications of request by plans. The commentator recommended that if the plan misclassified a request, the plan should have to provide the benefit or what is being contested until the appropriate complaint or grievance procedure had been completed.

The same commentator commented that the proposed regulation obscured the intent of Act 68 to allow enrollees to challenge a plan's decision by allowing enrollees to choose whether to file a complaint or grievance of a plan's decision. According to the commentator, Act 68 states that an enrollee can file a complaint and that an enrollee can file a grievance; therefore, Act 68 gives the right to enrollees, not to plans, to decide whether the matter should be a complaint or a grievance. The commentator recommended that the final-form regulations should say that the initial classification should belong to the enrollee, that the plan should respect this unless it is unclear, and then the plan can discuss the issue with the Department and make a decision.

The same commentator also recommended that the Department require a plan to counsel the enrollee as to whether to file a complaint or a grievance by including information in the notice, and discussing the matter with the enrollee. The commentator further suggested that the plan should have the burden of contacting the Department for reclassification, not the enrollee, as it states in the proposed regulations.

Several commentators also suggested that the proposed regulation would pervert the intent of Act 68 by allowing plans to classify any request for internal review they receive as they please, to their possible advantage, as either a complaint or a grievance, noting that the Department recognized this possibility in its Preamble. The commentators stated that Act 68 provides no authority for assigning this decision to the plan.

The Department has not changed the regulation to state that the enrollee may make the determination of the classification as a complaint or grievance. Under Act 68, the plan is responsible for processing complaints and grievances in accordance with prescribed requirements for complaint procedures and grievance procedures. The plan must bring the right procedure to bear and can be sanctioned or penalized if it does not. Not providing for plans to classify the issue as a complaint or grievance would mean that the plan is subject to

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penalty for following the wrong procedure when an enrollee has misclassified the issue in dispute. The Department has no desire to penalize the enrollee for such a mistake, but to penalize the plan for an enrollee's error would be unjust. The most reasonable way to implement Act 68 and ensure compliance is to place the duty to classify as a complaint or a grievance with the plan, provide for notice to enrollees with an appeal mechanism to the Department and to hold plans accountable for their classification decisions by penalties and sanctions.

Because time frames for complaints and grievances are equal, improper classification should not delay the proceedings. If the Department finds that a case has been classified incorrectly, it will instruct the plan to continue the process at the same level of review, but for the appropriate classification.

One commentator raised concerns over the handling of complaints regarding noncovered services. The commentator noted that services excluded by contract are not covered, even when medically necessary; however, some of these services have been handled inappropriately as grievances.

The Department takes the position that if there is a specific contract exclusion for a specific service, the matter is a complaint. However, if a requested service is covered by the plan in certain circumstances that relate to clinical or medical criteria, and if it is necessary to obtain the opinion of a physician to determine whether or not the requested service should be covered according to the contract terms, then the matter must be reviewed by another physician, and not by Insurance or the Department, in order for the enrollee to obtain an informed and relevant review of the enrollee's request. For example, the plan's contract may exclude weight loss programs except when medically necessary. The enrollee's provider documents the medical necessity for weight loss yet the plan determines there is insufficient evidence, or the enrollee's condition does not meet clinical thresholds. In both instances, the plan is rejecting the medical necessity assertions of the enrollee's provider in favor of, or according to, the plan's medical policy. The only possible way to intelligently and effectively evaluate the merits of the enrollee's provider's arguments for coverage versus the validity of the plan's denial is to have a physician objectively and clinically evaluate both sides of the argument. Neither Insurance nor the Department is in a position to determine if an enrollee's weight or cholesterol count is sufficiently high enough to warrant coverage of a weight loss program as medically necessary. The Department has treated these matters as grievances.

IRRC noted that proposed subsection (c)(4) waives the filing fee if a grievance is improperly filed as complaint. IRRC questions why paragraph (5) would not require a refund if a complaint were improperly filed as a grievance.

It is rare that a complaint will be improperly classified as a grievance simply because the plan incurs more cost in a grievance process particularly through obtaining the opinion of a matched specialist, a specialist who practices in the same or similar specialty as would typically manage or consult on the requested health care service, in the internal review, than in the complaint process. Further, the external grievance review may cost anywhere from \$300 to \$3,000. The Department agrees, however, that for the sake of consistency with paragraph (4), where a

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complaint has been filed as a grievance, the fee should be refunded. It has included language to this effect in subsection (c)(5).

One commentator supported the provision requiring Department monitoring of plan reporting of complaints and grievances in proposed subsection (c)(6), and recommended that this should include, under an enrollee controlled designation procedure, monitoring of the frequency with which plans seek reconsideration by the Department, and whether the pursuit of reconsideration is done in good faith and not so as to delay the proceedings and deny due process to an enrollee.

The Department is not creating an enrollee-controlled designation procedure. The Department is aware that there are concerns that improper classification, particularly of a grievance as a complaint, may harm the enrollee. Delay in the proceedings, however, should not be a factor, since both the complaint and grievance procedures adhere to the same time frames at all levels. The Department intends to monitor this situation closely, and will issue technical advisories as appropriate to clarify how to distinguish between complaints and grievances in greater detail than is possible in regulations.

One commentator took issue with proposed subsection (c)(6), which provides that the Department might audit or survey to verify compliance with Act 68 and Subchapter I. The commentator recommended that the audits and surveys be a regular part of auditing process rather than an option. The commentator also recommended that if the Department decided that this would be an option, then standards should be articulated as to when a survey would occur.

The Department has the responsibility under Act 68 to ensure compliance with that act. The Department needs flexibility to choose when audits or surveys are necessary. The Department also reviews plans' quarterly and annual reports for data concerning first and second level complaints and grievances, and makes determinations if there are problems at that time as well.

IRRC commented that proposed subsection (d)(1) would duplicate the requirements of proposed subsection (2)(d) and (3) as it applied to grievances. IRRC also commented that the term "unreasonable" in paragraph (1) was unclear. IRRC recommended that the Department either delete paragraph (1), or add the 15-day time period Act 68 permits for agency appeals.

One commentator stated that the Department should extend the "business day" definition to all time frames in the proposed regulations and under Act 68. The commentator stated that the same pressures that make business days a reasonable time period in short time frames apply in other time periods as well. The commentator also noted that NCQA uses business days.

IRRC recommended that the Department delete the term "calendar day" in paragraph (2) since time limitations in terms of days are considered to be calendar days. Another commentator also recommended deletion of this term, as Act 68 and regulations typically refer to "business" or to "days" without a modifier.

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That commentator also recommended that the time frames proposed in paragraphs (2) and (3) be the same and mirror Insurance's regulations.

One commentator noted that these time frames for enrollees to file complaints and grievances (45 days) differ from time frames under DPW's contracts, which allow 30 days. The commentator expressed concern that plans would have to go to considerable expense to change booklets and other documents. It also asked that the Department consider DPW's requirements when the Department audited plan compliance.

After reviewing all the comments on proposed subsection (d), the Department recognizes that the proposed subsection was inadvertently inconsistent with Insurance's final regulation. Since both agencies are responsible for the review of complaints, the regulations must be consistent on this topic. Therefore, the Department is adopting the text of Insurance's final regulation, and has deleted the substance of proposed subsection (a)(1) and (2). The Department has adopted Insurance's language relating to time frames in subsection (d), which provides at least 45 days for enrollees to file complaints and grievances. Plans not in compliance with this standard, even for DPW enrollees, are not in compliance with Act 68.

Section 9.703. Internal complaint process.

Proposed § 9.704 has been renumbered as § 9.703. The Department received over 120 comments on this proposed section.

The Department received several general comments on this proposed section, again referring to the Department's 1991 guidelines, and contending that the section lacks a fair and uniform procedure for how complaint and grievance hearings should be conducted, which had been included in those guidelines. One commentator also commented that the proposed regulations would not specifically provide procedures that would assure independent input in the complaint resolution process.

For reasons discussed earlier, the Department is adding to this section provisions from its 1991 guidelines to ensure a fair proceeding in the review of complaints. Those provisions are discussed in the discussion of the Department's response to comments on the individual subsections in this regulation.

Two commentators recommended generally that the Department add a new subsection which would state: "If the plan fails to act within the time frames established herein, the relief sought by the member shall be granted automatically by the plan."

The Department has not added this language to the regulations. If a plan violates the time frames of Act 68 or this subchapter, it is subject to sanctions under Act 68 and these regulations, including fines. Requiring a plan to provide the relief sought by the complaint in every instance when a plan fails to meet time frames is an extreme penalty, and removes discretion from the Department to fit the penalty to the violation.

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One commentator recommended that the Department delete this section entirely, as complaints are under the sole jurisdiction of Insurance, not the Department. As stated earlier, both the Department and Insurance are given authority over complaints by Act 68.

IRRC commented that the second sentence of proposed subsection (a) lacked clarity. That sentence stated: "The process shall address complaints concerning matters including participating health care providers, health plan coverage, plan operations, and plan management policies." IRRC recommended that the Department rephrase the sentence to follow the language of Act 68: "An enrollee shall be able to file a complaint regarding a participating health care provider, or the coverage, operation, or management policies of the managed care plan."

The Department's intention was to add clarity to the Act 68 definition; therefore, the Department did not track the language of Act 68 exactly. The Department has made revisions to the language to follow the language of Act 68 as suggested by IRRC.

IRRC also commented on the Department's use of the phrase "and is acceptable to the Secretary" in proposed subsection (a). IRRC noted that the complaint process shall meet the requirements of Act 68 and the regulations, and that the Department should either explain what additional requirements it means, or delete the phrase.

As discussed earlier, the Department's intention in including this phrase was to provide notice of its authority over the complaint and grievance process under both the HMO Act and the PPO Act, as well as under Act 68. As the regulations contain what would be acceptable to the Secretary, the Department has deleted the language.

Another commentator commented that the right to complain should be extended to former and potential enrollees who have contractual and legal rights for which there may be no other recourse but to file a complaint. For example, a former member may seek payment for a service that the plan denied as not covered, but was provided during a period of enrollment.

The Department has not changed its regulations to address this concern. Act 68 does not extend the right to file a complaint or grievance to a potential enrollee. See sections 2141(a) and 2161(a) of Article XXI. Therefore, the only persons able to file complaints or grievances are enrollees or, in the case of a grievance, providers with enrollee consent. Former enrollees have the same appeal rights as current enrollees, as long as there was a contract in effect at the time of the initial denial or event that triggered the complaint or grievance, even though the entire complaint or grievance process may run past the period of coverage. An enrollee must comply with the plan's time frame for the filing of a complaint or grievance. Once that time period passes, the individual no longer has the ability to file the complaint or grievance.

IRRC commented that the proposed regulations would allow oral or written complaints at both the first and second level review. IRRC noted that Act 68 only addresses oral complaints at the first level review. IRRC recommended that the Department revise the regulations to state that a written request would be required to initiate a second level review of a complaint.

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Although Act 68 is silent on allowing oral complaints at the second level, the Department proposed to permit second level oral complaints and has not changed the language. The Department believes that a plan must take an oral complaint at the second level from a person who is unable to make the complaint in writing. The intent of Act 68 permits this, and the demands of fairness require it. Further, were a plan to refuse to allow an oral appeal where an individual is unable to make a written one because of a disability, the plan could be in violation of the ADA.

One commentator objected that the proposed regulations would not include a requirement that the plan provide notices to an enrollee at each step of the appeal process.

The regulations require such notice from the plan at the receipt of the complaint, and after every level of the complaint process. See subsection (c)(1)(i) and (vi) and (2)(i) and (vi).

One commentator stated that it was particularly troubling that there was no requirement for all members of a review panel to be present at the hearing on the complaint.

The proposal did not state that members of the complaint review committee are not required to be present. To clarify this, however, the Department has added language to the regulations requiring members of the second level complaint review committee to be present at the review either telephonically or by videoconference, and have the opportunity to review any additional information provided during the review in order to vote. See subsection (c)(2)(iii)(I).

IRRC commented that the proposed regulation did not state that the first level decision was binding unless appealed, as did proposed § 9.704(c)(2)(iii).

The Department believes this language is unnecessary. An enrollee can appeal the decision if the enrollee chooses. The plan will obviously not appeal its own decision. If the enrollee does not appeal the decision, it will stand. The Department has deleted the proposed provision.

One commentator noted that there was frequent confusion about whether an enrollee's first contact with a plan constituted an inquiry, a complaint or a grievance. The commentator recommended that the Department require an acknowledgement from the plan to establish the date of the receipt for purposes of monitoring compliance with Act 68 time frames and to clarify whether the plan views the enrollee's challenge as a complaint or grievance, so that the enrollee may obtain help from the Department if necessary. Another commentator also recommended that the plan be required to notify the enrollee of receipt of the complaint.

The Department agrees that it is necessary to have plans confirm that complaints or grievances have been received, to establish the start of the review period and to allow the enrollee the ability to challenge the classification as appropriate. Further, the Department agrees that it is necessary for the plan to provide certain information to the enrollee before the start of the process, to ensure that the enrollee is aware of and is able to take advantage of certain procedures put in place for the enrollee's benefit. These would include the ability to contact the Department, to review plan information related to the complaint upon request, to submit additional information to the plan for review and to appoint a representative. The

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Department has included these requirements in subsection (c)(1). These requirements were included in the Department's 1991 guidelines.

The Department has also included the requirement that if the plan agrees to allow attendance at the first level review, the enrollee, and the enrollee's representative, if applicable, may attend the first level complaint review. See subsection (c)(1)(i)(E). The enrollee and the enrollee's representative, may attend the second level review as a matter of course. See subsection (c)(2)(iii)(A). The Department has also included language stating that the enrollee may request the aid of a plan employee who did not participate in previous plan decisions to deny coverage for the issue in dispute in preparing the enrollee's complaint. See subsection (c)(1)(iv) and (2)(iii)(F). These requirements were also included in the Department's 1991 guidelines.

IRRC commented that the Department should add "one or more employees of the plan" for clarity to proposed subsection (c)(1)(i). The Department has added the language as IRRC recommended. See subsection (c)(1)(ii).

One commentator commented that the proposed regulations did not include standards that would guarantee that the committee deciding complaints would remain unbiased.

The Department's proposed regulations would have prohibited involvement of any individual involved in a prior decision to deny the complaint. The Department has not changed that language. See subsection (c)(1)(ii) and (2)(ii).

Several commentators commented that the Department had failed to include language in the proposed regulations which would have given an enrollee access to information relating to the complaint. The commentators stated that without this information, the enrollee would be unable to prepare a case.

One commentator commented that the proposed regulations should require plans to provide access to documentation compiled on the specific matter being appealed, including, but not limited to, internal policies, nursing notes, extended evaluations, and the like.

The Department agrees that the enrollee or the enrollee's representative should have access to relevant information relating to the matter about which the enrollee has complained, and has added language to that effect to the regulations. See subsection (c)(1)(iii). This will enable the enrollee to determine what additional information the enrollee believes is necessary to support the case. The Department is, however, permitting the plan to charge a reasonable fee for the reproduction of any documents. *Id.*

Three commentators, including IRRC, requested that the Department clarify that a first level decision must be issued within 30 days, so that the 5-day notification period is not included in the 30-day review period. Proposed subsection (c)(1)(iii) stated that the plan was to complete its investigation and review within 30 days of receipt of the complaint.

It was not the Department's intention to add the 5-day notification period to the review period, and the proposed subsection did specify that notification was to occur after the committee's

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decision. Since this has created confusion, however, the Department has added the language "and shall arrive at its decision" after "review and investigation of the complaint" to clarify this issue. See subsection (c)(1)(v).

Two commentators commented that the proposed regulations do not include any allowance for postponements. One of these commentators commented that a plan should be able to ask an enrollee if the enrollee wished to extend the period for review when notifying the enrollee that despite using all due diligence, the plan would be unable to obtain the medical records needed to complete the review. The concern was that this could force the plan to proceed without the necessary medical information, and could force enrollees and plans into second level reviews unnecessarily.

The Department does not believe that any additional language is necessary. The plan has the ability to obtain an extension of time from the enrollee without the necessity of including this language in the regulations. The plan should, however, carefully document its request, and the reason for the request, as well as the enrollee's response in its case file, so that if necessary, the Department will be able to make a full review. The Department will be monitoring this closely to ensure plans are not exerting undue pressure on enrollees and are requesting extension with proper cause.

One commentator stated that if the complaint involved performance by a health care provider, the provider should be given a copy of the decision letter and instructions on how to appeal any adverse decisions.

Act 68 does not allow for appeals by providers of complaint decisions, only for appeals by providers of grievance decisions with the enrollee's consent. The plan may choose to investigate a complaint by notifying the health care provider and having the provider present at the complaint review. The decision of the Act 68 complaint review is not one to which the provider is a party, however. Any adverse action taken by the plan against a provider may be handled through the mechanisms set up by the plan and provider in their contractual arrangements, or through the credentialing procedure.

Several commentators raised issues concerning the lack of detailed standards for what is to be included in a decision letter. Proposed subsection (c)(1)(iv) would have required the notice letter to include the basis for the decision, and the procedures and time frame to file a request for a second level review of the decision of the initial review committee.

A few of these commentators further recommended that the notices of decisions contain a description of the reviewer's understanding of the substance of the dispute, and references to the evidence and documentation used as basis for the decision.

Two commentators recommended that the regulations require that the decisions contain a statement that the decision is binding unless the person appeals.

Two commentators recommended that the regulations require that the decisions be clear and detailed to permit an enrollee to respond further.

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One commentator recommended that the regulations contain a requirement that plans clearly articulate the reasoning behind decisions.

One commentator recommended that the Department should strengthen decision notices by requiring specific comprehensible information about decisional standards, although even this would be insufficient to allow enrollees to navigate the process with some success without access to information.

IRRC commented that the phrase "basis for decision" in proposed subsection (c)(1)(iv) was unclear, and could result in the denial of a complaint that an enrollee was unable to understand. IRRC commented that it was not clear from the regulations how much detail would be required. IRRC recommended that the Department provide further guidance on how detailed the information from the plan should be, for example, would the basis for decision be required to include reference to applicable contract provisions.

One commentator recommended that the Department add the following language to the proposed subsection: "The basis for the decision shall be detailed, and shall recite what information or documents were considered, what if any arguments were accepted and rejected, relevant contract provisions and the reasoning for accepting or rejecting the various arguments. The plan may not base a decision against the enrollee on any reason not stated in an initial decision." The commentator stated that this would show that the plan did more than rubber stamp its previous decision, and would prevent an unfair situation in which the enrollee has successfully addressed plan's rationale, but loses because plan has adopted a new, previously unarticulated reason for denial.

The Department agrees that a more detailed explanation of what is meant by "the basis for the decision" should be included in the regulations. The Department has added language that states the basis for the decision includes the following: (1) a statement of the issue being referred to the second level review committee; (2) the specific reason or reasons for the committee's decision; (3) references to the specific plan provisions on which the decision is based; and (4) if an internal rule, guideline, protocol, or other similar criterion was relied on in making the decision, either the specific rule, guideline, protocol or criterion, or instructions on how to obtain the internal rule, guideline, protocol or other similar criterion will be provided upon request. These are the current requirements included in regulations recently issued by the United States Department of Labor relating to new ERISA claims procedure rules (see 29 CFR Part 2560 (November, 20, 2000)) (ERISA rules). The Department is also requiring that the notice include a statement of when and how the enrollee may appeal to the second level. See subsection (c)(1)(vi).

The Department has not added a provision stating that the plan shall be prohibited from citing reasons for denying the claim that are different from those offered at an earlier stage of the process. The Department believes that in certain circumstances it may be necessary for a plan to deny a case based on a different reason than originally provided, due to additional information provided by the enrollee. The enrollee is not prohibited from introducing new and additional evidence throughout the process. Additional evidence may trigger other restrictions on services not previously cited by the plan.

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One commentator commented that the proposed regulations should detail more specifically what information a plan shall provide as the basis for its denial, stating that plans refuse to provide medical criteria used in making UR decisions, claiming they are proprietary. The commentator stated that plans should provide criteria they rely upon to deny service or level of service. The commentator also recommended that the regulations should specifically state that such criteria may be used as tools in making the decision, but may not be used as the sole basis for the decision.

The Department has specified, in § 9.750(b)(3) (relating to UR system standards) that a plan must make available to the provider, upon request, copies of the UR criteria it uses. The Department has also added the requirement that the UR tools cannot be used as the sole basis for the decision. See § 9.750(c).

IRRC also recommended that the Department reference § 9.702(d)(3) (relating to complaints and grievances) which gives an enrollee 45 days to file a second level complaint.

The Department has not referenced that provision. A time frame, as discussed in § 9.702, may or may not be established by the plan, depending on whether a plan chooses to set a time frame for the filing of a second level review. Under that section, the plan must give the enrollee at least 45 days, so the actual time frame may be greater than 45 days. Section 9.702 is a requirement for the plan, and it would not be useful to the enrollee for the Department to reference that section here.

The Department received many comments on proposed subsection (c)(2), relating to requirements for second level reviews.

Two commentators raised concerns that the Department had taken away many of the fundamental fairness standards contained in its 1991 guidelines, which the commentators stated governed the complaint and grievance process prior to the passage of Act 68. One of these commentators noted that these standards were extremely important to children with disabilities who often face HMO denials of their more costly and more specialized care. The other commented that the proposed regulations required a thorough revision to uphold the rights of enrollees.

Three commentators recommended including in the regulations a requirement that the second level review committee be prohibited from basing a decision against an enrollee on a reason not specifically raised in the first level review.

Three commentators recommended including in the regulations a requirement that enrollees have the right to appear at the review and the right to prepare for the review.

Two commentators recommended including in the regulations a requirement that enrollees have the right to be advised that they could be assisted by an uninvolved HMO staff person if they need help preparing the case.

Three commentators recommended including in the regulations a requirement that enrollees be given a description of the review committee's procedures.

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Several commentators recommended including in the regulations a requirement that plans schedule second level complaint and grievance hearings at mutually convenient times and with 15 days advance written notice. One commentator noted that this was important for children with disabilities, who may require time to make travel arrangements, to be present at a hearing.

One commentator recommended that the Department include a requirement that the second level review committee base its decision solely on materials and testimony presented at the hearing.

The Department's 1991 guidelines did require notice to the enrollee of the procedures to be followed during the second level review proceedings, and that the enrollee could be present. The Department agrees that this information is valuable to the enrollee, and that the enrollee should be notified of that information at the time the request for the second level review is made. The Department had originally included this requirement of notification of the right to appear in proposed subsection (c) (2)(ii), but has moved that requirement to subsection (c)(2)(i)(B).

The Department also agrees that the enrollee should be provided 15 days advance written notice of the review (subsection (c)(2)(iii)(B), the ability to be present at the second level review and to present the enrollee's case (subsection (c)(2)(iii)(A)), and have a plan employee not previously involved in the plan's decisions to deny coverage for the issue in dispute available to assist in the preparation of the complaint (subsection (c)(2)(iii)(F). These requirements were included in the Department's 1991 guidelines.

As discussed earlier, the Department has not added a prohibition against the plan citing to reasons for denying the claim that are different from those offered at an earlier stage of the process. The Department believes that in certain circumstances it may be necessary for a plan to deny a case based on a different reason than originally provided, due to additional information provided by the enrollee. The enrollee is not prohibited from introducing new and additional evidence throughout the process. Additional evidence may trigger other restrictions on services not previously cited by the plan.

One commentator recommended that the Department should provide the same flexibility, as with attendance, to time allotted for the enrollee's presentation and the committee's chance to ask questions while the enrollee is present. The commentator commented that HealthChoices HMOs are scheduling hearings too close together, causing committees to rush and not to fully digest information.

The Department has not changed the regulations to address this concern, as it pertains to Health Choices HMOs only. This concern may be best addressed by DPW through its oversight of HealthChoices contractors.

Several commentators recommended including a requirement that a plan staff person knowledgeable about the complaint be present at second level review to present the HMO's view of why the denial should be upheld, and that the staff person should be available for questions by the member and the committee.

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The Department believes that a requirement that the plan have employees available for questioning by enrollees is too burdensome for a plan. The Department has declined to include this requirement in the regulations.

One commentator recommended that the plan be required to present the entire case in full at the hearing, before the enrollee. The commentator further stated that for the enrollee to be able to prepare a meaningful response, the enrollee shall have access to information in the possession of the plan.

The Department is adding language to prohibit the committee's discussion of the case prior to the review meeting, and has also required that the decision be based solely upon the evidence presented at the review. See subsection (c)(2)(iii)(H) and (L). For the committee to discuss the case prior to hearing the enrollee on the matter could prejudice the committee and cause them to unfairly filter what the enrollee presents at the review through preconceived notions of the substance of the case.

IRRC commented that proposed subsection (c)(2)(i) was unclear because it contained two requirements, and recommended that it be broken into two parts. IRRC recommended that one part include the minimum size of the committee, and the other part include the prohibition on including persons as members of the review committee who had participated in earlier plan decisions on the matter.

The Department has revised the subsection as IRRC requested. See subsection (c)(2)(ii).

One commentator expressed concern that the proposed regulations would fail to include standards that guarantee that the committee deciding complaints remains unbiased.

One commentator also commented that there should be some method for an enrollee or physician to "discover" whether the members of the second level review committee were unbiased.

The Department has already provided for enrollees to contact the Department if they feel the process is unfair. The Department has added the requirement that the committee must be impartial. The Department will not put a "discovery" requirement in the regulation, as the review process before the plan is not a legal proceeding. The Department will, however, review any allegation of bias made to it.

One commentator raised a concern that the proposed regulation would allow the same persons who made the initial decision to make the second level review decision. This commentator recommended that the Department change the language "in first level review," to "with the initial matter being complained of."

The Department understands this concern, and has changed the language to read "did not previously participate in the matter under review." See subsection (c)(2)(ii).

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One commentator commented that the terminology typically used in reviews is "impartial" rather than "unbiased," and recommended that the Department change the language in its proposed regulation.

The Department has made this change. See subsection (c)(2)(ii)(B).

Three commentators recommended that the Department require the second level review committee to be made up of at least 1/3 HMO enrollees who were not employees of the plan, and that the consumer attending be told which members of the committee are staff and which are plan members.

Act 68 only requires that 1/3 of the members of the second level review committee not be employees of the plan. See section 2141(c)(1) of Article XXI. The Department has not changed the regulation to address this comment. The Department would recommend that committee members who are not plan employees have some familiarity with managed care and the functioning of the plan and take the position as a member of the committee seriously. The Department has added language prohibiting these nonemployee members from being employees of any related subsidiary or affiliate of the plan. See subsection (c)(2)(ii)(A).

With respect to the comment recommending that the enrollee be notified of the position of the individuals present at the review, the proposed regulation did include language stating that the persons present at the committee should be identified for the enrollee. See proposed subsection (c)(2)(ii)(C). The Department has maintained that language. See subsection (c)(2)(iii)(E).

One commentator stated that the proposed section would have omitted a number of provisions necessary to provide an enrollee a full and fair chance to present the enrollee's complaint. This commentator recommended that the Department add the following to proposed subsection (c)(2)(ii): "The plan shall permit the member to review the file and records of the plan as they relate to the matter at issue, and the plan shall produce and provide copies of related documents, including documents kept electronically, at no extra cost. The plan shall identify, state the position, if any, relative to the plan, and provide the qualifications of any individual who rendered the decision, if any, under review. The plan shall permit the member to request the presence of plan employees, and the plan shall assure the presence of plan employees at the review for questioning by the member."

The Department has included in the regulations a requirement that the plan provide an opportunity for the enrollee to obtain material relevant to the case; however, the Department is permitting that a fee be charged. See subsection (c)(1)(iii). The Department will not require plans to have employees present for questioning. Such a requirement would be too disruptive of plan operations.

With respect to the comment recommending that the enrollee be notified of the position of the individuals present at the review meeting, and their qualifications, the Department is, as it has said, retaining language from the proposed regulation which states that the persons present at the committee should be identified for the enrollee. See subsection (c)(2)(iii)(E). The only qualification for serving on the review committees is status as an employee or as a

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nonemployee. Employment, background, education, years of training or other qualifications are immaterial. The Department is requiring identification as to their role with respect to the plan. This is the only information the Department is requiring other than names of the committee members.

One commentator applauded the Department's proposed requirement that the plan provide reasonable flexibility in terms of time and travel distance when scheduling a second level review to enable enrollee participation at that review. See proposed subsection (c)(2)(ii)(A).

One commentator stated that the regulations would not require plans to accommodate enrollees when scheduling second level reviews.

IRRC and another commentator raised concerns that the term "reasonable flexibility in terms of time and distance" used in proposed subsection (c)(2)(ii)(A) was unclear. IRRC recommended that the Department provide more specific requirements for scheduling reviews similar to requirements in § 9.679(e). The other commentator also recommended that the regulations should be revised to require a plan to schedule a second level review hearing at a time and place that accounts for the enrollee's condition or other factors that warrant a shorter time or distance.

The Department has declined to attempt to set a minimum standard, given the difficulty to set a standard that would be acceptable to everyone involved. Therefore, the Department has changed the language of the subsection to require a plan to make reasonable accommodations to facilitate enrollee participation, and to take into account the enrollee's access to transportation and any other disability of the enrollee that might impede the enrollee's ability to travel. See subsection (c)(2)(iii)(C).

Two commentators recommended that it should be specified that the enrollee may be accompanied by a medical or a legal advocate. Proposed subsection (c)(2)(ii)(C) would have limited attendance at the second level review to members of the review committee; the enrollee or the enrollee's representatives, or both; the enrollee's provider or applicable witnesses; and appropriate representatives of the plan.

The Department agrees it is important to clarify that the enrollee's representatives could include legal representatives, as well as medical personnel or other attendants necessary to the enrollee. The Department did not intend to prohibit an enrollee from bringing an attendant to the review. Clearly, if an attendant is necessary to ensure that the enrollee can fully participate in the review then the plan must allow that individual or individuals to be present. It was the Department's intention to prevent either side of the matter from creating confusion at the review, or attempting to intimidate through numbers. After having considered the comments, however, the Department agrees that it would be beneficial to the enrollee for the regulation to specify that the enrollee will be permitted to bring individuals necessary for the enrollee to fully participate in the review meeting, which could include persons providing moral as well as physical support. See subsection (c)(2)(iii)(E).

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Relative to this same provision, IRRC commented that the word "or" could cause confusion in the phrase "enrollee's provider or applicable witnesses." IRRC recommended that the word "or" be replaced with "and."

The Department agrees and has made the change, but has also added language to clarify that, for purposes of confidentiality, the enrollee's provider should not be present at the review unless the enrollee has consented.

Three commentators commented that the regulations should include a requirement that the entire second level review hearing be transcribed by the HMO and the guarantee of the enrollee's right to transcribe and record the proceeding. One of these commentators noted that this was the only record which the Department or Insurance would have. This commentator stated that transcription was necessary, because, otherwise, mischaracterization of the facts to the plan's advantage is inevitable. The commentator urged that the member should also be guaranteed a right to record the hearing or have it transcribed. It contended that, otherwise, there would be no ability to rebut the characterization of testimony.

Another commentator commented that use of the word "deliberations" in proposed subsection (c)(2)(iv) implied something different than a recording of the proceeding. The commentator noted that deliberations were the part of the review where the committee voted and deliberations were off the record.

IRRC commented that the proposed regulation would allow deliberation of the second level review committee to be summarized or transcribed verbatim. IRRC asked whether a summary would be a sufficient record for appeals before the agencies.

The Department did not intend to require the transcription of the deliberations of the second level review committee which, like the deliberations of a jury, judge, hearing officer or agency, are not made public. The Department has added language requiring that the proceedings be recorded, either through an electronic recording, verbatim transcription or written minutes. See subsection (c)(2)(iv). This is in accordance with the Department's original guidelines on maintaining a record of a complaint hearing required some type of record, but made verbatim transcription optional.

Three commentators, including IRRC, requested that the Department clarify proposed subsection (c)(2)(v) and (vi). Proposed subsection (c)(2)(v) would have required the plan to complete the second level review within 45 days of the plan's receipt of the enrollee's request for review. Proposed subsection (c)(2)(vi) would then have required the plan to notify the enrollee of the decision within 5 business days of the decision.

IRRC and other commentators requested that the Department clarify that the 5-day notification period is not included in the 45-day review period.

It was not the Department's intent to include the 5-day notification period within the review period, and the proposed subsection did specify that notification was to occur after the committee's decision. Since this has created confusion, however, the Department has added

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language "and shall arrive at a decision" after "complete the second level review" to clarify this issue. See subsection (c)(2)(v).

IRRC and two other commentators recommended that the Department revise proposed subsection (c)(2)(vi) to require the plan to send notice of the second level review decision to an enrollee and the enrollee's representative.

The Department agrees that requiring notification of the enrollee's representative would be useful for enrollees who have obtained help through the process, and has added that language. See subsection (c)(2)(vi). To ensure that plans are aware that such a notification should be sent, the Department has also added language to subsection (c)(2)(vi) requiring that an enrollee or the enrollee's representative wishing to receive notification inform the plan of that fact prior to, or at, the second level review.

Several commentators commented on proposed subsection (c)(2)(vii). That proposed subsection would have required a plan to include in its notice to the enrollee the basis for the decision and the procedures and time frame for the enrollee to file an appeal to the Department or Insurance, including the addresses and telephone numbers of both agencies.

One commentator recommended requiring the notice to include the reasoning for accepting or rejecting the various arguments made.

Four commentators complained that the proposed regulations would not include a requirement that a plan clearly articulate the reasoning behind decisions, including references to standards used, references to the evidence considered and a description of the reviewer's understanding of the substance of the dispute.

One commentator recommended that the Department include a requirement that the second level review make available (in person or by telephone) those persons involved in the decision.

One of the commentators noted that the Department's proposed regulation would only require that the basis for the decision be included, stating that this was insufficient detail to ensure patient protections.

IRRC commented that the phrase "basis for decision" in the proposed subparagraph was unclear, and could result in the denial of a complaint that an enrollee was unable to understand. IRRC and another commentator recommended that the Department provide further guidance on how detailed the decision from the plan should be.

Two commentators commented that the enrollees should have access to all plan documents and information, or the enrollee would be unable to effectively discuss plan standards at the review meeting.

IRRC also recommended that since the procedures for appeal are specified in proposed § 9.705, that section should be referenced, and the 15-day time frame stated specifically.

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Two commentators recommended a prohibition against a plan changing its reasons after the review process has begun.

The Department agrees that clarification of the meaning of "basis for the decision" is useful to ensure the decision letters clearly articulate the plan's decision and how it is related to its policies and the contract provisions. This will give the enrollee an understanding of why the requested service is covered or is being denied. The Department has included the same requirements for the second level review decision as for the first level review decision. See subsection (c)(2)(vii). The Department has discussed similar comments to those raised here in more detail in the discussion of comments on proposed subsection (c)(1)(iv).

One commentator recommended that the Department strengthen its standards regarding UR and UR decisions so that the Department could effectively monitor UR practices.

Two commentators commented that the proposed regulations should also specifically state that such UR criteria may be used as tools in the complaint decision, but could not be used as the sole basis for the decision.

The Department is revising its section on UR entities to specifically set out standards for UR. The content of UR decision letters is addressed in that section. See § 9.750. The Department has also stated in § 9.750(c) that utilization review criteria cannot be the sole basis for a decision. Specific standards for complaint and grievance decision letters are set out in §§ 9.703 and 9.705. Several commentators commented that one of the fundamental fairness provisions that was missing from the proposed regulations was a requirement that the plan identify the individual making the decision by name, position or credentials. One commentator stated that it was impossible for the Department or the enrollee to determine whether the decision maker had an adequate degree of knowledge necessary to render a decision about the special area of medicine in question.

The Department has not changed the regulations to require that this information be made available. Because complaint decisions do not involve the medical necessity and appropriateness of a service, complaint decisions are not required to be made by licensed physicians or approved licensed psychologists. The Department will, therefore, not require a statement of what credentials are held by the persons making the complaint decisions. As discussed earlier, the only requirements for inclusion on the review committee is status as an employe or nonemploye. Education, training and expertise are immaterial.

Two commentators raised concerns with the last sentence of proposed subsection (c)(2)(vii), which stated that a decision shall be sent in a manner so that the plan can document receipt of the decision. One commentator commented that previous experience with such a process showed that members found it burdensome and inconvenient, and that it caused unnecessary delay in timeliness of receipt of the information. Both commentators stated that the requirement would increase costs.

One commentator asked whether the Department would accept as the receipt date either actual proof of receipt or the expiration of 5 business days after the date of the notification letter as proof of receipt.

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The Department has decided to eliminate this requirement. Since the plan issues the decision letter, it will be up to the plan to object to the timeliness of the enrollee's appeal before the Department. Depending upon the plan's reasons for contesting the timeliness of the appeal and the information provided to support the plan's position, the Department may issue an order to show cause to the enrollee to make a case against dismissing the appeal.

One commentator recommended that the Department add the toll-free telephone, fax and TDD numbers to the Department's address and telephone numbers included in proposed subsection (d).

The Department agrees that this would be advisable, and has added to this subsection its TDD number, fax number and toll free telephone number for the taking of complaints.

Section 9.704. Appeal of a complaint decision.

The Department received approximately 20 comments on this proposed section.

Three commentators, including IRRC, commented that the proposed regulations included no time frame for the Department's review and issuance of a decision. The commentators stated that specifying a time frame would help clarify the process and build appropriate expectations for plans and members regarding this stage of the appeal. One commentator suggested that the norm could be specified and provisions made for notice regarding delay.

Act 68 does not require the Department to specify a time frame. Because some cases are more complex than others, it would be difficult to set a time in which the Department must act. The Department intends to complete its review, on average, within a 60-day time period.

One commentator recommended adding the following language to the proposed section: "The Department will assist enrollees to identify and gather any of this information and material as is necessary to proceed with the appeal." The commentator stated that it was too burdensome to require enrollees to provide things like copies of all correspondence with the plan in its appeal to the Department. The commentator stated that this is particularly true for those enrollees who are frail or have some level of cognitive impairment. The commentator recommended that the Department should provide guidance for such individuals in the absence of an ombudsman.

The Department has not added the recommended language to the regulation. In these appeals, the Department sits as the arbiter of the case between the plan and the enrollee. The statute does not place the Department in the role of an ombudsman, nor is such a role practical or appropriate in an appeal process in which the Department is to act as the impartial judge. The enrollee has the opportunity to be represented before the Department by an attorney or by another individual.

One commentator recommended that the Department delete this proposed section, since complaints are under the jurisdiction of Insurance.

The Department and Insurance both have authority over complaints under Act 68.

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IRRC asked how the receipt of the decision by an enrollee would be determined. Proposed subsection (a) would have required an enrollee to file an appeal with either agency within 15 days of receipt of the second level complaint review decision.

The Department had proposed that plans issue the decision in a manner that would enable them to determine the date of receipt of the decision. See proposed § 9.704(c)(2)(vii). There was some comment on this matter, however, with commentators being concerned about whether enrollees would accept receipt of a certified letter and whether the cost to the plan would be wasted.

The Department has decided to eliminate this requirement. A plan will be able to object to the timeliness of an enrollee appeal filed with the Department. The Department will make determinations of timeliness on a case by case basis, depending on the facts presented to it by the plan and the enrollee.

IRRC recommended that the Department remove the reference to Insurance in subsection (a) since the Department has no authority over Insurance.

The Department feels the reference is necessary since under Act 68 appeals may be sent to either the Department or Insurance. This section is intended to remind enrollees and plans of that fact.

Two commentators recommended that enrollees be given a minimum of 30 days to file an appeal of a second level review complaint decision with the agencies.

One commentator stated that the ADA requires accommodation for enrollees with respect to the 15-day statutory time frame to file an appeal with Insurance or the Department.

The Department cannot alter the time frame in this section for filing an appeal of a plan decision on a second level review complaint, since the time frame is required by statute. See section 2142(a) of Article XXI. For enrollees who cannot write, the Department will make staff available to transcribe the complaint.

IRRC asked what the term "Insurance number" referred to in proposed subsection (b)(3). IRRC recommended replacing the word "Insurance" with "Identification."

The plan Insurance number is the number assigned by the health plan to the enrollee. The Department has written out the word "identification" as IRRC has recommended.

Another commentator recommended changing the word "shall" to "should" in proposed subsection (b), since minor omissions were bound to occur, and the proposed regulation should not penalize the enrollee by throwing out the appeal when this occurs. Proposed subsection (b) stated that "the appeal from the enrollee shall include the following:" and listed five items that were to be included in the appeal.

The Department sees no reason to alter this provision. The proposed subsection lists the information the Department will require with an appeal: The enrollee's name, address and

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telephone number; identification of the plan; the enrollee's plan Insurance number; a brief description of the issue being appealed; and correspondence from the plan concerning the complaint. The Department cannot process an appeal without being able to identify the enrollee and the plan, and it must have a statement from the enrollee as to what is the basis for the appeal. It is not the Department's intention to use this section, or permit plans to use this section, to move to quash appeals on the basis that enrollees fail to meet the requirements of the regulation.

IRRC recommended that the proposed regulations include Department notice to the enrollee of the status of the enrollee's filing (that is, late or timely).

Proposed subsection (c) did not state that the Department would provide notice to the plan. It stated that the Department would check with the plan to determine whether or not the enrollee's filing was timely, since under the proposed regulations it would have been the plan's responsibility to send the decision in a manner in which date of receipt could have been documented. This language is no longer necessary, since the Department has decided to delete language requiring a plan to verify receipt of the decision letter. The Department has deleted the substance of proposed subsection (c).

The Department agrees, however, that the notice suggested by IRRC would be useful to the enrollee; it can, however, provide that notice without including that requirement in regulation.

IRRC recommended that the Department revise proposed subsection (d). Proposed subsection (d) stated that "The plan shall forward the complaint file within 5-business days of the Department's request. Upon confirmation that the appeal was filed within the appropriate time frame, the Department will request the complaint file from the plan." IRRC recommended that the two sentences in the proposed subsection be combined to state that upon confirmation of a timely filing, the plan shall forward the file within 5-business days.

One commentator commented that the proposed subsection would not indicate what the complaint file was to contain. The commentator recommended that the minimum contents be listed. The commentator also recommended that the Department include a requirement that the plan automatically provide the case file to the enrollee when it is sent to the Department.

The Department will reverse the order of sentences in the subsection for clarification. The Department will also change the 5-day requirement to a 30-day requirement, since that is the timeframe required by Insurance. With respect to the question concerning what needs to be included in a complaint file, a complaint file needs to include all relevant documentation, including the contract language and any material considered in the previous two reviews of the case. The Department has also added this language to subsection (c), formerly subsection (d).

Proposed subsection (e), now subsection (d), would allow the plan and the enrollee to provide additional information for review and consideration to the Department as appropriate. One commentator recommended that both the plan and member provide simultaneous copies of any additional information to one another.

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The Department has decided that either party sending additional information will copy the other. This will afford each party the opportunity to review materials not previously considered, and possibly enable the parties to resolve the appeal without the need of further Department intervention.

IRRC recommended that proposed subsection (f), now subsection (e), be revised to state that time requirements for review would not be affected by a decision to change the agency reviewing the appeal. It is correct that the time requirements for review will not be affected by the decision to transfer a case from one agency to the other. The Department does not believe that this need be stated in regulation.

One commentator noted that, in proposed subsection (g), the Department states it has discretion to hold a hearing. The commentator stated that if no hearing were held, there would be no record to certify to the Commonwealth Court. This commentator suggested that a more prudent approach would be for the Department to notify the appellant of the right to a hearing, and the obligation to request one. The commentator noted that if an appellant did not request a hearing, the right to a hearing would be waived.

The Department has deleted the substance of proposed subsection (g), since it is unnecessary to restate what the law already requires, and since there is no corresponding language in Insurance's regulations.

Section 9.705. Internal grievance process.

The Department received more than 150 comments on this proposed section, which was titled "Enrollee and provider grievance system" in the proposed rulemaking.

One commentator recommended renaming this proposed section "Enrollee grievance system."

The Department agrees that it would be more consistent with the rest of the regulations and with Act 68 to change the title. Since health care providers with enrollee consent may file grievances as well as enrollees, however, the Department has declined to change the title as the commentator suggested. The Department has changed the title of the section to "Internal grievance process." This title reflects the title of the corresponding section of Article XXI. See section 2161 of Article XXI.

Several commentators stated that the proposed regulations would not provide a fair and uniform plan for how grievance hearings would be conducted. They expressed concern that patient protections in what they believed to be existing regulations had not been included in the proposed regulations. These included provisions dealing with information available to the enrollee about nature of the grievance process, the composition of review panels and the roles of attorneys in the process. These commentators recommended that patient safeguards should be included in the final-form regulations.

The Department is including in its final-form regulations many of the 1991 guidelines recommended by commentators, and will reference those provisions in the discussions relating

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to specific regulations. The Department does point out, however, that these guidelines were not part of the regulations that are being repealed. They were simply guidelines.

One commentator recommended the addition of a new subsection requiring that if the plan fails to act within the time frames established in the regulations, the relief sought by the member shall be granted automatically by the plan. The commentator argued that this would redress the imbalance caused by the fact that if an enrollee fails to meet the time frames, the enrollee has no recourse, but if a plan fails to meet the time frames, it acts with impunity.

The Department has not added the recommended subsection. If a plan violates the time frames of Act 68, it is subject to sanctions under Act 68, including fines. Requiring a plan to provide the remedy sought by the individual in every instance when a time frame is violated is an extreme penalty, and removes discretion from the Department to fit the penalty to the violation.

IRRC recommended that the Department either explain its use of the phrase "and is acceptable to the Secretary" in proposed subsection (a) or delete it.

As discussed earlier, the Department has deleted this language.

Several commentators recommended that the Department include language in the final-form regulations that would require plans to accept an oral grievance from an enrollee and reduce it to writing. The Department had included language in proposed subsection (b) that would have required the grievance to be in writing.

One commentator commented that Act 68 provides that there shall be a toll free telephone line at the plan to provide help to enrollees in filing a complaint or grievance. The commentator stated that it was fundamentally unfair to require sick, disabled or overwhelmed enrollees who lack time, strength or ability to file a written grievance. According to the commentator, it also made no sense to limit providers to filing written grievances, since they were busy with other administrative tasks. Another commentator stated that Federal law required an accommodation for enrollees for whom writing would impose a barrier.

The Department agrees that it would be helpful to enrollees who are unable to file a written grievance to have someone at the plan able to reduce a grievance to writing, and has added a requirement that plans do so to subsection (b). Under the ADA, if a person were disabled, the plan would have to make a reasonable accommodation. The Department, which is required to regulate plans covering all populations, and not only the MA population, will not go so far as to require that plans provide this service for persons other than those with disabilities or language barriers. The DPW can, and does, have its own requirements for its contractors.

Three commentators recommended that proposed subsection (c)(1), which proposed requirements for first level grievance reviews, should be revised to require the plan to notify the enrollee of the plan's receipt of the grievance, to assist the Department in monitoring compliance with Act 68.

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One of these commentators noted that there was frequent confusion about whether an enrollee's first contact with a plan constituted an inquiry, a complaint or a grievance. As with complaints, the commentator recommended that the Department require an acknowledgement from the plan to establish the date of the receipt for purposes of the Department monitoring compliance with Act 68 time frames and to clarify whether the plan views the case as a complaint or grievance so that the enrollee can obtain help from the Department if necessary.

Another recommended that the notice letter should be in a format that would encourage the enrollee to take time to read and understand enrollee rights to pursue an appeal. The commentator recommended that the notice should explain the differences between methods of dispute resolution (grievance and complaint) and should inform the enrollee of the consequences of choosing one over the other. The commentator recommended that the plan be required to tell an enrollee that a complaint is faster and can be filed orally, and can be reviewed without delays for reviews by medical specialists, while a grievance may be more thorough but may take more time, must be in written form and will include the review of a medical specialist. The commentator recommended that the notice should also inform an enrollee that if the enrollee chooses an inappropriate category, the plan may consult with the Department on whether the category is appropriate. The commentator recommended warning the enrollee that this consultation with the Department could take additional time and could result in reversal of the enrollee's designation of the matter as a complaint or a grievance.

As with complaints, the Department agrees that a notice letter should provide the enrollee with information necessary to present the enrollee's case, and, because of the deadlines in Act 68, it is important to know when the clock starts on a grievance. The Department has, therefore, required plans to confirm receipt of the grievance in writing. The Department has also required plans to include notice of the process, of the availability of help from the plan and of the option to contact the Department concerning the classification of the case. See subsection (c)(1)(i).

For reasons discussed earlier regarding complaints, the Department is not creating a process in which the choice of how to characterize the issue is up to the enrollee. Consequently, the Department has not added language relating to the differences between complaints and grievances. The difference between the two is difficult enough for persons who deal with the issues on a daily basis. The Department is relying upon the plan to characterize the matter correctly, knowing that the Department can correct the classification if the plan is incorrect.

With respect to the recommendation that a plan be required to provide advice to the enrollee to enable the enrollee to choose the best method of appeal, the enrollee does not make the classification. It is the nature of the case that determines whether the subject is a complaint or a grievance; the plan is in the best position to determine which process to follow, and is required to choose the appropriate classification. Any suggestion that a complaint may be processed more quickly than a grievance would be incorrect, since the timeframes for both complaints and grievances are the same at both the first and the second level. Further, the Department is requiring plans to accept oral grievances for those enrollees unable to file a written grievance to alleviate disparities between the complaint and the grievance procedures.

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Subsection (b) has been revised to require a plan to make staff available to transcribe an oral grievance from an enrollee who is unable to file a written grievance due to a disability.

Several commentators recommended that the Department include language in the regulations requiring plans to make available to the enrollee all documentation relating to the enrollee's dispute. These commentators expressed concern that this information was necessary at the first stage of the process to ensure the fairness of the process.

One of these commentators recommended adding language that would require a plan to produce and provide copies of all related documents, including documents kept electronically, at no cost to the enrollee.

Another expressed concern that without access to specific information, including internal policies, nursing notes, extended evaluations and the like, the enrollee would be unable to present a case that addresses all relevant considerations.

The Department agrees the enrollee or the enrollee's representative should have access to information relating to the matter of which the enrollee has complained. This would enable the enrollee to determine what additional information is necessary to support the enrollee's case. The Department has declined to specify the information required to be released, but has required that the plan release what is relevant. If an enrollee or provider believes a violation of the regulations has occurred, they may notify the Department, which can then investigate if need be. See subsection (c)(1)(iii).

Three commentators, including IRRC, recommended that the Department clarify proposed subsection (c)(1)(iii), which stated that the investigation and review of the grievance was to be completed within 30 days of receipt of the grievance. The commentators recommended that the regulation state specifically when grievance decisions are required. The commentators stated that without this clarification there could be a gap of indeterminate length between the completion of the investigation and the issuance of a decision.

One commentator requested that the Department clarify that the 5-day notification period for the plan to notify the enrollee of the decision of the review committee would not run within the 30-day review period.

It was not the Department's intention to add the 5-day notification period to the review period, and the proposed subsection did specify that notification was to occur after the committee's decision. Since this has created confusion, however, the Department has added the language "and shall arrive at its decision" after "review and investigation of the complaint" to clarify this issue. See subsection (c)(1)(v).

Two commentators commented that the proposed regulations did not make any allowance for postponements. One of these commentators commented that a plan should be able to ask an enrollee if the enrollee wished to extend the period for review for either a first or second level grievance when notifying the enrollee that despite using all due diligence, the plan would be unable to obtain the medical records needed to complete the review within the specified time frame. The commentator was convinced that this could force the plan to proceed without

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the necessary medical information, and could force enrollees and plans into second level reviews unnecessarily.

The Department does not believe that any additional language is necessary. The plan has the ability to ask the enrollee for an extension of time without the necessity of including this language in the regulations. The plan should, however, carefully document its request, and the reason for the request, as well as the enrollee's response in its case file, so that if necessary, the Department will be able to make a full review. The Department will be monitoring this closely to ensure plans are not exerting undue pressure on enrollees and are requesting extension with proper cause.

Proposed subsection (c)(1)(iv) stated that the plan was to notify the enrollee of the decision of the initial review committee in writing within 5 business days of the committee's decision. The proposed subsection also would have required the notice to include the basis for the decision, and the procedures and time frame to file a request for a second level review of the decision of the initial review committee. Several commentators raised issues concerning the lack of detailed standards on what should be included in a decision letter on a grievance.

Three of these commentators recommended that the notices of decisions contain a description of the reviewer's understanding of the substance of the dispute, and references to the evidence and documentation used as basis for the decision.

Two of these commentators recommended that the regulations require that the decisions contain a statement that the decision is binding unless the enrollee appeals.

Two of these commentators recommended that the regulations require that the decisions be clear and detailed to permit a member to respond further.

One of these commentators recommended that the regulations contain a requirement that plans clearly articulate the reasoning behind decisions.

One of these commentators recommended that the Department should strengthen decision notices by requiring specific comprehensible information about decisional standards, while at the same time the commentator suggests that even this would be insufficient to allow enrollees to navigate the grievance process with some success without access to plan information.

IRRC commented that the phrase "basis for decision" was unclear, and could result in the denial of a grievance that an enrollee was unable to understand. IRRC commented that it was not clear from the regulations how much detail would be required. IRRC recommended that the Department provide further guidance on how detailed the explanation provided by the decision issued by the initial review committee should be. IRRC wanted to know, for example, whether the decision should reference contract citations.

One commentator recommended that the Department add the following language: "The basis for the decision shall be detailed, and shall recite what information or documents were considered, what if any arguments were accepted and rejected, relevant contract provisions and the reasoning for accepting or rejecting the various arguments. The plan may not base a

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decision against the enrollee on any reason not stated in an initial decision." The commentator stated that this language would show that the plan did more than rubber stamp its previous decision, and would prevent an unfair situation in which the enrollee has successfully addressed plan's rationale, but loses because the plan has adopted a new, previously unarticulated reason for denial.

The Department agrees that a more detailed explanation of what is meant by "the basis for the decision" should be included in the regulations. The Department has added language that states the basis for the decision should include the following: (1) a statement of the issue being referred to the second level review committee; (2) the specific reason or reasons for the committee's decision; (3) references to the specific plan provisions on which the decision is based; (4) if an internal rule, guideline, protocol or other similar criterion was relied on in making the decision, either the specific rule, guideline, protocol or criterion, or instructions on how to obtain the internal rule, guideline, protocol, or other similar criterion will be provided upon request; and (5) an explanation of the scientific or clinical judgment for the decision, applying the terms of the plan to the enrollee's medical circumstances. These are the current requirements included in the new ERISA rules. The Department is also requiring that the notice include a statement of when and how the enrollee may appeal to the second level. See subsection (c)(1)(vi).

The Department has not added the prohibition that the plan be prohibited from citing reasons for denying the claim that are different from those offered at an earlier stage of the process, as was discussed earlier when this comment was made pertaining to complaints. The Department believes that in certain circumstances it may be necessary for a plan to deny a case based on a different reason than originally provided, due to additional information provided by the enrollee. The enrollee is not prohibited from introducing new and additional evidence throughout the process. Additional evidence may trigger other restrictions on services by the plan.

One commentator commented that the regulations must detail more specifically what information a plan must provide in the decision letter as the basis for its denial. The commentator claimed that plans refuse to provide medical criteria they used in making UR decisions, claiming it is proprietary. The commentator urged that plans should be required to provide criteria used to deny service or level of service. Two commentators also recommended that the regulations should specifically state that such criteria may be used as tools in arriving at the decision, but may not be used as the sole basis for the decision.

The Department has specified, in § 9.750(b)(3) that a plan must make available to the provider, upon request, copies of the UR criteria it uses. The Department has also added the requirement that the UR tools cannot be used as the sole basis for the decision. See § 9.750(c).

Several commentators commented that subsection (c)(1)(iv) would require notification to the enrollee but not the provider, which was contrary to the provisions of Act 68.

Act 68 requires written notification to the enrollee and the health care provider. See section 2161(c)(4) of Article XXI. The Department interprets this to mean that the provider should get

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notice only when the provider has filed the grievance. The Department has revised the subsection to require notice to the health care provider when the health care provider has filed a grievance on behalf of the enrollee. See subsection (c)(1)(vi). If the grievance was filed by the enrollee, the provider has no need of this information, and providing letters to the provider could be a breach of the enrollee's right to confidentiality.

IRRC also recommended that the Department reference § 9.702(d)(3), which gives an enrollee 45 days to file a second level complaint, in proposed subsection (c)(1)(iv).

The Department has not referenced that section. A time frame as discussed in § 9.702 may or may not be established by the plan, depending on whether a plan chooses to set a time frame for the filing of a request for a second level review of a grievance. Under that section, the plan must give the enrollee at least 45 days. The actual time frame may be greater than 45 days. Section 9.702 (d)(3) imposes requirements on the plan. A reference to that provision in this section would not provide useful information for the enrollee.

The Department received over 80 comments on proposed subsection (c)(2), which proposed requirements for second level reviews of grievances.

As previously discussed, the Department has included in the final-form regulations several requirements from its 1991 guidelines relative to the handling of complaints and grievances. For example, the Department has included a requirement in §§ 9.703(c)(2)(iii)(J) and 9.705(c)(2)(iii)(J) recognizing that the committee may have an attorney present. However, if there is an attorney present to represent the interests of the committee at the second level review hearing on a grievance, that attorney is not present to represent the interests of the plan. The committee's attorney must ensure the fundamental fairness of the review and that all disputed issues are adequately addressed. The attorney representing the committee may not argue the plan's position, or represent plan staff. See §§ 9.703(c)(2)(iii)(J) and 9.705(c)(2)(iii)(J). The Department has also reiterated the requirement in Act 68 that an enrollee may appoint a representative to act on behalf of the enrollee during the review process. See subsection (c)(1)(i)(B). The remainder of the Department's revisions regarding "fundamental fairness" will be discussed in commentary on the particular subsections to which they apply.

IRRC commented that proposed subsection (c)(2)(i) was unclear because it contained two requirements, and recommended that it be broken into two parts. IRRC recommended that one part address the minimum size of the committee and the other part address prohibiting the involvement of committee members who participated in prior decisions relevant to the grievance.

The Department has revised the subsection as IRRC recommended. See subsection (c)(2)(ii).

IRRC also commented that the phrase "reviewing a grievance appealed to the second level of review" in the proposed subsection (c)(2)(i) was unnecessary and should be deleted. The Department agrees, and has revised the subsection as IRRC recommended. See subsection (c)(2)(ii).

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Four commentators recommended that the proposed regulations be revised to include a requirement that the second level review committee members who were not plan employees should be enrollees. One commentator recommended that the enrollee be told which committee members were plan staff, and which were enrollees, and who could vote and who could not.

The Department has reconsidered the language in this subsection. In light of the language of Act 68, which states only that the committee be made up of persons not previously involved in any decision to deny payment (see section 2161(c)(1) of Article XXI), the Department has made no change to the regulation.

With respect to the comment concerning identification of persons at the review, the proposed regulations did require that the persons present at the review be identified for the enrollee, along with their roles. See proposed § 9.706(c)(2)(ii)(C). The Department has not deleted this language. See subsection (c)(2)(iii)(E).

One commentator commented that there should be some method for an enrollee or physician to "discover" whether the members of the second level review committee are unbiased.

The Department has already provided for enrollees to contact the Department if they feel the process is unfair (see § 9.702 (a)(2)) and added the requirement that the committee has a duty to impartial review. (See subsection (c)(2)(ii)(B)). The Department cannot put a "discovery" requirement in the regulation, as this is not a legal proceeding. The Department will, however, review any allegation of bias.

One commentator commented that the terminology typically used in reviews is "impartial" rather than "unbiased," and recommended that the Department change the language in its proposed regulation.

The Department has made this change to the final-form regulations in subsection (c)(2)(ii)(B).

One commentator commented that the notification referred to in proposed subsection (c)(2)(ii) should go to both the health care provider and the enrollee. The proposed subsection stated: "The plan shall notify the enrollee or the health care provider in writing of the right to appear before the second level review committee."

The Department has changed the regulation to require notification to the enrollee, and the health care provider if the health care provider has filed a grievance with enrollee consent. The Department believes it would be improper to allow a health care provider to appear at a grievance review without the request of the enrollee, if the provider does not have the enrollee's consent to grieve the matter. Any other construction of the statute could lead to a breach of confidentiality.

Several commentators complained that the proposed regulations did not require plans to give enrollees at least 15 days advance written notice of the date of the review.

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Four of these commentators recommended that the notice include the following: notice of the enrollee's right to appear, a description of the procedures before the review committee; and the right to prepare for the review, and to be advised by an uninvolved plan staff person in preparing the case.

One recommended adding a requirement that the review be scheduled at a mutually convenient time.

One of these commentators noted that a requirement that the plan provide advance notice to an enrollee of the right to appear is only a requirement that notice be given, and not a statement that the enrollee has this right. The commentator stated that enrollees need sufficient advance notice to arrange work schedules, assure availability of witnesses and representatives, and generally prepare for the review. The commentator felt that this was especially important since an enrollee has no mechanism to complain to the Department if a plan is not flexible or accommodating in its scheduling. The commentator recommended adding an advance notice requirement of at least 15-days prior to the review.

The Department agrees that the enrollee should have advance notice of the date scheduled for the second level review, as well as the right to be present at the review. The Department has added language to the regulations requiring the plan to send the enrollee and the enrollee's representative an explanation of the procedures to be followed during the second level review. The notice is to include statements that the enrollee may request the aid of a plan employee who had not previously been involved in the plan's decisions to deny coverage for the issue in dispute in preparing a grievance, and how to do so, that the enrollee and the enrollee's representative have the right to appear before the second level review committee and that the plan will provide the enrollee with 15 days advance written notice of the time scheduled for that review. The Department has also required the notice to be given to the enrollee and the enrollee's representative and to the health care provider if the provider has filed a grievance with enrollee consent. See subsection (c)(2)(iii)(A), (B) and (C). The Department has also included in the final-form regulations specific requirements that the enrollee, the representative or the health care provider be able to appear and present a case, and that the enrollee and the representative be given the aid of a plan employee who has not participated in previous plan decisions to deny coverage for the issue in dispute for the purpose of assisting the enrollee in preparing the grievance. See subsection (c)(2)(iii)(A) and (F).

Several commentators commented that the proposed regulations did not require the plan to make staff persons involved in the plan's decision to deny the services available for questioning by the enrollee and the plan at the second level grievance hearing. They recommended the addition of this language.

The Department will not require a plan to make employees available for questioning by enrollees. The Department believes that requiring a plan to have employees present during reviews would cause operational problems for a plan in terms of work assignments and other matters.

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Several commentators objected that the proposed regulations did not require the plan to provide the enrollee with the identification and credentials of the person or persons who made the decision.

The Department is not requiring the plan to release the names, positions and credentials of all those individuals involved in issuing the previous denials, as their status as plan employees or members of the committee conveys sufficient authority to render review decisions. An enrollee filing a grievance should focus on the medical necessity and appropriateness of the requested service, and not on other circumstances, since medical necessity and appropriateness are what the enrollee needs to show to prevail in the matter.

Four commentators commented that the proposed regulations did not require the plan to make available to the enrollee all documentation related to the dispute.

The Department agrees that enrollees and providers should have access to information, and has included this requirement in subsection (c)(1)(iii). The Department has also added language that would permit the plan to charge a reasonable fee for the reproduction of documents. The necessity for the information occurs during the first level of the process, when the enrollee or provider needs to review the plan's information relating to the denial. Therefore, this issue is addressed in that particular provision. See subsection (c)(1)(i)(C).

One commentator applauded language in proposed subsection (c)(2)(ii)(A) that would require a plan to provide reasonable flexibility in terms of time and travel distance to enable enrollee participation at second level hearings. IRRRC and another commentator raised concerns that the term "reasonable flexibility in terms of time and distance" used in this subsection was unclear. IRRRC recommended that the Department provide more specific requirements for scheduling reviews similar to requirements in proposed § 9.679(e) (relating to access requirements in service areas). The other commentator also recommended that the regulations should be revised to require a plan to schedule a second level grievance review meeting at a time and place that accounts for the enrollee's condition or other factors that warrant a shorter time or distance.

One commentator recommended including a reference to health care providers in this section.

Another commentator asked whether the proposed regulation would have required the location for the second level review to change based on the enrollee's county of residence. The commentator stated that if this were so, this would place unreasonable hardships on those plans that currently allow members to appear by telephone.

The Department is not requiring that the location of the review meeting be the enrollee's home county. The Department has declined to attempt to set a minimum travel standard given the difficulty to set a standard that would be acceptable to everyone involved. Therefore, the Department has included language in subsection (c)(2)(iii)(C) to require a plan to make reasonable accommodations to facilitate enrollee participation and the health care provider's participation when the provider has filed a grievance.

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One commentator commented that an enrollee should be permitted to bring persons other than representatives, witnesses, appropriate plan representatives or members of the committee to the review, so long as the process is not disrupted. Proposed subsection (c)(2)(ii)(C) would have limited attendance to those individuals and the health care provider. The commentator stated that an enrollee might wish to bring a friend or relative, or an attendant.

The Department did not intend to prohibit an enrollee from bringing an attendant to the review. Clearly, if an attendant is necessary to ensure that the enrollee can fully participate in the review, then the plan must allow that individual or individuals to be present. It was the Department's intention to prevent either side of the matter from turning the review into a circus, or attempting to intimidate through numbers. After having considered the comments, however, the Department agrees that it would be beneficial to the enrollee for the regulation to specify that the enrollee will be permitted to bring individuals for moral and physical support. See subsection (c)(2)(iii)(E).

Three commentators commented that the regulations should include a requirement that the entire second level review hearing be transcribed by the HMO and a requirement that the enrollee be guaranteed the right to transcribe and record the proceeding. One commentator noted that this would be the only record for an appeal to the Department or Insurance. The commentators were concerned that without transcription, there would be no ability to rebut the plan's characterization of the testimony.

Another commentator commented that use of the word "deliberations" in proposed subsection (c)(2)(iii) implied something different than a recording of the proceeding. The commentator noted that deliberations were the part of the review where the committee voted and should be off the record.

The Department did not intend to require the transcription of the deliberations, which, like the deliberations of a jury, judge, hearing officer or agency, are not made public. The Department has replaced the word "deliberations" with "proceedings." See subsection (c)(2)(iv).

The Department is requiring that the proceedings be recorded, either through an electronic recording, verbatim transcription or summary. This is in accordance with the Department's original guidelines that maintaining a record of a grievance hearing required some type of reliable record, but that verbatim transcription would be optional. Further, with respect to the comment that transcription is necessary for the record on appeal to the agencies, the appeal from a second level grievance review goes to a CRE, not the Department or Insurance. A CRE's standard of review during an external grievance review does not turn on the characterization of testimony, but on whether the health care service denied was medically necessary or appropriate under the terms of the plan. For these purposes, a reliable summary is sufficient.

The Department has also made minor changes to reflect the fact that a health care provider may also be involved in the review, and to replace the word "appeal" with the more accurate term "request for an external grievance review." See subsection (c)(2)(iv).

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The Department received several comments on proposed subsection (c)(2)(iv) and (v). Proposed subparagraph (iv) would have required that the plan complete the second level grievance review within 45 days of the plan's receipt of the enrollee's request for the review. Proposed subparagraph (v) would have required that the plan notify the enrollee of the decision of the second level review committee in writing, within 5 business days of the committee's decision. Two commentators requested clarification concerning the review period and the time by which a decision need be made.

It was not the Department's intent to include the 5-day notification period within the 45-day review period, and the proposed regulations did specify that notification was to occur after the committee's decision, which occurs on or before the 45th day. For clarity, however, the Department has revised proposed subsection (iv) to state that the plan must complete the review and arrive at a decision within 45 days. The Department has also renumbered this subparagraph as subparagraph (v) to take into account other revisions to the regulation.

Three commentators commented that proposed subsection (c)(2)(vi) would require the plan to provide notification of the committee's decision on the grievance to the enrollee, but not the provider. The commentators stated that this was contrary to the provisions of Act 68.

The Department has revised the subparagraph to require notice to the health care provider when the health care provider has filed a grievance on behalf of the enrollee. See subsection (c)(2)(vi) and (vii). Act 68 requires written notification to the enrollee and the health care provider. See section 2161(c)(4) of Article XXI. The Department interprets this to mean that the provider should get notice only when the provider has filed the grievance. If the grievance were filed by the enrollee, the provider would have no need of this information, and providing letters to the provider could be a breach of the enrollee's right to confidentiality.

The Department has also added language to require that notice is to go to the enrollee's representative, if the enrollee has appointed one. To prevent confusion, and make certain the plans are aware that an enrollee has a representative, the Department has added language to § 9.702 that requires the enrollee or the enrollee's representative to notify the plan of the designation.

The Department received several comments on proposed subsection (c)(2)(vi). That proposed subsection stated that a plan shall include in its decision letter the basis and clinical rationale for the second level decision on the grievance and the time frames for filing a request for an external grievance review.

Three commentators commented that the proposed regulations lacked standards to state specifically what a plan shall provide as the basis for its denial. One commentator noted that there was no requirement to issue decisions that were clear and detailed so that an enrollee would be able to respond further.

One commentator recommended that the decision letter be required to include the reasoning for accepting or rejecting the various arguments made.

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Four commentators commented that the proposed regulations lack a requirement that plans clearly articulate the reasoning behind decisions and refer to the standard used and the evidence considered.

Three commentators raised concerns that the proposed regulations would not include a description of the reviewer's understanding of the substance of the dispute, and references to the evidence and documentation used as basis for the decision. One of the commentators noted that the Department's proposed regulations would only require that the basis for the decision be included. According to the commentator, this was insufficient in detail to ensure patient protections.

IRRC commented that the phrase "basis for decision" was unclear, and could result in a denial letter that was incomprehensible to the enrollee. IRRC and another commentator recommended that the Department provide further guidance on how detailed the decision from the plan should be.

Several commentators recommended that the Department should strengthen decision notices by requiring specific comprehensible information about decisional standards, although even this would be insufficient to allow enrollees to navigate the process with some success without access to information.

One commentator recommended including a prohibition against a plan changing its reasons after review process has begun.

The Department agrees that the phrase "basis for the decision" should be clarified, and has included the same requirements for the second level review decision letter as it required for the first level review decision letter, and the decision letters in complaint reviews, with one addition. Because a grievance is based in medical necessity and appropriateness, the Department has added a requirement, similar to that included in the ERISA rules, that the decision letter include an explanation of the scientific or clinical judgment for the decision, applying the terms of the plan to the enrollee's medical circumstances. The Department has discussed similar comments to those raised here in more detail in discussions on the comments to proposed § 9.704(c)(1)(iv) (now § 9.703(c)(1)(vi)).

One commentator commented that plans are refusing to provide medical criteria used in making UR decisions, and are claiming that they are proprietary. The commentator recommended that a plan should be required to provide criteria it relies upon to deny a service or level of service. The commentator also recommended that the regulations specifically state that such criteria could be used as tools in making the decision, but could not be used as the sole basis for the decision.

The Department has specified in § 9.750(b)(3), that a plan must make available to the provider, upon request, copies of the UR criteria it uses. The Department has also added the requirement that the UR tools cannot be used as the sole basis for the decision. See § 9.750(c).

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IRRC commented that, since enrollees may have a representative, the Department should require notice to the representative as well.

The Department agrees that notice should be sent to the representative, if the enrollee has one. The Department has added this language to subsection (c)(2)(vi).

Two commentators recommended that the regulations should require that the enrollee be advised of the decision in all cases, regardless of whether the provider is pursuing the grievance, and that the provider should be notified in all cases as well. Another commentator stated that this was required by Act 68. The commentator stated that since the enrollee may be financially liable, the enrollee should receive a copy of the denial letter as well.

Because the provider must notify the enrollee if the provider decides not to pursue the grievance further, the plan denial letter will give the enrollee notice of what has occurred in the case and the reasons the plan is citing for continuing denials. The Department is, therefore, requiring that the enrollee receive a copy of the decision letter regardless of whether the enrollee or the provider filed the grievance.

One commentator commended the Department for including in its proposed regulations language requiring the second level review committee to remain unbiased, but recommended that the Department go further. This commentator, along with three others, recommended that the Department require that the second level review committee base its decision solely on the materials and testimony presented at the meeting.

The commentator raised concerns about plans and representatives engaging review committees in private, and placing the entire burden upon the enrollee, who would not be permitted to question the plan's spokesperson. The commentator stated that the purpose of Act 68 would be defeated by reviewers prejudiced by a one-sided, open-ended presentation by the plan occurring without the enrollee being permitted to take part in that presentation.

The Department agrees that the regulations should contain more requirements aimed at ensuring the impartial nature of the review. The Department has included language requiring that the second level review committee base its decision on the grievance on the materials and testimony presented at the review. See subsection (c)(2)(iii)(L). The Department has also included language in this subsection prohibiting the committee from basing its decision on any document obtained on behalf of the plan that sets out medical policies, standards or opinions or that specifies opinions supporting the decision of the plan unless the plan makes available for questioning at the review by both the committee and the enrollee an individual who is familiar with those policies, standards or opinions included in the document. The plan may choose the individual who will appear, so long as the individual is familiar with the information in question, and the individual need not appear in person, but may be present at the review by telephone.

The Department has also included several recommendations from its 1991 guidelines in the regulations for the purpose of emphasizing the need for a fair and impartial review of the case. A committee member who does not personally attend the review meeting may not vote on the case unless that person actively participates in the review meeting by telephone or

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videoconference, and has the opportunity to review any additional information introduced at the review meeting prior to the vote. See subsection (c)(2)(iii)(I). The Department has required that the committee proceedings at the second level review be informal and impartial to avoid intimidating the enrollee, and the Department has prohibited the committee members from discussing the case to be reviewed prior to the second level review. See subsection (c)(2)(iii)(H). As the Department has previously noted, it has prohibited the committee's attorney from representing the plan, and has required that if the committee has an attorney, the attorney will represent the interests of the committee, including ensuring a fair and impartial proceeding. See subsection (c)(2)(iii)(J).

Three commentators have raised concerns that the proposed regulations would not prohibit a plan from changing its reasons for the denial after review process has begun. The commentators recommend that the Department add this prohibition.

The Department has not added a prohibition that the plan be unable to cite reasons for denying the claim that are different from those offered at an earlier stage of the process. The Department believes that in certain circumstances it may be necessary for a plan to deny a grievance based on a different reason than originally provided, due to additional information provided by the enrollee. The enrollee is not prohibited from presenting new and additional evidence throughout the process. Additional evidence may trigger other restrictions on services.

One commentator raised concerns with the last sentence of proposed subsection (c)(2)(vi), which states that a decision shall be sent in a manner so that the plan can document receipt of the decision. The commentator stated that previous experience with such a process showed that enrollees found it burdensome and inconvenient, and that it caused unnecessary delay in timeliness of receipt of the information. Further, both commentators stated that the requirement would increase costs.

The Department has decided to eliminate this requirement from subsection (c)(2)(vii). Instead, plans will be required to make the decision concerning the timely nature of the request on a case by case basis. An enrollee may then raise the issue with the Department, or take whatever legal action the enrollee finds to be necessary under the circumstances.

The Department received several comments on proposed subsection (c)(3), which included proposed requirements for licensed physicians and approved licensed psychologists to sit on grievance review committees.

One commentator recommended that protections be added to the regulations to permit plans to safeguard the identity of the matched specialist who does not participate in the review meeting. The commentator noted that disclosure of the matched specialist's report and credentials could be made without disclosing the name.

The Department has not required the identification of the name of the matched reviewing specialist. The Department is, however, requiring the reviewing specialist's credentials within that individual's report since that is the only way to verify the appropriateness of the plan's choice of reviewing specialist. See subsection (c)(3)(iv).

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Two commentators raised issues concerning the scope of the review of a psychologist and asked for clarification. One commentator recommended that the standard included in § 9.743(d) (relating to CREs) be including in this section, and in §§ 9.707--9.709. Section 9.743(d) states that an applicant for CRE certification must certify that an approved licensed psychologist may perform a review of a behavioral health care service under certain conditions. The psychologist may only perform the review if the psychologist is in the same or similar specialty as the health care provider of the service in question, if the review is of a behavioral health care service within the scope of the psychologist's practice and if the psychologist's clinical experience provides sufficient experience to review that specific behavioral health care service.

The Department has not included the language in § 9.743(d) in this section or in § 9.708. Section 9.743(d) is taken from section 2152(d) of Article XXI (relating to operational standards), which gives the operational standards for UR, not for grievance reviews. This section and § 9.708 deal with grievance reviews, and not general UR. The matched specialist is not denying a service, but acting as part of a reviewing committee, and the standards are different for these functions.

The Department has not added the language to § 9.707, since that section deals mainly with how an external grievance review is sought and obtained, and the language would not be relevant.

The Department has not added the language to § 9.709, since that section already requires the use of a certified CRE, which has met the Department's requirements for certification in § 9.743, the rest of Subchapter K and the standards of Act 68. See sections 2151 and 2152 of Article XXI. Again, § 9.709 does not deal with UR, but with grievance reviews.

Two commentators commented that it would be appropriate to require a plan to place on the review committee a reviewer in the same profession as the provider who performed the service being reviewed on the review committee. One of these commentators recognized that Act 68 requires a denial to be made by a physician, but recommended that the Department require reviewers to consult with "peer" reviewers to determine whether the service in question fell within the standard of care for the particular profession of the individual that recommended the service. The other commentator stated that this would reduce professional discrimination against a provider who was not in the same profession as the reviewer.

The Department has not changed the proposed regulation. Act 68 requires the inclusion of the physician or psychologist in the review process. See section 2161(d) of Article XXI. The plan may always include a peer of the provider on the committee if it so chooses, or may obtain input from a provider. There is no necessity to require that the same type of provider be on the committee. The General Assembly realized the logistical difficulties in doing this when it enacted provisions permitting a review by an individual in the same *or similar* specialty.

One commentator commented that Act 68 created a different standard for physicians and for licensed psychologists in terms of type of provider subject to review, and that the proposed regulation followed Act 68. The commentator stated that both Act 68 and the regulations violated the equal protection clauses of both the Federal and State constitutions. U. S. Const.

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amend. XIV, § 1; PA. CONST. art. I, § 26. The commentator recommended that to avoid a constitutional challenge, the Department should change proposed subsection (c)(3)(i) to state that the reviewer should be licensed by the Commonwealth in the same profession and board certified in the specialty of the provider subject to review. The commentator stated that case law in the Commonwealth allows a constitutional defect to be cured by regulation.

The Department disagrees that either Act 68 or the regulations are constitutionally infirm. There is no suspect classification involved in this matter, nor is there a fundamental right in question. The rational basis test called for by equal protection analysis only requires that the Commonwealth's classification be rationally related to Act 68's purpose of protecting enrollees. The General Assembly has taken the position that a UR decision to deny a service must be made by a licensed physician, unless the decision involves a behavioral health issue. In that case, the denial may be made by a psychologist who has clinical experience in the area that provides sufficient expertise to review that health care service. The General Assembly clearly believed that psychologists, who are not medical doctors, should have additional experience before being permitted to deny a health care service. This does not prohibit any psychologist from reviewing behavioral health services as part of a UR decision. It merely places additional requirements on that psychologist, and it does not prevent a psychologist from practicing the psychologist's profession.

One commentator commented that it would be difficult if not impossible to have a professional in same or similar specialty as part of the review committee, particularly on the first level review.

The Department has said that the individual need not be present, but that the individual may not vote if not present, unless that person actively participates in the review meeting by telephone or videoconference and has the opportunity to review any additional information introduced at the review meeting prior to the vote. See subsection (c)(3)(ii). The matched specialist's opinion shall be read into the record, however, to become part of the review proceedings.

IRRC and another commentator have requested that the Department clarify the term "same or similar" in proposed subsection (c)(3)(i). That proposed paragraph stated that both the initial and second level grievance review committees were to include a licensed physician, or an approved licensed psychologist, in the same or similar specialty as that which would typically manage or consult on the health care service in question.

The intent of Act 68, by leaving the language open in section 2161(d) and 2162(c)(4) of Article XXI was to provide plans some flexibility in obtaining individuals in a same or similar specialty to review grievances. The Department has chosen not to attempt to refine this language, because of the great danger of setting in regulation comparisons between specialties, subspecialties, education, experience and so forth. For example, by introducing this language, the Department would be regulating when an orthopedist must be used as opposed to a neurosurgeon for spine surgery cases, and whether an ordinary orthopedist will do, or whether the orthopedist must have a fellowship in spine surgery, and whether a Harvard degree is comparable to a Yale degree. This is not appropriate material for regulation. The Department will require that plans use a specialist in a same or similar specialty when the

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service was provided by a specialist who is a physician or psychologist. See subsection (c)(3)(v). The Department's intention is to have physician-specialists and psychologist-specialists reviewing specialty areas, and primary care providers reviewing primary care areas. Family practitioners should not be providing expert medical opinion on brain surgery, pediatricians should not be providing expert medical opinion on cancer treatment, and general internists should not be providing expert medical opinion on spine surgery. Every enrollee in a managed care plan has a primary care provider who serves as the enrollee's medical manager, providing treatment as appropriate and managing the enrollee's care through referrals to specialists as necessary. This does not make the provider a specialist in the "same or similar specialty" by virtue of the fact that the provider coordinates referrals.

The Department received several comments on proposed subsection (c)(3)(ii), which stated that the matched specialist need not personally attend at the review, but had to be included in the hearing, discussion and decisionmaking by written report, telephone or videoconference.

Two commentators requested that the Department clarify whether a matched specialist has to be a voting member of the committee.

One commentator stated that the proposed regulations would allow the matched specialist to vote without being present at the review. The commentator commented that this would seriously erode the protections of the statute.

One commentator noted that Act 68 does not require physical presence at the review committee meeting, and requested clarification.

One commentator objected to the matched specialist being permitted to provide an opinion in writing. The commentator stated that the specialist should either participate in person or by conference call.

One commentator recommended deleting proposed subsection (c)(3)(ii) altogether.

The Department does not intend to delete this paragraph. It is necessary to require input from the physician or approved licensed psychologist in the review of a grievance, since Act 68 requires it (see section 2161(d) of Article XXI), and it is necessary for the Department to set standards for how that input is to occur.

The Department has already taken the position that it is not practical to require physical or telephonic presence of a "matched" specialist and had included this in the proposed regulation. See proposed subsection (c)(3)(ii). The Department did take the position, however, that the "matched" specialist's report could be read into the record and the opinion of the matched specialist would then become part of the record for the committee's review. The Department believes that allowing a written report is necessary to obtain the most specialized individuals, taking into consideration the possibility of a paucity of experts in the more specialized fields, and taking into consideration time constraints on these individuals and the unpredictable schedules they face providing services to patients.

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The Department has also clarified subsection (c)(3)(ii) by adding language that states that a licensed physician or approved licensed psychologist who does not personally attend the review meeting may not vote on the grievance, unless that person actively participates in the review meeting by telephone or videoconference and has the opportunity to review any additional information introduced at the review meeting prior to the vote. A specialist in the same or similar specialty who cannot vote on the grievance must, however, provide input by written opinion as stated in subparagraph (ii). The report of the specialist must be part of the record, regardless of whether the specialist is permitted to vote or not.

One commentator opposed the requirement in proposed subsection (c)(3)(iii) that plans provide the specialist's report to the enrollee, or the health care provider if the provider has filed the grievance, at least 7 days prior to the review date. The commentator recommended the elimination of that requirement. The commentator stated that the requirement represented a challenging time frame for a specialist's review. The commentator further stated that this requirement exacerbated the fact that the reviewer was not protected under the Peer Review Protection Act (63 P. S. §§ 425.1--425.4). The commentator noted that reviewers have been threatened with physical harm for their medical decisions. The commentator suggested that requiring the report to be provided will make it more difficult for plans to secure physician input.

The Department has not required plans to reveal the reviewer's name; it has required them merely to provide a copy of the reviewer's report to the enrollee or provider. The plan will also have to reveal the reviewer's credentials, either as part of the report, or at the review. See subsection (c)(3)(iv).

Two commentators recommended that the Department require that an expert's report be automatically shared with the enrollee and prescribing provider, without the necessity for a request, written or otherwise. One of these commentators stated that the regulations should require that the report be provided 2 weeks prior to the review date.

That commentator also stated that it was unclear whether the last sentence of subsection (c)(3)(iii), requiring a plan to disclose the report, is conditioned upon the reviewer not participating in the review.

The proposed subparagraph specifically deals with what would occur when the physician or approved licensed psychologist was not present during the review meeting. The Department has not changed this subparagraph in response to this comment. The Department believes that requiring a request for any report is not burdensome on the enrollee, or the health care provider, and that the 7-day time period is sufficient time for an enrollee or provider to review the report.

Section 9.706. Health care provider initiated grievances.

The Department received several comments on proposed § 9.703, which has been renumbered as § 9.706. One commentator supported the proposed section, and stated that it contained important protections that should be retained.

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Three commentators, including IRRC, recommended that the Department move this proposed section to a different part of the subchapter. One commentator recommended that the Department merge it with proposed § 9.706. One commentator recommended combining it with proposed § 9.707 or placing it directly before that proposed subsection. IRRC recommended moving it to place it with proposed §§ 9.706--9.708.

The Department agrees that this section should be moved and renumbered, but has not merged it with another section, since the subject matter warrants a separate and distinct section. The Department has renumbered this section as § 9.706, and, as previously discussed, has renumbered the intervening sections as follows: §§ 9.703--9.705 (relating to internal complaint process; appeal of a complaint decision; and internal grievance process).

One commentator requested that the Department clarify whether the Department has ceased to recognize provider appeal processes established as part of provider contracts and recognized by NCQA. The commentator noted that the Department stated in the Preamble to proposed rulemaking that after implementation of the Department's regulations, provider dispute mechanisms will require prior approval by the Department, as will alternative external grievance dispute mechanisms. The Department's current position, according to the commentator, is that, until promulgation of final-form regulations, provider appeals will not necessarily be limited to those that fall under the parameters of Act 68.

The Department continues to recognize and encourage alternate dispute mechanisms, including provider appeal mechanisms wherever found, but would prefer them to be in contracts or at least referenced in contracts. Act 68 provides for a specific type of alternative dispute mechanism, one providing an alternative to the external grievance process, which may be used only if the Department approves it. Act 68 does not prohibit other alternative dispute mechanisms, as long as the requirements of Act 68 are not violated. The Department has also specifically recognized a provider dispute mechanism for administrative denials of coverage. See § 9.711 (relating to alternative provider dispute resolution systems.)

Three commentators, including IRRC, recommended that the Department develop a consent form for plans to use as a model, and adapt it to the specific needs of their consent processes.

The Department agrees that the inclusion of the required elements for a valid consent would eliminate disputes and streamline the grievance process. The Department has, therefore, included in the regulation the elements of a valid consent form to be used by providers to obtain consent from an enrollee to file a grievance. See subsection (e). These elements must be present in a consent form for it to be valid.

Four commentators questioned whether the enrollee's consent had to be written, or could be verbal. One of these commentators asked that the Department clarify when verbal consent or implied consent would be sufficient for Act 68 compliance. Another asked whether time would begin to run on a provider grievance on behalf of a member only when a written consent form was obtained. One commentator stated that the consent had to be in writing, since Act 68 required it.

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Act 68 requires written consent from the enrollee for a health care provider to initiate a grievance. This ensures that the enrollee fully understands that the enrollee is giving up a right under Act 68. To leave out the word "written" in the Department's regulations was an oversight, and the Department has corrected the language to require written consent before a grievance may be filed. If the enrollee is a minor or incompetent, a legal representative may grant consent. See subsection (e).

Several commentators requested that the Department include specific language in proposed subsection (b) permitting providers to obtain written consent to file a grievance from the enrollee at the time of treatment. One commentator requested this language to ensure that providers are able to advocate for their patients. Several commentators stated that it was difficult to find certain enrollees after treatment to obtain consent, for example, MA enrollees. Proposed subsection (b) would prohibit an enrollee from providing consent as a condition precedent to treatment.

Another commentator stated that it was having difficulty having consent forms returned in time to file a grievance.

One commentator commented that providers should have to obtain consent from enrollees at each stage of the grievance process to avoid providers pursuing grievances based on blanket consents after the enrollee has been satisfied.

One commentator commented that this would be the appropriate section to underscore the fact that providers may not rely on standing consent obtained in advance of a disputed service or procedure to satisfy consent requirements.

IRRC noted that commentators have raised concerns about whether consent can be obtained at time of treatment, and requested that the Department clarify the proposed subsection.

The Department is willing to permit a health care provider to use an enrollee consent obtained prior to service, so long as that consent is not obtained as a condition precedent to the enrollee's receiving the service. The Department is aware that some providers serve populations who may be difficult to locate after the service has been rendered. The Department is also aware that some enrollees, not being held financially responsible for the service in any case, may have no motivation to support the provider's pursuit of a grievance. If the provider does not obtain consent at the time of the service, the provider may have difficulties in obtaining consents at a later date. The Department has, therefore, added specific language to the regulation stating that the provider may obtain a consent at the time of treatment. However, as proposed, the provider may not require the enrollee to sign a consent as a condition precedent to receiving treatment or service.

If the provider fails to file within the period of time allowed by the plan or by regulation, however, the enrollee will then be unable to file a grievance on the enrollee's own behalf. To protect the enrollee who gives a consent at the time of treatment, the Department is requiring that if the provider chooses not to pursue a grievance, the provider must notify the enrollee within 10 days of the receipt of the standard denial from the plan that the provider does not

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intend to file a grievance. See subsection (g). This will signal to the enrollee that the provider will not be pursuing the grievance and it is up to the enrollee to pursue it if the enrollee chooses to do so.

Once the health care service has been rendered, and the issue is purely one of retrospective payment, the provider and the enrollee are seldom in communication with each other about the intentions of one or the other to file a grievance. The practice of obtaining blanket consent from all enrollees is particularly troublesome when the provider fails to prosecute a case fully and effectively squanders the enrollee's right to file a grievance, which the enrollee has granted to the provider. The Department strongly supports plans and providers arriving at alternate means of settling payment disputes, other than blanket enrollee consent, in cases where enrollees are not financially responsible because of the plan-provider contract terms.

One commentator recommended that the Department delete the language "assumes responsibility for filing" in proposed subsection (c) and replace it with the word "files." Proposed subsection (c) stated that "Once a health care provider assumes responsibility for filing a grievance, the health care provider may not refuse to grieve the issue through the second level grievance review."

The Department has not changed the language. The Department has used this language to underscore the fact that the provider has a responsibility to the enrollee as soon as the enrollee waives the right to grieve a matter by allowing the provider to do so.

Another commentator recommended that the Department clarify its intent in this proposed subsection. The commentator noted that the provider is at risk when an external review is requested, since the losing party has to pay costs under Act 68. The commentator asked what would happen to a grievance if a provider decides not to pursue an external grievance. The commentator stated that the enrollee should be advised by the provider, since this should not be the plan's responsibility.

The commentator also stated that the plan should have the right to refuse to accept a request for an external grievance from an enrollee, even if the request was untimely due to failure of a provider to timely notify the member of the provider's refusal to grieve to that level.

The Department agrees that the enrollee should have notice of the provider's decision to cease pursuit of a grievance, so that the enrollee may choose to pursue a review of the grievance. The Department has, therefore, added subsection (g) to require that a provider notify the enrollee of its intention not to pursue a grievance or the next level of review. Further, if the external grievance is late in being filed, then the plan has the ability to refuse to accept the request for the external grievance. Act 68 sets the time frames for these requests (see section 2162(c)(1) of Article XXI), and if a grievance is not timely filed, regardless of the reason, the plan can refuse to accept it.

One commentator noted that since many appeals by providers occur where the enrollee is not required to pay for the service being grieved by the hold harmless terms of the provider contract, the provider should be permitted to drop the appeal after first level, and only go on if the enrollee requests.

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Another commentator stated that to require physicians to continue challenging a decision through the second level grievance process is a disincentive for physicians to file grievances. The commentator stated that this requirement is not supported by Act 68 and should be removed.

The Department's intention in including this language in the proposed regulations was to prevent a health care provider from obtaining enrollee consent to file a grievance, squandering the enrollee's rights by failing to fully pursue the grievance review, and then billing the enrollee when the enrollee no longer has recourse through the Act 68 grievance procedures because the enrollee's grievance rights have terminated without the enrollee's informed opportunity to fully exercise them. It does not matter to the Department whether the provider prosecutes the grievance through the external grievance review. What matters to the Department is that the provider not bill the enrollee until the enrollee's grievance rights have been pursued to the extent of the enrollee's desire. The provider may choose to drop a grievance if it does not, and will not, bill the enrollee for the services that are the basis of the grievance. If the enrollee chooses to rescind consent and carry on the grievance directly, the provider may bill the enrollee at that point. The provider should not be allowed to routinely obtain consent from enrollees and half-heartedly carry out the appeals, using up the enrollee's right to grieve, and then billing the enrollee when the provider no longer feels like prosecuting the case. The Department has revised the language of the subsection to address these concerns. See subsection (c).

Two commentators have questioned the Department's authority to prohibit health care providers from billing enrollees until matters that are the subject of the grievance are completely reviewed through the grievance process. See proposed subsection (d). One commentator stated that this proposed regulation would appear to conflict with the prompt payment provisions of Act 68. See section 2166 of Article XXI. The commentator asked why the provider should have to take full risk because it appealed when the plan only approved partial payment because the plan believes the services should be of shorter duration. Further, it asked why the provider has to take full risk when the health care system commonly requires disengagement of fees that were not appropriately paid if the plan's decision not to pay in full is eventually upheld.

Another commentator suggested that prohibiting physicians from billing enrollees until the external grievance process has been completed is a disincentive to file grievances.

The Department has the authority to determine what is acceptable in a grievance process because plans are required to establish and maintain grievance resolution systems, which are satisfactory to the Secretary. See section 364(e) of the HMO Act and section 630(e) of the PPO Act. Further, plans are required to adopt and maintain complaint and grievance processes that are compliant with Act 68 (see section 2111(8) and (9) of Article XXI), and the Department is charged with ensuring compliance with Act 68 (see section 2182(d) of Article XXI), specifically with respect to ensuring compliance to grievance and complaint review processes. See section 2181(a) of Article XXI.

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This prohibition against billing is a common sense requirement intended to protect the enrollee. It is the provider that has determined to appeal the decision, and it is the provider controlling how the appeal is pursued, not the enrollee.

With respect to the comment made related to prompt payment, prompt payment applies to a plan and to clean claims, (see definition of "clean claim" in section 2102 of Article XXI), and not to the enrollee. See section 2166 of Article XXI (relating to prompt payment of claims). The claims in question in this subsection have been processed as "clean claims" and have been denied. The prompt payment provision does not apply once a claim has been submitted, adjudicated and denied. There is no conflict between this section and the prompt payment provision of Act 68 and Insurance's regulations.

Lastly, the provider is not at full risk, but is only unable to bill the patient until the reviews are completed. There is no reason why the patient should bear the full financial responsibility as opposed to the provider. In fact, the fee provisions of Act 68, with respect to external grievances, make it clear that the enrollee is not to be at risk for the cost of the external grievance review no matter what the outcome. See section 2162(c)(7) of Article XXI. The Department's regulations are fully in line with the intent of the statute, which is to benefit the enrollee in terms of quality health care accountability and protection.

IRRC notes that commentators have asked whether billing may occur if the grievance is filed by an enrollee. IRRC requested that the Department clarify whether this proposed subsection (d) (now part of subsection (c)) would apply regardless of who initiates the grievance.

One commentator stated that it read proposed subsection (d) to prohibit provider billing only when the provider initiated the grievance.

Subsection (c) applies solely to health care provider-initiated grievances, as the title of the section would suggest. Providers may bill if contractually they are able to do so, and they have chosen to pursue a grievance and exhausted the grievance process without success. The regulations do not prohibit billing when the enrollee initiates a grievance.

One commentator requested clarification as to whom the word "it" referred in the phrase "until it chooses not to appeal an adverse decision" in proposed subsection (e). The commentator recommended that it should be the enrollee.

The word "it" does not refer to the enrollee, it refers to the health care provider, which is the entity in control of the appeal at this stage. The Department has revised proposed subsection (e), now subsection (d), to clarify that fact.

One commentator recommended adding language to proposed subsection (f) which would state " Pennsylvania law permits an enrollee of a managed care plan or, with the enrollee's written consent, a health care provider, to request that the plan reconsider a decision made concerning the medical necessity and appropriateness of a health care service. This request is known as a grievance."

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The Department has not added the recommended language, since it appears to provide a definition of "grievance," which is already included in § 9.602. The Department has decided, however, to delete the proposed text of the subsection since its subject matter will now be included in subsection (e), which includes the required elements for a valid enrollee consent to allow a provider to file a grievance on the enrollee's behalf.

Those elements include allowing a legal representative of the enrollee to provide the consent and automatic rescission if the provider fails to file a grievance. The consent to file a grievance shall identify the enrollee, the health care provider, and the managed care plan; shall provide a brief description of the service; and must include the dates of service. The consent to file a grievance must also clearly disclose to the enrollee in writing that the consent precludes the enrollee from filing a grievance on the same issue unless the enrollee, during the course of the grievance, rescinds in writing the previous written consent. The consent must also inform the enrollee of the right to rescind the consent at any time during the grievance process. These statements must be read by or to the enrollee, and be explained to the enrollee. The Department's intent in including these two latter requirements is to ensure that the enrollee is adequately informed as to what providing consent will mean.

Section 9.707. External grievance process.

The Department received several comments on this proposed section. One commentator supported the Department's removal of language from its draft regulations that would have permitted the Department to investigate plan definitions of "medical necessity" under evaluations by a CRE. The commentator also supported the elimination of language that stated that CREs could review a plan's definition of "medical necessity" and specifically comment as to whether it deviated from the usual and customary language regarding medical necessity.

One commentator commented that the proposed section was confusing and recommended that it should be simplified when possible.

One commentator repeated its earlier comment that it would be necessary to have a licensed peer of the health care provider who requested the review, or who made the request for services, on behalf of an enrollee participate in the review. The commentator stated that this would be appropriate since a clinical rationale must be given and such decisions are based on medical necessity and appropriateness. The commentator noted that nothing in the statute excluded the use of a "same licensed clinician" in the review process, and recommended revising the proposed regulations to include this requirement.

The Department has not made the recommended changes to the regulation. This section addresses procedures in obtaining an external review, and not substantive standards for the conduct of that review. The latter standards are included in § 9.708. This comment was more fully addressed in the discussion on the comments on proposed § 9.706.

Another commentator raised concerns that the language relating to standards for psychiatrist reviewers was not clear. The commentator recommended that the Department include the language in § 9.743(d) (relating to content of an application for certification as a CRE). The

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commentator recommended that the Department repeat this language in proposed §§ 9.706--9.708.

Because this section deals with procedural matters, it would not be appropriate to include language relating to the standards for reviewers in this section. This comment was more fully addressed in discussions of comments on § 9.705 (formerly § 9.706).

IRRC commented that proposed subsection (b)(1) would require an enrollee to appeal within 15 days of the receipt of the second level review decision. IRRC asked how the receipt of the decision was to be determined.

The Department has discussed this issue more fully in its response to comments on § 9.705. A plan will be required to make determinations on a case-by-case basis. Failure to do so fairly and consistently could lead to sanctions by the Department.

One commentator commented that an enrollee should have 30 days rather than 15 days to file for an external review. The Department cannot change this requirement, since the time frame is set by Act 68. See section 2162(c)(1) of Article XXI.

IRRC recommended that the Department clarify its use of the word "or" in proposed subsection (b)(2). The proposed subsection stated that notice should go to the Department, the enrollee or the health care provider. IRRC commented that the proposed subsection could be read to require provision of notice of the decision to either the enrollee or the provider.

Another commentator requested that the Department require that notice be provided to both the provider and the enrollee, even though the statute requires notice to the enrollee or the provider, if the provider is the one taking the appeal.

The Department has changed the language to require notification to the enrollee and the enrollee's representative always, and the health care provider also, if the health care provider is filing a grievance with enrollee consent. See subsection (b)(2).

IRRC and another commentator noted that the reference to subsection (k) in proposed subsection (b)(4) appeared to be in error.

The Department agrees that this reference is incorrect. The Department intended to refer to information included in subsection (b)(5). The Department has corrected the reference.

The Department is also changing subsection (b)(4) to clarify it and to use the terminology of Act 68. The subsection now reads "Along with the notification and request for an assignment of a CRE and the information in subsection (b)(5), the plan shall provide the Department with the name, title and phone numbers of both a primary and alternative external grievance coordinator."

One commentator asked whether a plan was still permitted to charge a nominal processing fee of \$25 or less in connection with the external grievance.

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The Department has not altered Act 68, which allows the imposition of a \$25 or less filing fee for the filing of an external grievance.

IRRC also commented that proposed subsection (b)(4) referred to an "external grievance coordinator," but that the term was not defined. IRRC recommended that the Department add a definition for this term.

The Department believes the phrase to be self-explanatory. The Department is not creating a job position, but rather is requiring plans to designate and name a primary and alternate staff person who will coordinate the processing of external grievances for the plan, so that the Department has a direct link to the plan, particularly in the event of an expedited review. It is up to the plan to decide who that person will be.

One commentator recommended that the Department develop a simple form for an enrollee to use to send a request to the plan for the assignment of a CRE, and that the Department should require plans to include the form with the second level grievance decision.

The Department agrees that a model form would be helpful, and has already developed a form for plans to distribute to enrollees with second level complaint decision letters. The Department does not want to require its use by regulation. This could create technical regulatory violations when enrollees and providers do not use the forms. The Department will develop and release a form by a technical advisory. It is possible plans may develop a method more "user-friendly" than what the Department would develop.

One commentator requested that the Department clarify that a member should send copies of correspondence that are readily available, but that the enrollee's failure to do so should not be considered grounds for the dismissal of the enrollee's external grievance request. The commentator stated that the requirement that an enrollee provide copies of any correspondence from the plan would be burdensome for the enrollee, and that the plan was in a better position to provide this information.

After reading this comment, the Department believes subsection (b) needs clarification. It is the plan that must provide copies of the correspondence, not the enrollee. For purposes of clarification, the Department has changed subsection (b)(5) to read "The plan's request to the Department for assignment of a CRE shall include the following." The Department has also revised subsection (b)(1) to include a minimum of what must be in the enrollee's or the health care provider's request for an external review.

IRRC requested that the Department replace the acronym "Insurance" in subsection (b)(5)(iv) with the word "identification," and asked whether this meant an Insurance number assigned to enrollee by plan, or some other number.

The Department has made the correction requested. The word "identification" is intended to refer to an identification number assigned to the enrollee by the plan.

The Department has also added a requirement to subsection (b)(1) that if a health care provider is requesting an external review, it provide evidence of the enrollee's written consent

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along with the name of the enrollee. This will ensure that it is clear that the provider has authority to file the appeal.

IRRC recommended that subsection (b)(5)(viii) and (6)(ii) specify what the Department would consider to be "reasonably necessary supporting documentation."

The Department agrees that "reasonably necessary documentation" should be defined, and has included language to define it in subsection (b)(5)(viii). Reasonably necessary information will include UR criteria, technology assessments, care notes, information submitted by clinicians regarding the enrollee's health status as it relates to the issue on appeal, opinions from matched specialists or peer reviewers and information submitted by the enrollee and the treating health care providers.

One commentator recommended that copies of all supporting documentation should be provided to the enrollee and, if applicable, to the provider. The commentator stated that the enrollee should know what the plan considered in reaching its decision.

One commentator commented that a plan should be required to provide to the CRE the contractual definition of "medical necessity" and other documentation that the plan used to make its internal decision. The commentator recommended that the section be revised to require that the information be provided to the enrollee and enrollee's physician without request.

One commentator recommended that the Department delete the requirement that the plan describe the remedy being sought by the enrollee in proposed subsection (b)(5)(vi).

The Department has stated that plans must make all relevant information available to the enrollee, so it is unnecessary to make the plan send a duplicate case file to the enrollee or the provider. A document list will allow the enrollee or provider to recognize if information they consider necessary has not been sent. The regulations require that a list be provided. See subsection (b)(7).

The Department is deleting from subsection (b)(5)(v) and (vi) the proposed requirements that the plan summarize the issue and the remedy being sought by the enrollee, as this information is contained in the enrollee's second level appeal letters and the review committee's decision. The Department has required that these items be provided by the plan to the Department along with the request for a CRE. See subsection (b)(5)(v) and (vi). These items are already a part of the case file and will provide an accurate description of the case, without the plan summarizing it. The Department is concerned that the plan's paraphrasing or characterizing of the appeal would give rise to further issues for the enrollee.

The Department has also revised proposed subsection (b)(7) to delete language requiring the plan to provide the enrollee or health care provider with the plan's description of the issue being appealed and the remedy being sought. The Department had proposed this to allow the enrollee or provider to challenge the plan's characterization of these items. Since, however, the Department has deleted these items from subsection (b)(5), in favor of the enrollee's or the

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provider's appeal letters and the committee's decision letters, there is no need for this provision.

The Department has revised subsection (b)(6) to require the plan to forward the written documentation concerning the denial to the CRE performing the external review. This is intended to place the responsibility on the plan to get the information to the external CRE, rather than requiring any CRE that handled the matter for the plan internally to do so on its own.

One commentator recommended that the enrollee should be permitted to send information to the external CRE directly, rather than through the plan as required by proposed subsection (b)(8). The commentator commented that as the proposed regulation was written, with no specific time requirements for plan to send it on, there was a potential for unnecessary delay and for loss of documents.

The Department intended to have the information routed through the plan to ensure that the plan was in a position to consider it. If this were to take place, perhaps the need for an external grievance review would be eliminated. The commentator's point is well taken, however, and the Department agrees that an enrollee or provider should be able to send information directly to the CRE. The Department has revised subsection (b)(8) to state that the provider or the enrollee may submit information directly to the CRE, but must provide copies of those documents to the plan at the same time as the documents are provided to the CRE.

One commentator recommended that, although proposed subsections (c) and (d) stated that the plan would be responsible to notify the enrollee that a CRE had been chosen, the Department should notify the enrollee as well. As the proposed regulation was written, the commentator stated that the enrollee and the provider would be at the mercy of the plan to provide information.

Act 68 requires the Department to notify the CRE and the plan of the CRE's assignment to the case, and requires the plan to notify the enrollee or health care provider of the name and address of the CRE within 2-business days. See section 2162(b)(2) of Article XXI. The Department's proposed amendment tracked this provision. It is, however, much simpler for the Department to notify all parties at the same time, and in this way, the Department will be assured that the enrollee and provider have the necessary information. The Department has revised subsection (c) to state that the Department will provide notice to the enrollee, the health care provider if the health care provider has filed the grievance and the assigned CRE. The Department has deleted the proposed text of subsection (d), which would have required the plan to notify the enrollee and health care provider of the identity and address of the CRE.

The Department has also deleted the last sentence of proposed subsection (g) (now subsection (f)), since that sentence would have required the plan to provide notice of the assignment of the CRE, regardless of whether it choose to challenge the assignment. Since the Department is now providing notice of the CRE assignment, this language is unnecessary.

One commentator recommended that the Department provide information from the CRE's accreditation automatically, since enrollees will not know to request it. Proposed subsection (e)

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stated that the Department would make additional information from the CRE's accreditation application to the plan, the enrollee or the health care provider upon request.

Proposed subsection (e) (now subsection (d)) did not state that the Department would provide information concerning the CRE's accreditation upon request, but, rather, that it would provide additional information from the CRE's application to the Department. Notice of this will come directly from the Department to the enrollee at the time the Department notifies the enrollee and the health care provider, if the provider is filing the grievance, of the CRE assignment. See subsection (d). The Department has not made the revision that was requested.

One commentator supported the language in proposed subsection (f) (now subsection (e)) that would prohibit a plan from selecting a CRE to do the external review that was affiliated directly or indirectly with the plan. Under proposed subsection (f), if the Department would fail to select a CRE within the time frame provided, a plan could choose a CRE from the list of approved CREs. The commentator recommended clarification regarding the nature of direct or indirect affiliation.

The Department has added language to subsection (e) to clarify the meaning of direct or indirect affiliation. By direct or indirect affiliation, the Department meant having a current contract, or being in the process of negotiating a contract, with the plan or its affiliates to perform UR. The Department has simply added the language: "The plan may not select a CRE that has a current contract or is negotiating a contract with the plan or its affiliates to perform UR to conduct the external grievance review or is otherwise affiliated with the plan or its affiliates," and has deleted the language "affiliated directly or indirectly." See subsection (e).

One commentator recommended that proposed subsection (g) should state that the 3 business days to object to the assignment of a CRE included in the proposed subsection applies whether the CRE is assigned by the Department or is designated by the plan under proposed subsection (f).

Another commentator recommended that the Department provide language stating how an objection is to be made, including the acceptable grounds for an objection, and to whom.

The Department agrees that proposed subsection (g) should be clarified to allow an enrollee or provider to object when the plan designates a CRE. It has added language to take that situation into account. See subsection (f).

The Department has added language to subsection (f) to provide the conditions under which a challenge may be made. The only acceptable reason for challenge to a CRE is on the grounds of conflict of interest. The Department does not require proof of conflict since the point is to arrive at a CRE both parties can accept as impartial. If both parties accept the impartiality of the CRE, the CRE's decision becomes more trustworthy. The Department's intention is not to provide a mechanism by which the enrollee or provider may prove that a claimed conflict is reasonable or unreasonable, but to create a process in which both parties can trust to resolve claims equitably.

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The Department has also decided to change the time period in which either party may challenge a CRE assignment from the date of receipt of notice of the assignment to the date on the notice of assignment. The Department was concerned that it would be impossible to determine date of receipt of the notice. The Department is compensating for the change by increasing the time period from 3-business days to 7-business days.

One commentator requested that the Department reconsider its position requiring the plan to pay for the health care service regardless of whether or not it chooses to appeal. The commentator stated that the plan should be able to request that implementation of the external review decision be stayed pending appeal, or that the implementation of the decision proceed subject to certain agreed limitations or protective arrangements that preserve the dispute as live. The commentator stated that the language of proposed subsection (k) would undercut a plan's right to judicial review by making the issue moot, even when expedited or injunctive relief could be sought.

The language of subsection (k) is taken from section 2162(c)(6) of Article XXI. The plan may always request a stay pending appeal from the court of competent jurisdiction to which it appeals. Neither the Department nor the CRE have any way of granting a supersedeas or a stay in such matters. The external review decision is not the decision of the Department, but of the CRE. The CRE is not a court of law, nor does it sit as a quasijudicial body. It proceeds by statute to review the plan's decision. The statute does not provide the CRE with authority to grant a supersedeas.

One commentator recommended that the Department add a provision from Act 68 that was omitted from the proposed regulations: "If the enrollee files the external grievance and the plan prevails, the plan shall pay all fees and costs."

The Department agrees that this language should be added, and has included it in subsection (k).

One commentator commented that proposed subsection (l) (now subsection (k)) would be a biased disincentive to health care providers to seek an external grievance, since this ability to assume fees and costs associated with external grievance is far less than the plan's if they are not the prevailing party. The commentator recommended that this proposed subsection be reviewed to determine a more equitable penalty process.

Section 2162(c)(7) of Article XXI sets the responsibility for the payment of fees and costs relating to external grievances. The Department cannot alter the statutory responsibility of a provider to pay fees and costs when the provider is the nonprevailing party.

One commentator recommended that the regulations should state how fees are to be handled in split decisions.

The Department agrees that language should be added to the proposed regulations to address split decisions, and has done so. If a decision is against the health care provider in its entirety, the health care provider shall pay the fees and costs associated with the external grievance. If the plan is not the prevailing party in that the decision is against the plan in full or

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in part, the plan must pay the fees and costs associated with the external grievance review, regardless of the identity of the grievant. See subsection (l). If a provider is responsible for payment of the fees when the appeal substantiates the services were not medically necessary or appropriate under the terms of the plan, it is a disincentive for providers to request external review for questionable or frivolous cases. If, on the other hand, the plan's denial is insupportable to any degree, the plan should pay for the entire cost of the external review.

Another commentator stated that the Department did not have the statutory authority to determine that attorney fees are not included in the fees imposed on the prevailing party, and recommended the deletion of the language. The commentator recommended that attorney fees be passed on to nonprevailing party

The statute specifically states that for purposes of the section, fees and costs do not include attorneys fees. See section 2162(c)(7) of Article XXI. The Department did not specifically use the term "fees and costs" in its regulation, and it will use this term to mirror the statute.

Section 9.708. External grievance reviews by CREs.

The Department received several comments on this proposed section.

IRRC recommended that the Department add to proposed subsection (a), which would include requirements for the issuance of an external review decision, a requirement that notice be provided to an enrollee's representative as well, since an enrollee can have a representative.

The Department agrees, and has made the change.

The Department has also included more specific requirements for an external grievance review decision. These requirements--credentials of the individual reviewer, a list of the information considered in reaching the decision and a brief statement of the decision (see subsection (a)), are in accord with recommendations made by commentators with regard to decisions issued by plans.

Several commentators also, in comments made on proposed §§ 9.704 and 9.706, requested that the enrollee be provided access to the credentials of the individual making the decision.

Although the Department has declined to require the production of credentials in complaint decisions for plan personnel and enrollee committee members, and in the standard UR decision prior to the grievance process, the Department is requiring the production of credentials of the matched specialist. See § 9.705(c)(3)(v). The Department believes that the production of the credentials of the external reviewer is also necessary to ensure that the match was apt, and to provide the enrollee and provider with information to support the inherent trustworthiness of the decision. Further, the Department believes that the information it is requiring in the external review decision allows the plan, enrollee and provider to invest in the system and believe in its inherent trustworthiness, and is therefore essential for the ultimate success of the external review process.

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One commentator recommended that the Department define the word "appropriate" in proposed subsection (b). Proposed subsection (b) would require that the CRE review the second level grievance decision based on whether the health care service denied by the internal grievance process was medically necessary and appropriate under the terms of the plan. The commentator questioned whether the word "appropriate" was intended to mean appropriateness of site or service. The commentator also questioned who would review the "appropriateness of site" questions. It further commented that the "appropriateness of service" review was a part of the medical necessity review and this should be clarified. The commentator recommended that "appropriate" should be defined to mean "appropriateness of site" and not "appropriateness of service," since the latter was part of the definition of "medical necessity."

The Department has made no change to the proposed regulations. Appropriateness pertains to both place and to service, and is all a part of the medical necessity and appropriateness review required by Act 68. See section 2162(c)(5) of Article XXI.

One commentator recommended that the Department clarify the language of proposed subsection (c) as follows: "The CRE may not make coverage decisions such as requiring plans to cover services not covered under the policy, or specifically excluded under the policy." The commentator noted that plans could exclude services by contract, and nothing in the CRE's review should be deemed to authorize it to breach a contract. The commentator noted that the CRE was statutorily prohibited from making coverage decisions.

The standard for CRE review is in section 2162(c)(5) of Article XXI and in subsection (b). There is no need to add further language. There is no presumption in Act 68 or in the Department's regulations that a service that is necessary is therefore covered. CREs are not authorized to require coverage of service that are specifically excluded. If, in the event of, a nonspecific exclusion, for example, an exclusion for experimental or investigational services, a CRE determines that a service is not experimental or investigational, then a CRE may require coverage, and the standard of review of Act 68 has not been ignored, or the contract breached.

One commentator noted that proposed subsection (c) would require the CRE to consider all information considered by the plan. The commentator recommended that the CRE be required to review all information submitted to the plan, whether or not the plan had considered it.

The Department has not changed the language of the regulation. The CRE is to consider all information considered by the plan, and information included in § 9.707. Both the plan and the enrollee, or a health care provider that has filed the grievance, have the ability to submit additional information to the CRE for its review under § 9.707(b)(8). If the enrollee or provider believe that a plan failed to review important information, they have the ability to resubmit that information to the CRE.

One commentator raised concerns that proposed subsection (d) seemed to allow for a lower standard for external reviews than for internal review. The commentator noted that proposed § 9.706(d)(2) would state that a reviewer can either be a physician in the same or similar specialty that typically manages or recommends treatment for the health care service being

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reviewed, or a physician in active clinical practice. The commentator asserted that this meant that a physician with no experience in a particular area, but active clinically in another totally unrelated area, could be reviewing a case in an area about which the physician knows nothing. The commentator acknowledged that this is what section 2162(c)(4) of Article XXI states, but suggested that this construction of the statute made little sense. The commentator stated that drafters of the bill with whom it has spoken have agreed that this is a drafting error. The commentator stated that the statute was intended to offer a combination of active clinical practice and in the same or similar specialty as an alternative to board certification and the same or similar specialty. The commentator recommended revision of the proposed regulations to take into account this mistake.

Another commentator also commented that the use of the word "or" after the phrase "in active clinical practice" appeared to be a mistake in the statute, and in proposed subsection (d)(2).

The Department, after reviewing the comments on this issue, believes that principles of statutory construction would permit it to ignore the use of the word "or" in the statute. If an interpretation of a statute would be clearly absurd, as it would in this case to read the word "or" in its place, that interpretation may be ignored to effectuate the intent of Act 68. See *Zimmerman v. O'Bannon*, 442 A.2d 674, 676-677 (1982) (it is axiomatic that the General Assembly does not intend a result that is absurd or unreasonable). Since the intent of Act 68, and this provision, is clearly to provide the greatest protection possible to enrollees by providing them with the best level of review possible, to read the statute otherwise would be a violation of that intent. The Department has revised its regulations accordingly.

One commentator recommended including language from § 9.743(d) to clarify the language of the proposed regulations relating to standards for psychologist reviewers.

The Department addressed the issue in discussion of comments on proposed § 9.706 (now § 9.705).

One commentator repeated its earlier comment that it would be necessary to have a licensed peer of the health care provider who requested the review or who made the request for services on behalf an enrollee participate in the review. The commentator stated that this would be appropriate since a clinical rationale must be given and such decisions are based on medical necessity and appropriateness. The commentator noted that nothing in the statute excluded the use of a "same licensed clinician" in the review process, and recommended revising the regulations to include this requirement.

Another commentator noted that the absence of peer review was evident, and should be corrected. The commentator recommended that a health care provider with the same professional preparation as the grieving provider should be included in the review.

The Department has not made the recommended changes to this section. Act 68 does not require that the reviewer have the same license, but that the reviewer be in the same or similar specialty. The statute's intent is to allow flexibility within certain parameters and not to force the CRE to obtain an opinion from a peer of the provider requesting the service. As discussed

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earlier, there are instances when a neurosurgical opinion may not be inappropriate and indeed may be more relevant than an orthopedic opinion given the nature of the case. Further, the Department will not require, as part of the reviewing group, a person in the same profession as the provider who recommended the health care service in question. The issue is not one of professional bias, but one of whether the enrollee was denied medically necessary and appropriate treatment. For this purpose, it is not necessary to have a provider with the same professional license to review the case.

Further, Act 68 requires the inclusion of the physician or psychologist as a reviewer. See section 2162(c)(4) of Article XXI. No other type of provider may perform this review. A CRE that used a provider other than a physician, or as Act 68 permits, a psychologist, would be in violation of Act 68, and in jeopardy of losing its accreditation.

One commentator recommended that the Department add a definition of "active clinical practice" to the definition section of the regulations.

The Department agrees that this should be done, and has added the definition from Act 68 to § 9.602: "The practice of clinical medicine by a health care provider for an average of not less than 20 hours per week." See definition of "active clinical practice" in section 2102 of Article XXI.

Three commentators recommended that the Department delete the reference to the definition of "emergency" in the enrollee's certificate of coverage, since the standards for emergency services in Act 68 are what should be used. Proposed subsection (e) would require the CRE to utilize the emergency service standards of Act 68 and this chapter, and the definitions of "medical necessity" and "emergency" in the enrollee's certificate of coverage in reviewing a grievance decision relating to emergency services.

The Department included a reference to the certificate of coverage in proposed subsection (e) because that is where the benefit levels and exclusions appear. The Department has clarified this in the regulation by deleting references to the definitions of medical necessity and emergency in that certificate, and requiring the CRE to review the certificate itself. The Department has also included the requirement that the prudent layperson standard of Act 68 be used by the CRE for the purposes of clarity.

Section 9.709. Expedited review.

The Department received several comments on this proposed section.

One commentator stated that additional language should be added to the section to require the plan to act on requests for nonformulary prescription drug coverage in an expedited manner, within 1 business day of the receipt of the request. The commentator recommended that the denial of such a request be subject to the expedited review process in this proposed section.

As the Department stated in its response to comments on proposed § 9.673, some objections to the denial of a request for a formulary exception could be considered to be

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grievances, depending upon the circumstances. The Department has added language to § 9.673 to require plans to treat requests for formulary exceptions as concurrent UR, and to reach a decision within 2 business days. Further, if the enrollee meets the qualifying criteria included in this section, the enrollee may request and obtain an expedited grievance review.

Another commentator raised concerns about the practicality of the time frames involved. The commentator stated that it could be physically impossible to gather all necessary case records for transfer to a CRE by the end of the next business day. The commentator also stated that confidentiality of medical records could be breached in a rush to complete the case file.

The plan does not have to create an entirely new file. The plan had sufficient documentation to issue the original denial, and to issue any other internal grievance denials, therefore it is not "starting from scratch." It is the enrollee requesting the review, and asking that the information be provided to an expedited reviewer. It is difficult to see how referral of the record already considered by the plan would breach confidentiality of medical records. Further, it should be noted that section 2131(c)(2)(i) of Article XXI specifically states that nothing in that section shall prevent disclosure necessary to review complaints or grievances, conduct UR, determine coverage or pay a claim.

One commentator commented that under the 1991 guidelines, disputes regarding denials of care alleged to be necessary and pressing were required to be decided within 48 hours regardless of whether the issue was one of medical necessity, and that similar language should be included in the regulations.

Act 68 now sets out requirements for grievances and complaints, and for expedited reviews. Act 68 requires a showing that the life, health or ability to regain maximum function of an enrollee is in jeopardy to secure an expedited review. The Department cannot go beyond this and create a different standard for an expedited review, by saying that any time the service is necessary and pressing, if only in the opinion of the enrollee, an expedited review must be conducted.

Several commentators stated that the regulations should include an expedited review process for those matters that do not involve issues of medical necessity, but which, if not resolved quickly, would jeopardize enrollee's health, life, or ability to regain maximum function. These commentators also expressed concern that there was no expedited review for complaints.

In fact, the review process proposed by the Department does not limit expedited review to those matters involving medical necessity. The words "medical necessity" or "grievance" do not appear in § 9.709. Instead, the language reads: "A plan shall make an expedited review process available to an enrollee if the enrollee's life, health, or maximum function would be placed in jeopardy by delay occasioned by the review process set out in this subchapter." The subchapter, of course, covers both complaints and grievances.

Three commentators strongly supported the proposed regulations allowing for an expedited review in all cases where life, health or ability to regain maximum function could be jeopardized by a delay in obtaining the recommended services.

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One commentator questioned the Department's authority to impose standards for an expedited review process, since Act 68 does not include language requiring these reviews. This commentator also recommended that the Department modify this proposed section to reflect the process adopted by most of the managed care industry. The commentator stated that the next step after the plan's expedited review decision would be for the grievance to proceed to second level grievance review and then to an external grievance review.

The Department has not changed the proposed regulations. Act 68 does provide for an expedited internal grievance process when the life, health or ability to regain maximum function of an enrollee is in jeopardy. See section 2161(e) of Article XXI. To ensure that this provision is effectuated, the Department is requiring an expedited external process whenever the enrollee meets the necessary criteria, that is, the enrollee's the life, health or ability to regain maximum function of an enrollee is in jeopardy. It would be absurd, and, therefore, legally impermissible, to construe the General Assembly to have created an expedited internal process, the benefit of which could be destroyed by a return to the normal 60-day external review process if the internal decision were appealed further. Further, it makes little sense to allow the categorization of the case to drive the enrollee's ability to obtain an expedited review. If the enrollee's life, health and ability to regain maximum function are in jeopardy, the review should be expedited.

One commentator recommended that grievances should also be subject to an expedited review when necessary.

The expedited review process does apply to grievances.

One commentator recommended that the regulations address how an enrollee appeals a plan's denial of an expedited review.

Three commentators recommended that the regulation identify the person responsible for determining if the enrollee meets requirements for expedited review. One of these commentators commented that the intent of an expedited review could be negated by a disagreement over the prognosis of the enrollee.

Another of these commentators recommended that the Department add language requiring the matter of whether an expedited review should be granted be decided by a nurse or physician primary care provider, and requiring that such a decision be conclusive. The commentator also recommended adding "and the plan shall grant" after the word "request" in proposed subsection (a). Proposed subsection (a) stated that "An enrollee may request an expedited review at any stage of the plan's review process."

One commentator recommended that the regulations make it clear that a plan makes the decision regarding whether or not the matter will be expedited.

The 1991 guidelines required plans to grant an expedited review at the enrollee's option. The Department is requiring that the request for an expedited review be accompanied by a statement from the enrollee's physician that the enrollee meets the qualifying criteria, which are included in section 2161(e) of Article XXI. The statement must also include the physician's

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clinical rationale for the opinion, and facts to support it. This is intended to prevent expedited reviews from being abused by either party. The Department is requiring that an expedited review be granted automatically upon presentation of such a statement. See subsection (c).

Given the haste with which an expedited case must be processed, the Department would expect the substantiating physician to seriously and critically evaluate the need for the enrollee to obtain the service within 48 hours. Substantiation from a physician as proof positive of the need for a 48-hour review imparts great responsibility on the physician to carefully evaluate the wants versus the needs of the enrollee. To do otherwise may prevent the enrollee from presenting the best case in such a short time span and may force the plan to make a decision it may not have made had it more time to investigate and deliberate. The focus of these cases should not be whether the substantiation is accurate but rather should be on determining the medical necessity and appropriateness of the request within the context of the terms of the plan. By requiring the plan to grant an expedited review upon receipt of the physician's statement, the Department is eliminating, as an appealable issue, a decision of whether to grant a review.

One commentator questioned language in proposed subsection (b) that stated that the internal expedited review process must meet the requirements of the second level review. The commentator asked whether this meant that the enrollee would bypass the first level review as indicated in proposed § 9.705(c)(1). The commentator commented that it would be more effective if plans were to meet requirements of the first level, and recommended making that change to the regulations.

The Department has not made the recommended change to the regulations. The proposed subsection was intended to require plans to meet the requirements of the second level review with respect to the holding of a hearing, the committee composition, the contents of the decision letter, the rights accorded the enrollee, and so forth. The Department has chosen the second level review standards, because of these heightened fairness requirements, which are necessary, given the serious nature of the issues involved. The Department realizes, however, that with the addition of fairness requirements to § 9.705, the need to review and respond to the enrollee with 48 hours may create problems for plans in meeting requirements other than timeframes. The Department has specified in subsection (b) what requirements of the second level review process may be altered, in an expedited review, to comply with the enrollee's need for an expedited decision.

One commentator recommended that the Department clarify proposed subsection (c) (now subsection (e)) to require a decision to be issued "48 hours from time the plan receives the appeal either by fax, mail or other electronic transmission."

IRRC commented that the subsection should specify that the plan would conduct an expedited internal review "upon receipt of the enrollee's request."

The Department has made the change that IRRC requested for the sake of clarity. The Department does not see the need to make the other recommended change to the subsection, since the language specifically requires the decision to be issued with 48 hours from the plan's receipt of the request. There is no need to specify how the request is to arrive. It may arrive in

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any manner. The Department has added language, however, to require that the request be accompanied by the physician's statement required by subsection (c).

One commentator requested that the Department clarify proposed subsection (e) (now subsection (g)). That proposed subsection would provide the enrollee with 2-business days from the expedited internal grievance review decision to contact the plan to request an expedited external review. The commentator questioned whether this meant that the plan only had one level of internal review in an expedited grievance. The commentator also asked whether this one level of review was to meet the first or second level review process. The commentator recommended that the second level be bypassed, and the enrollee go straight to an external review.

The plan only has one chance to review the matter internally. The expedited review must be conducted under the rules and procedures that govern the normal second level reviews, with some exceptions, as discussed previously. After that review, the decision may be appealed externally on an expedited basis as the regulations state.

Two commentators have commented that the implementation of the proposed section will require revision to member materials such as benefit documents, member handbooks and policies and procedures. One of these commentators requested that the Department show flexibility in terms of plan deadlines, and that it specifically address this in its final form-regulations.

There are many means of distributing information, for example, by special notices, announcements in member newsletters, revised subscriber contracts and additions to denial notices. The Department will not fine plans for noncompliance immediately upon adoption of the final-form regulations. The Department will work with plans to bring them into compliance as quickly as possible. This may involve some "stop-gap" measures until standard documents can be revised.

The other commentator noted that the concept of an expedited review did not appear in the Department's statement of policy. The commentator commented that having procedures reviewed and approved by Insurance, and distributing the new Act 68 grievance process in policy form changes, member handbook modifications and notices to members and providers had been a costly process. The commentator stated that the change in the handling of expedited grievance appeals would create significant costs for the managed care industry. If these changes are made, the commentator recommended that they should be coordinated with Insurance with sufficient lead-time prior to implementation.

The Department is aware that changes will need to occur to meet the requirements of the regulations. However, most notices regarding this subchapter are made through the review decision letters, and those changes involve a small number of letters (according to data from the 1999 plan annual reports, a total of 5,804 first level grievances and 12,379 first level complaints were filed in this Commonwealth and thereafter, the second number of second level cases drops to between 10-15%). These changes can be made by manual intervention, and must be made immediately. It should be noted that the policy statement was just that, policy, and that these regulations, including the expedited review requirement, were provided

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for public comment and have been before the public since December of 1999. The Department is not adverse to a longer timeframe for plans to come into compliance as long as the appropriate notices are made in the denial letters which will give the enrollee the information most necessary to exercise the right to appeal.

One commentator noted that not every request from an enrollee for an expedited review would meet the plan's definition of an expedited grievance. The commentator recommended the addition of the following language: "which has been determined to be an expedited appeal" in proposed subsection (f) (now subsection (h)), after the phrase "Within 1 business day of the enrollee request, the plan shall submit a request for an expedited external review"

The Department has added language to the regulation that requires a plan to provide an expedited appeal if the enrollee provides a letter from the enrollee's physician that the enrollee meets the qualifying criteria. Therefore, there is no need for the Department to make the requested change.

IRRC recommended that the Department specify in subsection (f) that submission will occur within 1 business day of receipt of the enrollee's request.

One commentator requested that the Department consider extending time frames in which the plan would be required to forward an enrollee's request for an expedited review to the Department, and for a plan to forward the complete case file to the CRE. The commentator recommended 2 business days for notification and 5 days for collection and forwarding as more practical.

The Department has made the change IRRC requested for clarity. See subsection (h). The Department has not changed the time frames included in the regulation to reflect the comment, since most information will already be in the plan's possession, and since the nature of the case warrants a more expeditious time frame for the collection and forwarding of materials than 5 days. The Department has, however, changed "1-business day" to "24 hours" to emphasize the need for expedition in these matters.

IRRC requested that the Department clarify language in proposed subsection (i) (now subsection (k)), which would require the plan to transfer a copy of the case file to the review entity for receipt on the next business day. IRRC questioned what would constitute receipt on the next business day.

The Department means that the documents arrive at the CRE by 5 p.m. the following business day.

One commentator noted that although the Department had referenced an appeal right for expedited external reviews in proposed subsection (j), it had not included similar language in proposed § 9.707. The commentator questioned whether the appeal right was only applicable to enrollees or providers, or whether the plan had a right to appeal. The commentator recommended that the appeal process be explained in more detail or be deleted.

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The Department is deleting the language from this section as well, on the theory that a plan or enrollee may attempt to appeal the matter to a court if they choose without the Department's stating that fact in regulation.

IRRC commented that proposed subsection (i) used the term "response" and proposed subsection (j) used term "decision." IRRC recommended that the Department change one or the other for consistency.

Since the Department has deleted proposed subsection (j), this comment is moot. The Department has, however, changed the language in subsection (i) from "response" to "decision" as "decision" is a more accurate term.

Section 9.710. Approval of plan enrollee complaint and enrollee and provider grievance systems.

The Department received several comments on this proposed subsection.

IRRC requested that the Department clarify whether approvals of complaint and grievance systems were required prior to implementation. IRRC asked how the changes initiated by the plan were to be approved. IRRC recommended that the Department add specific time frames and requirements for the Department's approval of complaint and grievance systems.

The Department is not requiring prior approval of the entire systems for complaint and grievance review, but only of changes to those systems for existing plans that have the potential to impact the process or the outcome of the complaint or the grievance process. See subsection (b). Consequently, the Department's review of the system will not interrupt or delay the current grievance and complaint processes and appeals. The Department will work with plans that are not in compliance with Act 68 and the regulations through the corrective action plan process to arrive at a complaint and grievance process that meets the terms of Act 68 and the regulations.

One commentator recommended deleting the portions of this proposed subchapter related to complaints since Insurance has the authority over complaints under Act 68.

The Department and Insurance both have responsibilities under Act 68; the Department has not changed the language of this section with respect to this comment.

One commentator requested that the Department clarify whether a plan would be required to submit its complaint and grievance process to the Department after that process had been approved by Insurance.

The Department has the responsibility to require compliance with the regulations governing grievance systems, and both agencies have the responsibility to require compliance with their regulations governing complaint systems. The Department will need to review and approve both complaint and grievance systems, even if Insurance has already reviewed them, since both agencies have jurisdiction over complaints, and the Department has sole jurisdiction over grievances.

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IRRC and another commentator recommended that the Department delete the requirement that the grievance process be satisfactory to Secretary, as the only goal should be compliance with Act 68.

The Department has deleted this language since the regulations themselves describe the standards that complaint and grievance systems must meet in order to be acceptable to the Secretary.

One commentator recommended that proposed subsection (b)'s requirement that a plan submit changes to its complaint and grievance systems to the Department for review, should apply only to material changes. The commentator also stated that the Department should require filing only, since the Department had no authority for prior approval.

The Department has authority to require prior approval of complaint and grievance systems. Act 68 gives the Department the authority to ensure compliance with its provisions. See section 2181(d) of Article XXI. The Department also has authority to review complaint and grievance systems under section 364(e) of the HMO Act and section 630(e) of the PPO Act, which provide that a grievance resolution system must be acceptable to the Secretary. The Department has the discretion to determine how it will ensure compliance. The most appropriate way to ensure compliance with all three acts is to ensure that the complaint and grievance systems meet the requirements of those acts before they are implemented, and before enrollees are harmed by procedures not compliant with Act 68, the HMO Act or the PPO Act. The Department is only, however, requiring prior approval of changes to the existing systems that have the potential to impact the processes or the outcome. This is intended to prevent disruption to existing processes, as it explained earlier. The Department will ensure compliance for existing systems by audits and reviews, and by requiring plans of correction as necessary.

IRRC requested that the Department state how far in advance it expects filings.

The Department will require plans to provide it with copies of proposed changes to the complaint and grievance processes 60 days prior to their implementation. The Department has included this language in subsection (b).

One commentator asked that the Department recognize that materials have already been submitted to and approved by DPW.

The Department is aware that DPW has contracted with certain HMOs for services to enrollees, including for complaint and grievance systems. However, the Department is one of the two regulatory agencies charged with ensuring complaint and grievance processes comply with Act 68, the HMO Act and the PPO Act. DPW approval cannot be considered to be a waiver of the plan's required compliance with the Department's regulations. As discussed earlier, there are many "stop-gap" measures that can be brought to bear to ensure the most necessary forms of compliance when full compliance may take some time. The Department will work with plans to ensure that enrollees have the necessary information as quickly and thoroughly as possible.

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One commentator expressed concern with the term "special populations" in proposed subsection (c). The commentator was concerned that the term was broad and potentially problematic. The commentator recommended that the Department clarify its intent in the Preamble or delete the term.

The term is defined in the regulation by the listing of the examples, Medicare and Medicaid HMOs. See subsection (c). Other populations similar to these would be covered, for example, enrollees covered by self-funded employers plans subject to ERISA.

Section 9.711. Informal dispute resolution system and alternative dispute resolution system.

The Department received several comments on this proposed section.

One commentator recommended changing the title of the proposed section to "Alternative dispute resolution systems" so that it would not appear to be talking about alternative providers.

One commentator commented that administrative denials were confusing and appeared to extend an alternative dispute resolution system to nongrievance issues, something not provided for in Act 68.

The Department has changed the title to "Informal dispute resolution system and alternative dispute resolution system," as more descriptive of the substance of the section. The Department's intention is to make it clear that this section involves other types of resolution systems as well as the alternative dispute resolution systems referenced in section 2162(f) of Article XXI. Act 68 does not prohibit alternative mechanisms for nongrievance related issues, and the Department will not prohibit them, as long as the mechanisms are entered into voluntarily, and are approved by the Department through its approval of provider agreements.

One commentator recommended that the Department create a new section on alternative dispute resolution systems (ADR) to the external grievance review process, which would include requirements and standards for ADRs. The commentator stated that this new section should make it clear that an ADR for external review cannot be used for grievances brought by enrollees. The commentator recommended that the informal dispute resolution mechanism should be included under § 9.702. The commentator noted that the ADR was voluntary and involved a waiver of provider rights, so that the Department had no valid reason to make the decision binding.

The Department will break up this section into two subsections, one dealing with informal dispute resolution mechanisms (see subsection (a)), and one dealing with alternative dispute resolution systems (see subsection (b)) as referenced in section 2162(f) of Article XXI. The Department has required alternative dispute resolution systems to be impartial, include specific and reasonable time frames in which to initiate appeals, receive written information, conduct hearings and render decisions, and provide for final review and determination of disputes. See subsection (b)(1). The Department has also required that these ADRs be included in the provider contracts, and be final and binding both on the plan and on the provider. See subsection (b)(2). The Department has also included language, as recommended by the

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commentator and included in Act 68, that an ADR may not be used when an enrollee files an external grievance. See subsection (b)(3).

The Department agrees with the commentator that both types of systems are voluntarily entered into by the parties. The Department reviews both by virtue of its authority over provider contracts, and by virtue of the Secretary's authority over grievance resolution systems, in the HMO Act, the PPO Act and Act 68.

The Department also agrees with the commentator that an informal process should not necessarily be final and binding on the parties. Therefore, the parties still have the option of going to the formal grievance process if the enrollee's consent can be obtained by the health care provider, although it need not be obtained for the informal process. The Department has deleted proposed subsection (d), which stated that nothing would preclude the parties from having an informal process, since the Department has specified in this section that such a process is permissible.

Several commentators supported proposed subsection (b), which would create a mechanism to correct routine procedural errors and denials between the plan and the provider without the need of enrollee consent.

One commentator commented that the substance of this subsection was inappropriate for this section.

Two commentators recommended that the dispute resolution not require written consent from the patient to allow the provider to seek resolution of procedural errors and administrative denials.

The Department's intent in allowing for an informal dispute mechanism was to alleviate the need for enrollee consent when the enrollee has no real interest in the matter, since the enrollee has been held financially harmless or has received all the services the enrollee requested. The Department has attempted to clarify this point in its revisions to this section, and has included an informal dispute mechanism in subsection (a).

One commentator asked whether proposed subsection (b) meant that plans would not have to accept member grievances where there was no member liability. The commentator asked whether these complaints would be handled through the alternative provider dispute resolution system because the issue was with the provider and not the enrollee. The commentator recommended that plans not have to accept an enrollee complaint or grievance where there was no member financial liability. The commentator recommended that if the provider was not satisfied with the payment, then the plan should have an alternative dispute resolution process to allow the provider to file a complaint or grievance.

The Department cannot remove the enrollee's right to file a grievance under Act 68 despite the existence of the informal dispute mechanism. Arguably the enrollee, who is held harmless, will have no reason to appeal, since the enrollee has not been denied a service or been required to pay out of pocket. However, if the enrollee chooses to appeal, the plan must accept the matter under Act 68.

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One commentator recommended that the subsection be clarified to state that the availability of a provider appeal for member hold-harmless matters precludes use of an Act 68 grievance appeal.

The Department cannot take away the provider's right to appeal through the grievance process. However, if a plan and its providers negotiate that the use of the informal process waives the provider's ability to use the Act 68 process, the Department would not refuse to approve the informal dispute resolution system based on that fact.

One commentator requested that the Department clarify that proposed subsection (c) would apply only if a plan establishes an ADR. Proposed subsection (c) would require that, if a plan had an alternative dispute resolution procedure, it be included in the provider-plan contract.

Although the Department believes that the clarification is unnecessary, the Department has added language to clarify that the informal dispute system must be agreed upon by a plan and its providers. See subsection (a)(3).

IRRC noted a typographical error, and pointed out that proposed subsection (c) should use the phrase "alternative dispute resolution system."

The Department has deleted this part of the subsection, in making revisions to address the informal dispute resolution system previously discussed.

One commentator commented that proposed subsection (e) should refer to compliance with Act 68 and not to the satisfaction of the Department.

The Department has deleted proposed subsection (e), and included its substance in subsection (b), which includes requirements for alternative dispute resolution systems. The Department has included the phrase in question in subsection (b), and so will respond to the comment. The Department promulgates these regulations not only under Act 68, but also under the HMO Act and the PPO Act, both of which require plans to have grievance resolution systems acceptable to the Secretary. The Department included this language in the section to indicate its authority under all three of these acts.

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Subchapter J. Health Care Provider Contracts

The Department received several comments on this proposed subchapter.

One commentator commented that under this proposed subchapter, health care providers could be deselected by plans at will.

The Department acknowledges that fact. Under general contracting terms, either party may refuse to renew a contract or may terminate without cause. This allows both parties to deselect at will, binding neither the provider nor the plan to a relationship that is no longer acceptable, regardless of reason. The Commonwealth does not have an "any willing provider" statute that would require a plan to contract with any provider willing to enter into a contract. Therefore, the Department does not have the authority to require plans to contract with certain providers. This would be a significant change in contracting law and would require a specific statutory mandate.

IRRC commented that the Preamble for the proposed rulemaking and the regulatory analysis form did not include information regarding cost of the requirements in this subchapter for plans or for the Department. IRRC requested that this information accompany the final-form regulation. IRRC also recommended that the Department consider whether there were less cumbersome and expensive alternatives for implementing Act 68.

The Department has addressed these issues in the section of this Preamble relating to cost and paperwork estimates.

Another commentator raised concerns that the Department was creating required provider provisions from its longstanding informal list of required provisions. The commentator requested that the Department consider costs associated with requiring plans to renegotiate contracts, distribute amendatory riders, inform providers of reasons for changes and related implementation issues. The commentator requested that the Department provide sufficient "lead time" for the plan to implement these changes.

The Department must be able to review the contracts discussed in this subchapter, to ensure compliance with Act 68 and to protect enrollees. The Department did not include information relating to cost for this subchapter, since it is not requiring plans to resubmit all currently approved contracts. The Department is already reviewing contracts for most of the requirements contained in this subchapter. The Department, therefore, did not anticipate great additional cost to the plans for this purpose, as discussed in the Department's response to the previous comment.

Two commentators commented that the proposed subchapter would not specify a time frame for the Department's approval of standard form provider contracts. They recommended that plans should be given notice as to length of time the Department would need to review and respond. One of these commentators also recommended that the Department include a provision that would permit plans to deem that the contracts were approved. The commentator recommended a 45-day time frame for review and approval, after which the contract would be deemed approved if not acted upon by the Department. The commentator also recommended

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inclusion of language stating that the Department would use reasonable efforts to request all additional information or clarifications at one time. Further, it was recommended that language be added providing that if the Department did not take additional action in the form of specific approval within 30 days after receipt of additional information or a written request for clarification, the contract would be deemed approved.

The Department has not included "deemer" language in the regulations. The Department has the responsibility under statute to review and approve provider contracts, as well as implementing certain provisions of Act 68, including, for example, provisions prohibiting financial incentives, prohibiting gag clauses and requiring confidentiality of medical records. For the Department to require itself to deem as acceptable a contract containing illegal language, simply because a regulatory, not statutory, time frame has run, is an abdication of the Department's responsibility under Act 68 and the HMO Act. The Department has added a provision to the regulations that states that the Department will review contracts within a 45-day period, and that if the Department fails to approve or disapprove the contract within that time frame, the plan may use the contract. The contract will be presumed to meet the requirements of all applicable laws. If the Department finds at any time that the contract contains violations of law, the plan must correct those violations. The plan is, of course, responsible for ensuring that it complies with Act 68 and any other law applicable to it, for example, the HMO Act.

Another commentator commented that, although it did not support the Department's attempt to regulate IDS arrangements formally, both Insurance and the Department should simultaneously regulate IDSs.

The Department and Insurance do both regulate IDS arrangements through the licensed entity. Insurance has not repealed its policy statement on IDS arrangements. See 31 Pa. Code Chapter 301, Subchapter I.

One commentator stated that its concerns were too numerous to include in comments. Its main concern, however, was that the proposed regulations would fail to limit the conflict of interest which could be found to exist between health care providers and their patients. The commentator stated that the proposed regulations would permit plans to give large financial incentives to providers who limit the care that they provide. The commentator stated that mere appearance of impropriety created a conflict of interest between patient and physician. Another commentator expressed the same concern.

The topic of conflict of interest is too broad to be defined, reviewed or disposed of in regulations. Act 68 is clear that a plan may not compensate a provider for providing less than medically necessary and appropriate care. Act 68 does, however, allow capitation arrangements. See section 2112 of Article XXI. At one extreme, fee-for-service reimbursements (payment made for services being provided) can be viewed as an absolute volume incentive to provide more care than may be necessary or appropriate, thereby creating an inherent conflict between the patient's needs and the provider's desire to generate more income. To the extent the patient is covered by insurance, the conflict may indeed be greater, as there is no "financial" harm done to the patient, only to the insurance company. At the other

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extreme, capitation can be viewed as an absolute volume disincentive, that is, to provide fewer services than medically necessary or appropriate.

In both scenarios, there is reliance on the provider and the health care profession to do "what is right" for the patient regardless of economic incentive, neither doing more nor doing less for economic gain. The Department cannot regulate the ethics of the provider to safeguard against all possible economic incentives in either a fee-for-service or a capitated scenario. Further, one person's incentive may not be incentive enough to another. It is impossible to know where to draw the line for each individual provider. In reviewing financial reimbursement terms, the Department reviews the overall economic structure, oversight mechanisms and safeguards the plan proposes to implement to detect and protect against under or over utilization.

Section 9.721. Applicability.

IRRC asked why the terms "health care providers" and "IDSs" are repeated twice in the section.

The terms were repeated because there are three contractual arrangements being addressed: the first arrangement is between the managed care plan and health care providers in general, whether organized as an IDS or not; the second arrangement is between a plan and an IDS; and the third arrangement is between an IDS and the providers who make up the IDS.

IRRC also commented generally on §§ 9.723, 9.724 and 9.725 (relating to IDS; plan-IDS contracts; and IDS-provider contracts), and questioned why the Department had used the term "HMO" rather than "plan," when the definition of IDS in proposed § 9.602 references "plans."

The Department is changing the references to "HMO" in the section to "plan," which is what it had initially intended.

Section 9.722. Plan and health care provider contracts.

The Department received over 40 comments on this proposed section.

IRRC commented that this proposed section would mirror existing regulations that cover HMO contracts with providers, but would extend the requirements to other managed care plans. IRRC commented that although the Department cited Act 68 for its authority to do so, Act 68 does not contain specific language allowing the Department to review contracts. Two other commentators also commented that the Department did not have the authority to extend these requirements to managed care plans generally. One of these commentators also stated that the Department did not have the authority for prior approval of contracts under the HMO Act.

The Department has the statutory authority to review and approve provider contracts prior to their implementation. This authority comes from several sources (Act 68, the HMO Act and the PPO Act), not simply from Act 68, as the Department has already stressed in its Preamble to proposed rulemaking. Section 8(a) of the HMO Act (40 P. S. § 1558(a)) gives the Secretary the

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authority to require renegotiation of provider contracts when they require excessive payments, fail to include reasonable incentives, or contribute to cost escalation. The PPO Act also requires that Insurance consult with the Department in determining whether arrangements and provisions for a PPO which assumes financial risk which may lead to under-treatment or poor quality care are adequately addressed by quality and utilization controls as well as by a formal grievance system. See section 630(e) of the PPO Act.

It is not necessary for Act 68 to specifically state that the Department has the authority to review provider contracts for the Department to be able to do so. Section 2111(1) of Article XXI requires a managed care plan to assure availability and access to adequate health care providers to enable enrollees to have access to quality and continuity of care. Section 2112 of Article XXI (relating to financial incentives prohibition) prohibits financial incentives to providers for providing less than medically necessary and appropriate care. Section 2113 of Article XXI (relating to medical gag clause prohibition) prohibits gag clauses, and lists specific activities a provider may engage in without reprisal from the plan. Section 2121 of Article XXI prohibits termination of providers in specific instances and requires notice if a provider is terminated due to a nonrenewal of credentials. Section 2131 of Article XXI governs medical record confidentiality and who may have access to the medical information the provider has. Section 2152 of Article XXI governs the process of plans reviewing and communicating UR decisions to providers. Section 2161 of Article XXI governs the grievance process and a provider's rights and responsibilities in pursuing a grievance on behalf of an enrollee. Section 2166 of Article XXI concerns prompt payment of claims to providers. Section 2171 of Article XXI prohibits exclusion, discrimination or a penalty against a provider by a plan for refusing to allow, participate, perform or refer for health care services based on moral or religious grounds, provided the enrollee was adequately informed. These sections cover extensive duties and obligations of plans and providers to each other and to patients. Not all of these areas will be, or should be, addressed in provider contracts; however, the Department has an obligation to ensure that there is no language in the contract which serves to obfuscate, obviate or obstruct the obligations of the plan or the provider in the performance of its duties. See section 2181(d) of Article XXI. For this reason, the Department has the authority and the duty to review all standard form contracts for all managed care plans, not just HMOs.

One commentator recommended that the title of the proposed section include pharmacy benefits manager (PBM) contracts, since a plan was responsible for all its contracts, including PBM contracts, according to the proposed regulations. The commentator felt that this required clarification since PBMs are not specifically defined as health care providers under Act 68.

The Department has made no change to the title of the proposed section. A PBM that has a contracted network of pharmacies, and, through a contract with a plan, makes that network available to the plan, is an IDS under the regulatory definition. A PBM that provides non-UR functions, including claims administration or pricing negotiations, is essentially a management services contractor, and is not considered to be an IDS. A PBM that performs medical management, with or without a pharmacy network, must adhere to the requirements of § 9.675 and the applicable requirements of Subchapter K. PBMs are reviewed by the Department according to their function and relationship with the plan. The Department has not listed PBMs in the title of each specific section of the regulations that apply to PBMs.

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One commentator recommended that the Department require renegotiation when reimbursement rates appeared to be inadequate and could jeopardize quality of care. This commentator recommended adding a paragraph to proposed subsection (f) to state that a provider contract could include no reimbursement system that would lead to undertreatment or jeopardize the quality of care.

The Department has not changed proposed subsection (f). As the Department has discussed in its response to the general comments on this proposed subchapter, the Department cannot guarantee that any reimbursement mechanism is completely and totally free from an incentive to do more or less than is medically necessary and appropriate. The duty to provide necessary and appropriate services rests largely with the ethics of the providers. The Department has not added the suggested language, since it is unenforceable.

Further, the HMO Act allows for renegotiation if the contract provides for excessive payment, fails to include reasonable incentives for cost-control, otherwise substantially and unreasonably contributes to the escalation of the costs of providing health care services or is otherwise inconsistent with the purposes of section 8(a) of the HMO Act. Clearly, from this language the financial viability of a hospital is not the purpose of the HMO Act. It is also not the purpose of Act 68. The Department's purpose in reviewing contracts from all plans is to ensure compliance with Act 68. Further, the Department only reviews and approves a standard contract and not the specific terms between plans and individual providers.

Two commentators raised issues concerning time frames in proposed subsection (a) for a plan to submit the standard form for each type of contract to the Department. One commentator commented on the lack of language allowing a contract to be deemed approved after a certain length of time, and recommended that it be included. The other commentator recommended the addition of time lines for reviews. This commentator also recommended the addition of language stating that nothing superseded review and approval by Insurance of those contracts subject to their review under section 40 Pa.C.S. § 6124 (relating to rates and contracts).

The Department has added language to subsection (a) of this regulation as discussed in its response to general comments on this subchapter.

With respect to the language regarding Insurance, to the extent that a contract is to be used by a hospital plan corporation, it must be reviewed by Insurance. If the same contract includes or incorporates related entities, subsidiaries or affiliates, and any of these associated or related entities is a managed care plan under Act 68, the contract must also be reviewed and approved by the Department.

IRRC noted that several commentators had stated that many contracts simply require general compliance with State and Federal regulations and laws, and a provider manual published by the plan. For some plans, provisions of this section may be included in provider manuals. IRRC suggested that rather than requiring each contract form to be submitted, it may reduce paper work requirements if the Department reviews and approves provider manuals referenced in the contracts.

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For the Department's purposes, language concerning general compliance with State and Federal laws is not sufficient, and a review of provider manuals is not sufficient. The Department does review provider manuals that are referenced in the contracts. Most providers are not aware of the vast number of statutory and regulatory provisions applicable to plan-provider contracts. In some circumstances, the contract must be explicitly clear and cannot rely on a reference to requirements that may be detailed elsewhere in provider manuals. In some circumstances, the contract may include language that could be viewed as inconsistent with the HMO Act or Act 68. Additionally, provider manuals may be nonbinding on either party when not incorporated by reference in the contract and cannot therefore be relied upon as contractual obligations and responsibilities. The Department has made no change to the proposed subsection to address this concern.

IRRC also recommended that the Department use the word "before" instead of the word "prior." The Department has made this change.

IRRC commented that requirements of this proposed section may be duplicative for HMOs under contract to DPW. IRRC asked if the MA requirements were similar, since the Department might be able to reduce paperwork costs by allowing HMOs to use the same documents they submit to DPW, or accept DPW's notice of approval rather than undertake a separate review. Another commentator also commented that submission of standard provider forms to the Department is duplicative of submission to DPW for HMOs participating in MA programs, because DPW already reviews and approves those contracts.

The Department cannot delegate its responsibility to determine compliance with the HMO Act and Act 68 to any other agency. DPW reviews and approves the contracts in question for its own purposes as a purchaser, and not specifically to ensure that the plans are in compliance with the act. The Department, not DPW, is the regulatory body with responsibility for ensuring managed care plans comply with the HMO Act and Act 68. DPW does not accept the Department's review and approval as sufficient for its purposes, nor should it given its different requirements and responsibilities. To suggest the reverse as appropriate is to suggest that both agencies have the same purpose and function. They do not. As a matter of practicality, nothing in the regulations prohibits a plan from simultaneously sending a contract to both agencies. Further, the Department always coordinates its review with appropriate DPW staff.

One commentator recommended that the Department add the word "standard" before the phrase "health care provider contract" to clarify that the section does not apply to amendments to contracts affecting only an individual provider.

The Department agrees that this was the intent of the proposed regulation, and has included the word "standard" in subsection (a). The Department has added the recommended language to subsection (b) as well, for purposes of clarity. The Department does not look at individual contracts on a preapproval basis, but only as needed to investigate a complaint or for compliance auditing.

Several commentators, including IRRC, commented that it would be burdensome for plans handling and mailing paperwork to the Department, as would be required by proposed

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subsection (b), whenever a minor change was processed. They recommended that the Department consider limiting types of changes for which a prior review is required to avoid unnecessary filing and review costs.

One of these commentators requested that the Department clarify that the required filings would not include new rates of reimbursement, because this too, would cause a significant and unnecessary staffing and resource burden on the plans as well as the Department. This commentator recommended language stating that the plan must submit any change or amendment to a standard form of health care provider contract, except new rates of reimbursement, to the Department no later than 10 days prior to implementation of the change or amendment.

The Department has added the word "standard" to clarify that the Department did not intend to review every deviation from the standard form contract, and has emphasized this by also adding the word "material" to describe the type of change or amendment that must be presented to it for review. The Department has also added language to subsection (b) excepting any change required by Federal or State laws or regulations. With respect to the issue raised concerning rates, the Department does not now require rates to be provided to it. What the Department requires, and what the plans provide are reimbursement methodologies. If the methodology submitted with a standard contract were to change, the plan would be required to provide the applicable amendment to the Department for review and approval.

Further, the Department has clarified its understanding of the term "contract" in subsections (a) and (b) by requiring that plans submit to it for review all documents incorporated by reference into the contract, and thus made a part of the contract. The Department is also requiring submission of all material changes to the documents incorporated by reference into the contract.

One commentator also recommended that the Department require that any changes to provider contracts be mutually agreed upon and communicated to providers within 30 days notice.

The Department cannot require plans to make changes only after mutual agreement between the plan and provider. This is beyond the Department's authority. The Department does require plans to give advance notice of the change prior to implementation to allow providers time for review and consideration, so that enrollees do not become caught in the middle between the plan and the providers, and face out-of-pocket costs.

IRRC recommended that the Department include in subsection (c) a reference to section 2121(e) of Article XXI, which prohibits exclusion or termination of a health care provider for having a practice that includes substantial numbers of expensive patients or for objecting to providing a service on religious or moral grounds. The Department agrees, and has added in subsection (c)(4) not only a reference to section 2121(e) of Article XXI, but also to section 2171 of Article XXI.

IRRC also asked what mechanisms are in place to ensure that these provisions are not violated.

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The Department will perform compliance monitoring, which is based on provider complaint reporting, and auditing of credentialing files, which is done as part of the external quality assurance review. The Department may also conduct investigations beyond an original complaint if the Department finds that other providers have also been treated improperly under these sections.

One commentator commented that subsection (c)(4) should state that no contract may exclude or terminate a provider for any of the reasons enumerated in section 2113(e) of Article XXI, except as that might violate the rights of the plan under section 2113(d) of Article XXI.

The Department has not changed the proposed paragraph to address this concern. The reference in the regulation is to section 2113 of Article XXI generally, and it includes subsection (d).

One commentator commented that proposed subsection (e)(1)(i) was not usual and customary for inclusion in nonHMO contracts, and related to enforcement of State and Federal laws that are outside the scope of managed care.

One commentator commented that the statutory authority for this provision applied only to HMOs.

Under 31 Pa. Code § 154.104(a)(3)(i) (relating to filing requirements), any gatekeeper PPO product filing must include NAIC/National Association of HMO Regulators (now called the National Association of Managed Care Regulators) hold harmless language.

One commentator commented that the historical intent and interpretation of the language in proposed subsection (e)(1)(iii) was to protect enrollees only in cases of plan insolvency and plan breach of plan-provider contract.

The language of the proposed paragraph was written as the Department intended.

One commentator commented that proposed subsection (e)(2) would require confidentiality, and it has pointed out the practice of PBMs sending out enrollee names and prescription information to drug manufacturers and preferred chain pharmacies. The commentator stated that this was a clear violation of confidentiality. The commentator recommended that the regulations state PBMs or other contractors should prohibit release of identifiable patient information.

Act 68 leaves to State and Federal laws the issue of whether or not information is confidential. See section 2131(a) of Article XXI. The act does not give the Department the authority to create a new category of confidential information. Further, it is likely that regulations proposed by the United States Department of Health and Human Services, known colloquially as the HIPAA regulations, and dealing with confidentiality of medical records in certain instances, will address this issue. See proposed rule regarding Standards for Privacy for Individually Identifiable Health Information. 64 FR 59967 (November 3, 1999).

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Two commentators commented on this proposed subsection (e)(2)(ii). One commented that the language was inconsistent with the requirements that the Department has placed on plans to date, and notes that the term "agents with direct responsibilities" is undefined. It recommended replacing "Department employees or agents with direct responsibilities" with "regulating agencies and their agents or designees."

Another commentator strongly recommended that the language be removed as unnecessary and inappropriate for addition to existing managed care contracts. The commentator stated that the language might be appropriate for internal Department standards, but not for managed care contracts.

The Department has not changed the regulation. The Department took this language directly from section 2131(c)(ii) of Article XXI. The Department does not find the language "Department employees or agents with direct responsibilities for the purpose of quality assurance, investigation of complaints or grievances, enforcement, or other activities relating to compliance" to be unclear. The language states for providers what persons may or may not have access to records, and, therefore, has a place in the contracts in question, particularly if existing contracts limit access to Department employees.

IRRC questioned the purpose of the general reference to State and Federal laws and regulations in proposed subsection (e)(5), and recommended that the Department reference specific laws with which providers must comply.

Another commentator noted that the majority of plan provider contracts require general compliance with State and Federal regulatory requirements. The commentator suggested that this was sufficient, and that the language could be included in a provider manual, rather than in the contract itself. The commentator noted that most plans require providers to comply with provider manuals.

The Department believes that this language, which addresses general compliance with State and Federal regulations relating to the business of the health care provider, should be stated specifically in the provider contract to underscore the importance of the matter. The Department does not intend to list all State and Federal laws and regulations regarding the provision of services by a health care provider, since these could vary by types of service. These could include relating to fraud and abuse issues, licensure requirements, payment issues and other matters of this nature. Further, the provider providing the service is charged with knowing what laws and regulations apply to that provider. The Department would be satisfied with a general statement of this nature in the contract for its purposes; providers, of course, may choose to negotiate specific requirements in any particular provider contract.

With respect to the comment concerning inclusion of the language in the provider manual, compliance with the provider manual may not be a requirement of the contract. The Department believes, however, that the inclusion in the contract of State reporting requirements for diseases is unnecessary. That language has been deleted, as plans do not enforce reporting requirements.

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IRRC asked what type of information concerning prompt payment of claims would be required under proposed subsection (e)(6). It further asked whether this was a reference to prompt payment provisions of Act 68 or in Insurance's regulations, and recommended that the Department should reference the statute and regulations if this was the case.

The Department agrees, and has added references to section 2166 of Article XXI and 31 Pa. Code § 154.18.

One commentator noted that proposed subsection (e)(7) would require the provider to provide 60-days advance written notice to the plan of termination of the contract, and that plans should also be required to provide notice. The commentator stated that, to the extent terminations without cause were lawful and not violative of public policy, a plan should be required to provide 60-days advance written notice to providers of termination without cause.

The Department has made changes to subsection (e)(7). The Department has revised the subsection to state that if the parties agree to include a termination without cause provision in the contract, neither party shall be permitted to terminate the contract without cause upon less than 60-days prior written notice. This allows for negotiation of the clause, rather than requires its inclusion, and also takes into account the plan's need to negotiate long-term contracts for the purposes of obtaining better rates for its enrollees.

Another commentator commented that the language should be revised so that plans would not be able to circumvent Act 68 protections by inappropriately deselecting health care providers at will at the end of the contract term. The commentator recommended that the regulations require that plans provide a reason for nonrenewal of the contract. The commentator also recommended that the regulations require an opportunity for health care providers to appeal nonrenewal decisions from the plan. The commentator stated that this language was needed to actualize the consumer and provider protection against plan retaliation in Act 68.

The Department has not made these changes. The Department can and will investigate any allegation by a provider that a plan has penalized, restricted or terminated that provider inappropriately for reasons prohibited under Act 68. This does not take the form of a provider appeal, however, but rather is an investigation of the plan for violations of Act 68. If the Department were to find a violation of Act 68, it would most likely fine the plan, although the Department could move to revoke the certificate of authority of an HMO, depending upon the nature of the violation. The Department is not in a position to require a plan to contract in perpetuity with any particular provider.

Nonrenewal of a contract is not the same as termination or refusal to grant renewed credentials, both of which prematurely end the term of the agreed to contractual relationship. A regulatory requirement that would prohibit a party to a contract from choosing not to renew a contract would have to be extended equally to both parties. This would prevent a provider from ending an unsatisfactory relationship with a health plan. In fact, neither party could choose to end an unsatisfactory relationship. The Department has and will continue to approve contracts with "evergreen" clauses, whereby the contract is continuously renewed until either party actively terminates the contract. There are many other contracting mechanisms available to

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arrive at long-term relationships. Prohibiting one party from nonrenewing an unsatisfactory relationship is not a balanced or appropriate regulatory requirement and could jeopardize enrollee care in the long run.

One commentator recommended several language additions to proposed subsection (e). The commentator recommended requiring the plan to give at least 30-days advance written notice of any changes to contracts, policies or procedures affecting health care providers and the provision and payment of health care services to enrollees.

The commentator also recommended requiring that any amendment to the contract must be mutually agreed to and confirmed in writing, except in the event of an amendment that is required by court order or by Federal or State laws.

Finally, the commentator recommended adding language stating that a contract is voidable by the provider if it is not approved by the Department prior to the contract's implementation.

The Department agrees that addition of some of the language recommended would be useful. The Department has added a subsection (e)(8) requiring plans to give 30-day advance notice prior to implementation, because implementation could affect provision of service and therefore affect enrollee coverage. The Department has, however, excepted from the notice requirement those changes that are required by law or regulation. The Department has no authority to require amendment by mutual agreement, however. If the Department finds that a plan has implemented a contract prior to approval, the Department will take action to review the document, and order correction of any deficiencies. Plans using contracts not approved by the Department may be sanctioned in accordance with § 9.606. Allowing parties to declare a contract void is not a penalty the statute affords.

IRRC questioned the level of detail the Department would require of plans concerning reimbursement methodology under proposed subsection (f)(1). IRRC recommended that, as part of the description of the reimbursement method, the Department should require details concerning the amounts and percentages used in the methods.

Another commentator recommended that the proposed paragraph be revised to require not just reimbursement methodology, but the amount and percentage of each method of reimbursement. This commentator stated that the method of reimbursement was not instructive. According to this commentator, all plans could list monthly capitation and bonus incentive systems, but the amounts and degrees to which these systems would corrupt the physician patient relationship could be very different.

Two commentators commented that the proposed paragraph lacked an objective standard to determine if a financial incentive compensated a health care provider for providing less than medically necessary and appropriate care to an enrollee.

The Department does not have the responsibility or jurisdiction to determine if the rates of payment represent fair and adequate reimbursement; therefore, the Department does not require plans to submit specific dollar amounts or rates. The Department does, however, review the methodology to determine if there are any theoretical incentives to under or over

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serve and what safeguards plans have in place to monitor performance under the contract and ensure that corrective action is taken. With respect to specific dollar amounts and percentages, the Department has stated its position in its discussion with respect to conflict of interest. The Department is not in a position to determine what specific dollar amount would corrupt each contracted provider. This is a completely subjective concept, since what corrupts one person may not corrupt others. There is no objective standard that could reasonably be set by regulation. Any methodology or rate of payment could corrupt at least one unscrupulous provider. Health care providers are first and foremost responsible for their own conduct in the performance of their duties including the degree to which financial terms influence them to do more or less than the patient requires.

As the Department stated previously in its discussion on conflict of interest, any reimbursement methodology can be corrupted by providers who place economic consideration over the needs of the patient. While the Department is concerned with over and under utilization, it is not possible to regulate every provider/patient relationship, nor is it possible to detect every instance in which a provider is providing more or less than medically necessary care. The concern of the Department is that the plan has a reasonable method for reimbursement that includes performance monitoring and the ability to take corrective action whenever providers are providing more or less services than is medically necessary or appropriate. The Department disagrees with the comment that disclosure of reimbursement methodology is not useful and favors disclosure of exact dollar amounts and percentages. There is no possible way for the Department to determine if a laboratory capitation rate of \$1.23 or 1% of the overall health care dollar is reasonable or if \$52 for an established patient office visit is a fair rate of reimbursement for some or all providers in some or all parts of this Commonwealth. The Department does not have the authority to regulate commerce between health plans and providers.

Further, reasonableness of specific reimbursement rates to some extent is reviewed by Insurance within the context of the benefits to be covered, the costs to the plan of covering the benefits and the anticipated usage of covered services for the proposed covered population. All of these factors are included in an actuarial model that ensures, in theory, that the plan charges enough premium to cover the contracted benefits. Periodic plan financial performance reporting to Insurance is closely monitored to determine if the actuarial model is borne out.

One commentator requested that proposed subsection (f)(1) be clarified to require the IDS to submit its PBM contracts to the Department for review, including all financial arrangements with the PBM, and the PBM's reimbursement to its pharmacy providers.

As the Department discussed with respect to § 9.722 (relating to plan and health care provider contracts), to the extent that a PBM contracts with a plan and includes in its services a pharmacy network, the PBM falls within the definition of an IDS, and is required to comply with all sections of the regulations which apply to IDSs.

The Department received several comments relating to proposed subsection (f)(2) concerning the percentage at which utilization performance could be weighed in determining incentives.

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IRRC commented that this proposed paragraph would allow low utilization to equal nearly 1/2 of the incentive. It requested an explanation of how the Department determined these proportions, and recommended that the Department consider the standards promulgated by the HCFA in 42 CFR 417.479.

Another commentator also noted that the HCFA defines substantial risk as 25% of potential payments for covered services. The commentator recommended that the Department include objective standards that would ensure that the protections in Act 68 are realized and applied uniformly.

The same commentator recommended that the Department change the proposed paragraph because it would permit plans to make inappropriately large payments to providers for low utilization rates. This commentator commented that plans could offer up to 49% of the total incentive reimbursement for low utilization rates. The commentator stated that this would allow plans to create an unacceptable conflict of interest between a provider and a patient by sanctioning substantial financial incentives to providers by the plans to limit care. The commentator stressed that the incentives would constrain physicians to limit communication with patients about treatment options to protect their own financial interests.

Another commentator noted that under the Department's proposed regulations, a physician could receive 51% of total payment in bonuses and other compensation, which could be linked to low utilization. According to the commentator, this would put the physician in conflict of interest with patients.

One commentator raised concerns that the Department's proposed UR provisions might negatively impact children with disabilities. The commentator complained that the Department would allow a plan to base up to half its risk pool distribution based on utilization. According to this commentator, this would have the potential effect of creating an underclass of the people who needed greater care, and for whom accessing care was an ongoing battle. The commentator stated that the Department should aggressively oversee UR practices to assure that they would not have a chilling effect on health care.

One commentator recommended changing the proposed paragraph because it would allow financial disincentives to serve and treat expensive patients by permitting plans to base economic incentives and disincentives on nonrisk adjusted factors. The commentator stated that economic incentives and disincentives should be prohibited unless they were risk adjusted. The commentator expressed concern that plans would use these incentives to drive out providers who specialize in treatment of patients with expensive conditions for financial reasons.

The Department has not changed this proposed paragraph. HCFA's Physician Incentive Program (PIP) rules (42 CFR 417.479) relate the 25% of the total potential payments to the most recent year's utilization and anticipated factors that will affect current year's utilization. In short, the maximum amount of money that can be used in an incentive plan is 25% of the total maximum payments that could be received. This limits the amount of the risk up or down to 25% of the value of the total of potential payments. Payments are defined for these purposes as amounts paid for services furnished directly, administration and costs of referral services.

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The total dollars payable to even a single provider over the course of a year is generally a considerable amount of money. Under the PIP rule, the physician can not be at risk (lose more or earn more) than 25% of the total yearly amount. This is a very different arrangement from what the Department is proposing.

The Department is not setting limits on the percentage of risk (up and down), but is stating that any incentive reimbursement system (money above and beyond that paid for services provided) must not include utilization as its sole criteria. The Department is requiring the plan to use other factors, and weigh those other factors (for example, patient satisfaction, provider cooperation with the plan) at least equal to utilization. The PIP rules, on the other hand, exclude payment for nonutilization factors from the formula entirely. The Department is insisting that nonutilization factors are important, are appropriate performance incentive measures and must be considered the equal of utilization factors.

Section 9.723. IDS.

The Department received five comments on this proposed section.

One commentator stated that the Department should expressly recognize the right of all plans to enter into IDS contracts, and that the Department should replace the term "HMO" with "plan." The commentator stated that the requirements of this section would provide sufficient oversight and protection to permit plans to subcontract for delivery of health care services on a risk transfer basis.

The Department has replaced the term "HMO" with "plan." The Department sees no need to explicitly state that plans may contract with IDSs. Nothing in State law or regulation absolutely prohibits this type of contract. The Department, recognizing the ability of plans to subcontract with IDSs, is attempting, through this and the other sections of this subchapter, to maintain some regulatory control over this arrangement, which has the potential to harm enrollees and providers.

One commentator commented that proposed subsection (a) was in conflict with proposed § 9.724(b) (relating to plan-IDS contracts), and requested that the Department clarify whether all IDS contracts were to be filed, or whether the plan could file form agreements.

The Department is adding the word "standard" to the proposed subsection to clarify its intent to review and approve standard contracts only.

The Department received three comments on proposed subsection (b), all concerning the question of whether a plan would be able to comply with the proposed notice requirements.

IRRC commented that the proposed 60-day notice requirement might not be possible with respect to litigation, since a plan might not have 60 days notice of litigation, and, in turn, could not provide 60 days notice to the Department. It recommended that the Department consider revising the proposed subsection to allow for flexibility when a plan did not receive 60 days advance notice of litigation.

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Another commentator suggested eliminating the word "proposed," as well as final phrase "including the institution of litigation, termination, or nonrenewal notice by either party." The commentator commented that the reason for providers being unable to deliver services was irrelevant to the Department. The commentator stated it would be onerous for plans to have to submit all proposed actions to the Department.

The third commentator also commented that many times a plan would not know 60 days in advance of these events. The commentator recommended that the Department require the plan or IDS to notify the Department within a certain number of days of acquiring knowledge of a proposed action or institution of litigation. The commentator stated that any other requirement would be difficult to meet.

The Department agrees that plans and IDSs could have had difficulty in complying with this proposed subsection under certain conditions. The Department has, therefore, changed this subsection to require notification in advance of any action that could prevent IDS participating providers from providing services. The 60-day time period has been deleted, as have the references to the reasons for which this disruption may have occurred. The Department has also deleted the requirement that it be notified of proposed actions. The Department's only concern is that it be given warning of a situation that could result in enrollees losing access to providers.

Section 9.724. Plan-IDS contracts.

The Department received several comments on this proposed section.

One commentator raised issues concerning safe harbor rules under fraud and abuse laws. The commentator stated that this section would affect the ability of an HMO to satisfy these safe harbor rules. The commentator pointed out that to meet safe harbor protections for management contracts and price reductions, the HMO must establish that the initial contract term is for 1-year. The commentator stated that safe harbor for management contracts may be applicable where there is a fee paid for the delegation of an administrative function. The commentator was also concerned that the section would hinder the ability of an HMO to enter into contracts with an IDS that insists on longer initial terms, particularly during the start up period when an IDS has a lot of startup costs. The commentator also commented that plans must have the ability to immediately terminate a contract with an IDS where there is the possibility of harm to the enrollees.

The Department does not believe that this section would in any way limit the term of a contract or require a 1-year minimum or maximum. Given the concerns raised, however, the Department is revising subsection (d)(13) to include language stating that if a plan and IDS agree to a termination without cause provision, neither party may terminate the agreement without cause upon less than 60 days prior written notice. The 60-day notice period is the minimum period the Department will accept. The plan and IDS may negotiate a longer notice provision if they wish, or may choose not to include a clause in the contract.

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The same commentator expressed concern that the regulation would discourage out-of-State limited service IDSs from doing business in this Commonwealth. The Department disagrees with this statement.

Another commentator stated that the contract reporting requirements are inadequate. The commentator believes that if HMOs are no longer at financial risk, they will not adequately monitor the health care being provided under the IDS contract. The commentator further claimed that if an IDS is at financial risk, it will not want the HMO interfering with its utilization decisions, its credentialing decisions, and similar decisions of that nature.

The Department has not changed the proposed section to address these concerns. The license of the HMO is at risk in this matter, and it will be held accountable for services provided to its enrollees.

One commentator raised concerns that proposed subsection (a) would permit a licensed entity to subcontract almost all of its functions to any type of entity, and to put that entity at risk for providing all health care services instead of the HMO. The commentator noted that the only function an HMO could not subcontract was soliciting and enrolling members. The commentator also noted that the grievance and complaint process could also be subcontracted to an unlicensed person, corporation or other entity. The commentator stated that the Department had no direct regulatory authority over these entities.

The Department will hold the licensed entity responsible for the appropriate operations of its subcontractors. Should the Department find that the subcontractors are not complying with the terms of Act 68, that failure will be imputed to the licensed entity, which has the responsibility to ensure that its subcontractors comply with the law. Therefore, the Department does not need regulatory authority over the nonlicensed entity to ensure that the provisions of Act 68 and the HMO Act are met.

With respect to grievance reviews, grievance reviews can only be performed by an entity licensed and regulated by the Department.

Another commentator recommended adding time lines for reviews to the proposed subsection. The commentator also recommended adding language stating that nothing would supersede review and approval by Insurance of those contracts subject to Insurance's review under 40 Pa.C.S. § 6124.

The Department has added time frames to § 9.722(a), which, by the terms of § 9.723 and additional language the Department has added to subsection (a), applies to contracts between plans and IDSs. To the extent that a contract is to be used by a hospital plan corporation, it must be reviewed by Insurance. If the same contract includes or incorporates related entities, subsidiaries, or affiliates, and any of these associated or related entities is a managed care plan under Act 68, the contract must also be reviewed and approved by the Department.

The Department has revised the language in proposed subsection (b) to reflect the Department's intention to extend this section to plans as defined by Act 68.

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One commentator commented that the proposed subsection contained inadequate remedies for an HMO failing to obtain prior approval of an HMO-IDS contract. The commentator noted that the proposed subsection would not prohibit such contracts without prior approval, rather it would require the contract to be renegotiated if prior approval is not obtained.

Another commentator recommended that the proposed subsection be amended to require review and approval of a contract only if it were not based on the approved generic contract already filed and approved by the Department.

The Department's intention is to review a plan's standard form contracts once, and to review any arrangements that are not based on that standard version. The Department is, however, requiring notice of all plan arrangements with an IDS and the nature of those arrangements to determine if CRE certification is required and to include the IDS in the Department's overall monitoring and compliance activities. The Department has revised the proposed subsection to impose these requirements.

The Department has, however, not added any enforcement language. The Department has the ability to take action against any plan that violates the terms of Act 68, the HMO Act or the Department's regulations. Should it become necessary to require a plan to submit a plan of correction involving the revision of contracts, the Department will take that action. Should it become necessary for the Department to consider fines in egregious situations, the Department has that option available as well.

One commentator recommended that the Department delete the requirement in proposed subsection (c) that plans submit copies of all IDS contracts with individual providers to the Department for approval. The commentator believed this requirement to be excessive. The commentator noted that the HMO was ultimately responsible for services being delivered, and that this level of review was an unnecessary administrative burden on the plan.

IRRC commented that this proposed subsection and § 9.723 were confusing because they would mix requirements for IDS and HMOs with IDS and health care providers. For example, IRRC noted that the proposed subsection would include the requirement that the HMO provide the Department with copies of contracts with IDSs, and also would include requirements for a contract between IDS and a provider. IRRC stated that these requirements should be included in separate sections.

The Department only intends to review the standard form contract between a plan and IDSs and not every single signed contract. The Department has revised this subsection to clarify that fact.

Further, the inclusion of requirements for IDS-provider contracts in this subsection was deliberate. The Department does need to include this language in this section since it pertains to the Department's approval of the overall plan-IDS contract. It is imperative that the Department verify that the relationship between the first level subcontractor and its second level subcontractors is consistent with the Department's requirements for traditional provider contracts. For this reason, the Department has added language in this subsection requiring notice that the providers have executed plan-provider contracts instead of IDS-provider

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contracts, or the plan must submit the standard contracts between the IDS and its providers for review and approval prior to the effective date of the plan-IDS contract.

One commentator questioned whether the Department really meant to say in proposed subsection (c)(1) (now subsection (d)(1)) that the ultimate provision of care remained the responsibility of the HMO. The commentator asserted that responsibility would be with the provider. The commentator recommended that the Department delete the term "ultimate" and use the term "HMO operations" as used in § 9.635.

The Department did not intend to imply that the plan was responsible for the care of providers in a medical sense; however, the Department does mean to make it clear that plans are ultimately responsible for benefits and services to enrollees. It has changed the language of this paragraph to reflect that fact.

Several commentators raised concerns that proposed subsection (c)(2) (now subsection (d)(2)) would permit an unlicensed person or an entity to deliver prepaid basic health services to enrollees and to perform administrative services without obtaining a certificate of authority. One commentator noted that consumers could enroll with an HMO, unaware that their health care has been subcontracted at full risk to an unlicensed entity. The commentator raised concerns that there would be no standards to determine adequate staffing, adequacy of networks or any other criteria necessary for a certificate of authority. The commentator stated that this almost totally unregulated, wholesale transfer of responsibility to unlicensed potentially unqualified entities was without statutory authority and should not be permitted.

Another commentator raised the concern that the HMO would be at risk with minimal protections for important functions such as credentialing and quality assurance.

The Department has abrogated no responsibility here. The licensed entity remains responsible for the subcontracted or delegated functions. This means that the Department will take action against a plan if its subcontractor is not performing in accordance with requirements imposed upon the plan. The Department has the authority to review provider contracts, and IDS is a provider arrangement; therefore, the Department has the authority to review and regulate IDS arrangements. The Department has no authority to prevent IDS arrangements from occurring.

Further, to the extent the IDS contracts with a plan covered by Act 68 for provision of services to enrollees, the IDS is subject to the Department's and to Insurance's regulations. IDS providers, through the IDS contract with the plan, and through the providers' contracts with the IDS, are required to be credentialed. The plan, by regulation, is required to take full responsibility for the benefits and services it provides through the IDS. See subsection (d)(1). The plan, by regulation, is required to ensure that its network is adequate. That network, including the IDS network, is reviewed by the Department. See § 9.679.

One commentator stated that proposed subsection (c)(5) (now subsection (d)(5)) exceeded the scope of the Department's statement of policy. The commentator acknowledged the Department's obligation to protect enrollees from potential disruption of services under HMO-IDS agreements, but it requested that the Department specify its statutory authority to

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excessively regulate IDSs through HMO contract agreements. For example, the commentator asked why the Department would require the IDS to acknowledge that the HMO was directly accountable to the Department for compliance and high quality cost-effective care. The commentator stated that there was nothing in the HMO regulations or in the HMO Act or Act 68 that would requires a plan to provide high quality cost-effective care.

The Department acknowledges that the use of the word "high" in the phrase "high quality cost-effective care" was inappropriate, and has deleted that word. With respect to the remainder of the comment, the Department is not regulating the IDS. The Department is regulating the plan, which remains responsible for the actual functions of the IDS. The Department has discussed its statutory authority to review contracts in its response to comments on § 9.722.

The Department requires an acknowledgement from the IDS that it is aware that the plan is accountable to the Department to ensure that the plan's responsibilities are clear to it and to all parties to the contract.

One commentator took issue with the proposed subsection (c)(13) (now subsection (d)(13)) requirement for the inclusion of the 60-day termination without cause clause in an IDS-plan contract. The commentator was concerned that a plan must have the ability to immediately terminate where there is the possibility of harm to the members. The commentator recommended that the Department make the paragraph consistent with § 9.722(e)(7), which states that an IDS must give at least 60 days notice to the plan prior to termination.

The Department has revised language in § 9.722(e)(7) and subsection (d)(13) to take into account situations in which the plan and provider do not negotiate a termination without cause provision, and situations in which the plan and provider choose to negotiate a notice period of longer than 60 days. The language in both sections is now the same.

Section 9.725. IDS-provider contracts.

The Department received three comments on this proposed section.

One commentator recommended that the Department add time lines for reviews of contracts between providers and an IDS that has contracted with a plan. The commentator also recommended the addition of language stating that nothing would supercede the review and approval by Insurance of those contracts subject to their review under 40 Pa.C.S. § 6124.

The Department has included time frames as discussed in comments to § 9.722. To the extent that a contract is to be used by a hospital plan corporation, it must be reviewed by Insurance. If the same contract includes or incorporates related entities, subsidiaries or affiliates, and any of these associated or related entities is a managed care plan under Act 68, the contract must also be reviewed and approved by the Department.

Another commentator commented that the proposed section should require IDSs to submit PBM contracts to the Department for review, and that PBM contracts should be held to the same standards as other IDS-provider contracts.

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The same commentator recommended that the title of the section include PBM contracts, since a plan is responsible for the performance of all its subcontractors according to the regulations, which would include PBM contractors. The commentator felt that this required clarification, since PBMs are not specifically defined as health care providers under Act 68.

As the Department discussed earlier in response to a similar comment on § 9.722, a PBM may or may not be considered an IDS. To the extent that a PBM arrangement includes a network of providers, a PBM contract will be covered by the regulations. The determination must be made on a case by case basis.

For the purposes of clarity, the Department has added language to subsection (a) to require an IDS to provide a copy of its contracts with providers so that the plan may provide those contracts to the Department.

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Subchapter K. CREs

The Department received approximately 80 comments on this proposed subchapter.

The Department received two comments relating to citation forms from a commentator, who disagreed with the Department's use of the word "the act" in references, for example, "to section 2152 of the act." The commentator stated that the Department should have used the term "Act 68." The commentator recommended that the Department make this change in §§ 9.743(c)(5)(iv) and 9.744(a)(4)(ii) (relating to content of an application for certification as a CRE; and CREs participating in internal and external grievance reviews). In both cases, the Department has declined to make the change. The sections referenced are sections of the Insurance Company Law of 1921, or the act, and not sections of Act 68.

The same commentator commented that the Department should change the word "chapter" in proposed § 9.742(b) to "subchapter." That section states that "The Department may subject a CRE to additional review if it determines that the CRE is failing to comply with Act 68 and this chapter." The Department intended to use the word "chapter" in this proposed section. The Department intends to require CREs to comply with other subchapters of the regulations, in particular, Subchapter I (relating to complaints and grievances) as well as Subchapter K (relating to CREs).

Several commentators raised concerns that there were no ongoing standards for UR, and recommended that the Department include language describing how it intended to enforce these requirements. After reviewing these comments, the Department has divided this subchapter into two parts, one dealing with certification standards, and the other with operational standards. The Department has revised the proposed regulations to include UR standards, and placed those in the part of the subchapter entitled "Operational standards." The Department has included three sections in the final-form regulations to address standards for a description of a UR system (see § 9.749 (relating to system description)), standards for the UR system (see § 9.750 (relating to UR system standards)) and standards for the time frames in which UR must be provided (see § 9.751 (relating to time frames for UR)).

The Department has deleted § 9.601(c), which discussed the applicability of § 9.742. The Department has, instead, expanded this section, which specifically discusses the scope of this subchapter. The Department has added language to § 9.741 to clarify that the sections dealing with certification apply to CREs as defined by the act (see section 2102 of Article XXI). Sections 9.749--9.751 include operational standards for UR. See subsection (b).

Section 9.742. CREs.

Two commentators complained that under subsection (c), a licensed insurer would not be required to go through the certification process to become a CRE. One commentator raised concerns that an insurance company could pose as an outside independent CRE for another insurance company, or its parent or subsidiary without having to be certified. Both commentators stated that the certification process was the only possible mechanism for sorting out potential conflicts of interest. At a minimum, these commentators recommended that

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licensed insurers be required to comply with sections 2151 and 2152 of Article XXI and be required to obtain certification.

The Department has deleted subsection (c). Act 68 clearly states that a licensed insurer or a managed care plan with a certificate of authority shall not be required to obtain separate certification as a UR entity. See section 2151(e) of Article XXI. Therefore, to require such entities to undergo certification would be a violation of Act 68. The Department has also deleted the term "licensed insurer" from § 9.601 since that term no longer appears in the Department's regulations. The comments concerning conflict of interest are discussed in § 9.743 (relating to content of an application for certification as a CRE).

Section 9.743. Content of an application for certification as a CRE.

The Department received one comment in support of this proposed section. Several commentators requested revisions to the proposed section.

Several commentators commented concerning what they viewed as the inability of the proposed regulations to prevent conflicts of interest from arising between plans and CREs, since this proposed section would not specifically request conflict of interest information. One commentator commented that the proposed amendments do not go far enough to implement the intent of Act 68 to protect against conflicts of interest. According to the commentators, an enrollee must be able to access conflict of interest information.

The Department does not see this conflict of interest analysis as useful in the context of standard UR, where, as discussed earlier, the CRE is compensated to perform UR functions by the plan. This can be viewed as an absolute conflict; however, since the CRE must have operating income to employ staff, and systems to conduct CRE, there is no possible way to avoid a situation in which a CRE is paid to perform UR. The Department has made no changes to the proposed section to address the comment. Service organizations are paid to provide the service, and in this case the plan is the one paying for the service. The safeguards are the Department's ability to monitor and investigate complaints and grievances, the external grievance review and the certification and recertification process.

IRRC commented that the proposed section should reference § 9.654, since a requirement of a certificate of authority is that an external quality assurance review be conducted, and this external quality assurance review includes the UR component that is equivalent of the certification of a CRE.

When performed by a plan, the system for conducting UR is assessed through the external quality assurance review. When performed by a CRE, the UR program may also be assessed by the external quality assurance review, but it is definitely assessed by the Department during the certification and recertification process.

One commentator recommended the addition of language to this proposed section stating that the responsibility for the conduct of UR activities shall be assigned to appropriate individuals, and plans shall ensure the mechanisms are in place enabling a provider to verify that an individual requesting information on behalf of that entity is a legitimate representative.

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The Department agrees that new language is necessary, and has added new sections substantially including this language. See §§ 9.749(c) and (d) and 9.750(d).

IRRC questioned the Department's intention, as set forth in proposed subsection (b), to make changes to the application form upon publication in the *Pennsylvania Bulletin*. IRRC stated that any changes to the application form that would be substantive in nature must go through the rulemaking process, and recommended that the subsection include language that any changes would be in accordance with this regulation, or consistent with current requirements in this section.

The Department has deleted proposed subsection (b), and has added subsection (e), which states that the applicant must provide other additional information to the Department which the Department finds necessary to review the application for compliance with Act 68 and this chapter. This is similar to language in § 9.631.

One commentator commented that a CRE be required to update the list of plans for which it performs UR, that it would identify in its application for certification under subsection (c)(4) (now subsection (b)(4)), no less often than at the time of renewal, which is every 3 years. The Department included this requirement in proposed § 9.748(b)(2)(iii), and has adopted that proposal.

One commentator commented that although it appreciated the Department's attempt in proposed subsection (c)(5)(i) (now subsection (b)(5)(i)) to fill a void in Act 68, the language referring back to standards in Act 68 still left the possibility that a CRE's telephone could ring for a significant period of time before being answered, since Act 68 does not provide a time period in which a call must be answered. The commentator recommended that the Department address this concern.

The Department has not changed this proposed paragraph. To set out the time period in which a call must be answered, is over-management of the CRE. The lack of a standard for this in Act 68 and in the regulations implies a reasonable period of time, and the Department is satisfied with that standard.

IRRC raised several questions with respect to proposed subsection (c)(5)(ii) (now subsection (b)(5)(ii)). First, IRRC questioned whether acceptable procedures and criteria for the selection and credentialing of peer reviewers included the requirement in section 2152(a)(5) of Article XXI that providers have current licenses in good standing or other required credentials. IRRC also questioned what was meant by the term used in the act "other required credentials," and requested clarification.

In response to IRRC's questions regarding section 2152(a)(5) of Article XXI, the phrase "other required credentials" refers to credentials of persons involved in the conduct of UR who may not be licensed as physicians, but who are nevertheless licensed as professionals and credentialed by the CRE. Because the intention is that these criteria and procedures provide the CRE with the information the CRE is required to obtain by Act 68, the Department has not changed this proposed subparagraph.

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IRRC has requested that the Department clarify what accrediting bodies meet the standards set forth in these regulations and Act 68. IRRC recommended that the Department designate these bodies in the regulations, or publish a list that is available to the public.

The Department has not made any change to proposed subsection (c)(5)(viii) (now subsection (b)(5)(viii)). The Department is not requiring accreditation nor adopting the standards of an accreditation organization through this provision. Further, the Department is not suggesting that accreditation bodies meet the standards of Act 68. This provision is merely a request for information. Whether or not the applicant is accredited, and by whom is useful information for the Department to have when considering the applicant because it can be indicative of the entity's structure, resources and operational standards.

One commentator also commented that although the proposed amendments require an applicant to state where it has been denied accreditation, they do not require the applicant to state why the application was denied.

The Department has only requested that the applicant provide information of accreditation by a Nationally recognized accrediting body, if it has such an accreditation. Again, the Department's only intention in requesting this information was informational. The language in that section, "if it has secured the approval, certification, or accreditation," was intended to explain that if the applicant did not have this approval, certification or accreditation, the requirement was not applicable.

IRRC and another commentator expressed concern over proposed subsection (c)(5)(ix) (now subsection (b)(5)(ix)), which would require a list of three clients to be included on an applicant's CRE application. Both commentators are concerned that this proposed requirement could prevent new companies from becoming certified.

This was not the Department's intention, and the final-form regulations have been revised to require a list of three clients, if any, for which the applicant has performed UR.

The Department received four different comments on proposed subsection (d) (now subsection (c)). One commentator recommended that the Department require that reviews be done by a licensed peer of the health care provider who requested the review. Another commentator stated that the proposed subsection was unclear in light of other parts of the proposed rulemaking regarding committee decisions, and would not reflect the input of peer review of the health care provider's grievance.

The Department has declined to make any change based upon these comments, but has changed the section to delete references to a licensed physician in the "same or similar specialty." The language in subsection (c)(1) was intended to track the language in Act 68. The statute requires a licensed physician, or, in certain instances, an approved licensed psychologist, to perform UR that results in the denial of a service. See section 2152(c) and (d) of Article XXI.

The Department received two comments dealing with the differences between physician reviewers and approved licensed psychologists. One commentator threatened a constitutional

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law suit against the Department if the Department failed to eliminate the language that would only permit a psychologist to perform a UR of behavioral health care services within the psychologist's scope of practice if the psychologist has sufficient clinical experience to review that specific behavioral health care service. See section 2152(d) of Article XXI.

Another commentator argued that the Department should clarify that psychologists doing medical necessity reviews can only deny services provided by or proposed to be provided by a nonphysician provider. According to this commentator, because psychologists do not have medical training, their denial of a physician-ordered service on medical necessity grounds would be outside the scope of a psychologist's practice, and would be an intrusion into the physician's responsibility to determine whether or not medication is appropriate.

The Department has made no change to the proposed subsection based upon these comments. The Department will presume the constitutionality of a statutory provision.

In this case, the purpose of the legislation is to protect consumers. The General Assembly has taken the position that UR decisions to deny services must be made by licensed physicians, unless the decision involves a behavioral health issue, in which case, the denial may only be made by a psychologist who has sufficient expertise to review the particular behavioral health care service. The General Assembly clearly believed that psychologists, who are not medical doctors, should have additional experience before being permitted to deny a health care service. This does not prohibit any psychologist from reviewing behavioral health services as part of a UR decision, it merely places additional requirements on that psychologist.

Further, the recommendation that the Department adopt a standard which calls for review by a same or similar specialist as that which would provide the service is not practical. It is a higher standard than any found in Act 68, and would cause extraordinary delays in turnaround time for reviews, as plans search to find reviewers who are willing to perform UR.

With respect to the issue raised by the second commentator, the Department has reiterated the requirements of Act 68, which prohibit a psychologist from reviewing the denial of payment for a health care service involving inpatient care or a prescription drug. This should be sufficient to meet the commentator's concerns.

IRRC commented that the language of subsection (c)(3) (now subsection (d)(3)) contradicts the language of Act 68. The act states: "Compensation to any person or entity performing UR may not contain incentives, direct or indirect, for the person or entity to approve or deny payment for delivery of any health care services." See section 2152(b) of Article XXI. IRRC stated that the proposed paragraph should not limit the application of statutory language to plans, and that the paragraph should reference section 2152(b) of Article XXI.

The Department has not changed the substance of the proposed paragraph, but will cross reference section 2152(b) of Article XXI for clarity. Compensation implies a reimbursement arrangement. The plan is the one paying for UR services, whether through contract, by salaries, or in some other manner. The Department has not limited the language of Act 68.

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The Department has also renumbered proposed subsection (c)(3) as subsection (d). Subsection (e) was added to clarify that information beyond that contained in the application may be required by the Department to determine compliance with Act 68 and the regulations.

Section 9.744. CREs participating in internal and external grievance reviews

The Department received comments from four commentators on this proposed section.

One commentator questioned the extension of additional requirements applicable for external grievances and additional filing fees to internal grievances.

The Department has made no change to the proposed section. The proposed regulations included a filing fee for CREs to cover the cost of the review in § 9.746. They also included an additional filing fee for external grievances (see § 9.746(a)), since the Department's review of an applicant wishing to perform external grievances is more comprehensive and involves a site review, which adds to the Department's costs.

One commentator commented that the proposed regulations would not specify what should be in an application for all CRE applicants, but only those that will do internal and external reviews. This commentator stated that the Department should require the same information for all CREs, not just those performing internal and external grievance reviews, since the initial UR decision is an important point at which an individual's health and the health care process may be significantly thwarted.

The Department believes that information should not be requested unless it will be used for some purpose. The information the Department is requesting in this section is information the Department will use in determining the applicant's ability to conduct internal and external grievance reviews. Because of the different nature of the grievance review versus the standard UR decision, the Department does not find the information in this section to be necessary for it to make a determination of whether an applicant should be certified to conduct UR. As was discussed earlier, the conflict of interest standard is essential to ensure the integrity of the external grievance process and, therefore, it will remain in that part of the application.

IRRC questioned why the language in proposed subsection (a)(3) was not included in § 9.743. IRRC commented that a CRE could avoid these disclosure requirements if it used the application procedures in that section. Further, IRRC stated that because the Department must monitor to ensure that all CREs meet the requirements of Act 68, the Department should have this information from all CREs, and not just those that perform external and internal grievance reviews. Another commentator also commented to this effect, and recommended that the Department define potential conflicts of interest, for example, stating that no entity participating as a reviewer for DPW's fair hearing process utilized in the Health Choices Medicaid managed care plans may be certified as a CRE.

The Department has not changed proposed paragraph as recommended. The Department finds that conflict of interest has no real meaning outside of the context of external grievance

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reviews. In general, a CRE that does standard UR will be performing those URs for a plan. At that stage of the standard utilization review, there is no requirement of, nor is there a pretence of an independent (from the plan and the enrollee) review. Even at the internal grievance level, the conflict of interest issues do not apply. Again, here, the CRE is performing the internal review for the plan. There is no requirement that a CRE have no conflict of interest in this case either, that is, be unconnected with the plan for which it is conducting the internal grievance review. Act 68 permits a plan to conduct its own internal grievance review, and, of course, the plan is connected to itself--the ultimate conflict of interest. Act 68 attempts to address problems in this area by making certain requirements of the review committees conducting the internal grievance reviews (see section 2161(b)(1) and (c)(1) of Article XXI). As discussed earlier concerning complaints and grievances, the Department has included fundamental fairness requirements, which would apply to plans and CREs conducting internal grievance reviews. See § 9.705.

Further, the Department believes that the requirements for CREs performing external grievance reviews must be more stringent than for those CREs conducting the initial UR. As the grievance progresses in the system, the stakes become higher for the enrollee, and for the plan. An external grievance review involves making an independent assessment to resolve a dispute between a plan and an enrollee or a provider. A higher standard is required for CREs that review these grievances because of the level of the dispute resolution (this is the reviewer of last resort, the last review by a clinical reviewer before the matter is resolved by a court), and the complexity of the issues that generally reach this level.

With respect to the issue concerning the fair hearing process used by Health Choices contractors, the Department disagrees that any difficulty exists. A Health Choices fair hearing contractor may not be involved in external grievance reviews for Health Choices cases, but the contractor would have no conflict with commercial plans that do not have a MA product. The contractor can be certified as a CRE, and can conduct grievance reviews for those plans.

The Department has added language to proposed subsection (a)(3) to clarify that the CRE applicant need only disclose any known potential conflict of interest.

The Department, after experience in certifying CREs, has decided that the language in proposed subsection (a)(4)(ii) needs to be further clarified. Because the Department is aware of the difficulty that CREs have in keeping all the necessary specialists under contract, the Department is not requiring that the CRE applicant have all possible types of reviewers under contract. The Department will require an applicant to have a contracted and credentialed network of providers, including, at a minimum, the general specialties represented by the American Board of Medical Specialties, the subspecialties of oncology and physician reviewers specializing in transplantation. The Department will be satisfied if the applicant provides it with a description of its ability to obtain the services of a qualified peer reviewer from any specialty or subspecialty required for an external grievance review within 24 hours.

The Department received one comment on proposed subsection (a)(4)(v). The commentator commented that a plan was unable to determine whether the bills it received were consistent with the Department's approved reasonable fees, and so recommended that the Department

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add language to this proposed subparagraph stating that "such fees shall be public information."

The Department has made no change to the proposed subparagraph to address this concern. The Department does not set fees and does not approve fees as reasonable. The Department is requesting this information so that, if necessary, it can investigate and decertify a CRE if its fees are found to be unreasonable. Fees, like reimbursement information in provider contracts, are considered by CREs to be proprietary information in the nature of a trade secret, and the Department has agreed to hold them as confidential and proprietary. A plan can refer billing and fee issues to the Department for review and response, and the Department will make comparisons between the fees of the various CREs to determine whether the fees in question are unreasonable or not.

Section 9.745. Responsible Applicant.

Two commentators raised issues with respect to this proposed section. One commentator commented that the proposed language would fail to inquire into the licensure and good standing of the applicant. The other commentator stated that the Department should look to current licensure and standing in medical profession as well as whether the applicant has been subject to violations of Act 68.

The Department has not changed the proposed subsection with respect to this comment. The licensure of the applicant would not necessarily be useful, since it is unlikely that the applicant itself, which is a corporation or entity and not an individual medical professional, will be an entity for which licensure is required. Managed care plans with certificates of authority and licensed insurers, two types of entities which could perform UR, and which do hold licenses or certificates, are not required to undergo certification. The Department has given itself, through the regulation, the ability to verify the credentials of any officer, director or member of the managing staff, and will include licensure of those individuals in this review. Act 68 itself requires the reviewers utilized by the applicant to be licensed in good standing. See section 2152(a)(5) of Article XXI.

The commentator also commented that the proposed section in general failed to establish uniform standards for UR, and suggested that this could lead to inconsistent decisionmaking. The commentator provided a list of what it believed the appropriate standards are. The commentator stated that the standards should be applied consistently and equitably, should require that the member's specific individual health status be considered, should be based on sound clinical and scientific evidence and should be made under the direction of the plan medical director. The commentator further stated that the standards should require that clinical standards for UR should be current, subject to input from plan providers and made known to plan providers; the standards should not have financial or other incentives that adversely affect the quality of care; the standards should comply with Act 68's prior authorization requirements, and include standards and time frames for prior authorization procedures of plans; and the standards should include review of the plan's "medical necessity" definition.

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The Department agrees that utilization standards should be created and included in the regulations, and has done so in §§ 9.749--9.751. The Department's standards are discussed at greater length in the discussion of the general comments to this subchapter.

One commentator commented that proposed subsection (a)(2)(i), which would allow the Department to consider whether management personnel, officers or directors of the applicant have filed for bankruptcy, was too broad and intrusive. The commentator stated that the personal bankruptcy history of individuals was not relevant, and could be deemed discriminatory. The commentator recommended that the paragraph be deleted.

After considering this comment, the Department agrees that the language of the proposed amendments should be altered. The Department did not intend to request information regarding personal bankruptcies. The Department has revised the subparagraph to require an applicant to provide the Department with information concerning whether management personnel, officers or directors of the applicant have ever been involved in a bankruptcy proceeding as an officer, director or senior manager of the corporation in question. This should protect the privacy of the individuals and provide the Department with the information it needs to make an informed decision about the applicant.

One commentator recommended that the Department delete the requirement in subsection (a)(2)(v) allowing the Department to consider whether the management personnel, officers or directors of the applicant have a history of malpractice or civil suits, penalties or judgments against them. The commentator argued that this, too, was intrusive and broad.

The Department has not changed this proposed subparagraph. The Department believes this information is necessary to determine whether the individuals in question are capable of operating the applicant in a reasonable manner.

Section 9.746. Fees for certification and recertification of CREs.

The Department received one comment on the proposed section. The proposed section would have required CREs already certified to pay the fee to the Department as well. The commentator commented that the Department had previously told CREs that there would be no application fee if an application were filed before the adoption of final-form regulations. The Department acknowledges that this comment is correct, and has revised the proposed section to remove the language in question.

Section 9.747. Department review and approval of a certification request.

The Department received comments from three commentators on the proposed section. One of these commentators recommended that the Department include in the regulations language providing the Department access to CREs' decisions, in order to review their compliance with Act 68 and the regulations.

The Department has added a subsection (c) to § 9.748 (relating to maintenance and renewal of CRE certification) to clarify that it has access to whatever information is necessary to determine a CRE's compliance with Act 68.

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Two commentators have recommended that the Department replace the word "will" with the word "shall" in proposed subsection (b). One commentator commented that the Department should more specifically state what other information will be necessary for it to determine compliance with Act 68 and the regulations.

The Department agrees that the regulation should more clearly provide it with authority to review this information, and has revised the regulation to require that the Department be given access. With respect to the issue regarding clarification of the term "other information," the language is sufficiently clear, and the Department has not changed it. The Department has stated it must have access to other information necessary to determine compliance with Act 68. Further, the proposed subsection was already fairly all-inclusive, in that it provides the Department with express authority to access books, records, staff and facilities.

Two commentators commented that the Department should not forgo inspection or monitoring to determine whether the CRE is in compliance with Act 68 merely because a Nationally recognized accrediting body accredits that CRE. The commentators stated that the Department should review the actions and inactions of the CRE to fulfill the Department's obligation to implement the requirements of Act 68.

The Department has considered these comments on this proposed subsection, but has decided not to change the proposed subsection to address them. The Department does have the responsibility to ensure that an applicant meets the certification requirements, and that a CRE continues to meet those requirements for the purpose of maintenance and renewal of certification. The Department may recognize the standards and accreditation of a Nationally recognized accrediting body, whose standards are accepted by the Department as meeting or exceeding the requirements of sections 2151 and 2152 of Article XXI (see section 2151(c) of Article XXI), as a supplement to the Department's review process. The Department may not delegate the discretionary part of this function, and it has not. The Department remains responsible for the final decision of whether the applicant or CRE meets and continues to meet criteria. The Department has not said that it will not make site visits or conduct inspections when it finds them to be necessary. The regulations merely give the Department the option of requiring an onsite inspection by a credentialing body. See § 9.748(a). Nothing in this regulation or any other regulation indicates that the Department is abdicating its responsibility to oversee or monitor CREs.

Section 9.748. Maintenance and renewal of CRE certification.

The Department received two comments on this proposed section. Both IRRC and another commentator commented that the Department should include specific language providing the Department with access to the same records and other information concerning a CRE as described in proposed § 9.747(b).

This was the Department's intention in stating that it would have the ability to perform an onsite inspection in proposed subsections (a)(1) and (b)(3). Since, however, there seems to be some confusion as to the scope of the Department's review in that onsite visit, the Department has added language in to clarify this point. See subsection (c).

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IRRC also commented that the proposed section should state that the Department will have access to and review UR decisions made by the CRE. According to IRRC, this would be necessary to allow the Department to monitor compliance under Act 68.

The Department has included language allowing it access to whatever information is necessary to review a CRE's compliance. To clarify this matter, however, the Department has also included language in subsection (c), which states that the Department will have access to the UR decisions of the CRE.

Two commentators stated that the Department should change the word "may" in subsection (a). One recommended that the Department change the word "may" to "will," another requested that the word be changed to "shall." Both commentators were concerned with clarifying that the Department would maintain a strong oversight over CREs on an ongoing basis, since it is the only agency responsible for that oversight.

The Department has not changed the proposed subsection to implement these recommendations. The Department is charged by the General Assembly with setting standards for certification of CREs, and granting, denying or revoking that certification. Therefore, the Department will monitor, investigate and take appropriate action to ensure compliance with the regulations and all aspects of the statute. The Department does not need to alter the language of the proposed subsection to make that clear. It was the Department's intention to use the word "may" and rather than "will" or "shall." CREs are subject to review, as Department finds necessary. The Department has, however, added a statement to the subsection that should clarify that CREs are required to comply with the requirements of Act 68 and the regulations to maintain certification.

Two commentators stated that maintenance and renewal of certification must include an onsite inspection by the Department.

The Department has not changed the proposed language of the subsection to address this concern. As the Department has discussed in its response to comments on proposed § 9.747(b), the Department is aware of its responsibility to ensure that an applicant meets the certification requirements, and that a CRE continues to meet those requirements for the purpose of maintenance and renewal of certification. The Department may use a Nationally recognized accrediting body, whose standards the Department finds meet or exceed the standards of Act 68, to perform certain administrative functions for the Department. It is the Department that is still responsible for the final decision of whether the applicant meets the criteria for certification, or the CRE continues to meet that criteria. The Department has not prohibited itself from making site visits or conducting inspections, nor has the Department said it will, in every case, use a Nationally recognized accrediting body to conduct inspections for it. The regulations merely give the Department the option of requiring an onsite inspection by an outside body. Nothing in this regulation or any other regulation indicates that the Department is abdicating its responsibility to oversee or monitor CREs.

One commentator recommended that the Department add language to subsection (b)(2)(i) stating that it would periodically validate the results of the accreditation process to ensure compliance.

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The Department has not made a change to this proposed paragraph. Section 9.748(a) already requires CREs to continue to comply with Act 68 and the regulations to maintain certification, and provides the Department with the ability to monitor that compliance as necessary. The Department does not need to restate its ability to validate the results of an accreditation review.

Section 9.749. UR system description.

One of the commentators recommended several specific additions to the Department's proposed regulations. It recommended adding language which states that the "plan shall use written criteria based on sound clinical evidence and specify procedures for applying those criteria in an appropriate manner," that "utilization management (UM) structures and processes shall be clearly defined and the plan will have a written description of its UM program including the program structure and individual's responsibility and accountability within the structure," and that "the plan conducts UM based on the medical necessity and appropriateness of the health care service being requested, makes UM decisions in a timely manner and communicates its decision in writing to the enrollee and health care providers."

The Department agrees with the commentator that a system for conducting UR should have standards, and has included in the regulations a section to set standards for a UR system. See § 9.750 (relating to UR system standards). The Department has required that the description of the system be in writing, and that the entity performing UR must make that description available to the Department for review. See subsections (a) and (e).

Rather than taking the commentator's recommendation of requiring a description of the individual's responsibility and accountability within the program, and getting into a discussion of when and how nurses should participate instead of doctors, the Department has chosen to require that a physician be involved in the UR program, and has included that requirement in § 9.750(a). This will provide for physician oversight without dictating resource allocation and job descriptions.

One commentator also recommended language requiring that "plans must demonstrate that UM decisions are appropriate and that there is consistency in application of UM clinical criteria and procedures among physician and non-physician professional review staff." The commentator urged that additional language would state that the "UM plan shall be evaluated and approved annually by an appropriate committee as outlined in the UM program."

The Department currently requires plans to conduct reliability studies of staff application of UR criteria through the NCQA external review. The Department has included language in subsection (b) to make this part of the UR system. There must, however, be a presumption that the UR criteria and decision are based on sound medical evidence. If the provider disagrees, there is the grievance process to challenge medical necessity and appropriateness. Therefore, the Department has added language that requires an entity performing UR to review its UR activities annually and report to the quality assurance committee or the board of directors regarding the appropriateness of criteria, application of criteria, consistency of decisionmaking, staff resources and training and timeliness of decisions. See subsection (b).

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The Department has also included language from section 2152(3) of the Article XXI requiring the entity performing UR to have a policy and procedure in place to allow a provider to verify that an individual requesting information for UR purposes is a representative of the entity performing UR. See subsection (c).

One commentator recommended that the Department add language which states that the plan shall have systems and procedures in place, including sufficiently qualified physicians, nonphysician staff and resources, to meet the timeframe requirements for UM decisionmaking and communications of those decisions.

The Department has added a requirement to § 9.654(d) that the external quality assurance assessment be done against Act 68's standards, including UR standards. The Department has also included language in subsection (d) of this section requiring that the entity performing UR have sufficient staff, resources and program oversight to ensure adherence to Subchapter K, and to section 2152 of the Article XXI.

Section 9.750. UR system standards.

One commentator recommended adding language requiring providers in this Commonwealth actively engaged in the delivery of health care to be involved in the development or selection of the clinical criteria and in the development and review of procedures for applying that criteria.

The Department has included language requiring entities performing UR to include input from health care providers in active clinical practice in the development of the clinical criteria for the UR program. See subsection (b). Requiring providers in this Commonwealth to be involved in the development of criteria is not practical in all instances. UR criteria is generally based on large data sets and purchased from standardized sources. Deviations are made regionally, geographically and on a case by case basis with the approval of the medical director or by medical policy. By requiring the medical director to have a Pennsylvania license, the Department has linked the physician to clinical standards in this Commonwealth. Medical policy, which is approved by the quality assurance committee, is generally arrived at by the highest level committee of the plan, meaning in many cases a National quality assurance committee, with review and modifications made as necessary due to regional or State variations. Improvements and progress in health care delivery evolves on a National level. No one state, including this Commonwealth, maintains a monopoly in terms of innovation and improvement. Standards based solely on experience in this Commonwealth, which would be the result if only physicians in this Pennsylvania were involved in the selection, development and review of standards, may serve to inadvertently limit progress.

One commentator recommended that the UR criteria be reviewed at regular intervals and updated as necessary. The Department has added this language in subsection (b)(2).

One commentator recommended that the Department add language that requires a plan to make the clinical criteria available upon request and state in writing how providers can obtain those criteria. The Department has included this language in subsection (b)(3). As discussed earlier, UR standards are generally taken from National sources such as Milliman and Robertson. Reluctance on the part of the plan to release criteria to providers may stem from a

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concern that the enrollee's condition could be made to fit the criteria instead of being objectively reported; however, health care providers generally come to know the plans' expectations and UR criteria through experience. Although the Department concedes that abuses can occur by reporting symptoms that would make the enrollee's condition meet the criteria for coverage, it also recognizes that those same abuses can occur now. The improvement in patient care that will come from the frank and forthright exchange of ideas and information between providers and plans in applying and modifying UR criteria is to the greater good.

One commentator recommended the addition of language that requires the plan to conduct UR based on the medical necessity and appropriateness of the health care service being requested, make UR decisions in a timely manner and communicate its decision in writing to the enrollee and health care providers. The commentator also recommended language stating that "The criteria for determining medical appropriateness shall be clearly documented and include procedures for applying criteria based on the needs of the individual patient, such as age, comorbidities, complications, progress of treatment, psychosocial situation and home environment as well as characteristics of the local delivery system that are available for that particular patient."

The Department has included language in subsection (c) requiring the UR decision to be based on the medical necessity and appropriateness of the health care service being requested. The Department will not go as far as commentators recommended with respect to what should be considered in determining medical appropriateness. The Department does, however, require that the entity performing review consider the individual's medical circumstances when making the UR decision, along with the applicable contract language, and the medical necessity and appropriateness of the requested service. Psychosocial factors and home environment, while they can be of concern, do not necessarily drive clinical decisions, and of themselves cannot be the sole causation for payment. For example, a mother who just delivered a baby may not want to be discharged, even though clinically her physician agrees it is appropriate to do so, because her house is being remodeled and is in disarray. The home environment may indeed not be fit for a newborn; however, the plan cannot be held responsible for the remodeling delay and should not be compelled to provide payment for additional days in the hospital that are not medically necessary.

The Department has also included language from section 2152(c) and (d) of Article XXI that specifies who may make a UR decision. This language is included in subsection (d). The Department is, however, cognizant of the fact that there are situations in which claims are processed in an automated fashion, without human intervention, according to decision logic. So long as this decision logic implements the clinical criteria developed and approved by the medical director, who is a licensed physician, the Department accepts that these are decisions made by a physician in accordance with the regulations and Act 68.

One commentator has recommended that the Department add language that requires a plan to notify the provider of additional facts or information required to complete UR within 48 hours of receipt of the request for service. The Department has included this language in subsection (e).

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The Department has included the requirement that decisions be communicated to enrollees and health care providers within specified time frames in a separate section. See § 9.751 (relating to time frames for UR). The Department has specifically stated in subsection (g) that, for purposes of internal grievance reviews, the decision must be communicated in writing to the enrollee, the enrollee's representative and the health care provider if the health care provider filed the grievance with enrollee consent.

Section 9.751. Time frames for UR.

IRRC and another commentator recommended that the Department include the time frames for prospective, concurrent and retrospective UR contained in section 2152 of Article XXI, as well as other requirements included in that section. The commentator also recommended that a plan give enrollees and providers written or electronic confirmation within that time period. The commentator noted that this was consistent with NCQA standards. The Department has added these requirements from section 2152 of Article XXI in subsections (a)--(c). Section 2152(a)(6) of Article XXI requires that all decisions be in writing. Therefore, the Department has drafted this section of the regulations to apply to all decisions, approvals as well as denials, consistent with the requirements of Act 68. See 2152(a)(6) of the Article XXI.

For clarity, the Department has also included language in subsection (d), which states that a grievance review decision must comply with the time frames and requirements of §§ 9.705 and 9.707.

One commentator commented on the lack of time frames, the failure of the regulations to ensure personnel conducting URs remain licensed in good standing, the failure of the regulations to address potential conflicts of interest between plans and CREs, and the failure of the regulations to prohibit incentives offered by plans to CREs. As discussed previously, the Department has added language regarding time frames in this section. Act 68 itself speaks to licensure requirements (see 2152(a)(5) of Article XXI) and financial incentives requirements (see 2152(b) of Article XXI), which the Department has not specifically added. The Department has, however, required that entities performing UR comply with the requirements of section 2152 of the Article XXI, which would include these requirements. See § 9.750(h).

With respect to conflicts of interest, there are two distinct situations that involve CREs: one is UR and the other is external grievance reviews. In the latter situation, the Department's regulations have addressed the issue. See § 9.707(f)--(i). For a standard UR decision, one can take the absolute position that there is always an inherent conflict of interest since the CRE is reviewing the matter for the plan, and not for the enrollee, and is compensated by the plan and not the enrollee. The check and balance to this is the ability of the requesting physician and the enrollee to appeal the denial as a grievance that will result in the matter being heard by an independent reviewing entity. It is for this reason the Department has included this language in § 9.707(f)--(i).

IRRC requested an explanation of how the Department will determine whether a CRE has the capability of meeting these requirements. The Department's application requests certification from the applicant that it can meet these time frames (see § 9.744(a)(4) and (5))

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and references. See § 9.743(b)(5)(ix). The Department will conduct readiness reviews and reference checks, and will investigate complaints lodged against CREs.

Several commentators requested the addition of language that would specifically state that the Department would develop mechanisms to ensure CREs would comply with the final-form regulations. The Department has made no change. The Department is charged with enforcement under Act 68. Therefore, it will monitor, investigate and take appropriate action to ensure compliance with this and all aspects of the statute and regulations. It is unnecessary to include language to make that clearer in this section than in any other.

One commentator also requested the addition of language that would prohibit plans from retrospectively denying payment for a health care service if an authorized representative of the plan had previously authorized provision of the service. The commentator stated that a plan should not be able to retroactively deny payment if the provider had not withheld any information considered to be reasonably necessary to grant prospective or concurrent authorization.

The Department has declined to add this language. As discussed earlier, retrospective review is clearly permissible under section 2151(a)(4)(iii) of the Article XXI. If the only decision a plan can make retrospectively is to approve payment, and it can never deny payment, the only course of action left to the plan is to deny all services prospectively and concurrently and pay those that are appropriate based on retrospective review. In the Department's opinion, a plan should have the ability to deny retrospectively if the service was not necessary or appropriate. This would only be done if the actual situation turns out to be different from how it was represented at the time services were prospectively or concurrently approved. Practically speaking, this can happen even if there was no withholding of reasonably necessary information.

The commentator also recommended the addition of several specific standards from Act 68, requirements for telephone access; requirements for maintenance of adverse decisions for 3 years; requirements for maintenance of decisions as confidential; requirements for utilization management personnel; prohibitions against financial incentives to approve or deny payment; and a requirement that denials must be conducted by physicians or approved licensed psychologists. See 2152 of Article XXI.

Again, the Department has included these standards either specifically in §§ 9.748--9.751 or by its reference in § 9.741(c) to section 2152 of Article XXI, which contains those standards.

The commentator also recommended that the Department require disclosure of the name and credentials of the physician or psychologist reviewing the decision.

All denials of coverage for a requested health care service must be made by a licensed physician or an approved licensed psychologist if the act permits. See subsection (d). The Department takes the position that reviewing physicians provide expert opinions to the plan and the plan is responsible for its actions as a result of those opinions. To require disclosure of the physician's name and credentials could unintentionally expose the reviewer to intimidation or reprisal from enrollees, family members or the medical community, and may serve to

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dissuade physicians from providing expert opinion which would seriously erode the caliber and content of UR decisions.

Several commentators recommended that the Department require plans to provide clinical rationales in denial decision letters. Although this is required generally in Act 68, for further emphasis, the Department agrees that UR standards should require clear clinical rationale in the decisions, and has added language to that effect in § 9.750(f).

One commentator commented that the Department should add language requiring plans to comply at all times with the requirements of Act 68. The commentator stated that the Department should clarify that without the ability to meet certain requirements, and an affirmation that the applicant will meet the requirements, certification as a CRE will not be granted. Further, the commentator stated that the Department must be able to subject a CRE to additional review if it believes the CRE is failing to comply with Insurance's regulations.

For the purposes of clarity, the Department has added a statement to § 9.748(a) stating that a CRE must continue to comply with the requirements of Act 68 and the regulations to maintain certification. However, since Insurance is not responsible for the regulation of CREs (see generally sections 2151 and 2152 of Article XXI), adding the language recommended with respect to a CRE's failure to comply with Insurance's regulations would be meaningless.

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Subchapter L. Credentialing

The Department received several comments on the single section in this proposed subchapter. One commentator supported the Department's proposed regulation, stating that the section would help to support the spirit of Act 68, specifically the intent to enhance the access of this Commonwealth's citizens to the quality health care provided by CRNPs, particularly in medically underserved areas. The remainder of the comments recommended language changes.

Proposed § 9.761 proposed requiring a plan to create a credentialing system, and to develop certain policies and procedures for that system. One commentator commented on the lack of minimum credentialing standards, and recommended that the Department set those standards. The Department agrees that such standards are necessary, and has included them in § 9.762.

Section 9.671. Credentialing.

Two commentators raised concerns that the proposed section would not require plans to comply with their own credentialing systems, and that the proposed section contained no enforcement authority for the Department to ensure that they would do so.

Section 9.606 delineates the Department's enforcement authority; it does not need to be repeated or cross-referenced in each section for the Department to be able to enforce compliance with the regulation. The Department has, however, added language to subsection (a) stating that a plan must adhere to the credentialing system it establishes.

One commentator also commented that the proposed section would contain no mechanisms for the Department to become involved in credentialing decisions.

The Department has made no change to the proposed section in response to this comment. The statute does not give the Department the authority to be an appellate body on credentialing issues. Act 68 only requires that a plan give the provider a clear basis for its decision. See section 2121(f) of Article XXI. The Department does have the authority to, and will investigate the plan's compliance with policies and procedures, and with Act 68 and the regulations.

Two commentators commented on proposed subsection (a)(2). One commentator questioned whether the recredentialing requirement would include individuals such as durable medical equipment suppliers, physical therapists, registered nurses and physicians' assistants. The commentator noted that Act 68 defines these types of individuals as health care providers, and the Department uses the term "health care provider" in proposed subsection (a). The commentator raised the issue because NCQA does not require credentialing of these individuals, and HCFA does not include durable medical equipment suppliers as providers of health care.

Another commentator requested that the Department clarify whether proposed subsection (a)(2) would apply only to professional providers, or whether it would apply to facility providers as well. The commentator stated that facility providers should not be recredentialed every 2

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years because they are subject to their own credentialing programs which assure quality of care is being provided, for example, during the reviews of the Joint Commission on Accreditation of Health Organizations (JCAHO).

After reviewing these comments, the Department agrees that these issues need to be addressed in the regulations. The Department has, therefore, added a section addressing credentialing of those health care providers who are not physicians. To the extent the nonphysician provider is required by law to be licensed and to maintain malpractice insurance, the plan must verify at least these two items. See § 9.763 (relating to nonphysician providers at facility, agency or organization). Section 9.763 eliminates the requirement that plans credential nonphysician providers in cases where the providers are credentialed by the facility. First, the plan must make the determination that the nonphysician providers practice under the auspices of a facility, organization or agency that credentials those providers. Second, the facility, agency or organization must also conduct credentialing according to the credentialing standards in § 9.762 (relating to credentialing standards). If this is the case, the plan need not credential those nonphysician providers.

Generally, plans only credential physicians. Act 68's definition of a health care provider expands credentialing to all types of providers. See section 2121(a) of Article XXI. Section 9.763 will allow plans to contract with pharmacies without having to credential each pharmacist, home health agencies without credentialing each home health aide, hospitals without credentialing each nurse and ambulance companies without having to credential emergency medical services personnel.

The Department has revised subsection (a)(2) to require credentialing of health care providers every 3 years, to take into account a change in the requirements of the Nationally recognized accrediting body approved by the Department.

One commentator commented that proposed subsection (a)(3) would extend credentialing, which is now only required for primary care providers, to all health care providers. The commentator noted that NCQA has removed specialists from the specific credentialing requirements cited in this proposed section. The commentator recommended changing the language of proposed subsection (a)(3) to limit its application to primary care providers.

The Department acknowledges that NCQA has made changes in its credentialing requirements specifically deleting the requirement of an office site audit in the case of high volume specialists. Act 68, however, requires credentialing for health care providers, a term that encompasses more types of providers than the term "primary care provider." Compare the definition of "health care provider" in Act 68 with that of "primary care provider." See section 2102 of Article XXI. Subsection (a)(3) was based upon section 2111(1) of Article XXI, which requires a plan to assure the availability and accessibility of adequate health care providers, and section 2121(a) of Article XXI, which requires a plan to establish a system for credentialing health care providers. Act 68 then extended those access and availability elements that were traditionally limited to primary care providers to all health care providers.

Because the requirements of this proposed paragraph were intended to apply to more than primary care providers, the Department has determined that certain revisions to the paragraph

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are necessary to reflect that fact. Therefore, the Department has deleted references to appointments and to routine physical examinations, and has included in the final regulation references to the more general term "care." For example, subsection (a)(3) requires a review of a provider's ability to provide urgent care, rather than urgent care appointments.

One commentator stated that Department would violate the intent of Act 68 by including the language of proposed subsection (a)(8) in the final-form regulations. The commentator stated that plans could use credentialing procedures to limit access to obstetrical and gynecological services.

Another commentator made the same comment, and requested that the Department add specific language prohibiting plans from using credentialing practices to prevent family physicians from providing obstetrical and gynecological services. The commentator stated that nothing in Act 68 would preclude a physician who was experienced, well trained and could provide quality of care in obstetrical and gynecological services, for example, family physicians, from being accessed by patients under the direct access provision of the act. The commentator recommended that, to the extent this proposed paragraph would permit prohibition of direct access, it should be deleted.

The Department is aware, as the commentator noted, that at least one plan is taking the position that, since Act 68 requires plans to credential providers for the provision of directly accessed obstetrical and gynecological services, it can establish acceptable credentials for those providers. The Department has given serious consideration to this issue. It is aware of the importance to the provider groups whose members believe they have the expertise and experience to provide quality health care in these areas. After review of the comments, however, the Department, does not believe that the language it proposed would violate Act 68, and it has made no change to that language. Act 68 requires that a plan provide access to services, not to providers. See section 2111(7) of Article XXI. (Provide direct access to obstetrical and gynecological services by permitting an enrollee to select a health care provider participating in the plan to obtain maternity and gynecological care.) A plan that wishes establish acceptable credentials and thereby provide direct access to obstetrical and gynecological services only through certain types of providers, may do so. This would place no restraint upon an enrollee's direct access to obstetrical and gynecological services.

One commentator has raised a similar issue with respect to standing referrals. The commentator has recommended the addition of language to proposed subsection (a)(9), which would require the primary care physician to determine if a patient requires referral to a specialist to act as a primary care provider. The commentator recommended additional standards for this determination, including that the medical condition be severe, and a listing of examples of severe medical conditions warranting referral.

The Department has not made the change recommended by the commentator. Act 68 makes it the enrollee's option to request a standing referral and the plan's option to permit it. It does not give the primary care provider veto power or the right to determine if the enrollee's condition warrants a standing referral. The recommended language could create limitations on an enrollee's right to obtain a standing referral or to have a specialist designated as a primary care provider. The statute does not require the primary care provider's consent for this

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designation, the statute does not even specifically require the primary care provider's involvement. Initiation of the request is made by the enrollee, and may be made directly to the plan, unless the plan's procedures permit otherwise. It is up to the plan to set standards for whether or not the request is granted.

Further, Act 68 states that an enrollee may request a referral or designation of a specialist if the enrollee has "a life-threatening, degenerative or disabling disease or condition." See section 2111(6) of Article XXI. The adoption of the recommended standard, "severe medical condition," would go beyond the terms of the act, and be unduly restrictive.

The Department has added subsection (a)(10) to clarify that the policies and procedures must ensure that enrollees have access to only those participating providers who have been properly credentialed. This states the obvious, but is intended to prevent situations in which plans or their contractors have unwittingly permitted enrollees to be served by noncredentialed participating providers.

The Department received several comments on proposed subsection (b) requesting clarification on the requirement that a plan must submit its credentialing plan to the Department for approval. One commentator questioned what type and what amount of information must be submitted regarding the credentialing process. This commentator pointed out that demonstration of compliance could range from being NCQA accredited to providing the Department with updates on numbers of practitioners credentialed, recertified and terminated for quality reasons every 2 years.

IRRC requested that the Department clarify that the credentialing plans would, in fact, be submitted to the Department for approval. A plan must submit its credentialing process, including policies and procedures, to the Department for its approval. As IRRC requested, the Department has added language to subsection (b) to clarify this. The Department, as a matter of course, has already reviewed and approved the credentialing plans for all HMOs as part of the external quality assurance review conducted by NCQA. The Department has, therefore, changed the language so that the final-form regulations require applicants to provide credentialing processes for review and approval prior to implementation or when modified. A plan whose credentialing process has been approved will then need to only submit changes to that credentialing process for approval prior to implementation.

The Department has also clarified the proposed subsection to require the plan to make a report of credentialing activities as required by section 2121(b) of Article XXI, including the number of applications for credentialing made, and the number of applications approved, rejected and the number of providers terminated for reasons of quality. The report must be submitted by a plan to the Department every 2 years. See subsection (f).

The Department has also clarified the proposed subsection to require the plan to make a report of credentialing activities as required by section 2121(b) of Article XXI, including the number of applications for credentialing made, and the number of applications approved, rejected and the number of providers terminated for reasons of quality. The report must be submitted by a plan to the Department every 2 years. See subsection (f).

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IRRC also stated that the Department should provide, in the regulation, the process and time frame for review and approval of the credentialing plan. The Department believes that the process was sufficiently set out in proposed subsection (b). A plan will submit its credentialing process to the Department for review and approval, and the Department, through its staff will review the process. Most likely, the Department will find it necessary to discuss aspects of the credentialing process with the plan. The Department has declined to set time limits for review in its final-form regulations, but the Department will make every effort to approve credentialing plans within 60 days of their being submitted in complete form to the Department.

The Department received three comments on proposed subsection (c). One commentator questioned how the plan would demonstrate that its credentialing plan meets or exceeds the standards of a Nationally recognized accrediting body. The commentator recommended that the Department accept a credentialing system that meets the requirements of an accrediting body, and change the word "may" included in the proposed subsection to "shall."

The Department has made no change to this proposed subsection. A plan may show the Department it meets the requirements of a Nationally recognized accrediting body by sending to the Department a copy of the certification letter sent to the plan by the accrediting body. Additionally, the plan must provide the Department with a copy of the full external quality assurance assessment report in accordance with § 9.654, and the Department is therefore able to review that portion of the assessment relating to credentialing.

Because the Department is responsible for determining whether or not the plan meets the standards of Act 68 and the regulations, the Department cannot cede this responsibility to any outside body. Therefore, the Department will review the report of the accrediting body, and make a determination of whether to accept or reject the report, or whether to conduct further investigation. Therefore, the Department will not change the language of this subsection.

Another commentator requested that the Department state when it intended to publish a list of Nationally recognized bodies for credentialing purposes. The Department will publish a list of acceptable accrediting bodies in the *Pennsylvania Bulletin* at least annually.

The Department received one comment on proposed subsection (d), which strenuously opposed the proposed regulation on the grounds that it would create serious liability issues for plans.

The Department has not changed the proposed subsection. Insurance's regulations also prohibit a plan from requiring full credentialing of nonparticipating providers as a plan condition in a continuity of care situation. The Department's language is consistent with Insurance's language. Since full credentialing generally takes at least 90 days to complete, requiring full credentialing of a nonparticipating provider before allowing the enrollee to continue care with that provider would vitiate the 60-day continuity of care period allowed by statute. See section 2117(a) of Article XXI. Plans have complained that not fully credentialing providers will create tort liability for them. The Department has said that it will minimally allow plans to require verification of current licensure and malpractice coverage should plans wish to do so, since these items can be verified within days, and will not jeopardize the enrollee's ability to benefit from the continuity of care provision. Other options may be available to protect against liability;

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for example, plans may obtain waivers from any enrollee who wishes to continue care with a provider who is not fully credentialed.

The newly effective health plan should, at the least, verify licensure and malpractice coverage of health care providers so the enrollee has a financial protection if malpractice occurs.

The Department received one comment on proposed subsection (e). A commentator recommended that the Department change the language to require plans to provide the credentialing requirements automatically along with the application packet.

The Department has declined to make this change, given the cost to the plan of providing the information automatically. This information is not useful to providers already contracted to the plan. If an applicant particularly wants the information, it is available to the applicant upon request.

Section 9.672. Credentialing standards.

Section 9.672 will require minimum standard for credentialing. Subsection (a) requires a plan to verify certain specified credentialing elements for primary care providers and specialists, including current licensure, education and training, board certification status, Department Drug Enforcement Agency (DEA) certification, current and adequate malpractice coverage, malpractice claims history, work history, hospital privileges if the provider provides services at hospitals and any other information the Department may require upon prior notice in the *Pennsylvania Bulletin*. Subsection (b) includes minimum requirements for credentialing of nonprimary care providers and nonspecialists. The section requires a plan to at least verify a provider's current licensure and malpractice coverage, to the extent that licensure and malpractice coverage is required by State and Federal laws.

Cost And Paperwork Estimates

A. Cost

The final-form regulations will have no measurable fiscal impact on local governments or the general public. The members of the general public enrolled in managed care plans governed by the regulations may ultimately experience some increase in health care costs due to the statutory requirements, such as external grievance filing fees.

The replacement and revision of the previous regulations in Chapter 9 will create no additional cost to the Commonwealth, since these revisions reflect the current operations of the Department. There is no fiscal impact even though there are additional monitoring duties placed on the Department by Act 68. Those duties are reflected in provisions of the final-form regulations relating to health care accountability and access, complaints and grievances, provider contracts, accreditation of UR entities, and credentialing. The Department is, among other things, required to review additional contracts and grievance and complaint procedures submitted by managed care plans, and requests for certification from UR entities. The Department also coordinates the external review procedure set out in Act 68, which requires

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the Department to certify, appoint and monitor the operations of the certified review entity conducting the review.

The final-form regulations relating to HMOs do not have a significant fiscal impact upon HMOs since comprehensive revision and updating of the HMO regulations should make compliance with those regulations easier. HMOs are filing standard form contracts for providers and IDS agreements with the Department now. HMOs do not send to the Department every contract entered into between an HMO and a provider. The Department did not propose that it review and approve every contract entered into. The incremental cost for an HMO of continuing the practice of filing standard form contracts is negligible.

It is possible that the Department's review period will postpone the plan's ability to use a contract through which it intends to implement cost savings. The Department cannot quantify the amount of money lost in savings during that review period, since each specific contract would have its own unique associated savings, paperwork reduction or operational efficiencies, for example. There could also be reduced reimbursements associated with a new contract; however, reduction in plan reimbursement does not currently require a new contract and would not be the sole purpose for a plan changing its standard form contract.

Under the final-form regulations, managed care plans that are not HMOs will also be required to file standard form contracts. If a non-HMO plan uses provider contracts already approved for a related HMO, the requirement would place little burden on the plan. It is common practice for a plan with multiple lines of business (HMO, PPO, Point-of-Service, indemnity) to use one standard form contract and address variations in reimbursements or terms through specific amendments or exhibits. The cost to the plan of the Department reviewing contracts is, in concrete terms, made up of minimal copying and postage fees.

Depending upon how HMOs and other managed care plans operated their grievance systems prior to Act 68, that act and the Department's regulations may create additional costs, because of the Department's inclusion in the regulations of its "fundamental fairness" guidelines for complaint and grievance reviews. These requirements may increase HMO and non-HMO plan staff time in setting up procedures, and in preparing for individual reviews. There may also be some increased cost to HMO and non-HMO plans since the regulations and Act 68 require a certain composition of review committees, which may add to the cost of the review. The additional disclosure requirements of Act 68 may also have a fiscal impact upon managed care plans, including HMOs.

The final-form regulations also create a fiscal impact on entities wishing to be certified as UR entities. The Department is adopting an application fee for entities requesting certification, as Act 68 authorizes it to do. This certification requirement does not apply to licensed insurers or managed care entities with certificates of authority.

B. Paperwork

There will be changes in paperwork requirements associated with the final-form regulations. Although the paperwork requirements for HMOs to obtain and maintain certificates of authority will not be significantly altered, the regulations implementing Act 68 require submission of

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documents from entities not previously regulated. These requirements require the Department to review additional contracts and grievance and complaint procedures submitted by managed care plans, and requests for certification from UR entities. The Department also coordinates the external grievance review procedure required by Act 68, which requires the Department to appoint and oversee the operations of the certified review entity conducting the review.

There may be additional paperwork for managed care plans that are not HMOs, since they will be required for the first time to submit provider contracts and complaint and grievance procedures and data to the Department. This paperwork could be minimal, depending on whether the non-HMO plan uses an already approved contract in use by an affiliated HMO. HMOs were required by previous regulations to make these submissions.

Act 68 creates additional paperwork, since the plans must comply with the mandated complaint and grievance systems detailed in that act. Depending upon how plans operated their grievance systems prior to Act 68, that act and the Department's regulations may require additional paperwork of the plans. The Department is including in the final-form regulations its guidelines on how to conduct a fair complaint and grievance review. Depending upon how a plan is currently conducting reviews, the plan may need to revise policies and procedures to comply with the act and the final-form regulations.

Further, again depending upon how managed care plans operated prior to Act 68, that act's requirement that certain disclosures be made to enrollees may result in an increase in paperwork. Act 68 also creates additional paperwork for CREs. Under Act 68, CREs are required to obtain certification from the Department to perform URs of health care services delivered or proposed to be delivered in this Commonwealth. Prior to the passage of Act 68, this requirement did not exist.

Act 68 and the regulations may also create some different or additional paperwork for those members of the general public who obtain health care through managed care plans covered by Act 68. Depending upon the dispute resolution system established by plans prior to Act 68, there may be alterations in the manner in which an enrollee must utilize these procedures.

Effective Date/Sunset Date

The final-form regulations will be effective immediately upon final adoption. No sunset date has been established. The Department will continually review and monitor the effectiveness of these regulations.

Statutory Authority

The Department's authority to promulgate these final-form regulations is based upon three statutes: the HMO Act, the PPO Act and Act 68.

The Department has authority to promulgate regulations relating to the certification and operations of HMOs under section 14 of the HMO Act. Section 5.1(a) of the HMO Act provides the Department with the authority to determine what information will be contained in a corporation's application for certification as an HMO. Section 5.1(b)(1)(i) of the HMO Act

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provides the Department with authority to determine whether an HMO has demonstrated potential ability to assure both availability and accessibility of adequate personnel and facilities in a manner enhancing availability, accessibility and continuity of services. Section 5.1(b)(1)(ii) of the HMO Act provides the Department with authority to determine whether an HMO has demonstrated it has arrangements for an ongoing quality of health care assurance program. Section 5.1(b)(1)(iii) of the HMO Act provides the Department with authority to determine whether an HMO has appropriate mechanisms to effectively provide or arrange for the provision of basic health care services on a prepaid basis. Section 8(a) of the HMO Act allows the Secretary to require renegotiation of provider contracts when those contracts provide for excessive payments, fail to include reasonable incentives, or contribute to escalation of costs of health care services to enrollees. Section 8(a) of the HMO Act also permits the Secretary to require renegotiation when the Secretary determines that the contracts are inconsistent with the purposes of the HMO Act. Section 10(e) of the HMO Act requires that an HMO establish and maintain a grievance resolution system satisfactory to the Secretary. Section 11(c) of the HMO Act provides the Secretary and the Secretary's agents with free access to all books, records, papers and documents that relate to the nonfinancial business of the HMO. Finally, section 15 of the HMO Act provides the Department with the authority to suspend or revoke an HMO's certificate of authority, or to fine the HMO for violations of the HMO Act.

The Department has authority to promulgate regulations relating to health care accountability and protection and facilitating the implementation of Article XXI under section 2181(e) of that article. Article XXI governs managed care plans as defined by Act 68, which include, inter alia, HMOs and gatekeeper PPOs. See 2102 of Article XXI (relating to the definition of "managed care plan"). Article XXI also regulates UR entities operating or wishing to operate in this Commonwealth. See section 2151 and 2152 of Article XXI. The Department has authority to enforce compliance with Article XXI under section 2181(d) of Article XXI, and to impose fines, obtain injunctions, require plans of correction and ban enrollment under section 2182 of Article XXI.

Section 2102(g) of The Administrative Code of 1929 (71 P. S. § 532(g)), provides the Department with general authority to promulgate its regulations.

The Department also has authority to review and approve grievance resolution systems and to require quality and utilization controls of certain PPOs under the PPO Act. Section 630(e) of the PPO Act requires that Insurance consult with the Department in determining whether arrangements and provisions for a PPO which assumes financial risk, which may lead to undertreatment or poor quality care, are adequately addressed by quality and utilization controls, as well as by a formal grievance system.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on December 8, 1999, the Department submitted a copy of notice of proposed rulemaking published at 29 Pa. B. 6409 (December 18, 1999) to IRRC and the Chairpersons of the House Health and Human Services Committee and the Senate Public Health and Welfare Committee for review and comment.

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In compliance with section 5(c) of the Regulatory Review Act, the Department also provided IRRC and the Committees with copies of all comments received, as well as other documentation.

Under section 5.1(d) of the Regulatory Review Act (71 P. S. § 745.5a(d)), the Department submitted a copy of the final-form regulations to IRRC and the Committees on February 28, 2001. In addition, the Department provided IRRC and the Committees with information pertaining to commentators and a copy of a detailed regulatory analysis form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

In preparing this final form regulations, the Department has considered all comments received from IRRC, the Committees and the public.

Under section 5.1(d) of the Regulatory Review Act (71 P. S. § 745.5a(d)), these final-form regulations were approved by the House Committee on April 2, 2001, and approved by the Senate Committee on March 27, 2001. IRRC met on April 5, 2001, and approved the final-form regulations in accordance with section 5.1(e) of the Regulatory Review Act.

Contact Person

Questions regarding these final-form regulations may be submitted to Stacy Mitchell, Director, Bureau of Managed Care, Department of Health, P. O. Box 90, Harrisburg, PA 17108-0090 (717) 787-5193. Persons with disabilities may submit questions in alternative formats such as audio tape, Braille or by using V/TT (717) 783-6514 for speech and/or hearing impaired persons or the Pennsylvania AT&T Relay Service at (800) 654-5984 [TT]). Persons who require an alternative format of this document may contact Stacy Mitchell at the address or telephone numbers previously listed so that necessary arrangements may be made.

Findings

The Department finds that:

(1) Public notice of the intention to adopt the final-form regulations adopted by this order has been given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202), and the regulations thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law and all comments were considered.

(3) The adoption of final-form regulations in the manner provided by this order is necessary and appropriate for the administration of the authorizing statutes.

Order

The Department, acting under the authorizing statutes, orders that:

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(a) The regulations of the Department at 28 Pa. Code Chapter 9, are amended by deleting §§ 9.1, 9.2, 9.31, 9.32, 9.51--9.55, 9.71--9.77, 9.91--9.97, 9.401--9.416 and 9.501--9.519 and by adding §§ 9.601--9.606, 9.621--9.623, 9.631--9.635, 9.651--9.654, 9.671--9.685, 9.701--9.711, 9.721--9.725, 9.741--9.751 and 9.761--9.763 to read as set forth in Annex A.

(b) The Secretary of Health shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for approval as required by law.

(c) The Secretary of Health shall submit this order, Annex A and a Regulatory Analysis Form to IRRC, the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare for their review and action as required by law.

(d) The Secretary of Health shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(e) This order shall take effect upon publication in the *Pennsylvania Bulletin*.

ROBERT S. ZIMMERMAN, Jr.,
Secretary

(*Editor's Note:* For the text of the order of the Independent Regulatory Review Commission, relating to this document, see 31 Pa.B. 2238 (April 21, 2001).)

Fiscal Note: Fiscal Note 10-160 remains valid for the final adoption of the subject regulations.