

September 1, 2023

Director Katie Merritt
Director of Policy and Planning
Pennsylvania Insurance Department
1326 Strawberry Square, Harrisburg, PA 17120

Dear Director Merritt:

Johnson & Johnson (“J&J”) is pleased to submit the following comments in response to the Pennsylvania Department of Insurance *Commonwealth Essential Health Benefits Benchmark Plan—Public Comment Period; Notice 2023-14 [53 Pa.B. 4072]* published on July 29, 2023. J&J is the world’s most comprehensive and broadly-based manufacturer of healthcare products for pharmaceutical, medical devices, and diagnostics markets. For nearly 130 years, we have led the way in innovation and are continuing this heritage today by bringing important new pharmaceutical products and MedTech innovations to market in a range of therapeutic areas on behalf of all our current and future patients, including Medicare, Medicaid, and Marketplace beneficiaries. **In defining the scope of “prescription drug” as an essential health benefit, we ask the Department to deem all covered prescription drugs as essential in its EHB benchmark plan when used to treat conditions covered by the plan. Furthermore, by extension, the Department should require all state marketplace plans to treat all covered prescription drugs as essential as well.**

I. The Problem: Third-Parties Are Deeming Certain Prescription Drugs as Non-Essential to Exploit Assistance Programs and Harm Patients

We submit these comments because over the past few years, pharmacy benefit managers (PBMs) and health plans have reclassified lifesaving or life-extending specialty drugs as non-essential health benefits to avoid the Affordable Care Act’s (“ACA”) cap on patient out-of-pocket (“OOP”) costs. Once reclassified as non-essential and thereby removed from the purview of the ACA’s maximum out-of-pocket limit, PBMs carve out a list of specialty drugs for third-party companies to manage. These third-party companies can increase the patient’s copay for the given drug to an artificially high amount—often thousands of dollars per dose. They then use this inflated copay to coerce patients into signing up for programs that extract the inflated amounts from charitable foundation and manufacturer assistance programs. The third parties then do not allow such assistance to count toward the patient’s deductible and maximum out-of-pocket cap. These programs are referred to as “non-EHB copay maximizer programs.”

The absence of this cap can increase the OOP burden on patients and allows charitable foundation- and manufacturer-provided copay support that is meant to benefit patients instead of being misappropriated for the benefit of payers and insurance companies. The discretion afforded to PBMs and health plans to determine which therapies are non-essential has created a system in which any medication, without regard to its actual medical necessity or its impact on patient health and safety, can be deemed by a PBM as “non-essential” to the detriment of patients and their continuity of their care.

II. The Solution: All Covered Prescriptions Should Be Considered Essential

As such, we applaud Pennsylvania Department of Insurance's interest in exploring the possibility of updating the Commonwealth's Essential Health Benefits benchmark plan (EHB benchmark plan). To ensure that PBMs, health plans, and other third-parties can no longer circumvent the ACA cap on patient's annual OOP obligations, **the Department should explicitly state that all prescription drugs covered by an EHB benchmark plan are essential when used to treat conditions covered by the plan. Furthermore, by extension, the Department should require all state marketplace plans to treat all covered prescription drugs as essential as well.**

Reclassifying covered prescription drugs as "non-essential" can be harmful to patients.

Non-EHB maximizer programs can be harmful to patients. Rather than a streamlined enrollment process with the manufacturer that directly provides patients with the copay support they need for their therapy, patients must enroll separately in third-party copay non-EHB maximizer programs to avoid paying extraordinary OOP costs imposed by the inflation of certain medications' copay amounts. Patients who fail to enroll in applicable manufacturer copay assistance, or exhaust the funds provided by the manufacturer, could be responsible for the potentially devastating increased copay costs. This process makes it challenging for patients to access, afford, or stay adherent to life-extending and life-saving medication, and disproportionately harms more vulnerable patient populations.¹ In addition, even when the patient is not exposed to the increased copay costs on one drug, the patient is not able to apply their co-pay support against the individual or family deductibles for a given year, which also makes it harder for families to afford life-extending and live-saving medication.

Racial and ethnic minority patients are disproportionately harmed by copay assistance diversion programs, such as maximizer programs.

Furthermore, research suggests that copay assistance diversion programs, such as non-EHB maximizer programs have the potential to exacerbate racial and ethnic disparities in access to medications.² This data analysis shows that copay card use does not differ by the race and ethnicity of patients; however, the potential for a patient to be included in a maximizer program is much higher among non-White patients as opposed to White patients.³ Non-White patients are therefore more likely to be exposed to programs that do not count copay assistance toward their deductible or maximum out-of-pocket limit.⁴

In sum, in defining the scope of "prescription drug" as an essential health benefit, we ask the Department to deem all covered prescription drugs as essential in its EHB benchmark plan and require all state marketplace plans to follow the same standards. We appreciate your commitment to make positive impacts on Commonwealth residents enrolled in individual and small group health insurance plans. Please feel free to contact me at msprout@its.jnj.com or 717-603-2939 if there is any further information we can provide or if the Department has additional questions about the topics discussed in our comments.

¹ <https://www.jmcp.org/doi/full/10.18553/jmcp.2023.23021>

² <https://pubmed.ncbi.nlm.nih.gov/37548953/#:~:text=CONCLUSIONS%3A%20In%20an%20adjusted%20analysis,higher%20among%20non%2DWhite%20patients.>

³ <https://pubmed.ncbi.nlm.nih.gov/37548953/#:~:text=CONCLUSIONS%3A%20In%20an%20adjusted%20analysis,higher%20among%20non%2DWhite%20patients.>

⁴ <https://pubmed.ncbi.nlm.nih.gov/37548953/#:~:text=CONCLUSIONS%3A%20In%20an%20adjusted%20analysis,higher%20among%20non%2DWhite%20patients.>

Sincerely,

Meaghan Sprout

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Director, State Government Affairs
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