National Pharmaceutical Council

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July 25, 2023

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted electronically via: https://www.regulations.gov

RE: Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program (CMS-2434-P).

Dear Administrator Brooks-LaSure:

The National Pharmaceutical Council (NPC) appreciates the opportunity to submit comments regarding the Centers for Medicare & Medicaid Services (CMS) Notice, *"Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program (CMS-2434-P)."*

NPC is a health policy research organization dedicated to the advancement of good evidence and science and to fostering an environment in the United States that supports medical innovation. We have rich experience conducting research and disseminating information about the critical issues of evidence, innovation and the value of medicines for patients. Our research helps inform important healthcare policy debates and supports the achievement of the best patient outcomes.

We appreciate the opportunity to provide input on the Medicaid Drug Rebate Program (MDRP) proposed rule and provide recommendations as summarized below:

1. **Eliminate the proposed changes to the Best Price determination,** which require "stacking" of price concessions across supply chain entities in a manner that is both inconsistent with MDRP statute and operationally untenable.
2. **Withdraw the proposal for a manufacturer drug price verification survey**, which exceeds CMS's statutory authority for price verification surveys while presenting logistical and feasibility concerns for manufacturers and states and lacking transparency on the role of survey data in existing negotiation practices.
3. **Remove the unnecessary and limiting proposed definition of vaccine** that ignores the evolving scientific landscape of vaccines and places patient access to valuable innovation at risk.
4. **Evaluate the potential administrative burden on providers of requiring diagnosis codes on Medicaid prescriptions.**

1. **Eliminate the proposed changes to Best Price determination.**

CMS is proposing major changes to the calculation of Best Price, which is unambiguously defined in statute as the single "lowest price available from the manufacturer" "to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity."[1] Since the inception of the MDRP, price concessions have been aggregated only when extended to the same entity on the same unit of product,[2] consistent with the statutory definition; the price "available from" the manufacturer is that which the manufacturer has made available to a single purchaser. Requiring manufacturers to "stack" price concessions at the individual drug level, regardless of whether those concessions are received by multiple independent entities, represents a significant policy change inconsistent with statute.

The "Follow the Pill" approach proposed in the MDRP proposed rule would impose untenable operational challenges for manufacturers. Current government reporting systems do not track stacked price concessions based on the unit or the drug. Rather, prices are tracked by sale to a specific customer. Manufacturers lack visibility across all supply chain entities and channels, including, for example, discounts applied by wholesalers at the site of care and units billed under payer agreements. Tracking all discounts, rebates, and other price concessions at the unit or drug level across independent entities throughout the chain of purchase creates significant challenges for manufacturers to comply with these new Best Price reporting requirements. Similarly, the approach proposed by CMS could create legal challenges as much of the data necessary for tracking these sales is proprietary to downstream customers who may be unwilling to share such data with manufacturers.

Beyond presenting operational challenges, this significant alteration to the interpretation of MBP calculation introduces administrative burden and uncertainty that may place value-based purchasing (VBP) agreements at risk. Manufacturers participating in value-based arrangements are permitted to report varying best price points for a single dosage form and strength. NPC research has shown that the Best Price provision is a significant regulatory barrier for payers and manufacturers looking to implement value-based purchasing agreements, but that the policies allowing manufacturers to report multiple best prices has alleviated some of these concerns by reducing financial risk and rebate volatility.[3,4] Value-based purchasing agreements can expand Medicaid beneficiary access to innovative therapies while reducing costs, but the proposal to change the definition of Best Price increases administrative burden and potential for confusion and therefore may reduce participation in these agreements.

Finally, CMS is proposing to change the definition of Best Price when there is a pending cert petition in the *Sheldon v. Allergan* case. 24 F.4th 340 (4th Cir. 2022) (vacated en banc, petition for cert. pending).

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[1] Social Security Act § 1927(c)(1)(C)(i).

[2] Centers for Medicare and Medicaid Services. (2016) Covered Outpatient Drug Final Rule with Comment (CMS-2345-FC) Frequently Asked Questions. Available at: https://www.medicaid.gov/federal-policy-guidance/downloads/faq070616.pdf

[3] National Pharmaceutical Council. Regulatory Barriers Impair Alignment of Biopharmaceutical Price and Value. https://www.npcnow.org/sites/default/files/media/NPC_PriceBarriersWhitePaper_Final.pdf

[4] Casey Quinn, Michael Ciarametaro, Brian Sils, Sharon Phares & Mark R. Trusheim (2023) Value-based performance arrangements for chronic conditions: an economic simulation of Medicaid Drug Rebate Program reforms, Expert Review of Pharmacoeconomics & Outcomes Research, 23:5, 535-546, DOI: 10.1080/14737167.2023.2193331

Changing the definition of Best Price while litigation is ongoing will likely create confusion and excessive burden if definitions are changed and modified again. Given that the proposed changes to Best Price determination would be inconsistent with the statutory definition of Best Price, combined with the excessive operational burden, potential impact of uncertainty on VBPs, and ongoing litigation, NPC urges CMS to eliminate the proposed changes.

2. Withdraw the manufacturer drug price verification survey proposal.

In proposing to survey manufacturers and wholesalers regarding pricing-related information for select high-Medicaid-spend covered outpatient drugs (CODs), CMS exceeds its limited statutory authority to survey manufacturers for the purpose of price verification.[5] The proposed price verification survey requires manufacturers to provide extensive information unrelated to the verification of the accuracy of reported pricing data. These diverse data collection elements, ranging from pricing and utilization data to clinical information and costs of research and marketing, are in no way supported by existing statutory authority. Furthermore, while these survey elements are listed in the proposed rule, the proposal lacks transparency surrounding how the Agency will use this information or how it will impact state-level negotiations. Notably, manufacturers and states already engage robustly on rebates, and states often have drug utilization boards and processes in place.

The data elements proposed in the survey introduce a significant response burden. For example, responding to specific questions on research and development costs, unit costs, and market data with both accuracy and clarity requires extensive time for manufacturers. Historical development costs alone may easily date back two decades. Furthermore, variable approaches across the industry to characterizing the elements listed in the proposed survey impose a burden on states to assess and accommodate variation to avoid inappropriate comparisons during manufacturer discussions.

The proposed drug price verification survey exceeds CMS's limited statutory authority to survey manufacturers for the purpose of price verification and creates logistical and feasibility concerns while creating potential downstream effects delaying beneficiary access to medications. Accordingly, NPC urges CMS to withdraw its proposed drug price verification survey.

3. Remove the unnecessary and limiting proposed definition of vaccine that ignores the evolving scientific landscape of vaccines.

Vaccines have been excluded from the definition of COD[6] since the enactment of the rebate statute. In the MDRP proposed rule, CMS puts forth an unnecessary and limiting definition of vaccine: "a product that is administered prophylactically to induce active, antigen-specific immunity for the prevention of one or more specific infectious diseases and…included in a current or previous FDA published list of vaccines licensed for use in the United States." NPC is concerned that this definition of vaccine - a shift from a long-established understanding of what is considered a vaccine - is unnecessarily narrow. The definition excludes therapeutic vaccines developed through innovative and rapidly evolving science in

[5] Social Security Act §1927(b)(3)(B)
[6] 88 Fed. Reg. at 34,258.

disease states of significant public health concern, including cancer.[7,8] Furthermore, limiting the definition of vaccine to include only products for the prevention of infectious diseases ignores developing research towards vaccines in disease states like substance abuse[9] and autoimmune diseases.[10]

The exclusion of therapeutic vaccines, immunotherapies, and vaccines against conditions beyond infectious diseases from the vaccine definition – and thereby classifying them as covered outpatient drugs – sends a signal to manufacturers that innovative vaccine development beyond CMS's narrow definition is less valued, which may disincentivize drug development at the forefront of immune science. Further, innovative vaccines that are excluded from classification as a vaccine may be subjected to utilization management techniques employed by state Medicaid programs for CODs, negatively impacting patient access. NPC therefore urge CMS to remove the unnecessary and limiting definition of vaccine that ignores the evolving scientific landscape of vaccines.

4. **Evaluate the potential administrative burden on providers of requiring diagnosis codes on Medicaid prescriptions.**

The MDRP proposed rule includes a request for information on requiring the submission of diagnosis codes on Medicaid covered outpatient drug claims, a major change to well established prescribing practice. While NPC appreciates the value this data may provide in better understanding medication use, we encourage CMS to consider that the use of diagnosis codes on claims may create undue burden on providers and create operational challenges at the claims-review level. For example, pharmacies may not always have access to the diagnosis underlying routine prescriptions, which could create additional burden on pharmacy and physician office staff, resulting in delays for patients. Past literature suggests that prior authorizations and missing prescription information account for nearly half of all communications between pharmacies and physician offices.[11] In the same study, the elapsed time to clarify prescriptions was as high as two weeks, and nearly one in five (17%) prescription clarification cases were unresolved.[12] Given the substantial provider burden and logistical challenges associated with changing long-standing prescribing practice, NPC recommends CMS solicit and engage with key provider stakeholders to evaluate the potential administrative burden on providers of requiring diagnosis codes on Medicaid prescriptions.

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[7] Jou J, Harrington KJ, Zocca MB, Ehrnrooth E, Cohen EEW. The Changing Landscape of Therapeutic Cancer Vaccines-Novel Platforms and Neoantigen Identification. Clin Cancer Res. 2021 Feb 1;27(3):689-703.

[8] Morse, M.A., Gwin, W.R. & Mitchell, D.A. Vaccine Therapies for Cancer: Then and Now. Targ Oncol 16, 121–152 (2021). https://doi.org/10.1007/s11523-020-00788-w

[9] Heekin RD, Shorter D, Kosten TR. Current status and future prospects for the development of substance abuse vaccines. Expert Rev Vaccines. 2017 Nov;16(11):1067-1077.

[10] Zhang N, Nandakumar KS. Recent advances in the development of vaccines for chronic inflammatory autoimmune diseases. Vaccine. 2018 May 31;36(23):3208-3220.

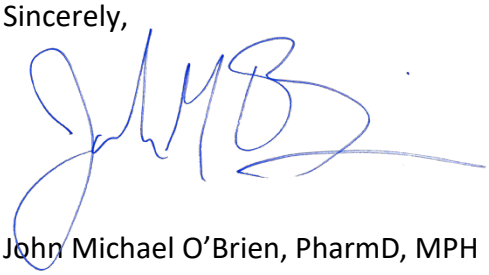
[11] Smith M, Sprecher B. Pharmacy communications with physician offices to clarify prescriptions. J Am Pharm Assoc (2003). 2017 Mar-Apr;57(2):178-182. doi: 10.1016/j.japh.2016.12.072

[12] Smith M, Sprecher B. Pharmacy communications with physician offices to clarify prescriptions. J Am Pharm Assoc (2003). 2017 Mar-Apr;57(2):178-182. doi: 10.1016/j.japh.2016.12.072

Conclusion

The National Pharmaceutical Council appreciates the opportunity to provide comments in response to the proposed rule and would be happy to meet to expand upon our comments and share our research. Please contact me at john.obrien@npcnow.org or (202) 827-2080 if we may provide any additional information.

Sincerely,



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