Johnson & Johnson
WORLDWIDE GOVERNMENT AFFAIRS & POLICY

BY ELECTRONIC SUBMISSION AT: http://www.regulations.gov

July 25, 2023

Daniel Tsai
Deputy Administrator and Director
Center for Medicaid and CHIP Services
Centers for Medicare & Medicaid Services
Attention: CMS–2434–P, Mail Stop C4–26–05
7500 Security Blvd
Baltimore, MD 21244

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

Dear Deputy Administrator Tsai:

Johnson & Johnson ("J&J") appreciates the opportunity to submit the following comments in response to the Misclassification of Drugs, Program Administration, and Program Integrity Updates Under the Medicaid Drug Rebate Program (herein referred to as the MDRP or *Program*) proposed rule published by Centers for Medicare & Medicaid Services (CMS) on May 26, 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 continue 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.

J&J is very concerned with the substantial changes CMS proposes to the MDRP, which would markedly alter longstanding definitions and program operations, significantly impacting manufacturers and reporting requirements under the Program.

J&J has long supported the CMS, state, and manufacturer partnership critical to ensuring the Program's success for the nearly 94 million Americans served by Medicaid and CHIP. We strongly value the Program and are proud to bring the best innovation life sciences offers to the millions of families, children, pregnant women, adults without children, seniors, and people

living with disabilities served by Medicaid. We also recognize that policies and Program operations may need to evolve to keep pace with the complex and dynamic US healthcare system. J&J welcomes the opportunity to engage with CMS to advance our shared goal of bringing world-class life sciences innovation to those most vulnerable populations while preserving affordability to the beneficiary and efficient Medicaid program operations.

J&J does not object to the purported objective of the proposed rule to enhance the MDRP integrity and improve Program administration through new policies that would assure greater consistency and accuracy of drug information reporting, strengthened data collection, and efficient operation of the MDRP. What we do have is significant concern that the policies advanced in this proposed rule upend well-established policies within the Program, severely risk the ability of life sciences companies to serve this critical population and fail to appreciate the importance of our critical partnership in collectively advancing the goals of the MDRP.

We therefore strongly recommend CMS withdraw the majority of this proposed rule and, in its place, directly seek stakeholder feedback, notably including that of manufacturers as the critical partner within the MDRP, so that we collectively may identify, analyze, and comprehensively respond to those most pressing needs of the Program.

In addition, please see our specific section-by-section recommendations below:

- **Maintain the current methodology for calculating Best Price:** The proposed regulatory change to require manufacturers to aggregate, or stack, price concessions across different best price eligible entities conflicts with the statute and defies both Congressional intent and Agency authority. (*Section II. D. Proposal to Account for Stacking When Determining Best Price*)
- **Maintain the current definition of *Covered Outpatient Drug*:** We urge CMS not to finalize the proposed expanded definition of "Covered Outpatient Drug" as it conflicts with the Medicaid Statute. (*Section II.C.1.a. Proposal to Modify the Definition of Covered Outpatient Drug*)
- **Withdraw the proposed open-ended definition of "*Drug Product Information*".** (*Section II.C.1.b. Proposal to Define Drug Product Information)*
- **Withdraw the proposal for a manufacturer drug price verification survey.** (*Section J. Proposal to Establish a Drug Price Verification Survey Process of Certain Reported CODs*)
- **The proposed misclassification notification and payment process require an error validation process before advancing a clock on a corrective action.** (*Section II.F.1.b. Manufacturer Payment of Unpaid Rebates Due to Misclassification*)
- **Withdraw the Proposed *"Manufacturer"* Definition:** CMS Lacks the authority to establish the proposed "Manufacturer" definition. *(Section II.C.1.d. Proposal to Revise Definition of Manufacturer for NDRA Compliance)*
- **Support CMS' proposed definition of *"Market Date."*** *(Section II.C.1.e. Proposal to Define Market Date)*
- **Support requirement for NDC numbers on COD and PAD claims and in MCO utilization data.** *(Section II.L. Federal Financial Participation (FFP): Conditions Relating to Physician Administered Drugs)*

- **Support proposals to increase Pharmacy Benefit Manager (PBM) transparency with Medicaid managed care plans.** *(Section II.B.2. Drug Cost Transparency in Medicaid Managed Care Contracts)*
- **Support proposal to include Medicaid identifiers on beneficiary identification cards.** *(Section II.B.1.BIN/PCN on Medicaid Managed Care Cards)*
- **CMS significantly underestimates burden associated with its proposals.** (*Section III.C. Summary of Proposed Burden Estimates*)

I. Maintain the current methodology for calculating Best Price: The Proposed Regulatory Change to Require Manufacturers to Aggregate, or Stack, Price Concessions Across Different Best Price Eligible Entities Conflicts with the Statute and Defies Both Congressional Intent Agency Authority. (S*ection II. D. Proposal to Account for Stacking When Determining Best Price*)

We have significant concerns with the proposed change to the regulatory definition of best price that would require manufacturers to aggregate, or stack, price concessions across all different best price eligible entities rather than to determine the best price to a single best price eligible entity. The proposed regulatory change does not align with Congressional intent, the clear statutory text, or the 30-year history, as demonstrated by CMS' own best price regulations, of how best price is to be determined. CMS' proposed definition of best price flouts the clear direction from Congress that best price should represent an actual net price to a single customer.

The Statutory Text, as Well as Congressional Intent, Clearly Defines the Definition of "Best Price"

Best Price was always designed to be an actual price available from the manufacturer to a best price eligible entity. This is plain from the legislative debate and conference surrounding the passage of the Program, and from the plain text of the statute that defines "best price" as the lowest price available from the manufacturer to any of the enumerated best price eligible entities[1]. In contrast, the proposed regulation purports to clarify that the determination of best price should be an aggregation of prices (inclusive of cumulative discounts and rebates) to different best price eligible entities, even when those separate discounts are not designed to flow through to a single best price eligible entity. The proposed change to the regulatory definition of best price departs from the statutory text and in essence would create a 'best price' that is a mathematical construct, i.e., not a 'price' that is available from the manufacturer to 'any' of the best price eligible entities. J&J is aligned with the Pharmaceutical Research and Manufacturers of America (PhRMA) and Biotechnology Innovation Organization (BIO) comments on this inconsistency of the proposed regulation with the Program statute, as well as the assertion that CMS lacks the authority to substantially change the definition of best price through regulation when the statutory definition is clear.

Congress made its intent clear when the Medicaid rebate statute was first implemented. Congress sought to assure the government would benefit from the best price in the commercial market, akin to a most-favored nations clause in a contractual arrangement to a commercial customer. Congress specifically stated that the purpose of the Medicaid rebate statute was to "give Medicaid the benefit of the Best Price for which a manufacturer sells a prescription drug to

any public or private purchaser" and that Medicaid "should have the benefit of the same discounts that other large public and private consumers enjoy."[1] The statutory language defining best price captures this point clearly; it specifically refers to the price available to any best price eligible entity. What CMS now proposes is a calculation that is not a price as contemplated by the statute but rather a construct summing discounts to various parties.

Relevant Regulatory History, including CMS' FAQs and a Public Presentation, Defies the Assertion that the New Proposed Definition of Best Price is a Clarification

Not only is the statutory text and expression of Congress' intent clear, but over the thirty-plus year history of the Program, CMS itself has conveyed its view that the best price is intended to reflect discounts/rebates conveyed to a single best price eligible entity with the qualification that when discounts or rebates are given to a customer, such as a PBM, that are designed to be passed on to a best price eligible entity, those cumulative discounts to the best price eligible entity must be aggregated or stacked. In the preamble to the 2016 Medicaid Covered Outpatient Drug final rule[2] CMS responded to numerous comments on this point. Specifically, CMS responded that:

- best price "include[s] all discounts that subsequently adjust the price available from the manufacturer;"
- best price "includes PBM rebates, discounts or other financial transactions, including their mail order purchase, where such rebates, discounts or price concessions are designed to adjust prices at the retail or provider level," and,
- "manufacturers must adjust the best price if cumulative discounts, rebates or other arrangements subsequently adjust the prices available from the manufacturer."

In each, CMS refers to prices available *from the manufacturer*, or prices *designed by the manufacturer to pass through to a best price eligible entity*.

CMS also stated that it was making 'no substantive changes . . . in this final rule regarding a manufacturer's treatment of financial transactions that subsequently adjust prices to best price-eligible entities."[3]

CMS' presentation to industry on February 10, 2016, and CMS' subsequent FAQs[4] aligned to this interpretation of Best Price. Over time, we, and presumably other manufacturers, have directly shared reasonable assumptions[5] with CMS that reflected practical examples of how and when stacking is and is not appropriate. At no time, including during the OIG reasonable assumptions assessment of the MDRP AMP and BP calculations, was there disagreement by the OIG or rebuttal by CMS with industry's reliance that stacking of discounts or rebates across different entities ***was not required***, with the limited exception of those circumstances where a rebate was given to Party A and designed to be passed on and adjust price to Party B, a different best price eligible entity.

[2] 81 Fed. Reg. 5253
[3] 81 Fed. Reg. 5253 (Feb 1, 2016)
[4] https://www.medicaid.gov/federal-policy-guidance/downloads/faq070616.pdf
[5] https://oig.hhs.gov/oei/reports/oei-12-17-00130.pdf

Reasonable Assumptions Must be Made by Manufacturers on When Discounts to One Entity are "Designed to adjust the price" to a Different Best Price Eligible Entity

Importantly, manufacturers regularly make reasonable assumptions to account for cumulative discounts to a single best price eligible customer, including those that may be designed to pass through other entities. In a 2018 OIG survey, most manufacturers confirmed that they make reasonable assumptions related to best price stacking. We believe it is appropriate for manufacturers to stack or accumulate discounts to best price eligible entities when those discounts *are designed to pass through* another entity as a discount to a specific best price eligible customer who realizes the total value of the accumulated discount. In the absence of perfect information in terms of which intermediaries may actually pass through discounts, how much is passed through, and to whom that discount may be passed through, CMS' proposed rule appears to make an *unreasonable* assumption that every discount offered to any entity is passed through to a single best price eligible entity. Not only does that position not comport with the statute, but it is demonstrably false in many instances.

The Impact of the Proposed Definitional Change Is Untenable

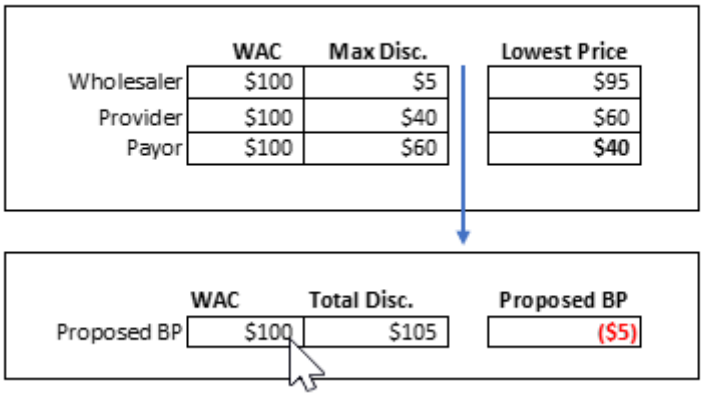
The proposed change to best price stacking treatment upends the last 30 years of historical interpretation, with the prior interpretations being consistent with the clear statutory text. CMS proposes a substantive and untenable change that could result in a best price in excess of 100 percent of WAC. It is unreasonable that a manufacturer would offer a price to any entity where a manufacturer would pay that entity to purchase its product.

To demonstrate our concerns, here is an example that assumes WAC for a product is $100. Suppose a manufacturer provides independent discounts to 3 separate best price eligible entities, as follows:

- $5 discount to a nationwide wholesaler to distribute the drug.
- $40 discount to one provider in California who dispenses the drug.
- $60 discount to a regional payor in New England (extended to a PBM and designed to be passed through to the payor)

In this example, based on the proposed rule, the total Best Price discount would be the sum of these maximum discounts by channel--total of-- $105 (wholesaler $5 + provider $40 + payor $60). But in reality, these are entirely separate transactions with entirely separate customers, and a practically zero chance that the product unit itself would encounter all three discounts.

The best price is negative $5 and is calculated as WAC $100 less $105 total discount.



As illustrated, vertically stacking discounts across all different best price eligible entities resulted in a negative best price, with the total discount exceeding 100% WAC, and we do not currently offer products at a negative price. In the example above, the lowest price from the manufacturer to an eligible best price entity is $40. The proposed best price of negative $5 is not a price available to any eligible best price entity. The illogical mathematic result is even more significant for a 5i AMP calculation method.

AMP calculation using the 5i method for those drugs "not generally dispensed through a retail community pharmacy" was finalized in the 2016 rule. 5i AMP calculations include all eligible price concessions in the market and represent an average price. Suppose discounts to different entities are also vertically stacked for purposes of the best price calculation. In that case, the Medicaid Base Rebate calculation effectively accounts for the eligible discounts twice—once as part of the average that represents the 5i AMP and once when subtracting the vertically stacked discounts. As illustrated below, this could routinely lead to a negative Medicaid Base Rebate (AMP – BP) or Base Medicaid Rebate that exceeds 100% AMP. And when the 5i AMP method of calculation is used, the proposed change to Best Price stacking requirements is particularly egregious.

	Medicaid Base Rebate (AMP-BP)				
Best Price	WAC	AMP	BP	Base Rebate	% AMP
Current Rule	100	60	$40	20	33%
Proposed Rule	100	60	($5)	65	108%

II. Covered Outpatient Drug (COD)

Maintain the current definition of *Covered Outpatient Drug*: We urge CMS not to finalize the proposed expanded *Definition of Covered Outpatient Drug* as it conflicts with the

Medicaid Statute (*Section II.C.1.a. Proposal to Modify the Definition of Covered Outpatient Drug*)

CODs are defined in section 1927 of the Social Security Act (SSA) to exclude "any drug, biological product, or insulin provided as part of, or as incident to and in" inpatient hospital services, outpatient hospital services, and other care settings."[6] Further, the statute continues "(and for which payment may be made under this title as part of payment for the following and not as direct reimbursement for the drug): (A) Inpatient hospital services, (B) Hospice services, (C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs, (D) Physicians' services, (E) Outpatient hospital services, (F) Nursing facility services and services provided by an intermediate care facility for the mentally retarded, (G) Other laboratory and x-ray services, (H) Renal dialysis."[7] For the past three decades, this definition has consistently excluded drugs delivered or administered as part of a bundle with other services and procedures, for example, within the inpatient Diagnosis Related Group (DRG) system and other healthcare settings. CMS has confirmed and reinforced this application historically.[8]

However, in this proposed rule, CMS inexplicably intends to disrupt this longstanding terminology and define "direct reimbursement for a drug" to include "both reimbursement for a drug alone, or reimbursement for a drug plus the service, *in one inclusive payment*, if the drug and the itemized cost of the drug are separately identified on the claim." CMS states that it is proposing this definition to provide clarity, but in fact, CMS' proposal represents a significant and concerning change to a definition that is foundational to the Program, which would broadly expand drugs that are subject to rebates beyond what is outlined in statute.

A drug that is provided as part of a bundled service is not separately reimbursed and, therefore, should not be included under the Program. Therefore, we urge CMS to maintain the existing definition of CODs and strongly recommend that CMS clarify its commitment to upholding the statute's intent, which outlines explicit exclusions for drugs provided and billed as part of other services.

III. Drug Product Information

Withdraw the Proposed Open-ended Definition for "*Drug Product Information"* (*Section II.C.1.b. Proposal to Define Drug Product Information)*

J&J is concerned with CMS' proposed definition for "drug product information" as "information that includes, but is not limited to, NDC number, drug name, units per package size (UPPS), drug category ("S," "I," "N"), unit type (for example, TAB, CAP, ML, EA), drug type (prescription, over-the-counter), base date AMP, therapeutic equivalent code (TEC), line extension drug indicator, 5i indicator and route of administration, if applicable, FDA approval date and application number or OTC monograph citation if applicable, market date, COD status,

[6] Social Security Act, §1927(k)(3) [42 U.S.C. 1396r–8]
[7] Social Security Act, §1927(k)(3) [42 U.S.C. 1396r–8]
[8] 77 FR 5322

and any other information deemed necessary by the Agency to perform accurate [unit rebate amount] URA calculations."

CMS' proposal to define drug product information to include "any other information deemed necessary by the Agency to perform accurate URA" does not provide manufacturers with the clarity and predictability needed to ensure accurate reporting and compliance. Including "any other information deemed necessary" contradicts the intent of establishing a uniform definition and leaves open the opportunity for inconsistent application year to year. CMS'CMS should remove this language from the proposed definition and define "Drug Product Information" with clear and reasonable data points.

We further oppose CMS' proposed inclusion of "drug product information" in its definition of "misclassification," in particular if the final definition of drug product information includes the objectionable language pertaining to "any other information deemed necessary." CMS should limit the definition of misclassification to encompass misclassifications within the drug category (innovator or non-innovator).

Finally, we question the intent and value of reporting the same data points listed in the proposed definition repeatedly. While J&J manually tracks most of the data outlined in CMS' proposed definition, we do not have a mechanism or ability to plan for reporting open-ended data. The inability to plan for potential data requests will put an unexpected and undue burden on manufacturers. Further, CMS needs to explain why it proposes imposing these new reporting requirements on manufacturers when the relevant information required to perform government pricing rebate determination is already available to and used by the Agency today to calculate URA. All attributes listed in the proposed definition are reported by the manufacturer when the product originates in the Program, following FDA approval, and before the first month's AMP submission, and these attributes are updated when there are changes. Therefore, CMS should not require regular reporting of these data points.

IV. Price Verification Survey

Withdraw the proposal for a manufacturer drug price verification survey. (*Section J. Proposal to Establish a Drug Price Verification Survey Process of Certain Reported CODs*)

J&J is very concerned with CMS' proposal to establish a drug price "verification" process for certain reported CODs among manufacturers and wholesalers through a new "survey". Section 1927(b)(3)(B) of the Social Security Act (the Act) states "[t]he Secretary may survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary, to verify manufacturer prices and manufacturer's average sales prices (including wholesale acquisition costs) if required to make payment reported under subparagraph (A)."[9] In the proposed rule, CMS states that its primary intention is assurance that Medicaid payments are simultaneously "economical and efficient, as well as sufficient to provide access to care by helping states negotiate supplemental and/or value-based rebates for these drugs"[10,11] CMS

[9] Social Security Act §1927(b)(3)(B)
[10] 88 Fed. Reg. 34268 (May 26, 2023)
[11] 88 Fed. Reg. 34271 (May 26, 2023)

further states that in establishing this survey, it will be able to "verify manufacturer prices and manufacturer's average sales price (including wholesale acquisition costs)" not to "limit or deny access to any of the CODs included on the survey list, assess cost effectiveness of such drugs, or supplant findings from the applicable FDA approval process."[12]

Despite its stated intention and aim in proposing this survey, CMS fundamentally exceeds its authority, fails to adequately define the challenge for which the survey is aiming to remedy, emulates concerning approaches to "negotiate" drug prices as seen in other programs, places an overemphasis on transformative therapies and cell and gene therapies, and poorly defines and protects proprietary and confidential information. As such, we strongly urge CMS to withdraw this proposed survey.

The price verification survey exceeds CMS' authority

The proposed survey and the extent of requested data exceeds CMS' legal authority and should be withdrawn entirely. CMS claims its authority to propose and carry out this survey is outlined within Sections 1927(b)(3)(B) and 1902(a)(30)(A) of the SSA. The Agency further states that its intention in conducting this Survey is to verify manufacturer prices and information and notes that among the types of pricing data within its authority to collect are a manufacturer's "AMP [average manufacturer price], best price, average sales price (ASP), and in certain cases wholesale acquisition cost (WAC) for a drug".[13] However, the Agency proposes to collect information such as pricing, charges, and utilization; the product's clinical information, benefits, and risks; information of production, research, and marketing; and finally, a broadly defined category for other information that the Secretary would determine specific to the COD; such requests for data exceeds the statutory allowance of "manufacturer prices reported under subparagraph (A)"

As proposed, this degree of information is not needed, nor authorized, for *verifying* a COD's price as this data has no bearing or clear connection in assisting the Agency to verify prices. Instead, the data seeking to be collected from manufacturers would enable CMS to assess selected CODs and gather additional information for negotiation and justification, well beyond CMS' authority as described in either Section 1927(b)(3)(B) or 1902(a)(30)(A) and stated intention within the proposed rule.

The purpose of the proposed survey remains unclear and unjustified

At present and as outlined in the proposed rule, it is unclear what the purported problem CMS is seeking to solve with this Survey and why it is *necessary*, as required by §1927(b)(3)(B) of the SSA. The proposed rule makes a brief mention of issues related to the limited nature of centrally located information available to CMS on CODs purchasing and reimbursement and notes other goals related to rebates. The justification presented in the proposed rule hardly demonstrates the necessary nature of conducting a survey and thus fails to meet additional statutory standards.

[12] 88 Fed. Reg. 34268 (May 26, 2023)
[13] 88 Fed. Reg. 34244 (May 26, 2023)

Further, the additional information, as outlined here, is unnecessary for Medicaid reimbursement and the functioning of the MDRP. As such, the value of establishing a new Survey appears to be nominal, particularly when existing parameters utilized by manufacturer government price reporting are clear and well-adopted. Within current law and the existing State Medicaid program, CMS has effectively worked with manufacturers to ensure accuracy in reported prices and determine Medicaid beneficiary access through efforts like the National Average Drug Acquisition Cost. In introducing new initiatives, such as the Survey, CMS risks disrupting already well-established practices and functioning program, adding unnecessary burden to manufacturers that wish to be good partners to CMS, and collecting information that the Agency is not adequately equipped to consider.

The proposed survey adopts concerning data collection approaches to "negotiation"

In line with the Agency's clear overstep of its authority, this survey seeks to collect sweeping and broadly defined data elements from manufacturers that adopt concerning approaches to negotiation within the MDRP. Similar to the Agency's approach in implementing the Medicare Drug Price Negotiation Program, the Agency adopts data collection practices that are poorly defined, misaligned with typical business practices, and unfeasible in their reporting. This approach erodes predictability and the well-functioning nature of the MDRP, risking fair and appropriate Medicaid beneficiary access.

The survey's intention to verify prices for novel therapies is unclear and poorly defined

We are also concerned that the survey approach appears to focus on novel, transformative therapies such as cell and gene therapies. For instance, CMS proposed to extend the survey to target drugs approved under the accelerated approval pathway. Among the proposed CODs selected, CMS suggests including CODs with treatment costs greater than $500,000, which overwhelmingly targets novel cell and gene therapies. Further, CMS notes that recent distribution model arrangements that have recently emerged with specialty cell and gene therapy drugs are unique and did not exist at the inception of the Program, thus warranting the need to be included in the proposed survey.

Considering the rapidly evolving nature of available transformative medicines, such as cell and gene therapies, we understand and appreciate the Agency's desire to gather new information, experiences, and data on this topic. However, the proposed survey does not appropriately do this. Instead, we encourage the Agency first to delineate a clear set of questions it seeks to answer and engage with the appropriate stakeholders to learn more about this frontier of medicines. In doing so, we believe CMS will be in a stronger position to more accurately and appropriately consider the range of reforms needed to ensure appropriate Medicaid beneficiary access and maintain program integrity within the Agency's authority.

Proprietary information and confidentiality standards need to be more adequately defined

We are also concerned that CMS seeks to make public information collected in the survey. While the Agency states that proprietary information would not be made available, the Agency fails to clarify what information would be considered proprietary and how such a determination would

be achieved. We strongly recommend that CMS allow manufacturers to mark proprietary information that should not be released to the public.

V. Misclassification

The Proposed Misclassification Notification and Payment Processes Require an Error Validation Process, Before Advancing a Clock on a Corrective Action. (*Section II.F.1.b. Manufacturer Payment of Unpaid Rebates Due to Misclassification*)

CMS proposes a process for when the Agency determines there is a misclassification, under which the Agency sends a written and electronic notification to the manufacturer that misclassified a drug of such misclassification and any past rebates due. Under this process, CMS proposes that the manufacturer would have 30 calendar days from the date of the notification to submit the product and pricing information necessary to correct the misclassification or the incorrect product information and re-calculate the accurate rebate obligations. J&J is concerned that there is limited opportunity for manufacturer engagement in this process and, specifically, that the proposed process does not allow the manufacturer to confirm or verify CMS determinations of a misclassification. Therefore, we urge CMS to recommend a process by which manufacturers are afforded the opportunity to investigate and validate suspected misclassifications with the Agency before the start of the corrective action. Specifically, we recommend that the 30-day correction period start once the manufacturer has validated with the Agency that a correction is needed.

Similarly, CMS proposes to require manufacturers within 60 calendar days of the date the notice is sent to pay rebates from misclassifications to the respective state(s)and provide documentation to the Agency that all past due rebates have been paid. J&J again asks the Agency to provide manufacturers with the opportunity to verify and align with CMS determinations. We ask CMS to start the 60-day timeframe when the URA is updated in the MDP system.

VI. Definition of Manufacturer

Withdraw the Proposed "Manufacturer" Definition; CMS Lacks the Authority to Establish the Proposed "Manufacturer" Definition *(Section II.C.1.d. Proposal to Revise Definition of Manufacturer for NDRA Compliance)*

J&J is aligned with the comments submitted by PhRMA, expressing our shared position that CMS' proposed definition for the manufacturer is overly broad, particularly in its inclusion of "all associated entities." The proposed definition far exceeds the definition established in the statute[14] and is unworkable. We request that CMS withdraw this proposal.

VII. J&J supports the following proposals

Support CMS' Proposed Definition for Market Date *(Section II.C.1.e. Proposal to Define Market Date)*

[14] https://www.ssa.gov/OP_Home/ssact/title19/1927.htm#:~:text=(5-,),-Manufacturer.%E2%80%94The

CMS is proposing that for purposes of determining the base date AMP quarter and base date AMP, to define "market date" based on "the earliest date on which the drug was first sold, by any manufacturer, under any NDC," and be based on the first sale of the drug, rather than the date the drug was first available for sale. This proposed definition provides additional clarity compared to using the date the drug was first available for sale and minimizes the need for manufacturers to make reasonable assumptions regarding the market date used to calculate AMP, for example, when there are no sales in a given quarter. CMS is requesting comments on how to define "sold" for this definition. J&J suggests that CMS define "sold" based on the customer invoice date, as this definition would provide finality and clarity.

Support Requirement for NDC numbers on COD and PAD Claims and in MCO Utilization Data *(Section II.L. Federal Financial Participation (FFP): Conditions Relating to Physician Administered Drugs)*

J&J agrees with CMS' proposal for states to require providers to submit claims for all covered outpatient drug single source and multisource physician-administered drugs using NDC numbers to collect FFP and secure rebates and for managed care plans to report utilization data using NDC numbers. HCPCS codes are not specific enough to identify the manufacturer, whereas NCD numbers identify the specific manufacturer, product, and package size. This level of detail is needed for states to bill for rebates and manufacturer verification processes accurately, and we support the inclusion. While aligned with the proposal, we ask CMS to consider a glide path toward adoption to account for the provider burden.

Support Proposals to Increase Pharmacy Benefit Manager (PBM) Transparency with Medicaid Managed Care Plans *(Section II.B.2. Drug Cost Transparency in Medicaid Managed Care Contracts)*

J&J supports CMS' proposal to improve transparency in Medicaid Managed Care by requiring Medicaid managed care organizations (MCOs) to require subcontractors, including PBMs, to provide additional claims level detail and to itemize claims. Specifically, the proposal is seeking to reduce or limit 'spread pricing," whereby subcontractors, including PBMs, retain the difference between what is paid by the Medicaid MCOs to the PBM, and the price ultimately paid by the PBM to the provider for the cost of dispensing the drug. We believe increased transparency, including itemized claims, will help reduce the practice of spread pricing and result in cost savings for the Medicaid program.

Support Proposal to Include Medicaid Identifiers on Beneficiary Identification Cards *(Section II.B.1.BIN/PCN on Medicaid Managed Care Cards)*

We support CMS' proposal to require States that contract with Medicaid MCOs, prepaid inpatient health plans (PIHPs), or prepaid ambulatory health plans (PAHPs) that provide coverage of CODs to require those managed care plans to include unique Medicaid-specific BIN, PCN (Beneficiary Identification Number and Processor Control Number), and group number identifiers on all Medicaid managed care beneficiary identification cards for pharmacy benefits. Doing so will enable pharmacies to more easily identify beneficiaries enrolled in MCOs and help to avoid erroneous duplicate discounts, which often occur when a claim is not identified as a

340B claim prior to being sent to the State. Including unique Medicaid BIN / PCN / group numbers on ID cards is a step toward reducing these inappropriate and erroneous duplicate discounts. However, inclusion on the ID cards alone is insufficient if pharmacies are not required to input the information provided into their systems. Therefore, in addition to asking CMS to provide visibility to this information to states and manufacturers, we further suggest that CMS reject claims that do not include the appropriate identifier and consider other ways to educate and require pharmacies to record the ID numbers included on cards.

VII. Regulatory Burden

CMS Significantly Underestimates Burden Associated with its Proposals (*Section III.C. Summary of Proposed Burden Estimates*)

In addition to our points above, J&J is concerned by the significant underestimation of the burden associated with the proposed rule. Specifically, the proposed definition of "drug product information" imposes a significant burden for new monthly reporting requirements on numerous new data points, and the proposed open-ended definition for "drug product information," which includes "any other information deemed necessary," creates an unmeasurable burden. As defined, manufacturers would be unable to predict what information will be required and, therefore, unable to develop and implement a sustainable, repeatable process for reporting undefined drug product information. As a result, any new data requests required under this proposed open-ended definition would be very burdensome to manufacturers.

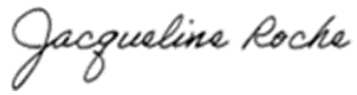
In addition, about the ICRs Regarding Definitions (447.502), we do not agree with the Agency that the newly introduced terms and definition modifications and clarifications would not require any effort or impose a burden on public or private entities. As described above, such changes would, indeed, result in a significant burden on the manufacturer and thus are subject to the requirements of the PRA.

Similarly, in response to ICRs Regarding the Verification Survey of Reported CODs through Data Collection (447.510), the proposed verification survey would result in a significant burden. The Agency has not finalized content requirements for the survey, so the suggested five-hour estimate, already woefully underestimated, is based on a proposal that is not established, with an unclear rationale for collecting additional data beyond the current manufacturer requirements within the Program.

Conclusion

Thank you for the opportunity to comment on the CMS Notice of Proposed Rulemaking: Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program (CMS-2434-P). Should you have any questions regarding J&J comments, please do not hesitate to contact me at jroche8@its.jnj.com.

Sincerely,



Jacqueline Roche, DrPH
Head Payment and Delivery Policy & Global Policy Institute
Johnson & Johnson Worldwide Government Affairs & Policy