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Via Electronic Filing

July 25, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services
Attention: CMS–2434–P
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 Administrator Brooks-LaSure:

The Biotechnology Innovation Organization (BIO) appreciates 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)*.[1] We oppose the major provisions of this proposed rule because they would have a detrimental impact on patients, the commercial marketplace, and the Medicaid program.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than thirty other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In these ways, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO membership includes biologics and vaccine manufacturers and developers, which have worked closely with stakeholders across the spectrum, including the public

[1] 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)*, Federal Register, May 26, 2023, Vol. 88, pg. 34238-34291.

health and advocacy communities, to support policies that help ensure access to innovative and life-saving medicines and vaccines for all individuals.

General Comments

As we detail in our comments that follow, we strongly oppose the major provisions of this proposed rule. We have significant concerns that CMS is seeking to take action in areas in which it does not have the statutory authority to implement the proposed changes — particularly regarding stacking of discounts for calculation of Best Price and conducting a survey to verify pricing metrics. In many instances, CMS claims to justify this statutory overreach as making mere "clarifications." In fact, the agency is proposing to unilaterally upend more than thirty years of historical precedent in implementing the Medicaid Drug Rebate Program (MDRP).

As CMS has recognized,[2] the Medicaid rebate provisions of §1927 of the Social Security Act represent a carefully balanced compromise ("grand bargain") made by Congress to ensure the government has access to the lowest available price for covered outpatient prescription medicines – via a statutorily mandated rebate – while also ensuring that manufacturers' products are accessible to Medicaid recipients where medically necessary. The Medicaid program is guaranteed a manufacturer's "Best Price," as defined in statute. In addition, Medicaid receives an inflationary rebate to protect states from price increases that rise above the consumer price index. Moreover, states can negotiate rebates higher than what is statutorily mandated through supplemental rebates. BIO is concerned that this proposed rule purports to reinterpret the "grand bargain" in ways that are contrary to the statute and threaten to upend the entire program.

In addition, we have significant concerns regarding CMS's underestimation of the negative impact its proposed policies would have on patient access and the commercial market, as well as the significant burden placed upon states, manufacturers, and the Agency to implement the myriad proposed changes. Manufacturers are already subject to significant reporting requirements under Section 1927. The price verification survey would not only add to those burdens, but also impose significant financial costs. Likewise, there would be a substantial burden placed upon states, as well as the agency itself.

Moreover, we are concerned that CMS has not taken into consideration the full impact that these proposed changes would have on other federal programs, particularly the 340B Drug Discount Program. The 340B program continues to grow unchecked to the benefit of hospitals over patients, and the changes proposed by

[2] CMS MassHealth Demonstration Amendment Approval letter to Asst. Secretary Tsai, MassHealth, June 27, 2018. Accessed: July 10, 2023. https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ma/MassHealth/ma-masshealth-demo-amndmnt-appvl-jun-2018.pdf

CMS could exacerbate this inappropriate growth through expansion of the price concessions reflected in the Best Price calculation, as well as add confusion regarding the definition of "covered outpatient drug" between the two programs. In the end, providers would benefit, while they are not helping patients in the way the program intended. DSH hospitals now account for more than 80% of 340B sales.[3] While the number of 340B DSH hospitals have exploded in growth, they have been providing less charity care. Studies show a large majority (nearly two-thirds) of 340B DSH hospitals (63%) provide charity care at a level less than the national average of all hospitals.[4] Further "nearly one-third (29%) of 340B DSH hospitals provide charity care that represents less than 1% of their total patient costs."[5] Indeed, a recent analysis of hospitals receiving at least $50 million in CMS's proposed 340B remedy payments only dedicated an estimated 1.33% of their operating costs to uncompensated care.[6] Further, abuses by 340B hospitals are hurting patients in other ways as outlined below. CMS policies should not be emboldening these covered entities in ways that increase health care costs and out-of-pocket expenses for patients.

Further, CMS seriously underestimates the regulatory impact upon manufacturers. The lack of consideration given to the pharmaceutical supply chain and the inability of manufacturers to "follow the pill," as well as the discounts, would present significant operational difficulties throughout the supply chain.

Stacking of Cumulative Discounts in Calculation of Best Price—§ 447.505

CMS is proposing to require that discounts to distinct entities on a single unit be stacked for Best Price calculation purposes. This is a patently unlawful reinterpretation of the definition of Best Price and a marked departure from policy that has existed for more than 30 years. This is ***not*** a "clarification" as CMS asserts. We believe that this proposal runs counter to the statutory authority and intent of Best Price, is operationally infeasible, and creates misalignment with the commercial market, which will have a negative impact on patients. We therefore strongly oppose this policy change.

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[3] MedPAC. Overview of the 340B Drug Pricing Program. May 2015. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf (Accessed: April 25, 2023)

[4] "Left Behind: An Analysis of Charity Care Provided by hospitals enrolled in the 340B Discount Program," Air340B, November 2019. https://340breform.org/wp-content/uploads/2021/04/AIR340_LeftBehind-v6.pdf (Accessed: April 25, 2023)

[5] Ibid.

[6] Kacik, Alex, & Broderick, Tim, "Biggest 340B benefactors provide relatively less uncompensated care," *Modern Healthcare,* July 24, 2023.

The Medicaid statute plainly defines Best Price as "the lowest price available from the manufacturer during the rebate period to ***any***" Best Price eligible entity.[7] In other words, Best Price reflects the price concessions realized by a *particular* Best Price eligible entity, not the sum of all price concessions realized by *all* such entities. The current long-standing regulations reflect this reading. This means that "stacking" or aggregating discounts, is currently required only when the discounts are offered to the same entity. CMS now proposes to "stack" cumulative "discounts, rebates or other arrangements provided to different Best Price eligible entities," essentially aggregating the discounts of distinct entities in the supply chain. But no entity in fact would have realized all such price concessions.

- For example, if distinct entities were to receive discounts or rebates as follows: 15% for a wholesaler, 20% for a pharmaceutical benefit manager (PBM), and 5% for a pharmacy, the proposal would generate what appears to be a 40% discount; however, none of the entities would have received any such discount.

This proposal flatly contradicts the plain terms of the statute.

In addition to this fundamental legal concern, the proposal presents significant operational and policy concerns. It is not possible for a manufacturer to follow each unit of a covered outpatient drug (COD) through each transaction by each entity in the pharmaceutical supply chain in order to implement the proposed stacking approach. And, even if a manufacturer were able to track each unit, the proposal would severely restrict the marketplace-based tools that manufacturers can employ to help ensure appropriate access by patients to needed therapies, threatening such access.

CMS lacks statutory authority to require "stacking" across distinct entities for purposes of reporting Best Price; Unlike AMP, Best Price is a single price made available to a particular Best Price-eligible entity

We do not agree with CMS that the relevant statutory provision in section 1927(c)(1)(C) of the Act, supports CMS's proposed requirement that manufacturers implement a "stacking" methodology for purposes of reporting Medicaid Best Price. Citing the Fourth Circuit's decision in *United States ex rel. Sheldon v. Allergan Sales, LLC*, which held that Allergan's failure to aggregate discounts provided to separate customers for purposes of determining Best Price was not unlawful due to the lack of "authoritative guidance" from CMS on the issue, CMS is proposing to reverse 30 years of precedent and revise 42 C.F.R. § 447.505(d)(3) to require manufacturers to "stack" price concessions across distinct entities.[8] In support of its

[7] SSA § 1927I(1)(C)(i) (emphasis added).
[8] 88 Fed. Reg. at 34,260.

proposed purported "clarification," CMS asserts that such "stacking" of price concessions in the context of Best Price follows from the requirement that manufacturers take into account rebates "for multiple entities ***when calculating AMP***."[9] According to CMS, for "logical reasons," Best Price should reflect the "stacking" of price concessions across distinct entities "since including them in AMP and not accounting for them in Best Price could result in AMP being lower than Best Price."[10] CMS's logic founders under even a cursory examination of the statute. By its nature, AMP reflects an average, and thus necessarily requires an aggregation of pricing across the market. In contrast, Best Price is statutorily defined by reference to a single price available to a particular entity. This reading was affirmed by the District Court, and upheld by the Fourth Circuit,[11] that the "'plain and natural reading' of the Rebate Statute means that Best Price entails 'the lowest price available by the manufacturer, including all price concessions, to any one of the listed entities, but not to multiple entities.'"[12]

Further, CMS's invocation of AMP does not, in fact, support CMS's conclusion that it "logically" follows that "stacking" rebates across distinct entities is appropriate for Best Price. If anything, the opposite is true. CMS's reasoning draws a false connection between AMP and Best Price and suggests that an AMP lower than the Best Price would be "illogical." This reasoning conflates two pricing benchmarks that are decidedly distinct both in nature and in purpose.

Unlike AMP, the MDRP statute unambiguously defines "Best Price" in relevant part as the single lowest price available "from the manufacturer" "to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity."[13] The price "available from" the manufacturer is the price the manufacturer made available "to [a]" specific ***purchaser***. Best Price is not defined to reflect the lowest amount realized by the ***manufacturer*** for a given unit of a drug, taking into account all discounts to all entities along the supply chain. Had Congress intended such a result, it would have defined the term "Best Price" to be the single lowest price "realized by" or "paid to" (rather than "available from") the manufacturer. Indeed, that is the approach Congress took with respect to AMP, which is defined as "the average price ***paid to*** the manufacturer for the drug in the United States."[14] That is, while Congress clearly knew how to define a drug manufacturer's price reporting obligations by reference to the total price paid "to the manufacturer," it defined Best Price as the lowest price available "from the manufacturer" to "any" individual customer (where the list of customers employs

[9] 88 Fed. Reg. at 34,260 (emphasis added).
[10] Ibid.
[11] The US Supreme Court has since vacated and remanded the case for reconsideration on other grounds. Our reference regarding the stacking and the Best Price definition refers to the historical record.
[12] *United States ex rel. Sheldon v. Allergan Sales, LLC*., No. 20-2330 (4th Cir. Jan. 25, 2022).
[13] SSA § 1927(c)(1)(C)(i).
[14] SSA § 1927(k)(1)(A) (emphasis added).

the disjunctive "or"). Given the stark difference in the language between these two definitions, Congress clearly intended for the terms to have different meanings.

The legislative history of the MDRP statute supports the view that Best Price is a single price made available by the manufacturer to a single customer. In enacting the MDRP, Congress explained that "Medicaid, the means-tested entitlement program that purchases basic health care for the poor, should have the benefit of the same discounts on single source drugs that other large public and private consumers enjoy."[15] The purpose of the Medicaid Rebate Statute thus was to "give Medicaid the benefit of ***the Best Price for which a manufacturer sells a prescription drug to any public or private purchaser***."[16] Therefore, the purpose of the MDRP is to ensure that Medicaid is treated on par with the manufacturer's most favored commercial customer, not to advantage Medicaid over all commercial customers. In other words, the Medicaid grand bargain as referenced earlier, was meant to ensure state Medicaid programs enjoy parity with the commercial marketplace, not a windfall relative to the commercial market.

Thus, CMS's characterization of its proposed regulatory change as a "clarifying" amendment[17] is incorrect. CMS's proposed mandated stacking for purposes of determining Best Price represents a significant policy change after more than 30 years. CMS lacks the statutory authority to adopt the proposed stacking policy.

CMS's proposed "stacking" policy is operationally infeasible

Due to the complexity of the pharmaceutical supply chain, manufacturers do not have visibility to track a single unit through the various channels. After the unit is sold to a wholesaler, a manufacturer cannot meaningfully track which set of discounts are applied to which unit as the distribution to the site of care is not managed by the manufacturer but rather by the wholesaler. In addition, manufacturers do not have sufficient data to determine whether specific units subject to payer agreements were also subject to provider discounts as the manufacturer does not control the dispensing of product to the patient. Indeed, tracking such information would likely place a significant burden on other entities in the supply chain, as well as require these entities to divulge their own proprietary data, and possibly even protected health information (PHI).

Further, CMS's proposal assumes that, beyond having visibility into which set of discounts were realized on each unit, manufacturers have visibility into how those discounts were allocated by the customer to determine whether those discounts "adjust the prices available" to another customer. This fundamentally

[15] H.R. Rep. No. 101-881 (1990), reprinted in 1990 U.S.C.C.A.N. 2017, 2108.
[16] Ibid. (emphasis added).
[17] 88 *Federal Register* 34,260.

misunderstands the role of the manufacturer in the pharmaceutical supply chain and places inappropriate reporting requirements on the manufacturer given that downstream customers are generally unwilling and, in any event, similarly unable to provide supporting detail to allow for such "stacking" methodology. Thus, manufacturers would be put in the precarious position of being required to certify their Best Price submissions without having access to the data necessary to validate such submissions.

CMS's proposed "stacking" policy does not reflect the complexities of the commercial marketplace

As discussed above, manufacturer systems do not allow meaningful visibility to track discounts across distinct entities and contracts in the distribution channel on a given unit; therefore, manufacturers would be required to make significant assumptions to comply with CMS's proposal. CMS's proposal does not address the intent of commercial contracting strategies to avoid duplicate discounts. For example, many payer discounts are intended to apply only to the retail segment, such that units invoiced under a retail benefit are not intended to have already been subject to inpatient or outpatient discounts. ***Inadvertent*** duplicate discounts should not be considered in a "stacked" Best Price calculation. The Proposed Rule lacks sufficient details regarding the operationalization for manufacturers, as well as the various supply chain entities.

CMS's proposed policy could have grave consequences for patients

There would be grave negative consequences for patients as a result of this proposal. While it is impossible to predict the actions of individual manufacturers, if the proposal were finalized, some manufacturers might withdraw many price concessions from the market, which we understand is not CMS's intent. Implementing such policies could compromise the use of price concessions to reduce barriers to patient access. To further illustrate this point, this stacking proposal would have a dramatic impact on the 340B Drug Discount Program. Under the proposed policy, the inextricable link between Best Price and the 340B Ceiling Price would result in drastic inflation of the value of price concessions in the 340B Program. The 340B Program is already on track to become the largest federal drug program because of well-documented ongoing abuses thereunder. Some examples of such abuses are:

- As highlighted in the *New York Times*, Ben Secours Mercy Health (Mercy) in Richmond, Virginia opened new clinics in suburban more affluent areas with the 340B profits from Richmond Community Hospital, which serves a predominantly Black neighborhood. Mercy had slashed services at Richmond Community Hospital, leaving it with a

radiology unit in disrepair and closing its intensive care unit. The hospital exists today with a mere emergency room and a psychiatric ward. Yet, Richmond Community Hospital has the highest profit margins of any hospital in Virginia generating as much $100 million per year because of its 340B purchases. Unfortunately, while services have been cutback in a community that sorely needs it, Mercy has used that money to open nine off-site clinics in wealthier parts of Richmond since 2013.[18]

- *The Wall Street Journal* reported that The Cleveland Clinic, in Cleveland, Ohio, adopted the 340B program in April 2020. While the hospital's main campus is in a medically underserved area, it has hundreds of off-site clinics in wealthier areas with more private health insurance. The hospital's 340B profits for the three quarters it participated in 2020 were a staggering $136 million.[19]

Financial incentives have caused trends in which newly registered 340B DSH hospitals and clinics, beginning in 2004, have tended to be in higher-income communities compared to hospitals that joined the 340B program earlier.[20] These locations are more affluent areas, and the patients tend to be more fully insured than in other areas, further exacerbating health inequities. This runs counter to the original intent of the 340B Program itself. The 340B Program should be reserved for true safety-net providers and the medically underserved patients they treat.

These trends also appear to be leading hospitals to steer patients toward more expensive drugs. The GAO found, "on average, beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other hospitals in GAO's analysis. For example, in 2012, average per beneficiary spending at 340B DSH hospitals was $144, compared to approximately $60 at non-340B hospitals. The differences did not appear to be explained by the hospital characteristics GAO examined or patients' health status."[21] This stacking policy could exacerbate this problem, ultimately resulting in an increase in health care expenses and out-of-pocket costs for patients not on Medicaid.

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[18] Thomas, Katie, and Silver-Greenberg, Jessica, "Profits Over Patients: How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits," *New York Times*, September 27, 2022. https://www.nytimes.com/2022/09/24/health/bon-secours-mercy-health-profit-poor-neighborhood.html?smid=tw-share (Accessed: April 25, 2023)

[19] Mathews, Anna Wilde, et al., "Many Hospitals Get Big Drug Discounts. That Doesn't Mean Markdowns for Patients.," *Wall Street Journal*, December 20, 2022. https://www.wsj.com/articles/340b-drug-discounts-hospitals-low-income-federal-program-11671553899 (Accessed: April 26, 2023)

[20] Conti RM, Bach PB. The 340B drug discount program: hospitals generate profits by expanding to reach more affluent communities. *Health Affairs, 2014*. https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.0540 (Accessed: April 25, 2023)

[21] "Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals" U.S. Government Accountability Office, June 2015. https://www.gao.gov/assets/gao-15-442.pdf (Accessed: April 25, 2023)

According to a study by the Community Oncology Alliance, "340B hospitals' own self-reported pricing data reveals that they price the top oncology drugs at 4.9 times their 340B acquisition costs, assuming a 34.7 percent discount, which is a conservative estimate based on 340B hospital survey data collected by the Centers for Medicare & Medicaid Services (CMS)."[22] It follows that there is an increase in out-of-pocket costs because patient cost-sharing is based on the amount the off-site clinic and hospital are reimbursed for the drug, not the amount they paid. This is supported by additional study results that indicate that hospital 340B participation increases cost-sharing amounts billed to Medicare beneficiaries by 16.79%.[23]

This stacking policy may increase the incentive for those 340B covered entities to exploit the 340B Program. It might also result in significant shifts in the marketplace resulting in a reduction in discounts in the drug supply chain that help reduce barriers to patient access and reduce egregious and devastating utilization controls. For example, payers would increase the use of prior authorization or step therapy.

Verification Survey of Reported Covered Outpatient Drug Pricing—§447.510

Blatant Overreach of CMS's Limited Legal Authority

BIO has several serious concerns regarding the proposal to survey and post publicly a host of information related to CODs. First, we believe this proposal is a blatant overreach of the agency's limited legal authority to "verify" the Average Manufacturer Price (AMP) and Best Price.

The authority to "verify" prices under Section 1927 is expressly limited. Section 1927(b)(3)(B) provides a very specific and very narrow grant of authority for the Secretary to survey manufacturers to ". . .verify manufacturer prices . . . reported under subparagraph (A)." CMS's proposal misconstrues the breadth of the survey authority in Section 1927, overreading this narrow grant of authority to purport to justify its aspirational ability to collect information, much of which is confidential, that cannot possibly address the stated goal of "verifying" prices. This reading is inconsistent with the terms of the statutory survey authority and with the broader context of Section 1927(b)(3) generally. Subsection (b)(3)(A) instructs

[22] "Examining Hospital Price Transparency, Drug Profits, and the 340B Program 2022," Community Oncology Alliance, September 12, 2022. https://mycoa.communityoncology.org/education-publications/studies/examining-hospital-price-transparency-drug-profits-and-the-340b-program-2022 (Accessed: May 3, 2023)

[23] Nikpay, Sayeh, et al., "The Incidence of Hospital Drug Price Subsidies: 340B, Drug Utilization, and Subsidized Medical Care," Conference Study Paper, American Society of Health Economists Conference, American Society of Health Economists. June 26, 2019. https://ashecon.confex.com/ashecon/2019/webprogram/Paper8192.html (Accessed: May 3, 2023)

manufacturers on the type of price and drug product information required to be submitted to CMS. Specifically, under subparagraph (A) manufacturers are required to report, as applicable, Average Manufacturer Price, Best Price, Average Sales Price, Wholesale Acquisition Cost, and the total number of units that are used to calculate these prices.

All four of these prices are calculated using statutorily defined formulas. At most, then, the use of "verify manufacturer prices . . . reported under subparagraph (A)" means that Congress provided CMS the authority to survey a manufacturer to ensure the prices reported were calculated correctly, consistent with the formulas set forth in the statute. What CMS proposes instead is to collect information under this survey to determine if certain pricing inputs are sufficient to ***justify*** the price. CMS's proposal is flatly inconsistent with the plain reading of its authority under subsection (b)(3). CMS says as much in the fact sheet accompanying the proposed rule, indicating that it is conducting these surveys to "assure that Medicaid prescription drugs are consistent with economy, efficiency, and quality of care." That, however, is not the purpose of the survey provision of Section 1927(b)(3)(B), which states specifically that CMS may survey manufacturers only to "verify" the prices reported under that subsection of the Social Security Act. Much of the information CMS proposes to collect (e.g., costs of production/distribution) are not relevant factors in the calculation of the prices at issue. And, notably, Congress has not granted CMS authority to negotiate prices under the Medicaid program.

In addition, it is necessary to mention another important limitation within the act. The statute limits CMS authority to survey only "wholesalers and manufacturers that directly distribute their covered outpatient drugs."[24] CMS cannot survey any and all manufacturers simply because it wants to question its pricing.

CMS cherry-picked a definition of "verify" to support its position

Moreover, what is even more troubling is that CMS points to the definition of "verify" in the *Oxford Dictionary*, which defines "verify" as "to make sure or demonstrate that (something) is true, accurate, or *justified*,"[25] in order to support its ability to "justify" prices. However, even this appears to be a cherry-picked definition to support CMS's own actions. Three other noted and commonly used dictionaries do not use the word "justify" to define "verify."

[24] Section 1927(b)(3)(B)
[25] 88 Federal Register 34,268. (Emphasis added)

- The *Cambridge Dictionary*: "to prove that something exists or is true, or to make certain that something is correct."[26]
- The *Merriam-Webster Dictionary*: "to establish the truth, accuracy, or reality of; to confirm or substantiate in law by oath."[27]
- The *Collins Dictionary*: "to prove to be true by demonstration, evidence, or testimony; confirm or substantiate; to test or check the accuracy or correctness of, as by investigation, comparison with a standard, or reference to the facts."[28]

Out of these four common dictionaries, *The Oxford Dictionary* is the only definition that includes "justify" as part of the definition of "verify" and this is not even in American English.

Additional criterion for exemption from the survey necessary if CMS intends to proceed with its unlawful policy

CMS estimates that it will select approximately 200 drugs for potential selection for the survey. The agency plans to select these potential drugs under the following criteria:

(i) The highest Medicaid drug spend per claim, which is when the claim is in the top 5th percentile of Medicaid spending per claim.

(ii) The highest total Medicaid drug spend, which is when the annual Medicaid drug spend, net of Federal Medicaid drug rebates, is greater than 0.5 percent of total annual Medicaid drug spend, net of Federal Medicaid drug rebates.

(iii) The highest 1-year price increase among single source covered outpatient drugs, which is when the covered outpatient drug falls in the top 1 percent of covered outpatient drugs with the highest median Wholesale Acquisition Cost (WAC) increase over 12 months; or

(iv) The highest launch price, which is a launch price estimated to be in the top 5th percentile of Medicaid spending per claim, or a launch price that is estimated to result in a total annual treatment price that is greater than $500,000 (indexed annually for inflation using the Consumer Price Index for all Urban Consumers (CPI–U)).[29]

CMS states that it will exclude drugs for which the manufacturer has:

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[26] *Cambridge Dictionary*, 2023. Accessed: July 12, 2023. https://dictionary.cambridge.org/us/dictionary/english/verify

[27] *Merriam-Webster Dictionary*, 2023. Accessed: July 12, 2023. https://www.merriam-webster.com/dictionary/verify

[28] *Collins Dictionary*, Accessed: July 12, 2023. https://www.collinsdictionary.com/us/dictionary/english/verify

[29] 88 Federal Register 34,294

> *(i) participated in any CMS pricing program or initiative under which participating manufacturers negotiate a covered outpatient drug's price directly with CMS; or,*
> *(ii) negotiated CMS-authorized supplemental rebate with at least 50 percent of States, that when in combination with the Federal rebate results in a total (State and Federal) rebate for the drug of interest to total Medicaid spend (State and Federal) for the drug of interest, that is greater than the total Medicaid rebates (State and Federal) to total Medicaid drug spend for States that cover CODs only through the FFS delivery system.*[30]

CMS also notes that further consideration will be given to manufacturers that have attempted to enter into innovative purchasing arrangements (such as subscription and value-based purchasing arrangements). However, CMS's stated purpose for conducting the survey is to support states to enter into supplemental rebates including those via value-based purchasing arrangements, such as the CMS-endorsed multiple Best Prices approach. Therefore, while we disagree with CMS's proposed policy, and believe it does not have the authority to enact such a provision, application of the Agency's stated purpose would also require as a clearly stated third criterion for elimination of any drug that already participates in a value-based purchasing arrangement with a state and/or has offered the state a value-based purchasing agreement via the multiple Best Prices approach (CMS portal).

The current proposal recommending state input on value-based purchasing arrangements as one of several possible criteria that may be outlined for further consideration does not provide certainty of exclusion from participation in the survey. As a result, drugs that have already been entered into value-based purchasing arrangements, either via state plan amendment or the multiple Best Prices approach, are still at risk for required participation in the survey to justify price points. The addition of a clearly stated third elimination criteria is in line with the stated purpose of the rule, specifically for those drugs that already participate in a value-based purchasing arrangement with a state and/or those drugs for which the manufacturer has offered the state a value-based purchasing agreement via the multiple Best Prices approach.

Additionally, this regulatory overreach is likely to have a negative implication for patient access to therapies for serious and/or rare conditions. As such, if CMS intends to move forward regardless, it should eliminate from the survey any drugs that have received special designation from the US Food & Drug Administration including orphan designation, breakthrough designation, fast track designation, regenerative medicine advance therapy designation, and accelerated approval pathway. FDA has provided these designations and the accelerated approval

[30] 88 Federal Register 34,294

pathway to support patient access to therapies for serious and/or rare conditions. Subjecting these therapies to unnecessary scrutiny could threaten patient access. The Food and Drug Omnibus Reform Act of 2022 has imposed new requirements on study sponsors to complete post-approval studies for accelerated approval in a more rapid fashion. This is already a highly regulated area and manufacturers work with HHS to ensure regulatory requirements do not hinder patient access.

The proposed rule indicates that it will survey reported pricing data for select drugs. According to the preamble, the drugs the agency intends to target are likely those of cell and gene therapies. Many of these therapies address rare diseases and are among the riskiest and costliest medicines to develop. The cost of developing a new drug has increased exponentially since the 1970s. A study conducted by the Tufts Center for the Study of Drug Development found that developing a drug that gains market approval can take over ten years, and cost roughly $2.6 billion.[31] Part of the consideration in these costs is that overall probability for a drug or compound in clinical testing to reach final approval is less than 12%.[32] Because of this, the pharmaceutical industry spends significantly more than almost every other industry on research and development.

Faced with the prospect of additional regulations and restrictions on products, researchers and investors may be discouraged from continued investment into drugs to potentially treat additional diseases and conditions for which patients are desperately waiting for cures and treatments. IQVIA data from 2020 show that since Congress passed the Orphan Drug Act in 1983, the FDA has granted 838 orphan drug indications to 564 distinct drugs.[33] Still, much more research is needed. More than 90% of rare diseases have no FDA approved treatment.[34] CMS claims this new reporting scheme is to assist states in negotiating supplemental rebates, particularly within the context of value-based arrangements. However, we do not believe this takes into proper account the efforts undertaken to negotiate supplemental rebates nor does it consider the complexities of value-based and alternative payment arrangements, which many states still shy away from.

Further, CMS seems to assume that states are doing everything they can to achieve economy of scale and maximize savings in the drug rebate program, which is not always the case. BIO is concerned that CMS also appears to presume that

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[31] Lamberti M. and Getz, K. Profiles of New Approaches to Improving the Efficiency and Performance of Pharmaceutical Drug Development. Tufts Center for the Study of Drug Development. May 2015.
[32] Research and Development in the Pharmaceutical Industry, Congressional Budget Office. April 2021. Accessed: April 3, 2023. https://www.cbo.gov/publication/57126
[33] See: https://www.iqvia.com/insights/the-iqvia-institute/reports/orphan-drugs-in-the-united-states-rare-disease-innovation-and-cost-trends-through-2019
[34] NORD Policy Position Paper, https://rarediseases.org/driving-policy/public-policy-positions/

manufacturers are not working with states to reach supplemental rebate agreements, especially within the context of value-based arrangements. Regarding standard supplemental rebate agreements, the vast majority are based upon preferred drug list (PDL) placement. However, with respect to the types of drugs this survey is targeting, cell and gene therapies, because they are rare diseases and/or first-in-class types of treatments, there is no preferred drug list placement to be had. In addition, at least three states[35] do not even negotiate supplemental rebates. Also, many states that negotiate supplemental rebates do not always negotiate for every class for which they might get these rebates. With respect to supplemental rebate agreements that pertain to outcomes-based arrangements, as of March 2023,[36] only 16 states have approved State Plan Amendments allowing for value-based arrangements.

Several of our members have informed us that there still appears to be resistance among many states to value-based arrangements. Part of this resistance may lie in the complexity of the arrangements. It can be sometimes difficult for states and manufacturers to come to terms suitable to both parties for many of the metrics. For example, some of the complex challenges that manufacturers and payers, including states, may need to overcome when negotiating these agreements include, but are not limited to:

- Selecting the right outcome: Research indicates that an outcome needs to be meaningful (to payers, providers, patients and manufacturers); measurable within a reasonable timeframe; readily available (i.e., via claims data); and not be subject to variability.[37]
- Patient tracking: There is a need to ensure that state Medicaid programs, have a responsibility to track patients as part of a VBP contract. Issues include patient portability or patients lost to follow-up, which likely means treatment success. State payers have to be equal partners and the responsibility of tracking patients is a mutual one between manufacturers and states.

In addition, this approach appears to be punitive in nature for manufacturers that are already participating in the Medicaid program. Voluntary supplemental rebates are exactly that, "supplemental," and are not required by the program itself. Yet, CMS is functionally penalizing manufacturers, through additional reporting requirements, who may not be participating in supplemental rebate agreements, without regard to the underlying value of therapy or the inflation penalties assessed

[35] CMS Supplemental Rebate Agreements Table. Accessed: July 18, 2023. https://www.medicaid.gov/medicaid/prescription-drugs/downloads/sra-table-mar-2023.pdf
[36] Ibid.
[37] Massachusetts Institute of Technology has done extensive work in this area. See MIT work here: https://newdigs.tuftsmedicalcenter.org/white-paper-a-practical-approach-for-defining-outcomes-and-thresholds/

to those manufacturers. It is also important to note, the proposed rule suggests that the survey factors (1) highest spend per claim and (2) highest launch price selection criteria fail to consider a therapy's value, i.e., a high-value therapy that meets either criterion isn't necessarily inappropriately priced, and should be reconsidered accordingly.

Much of the data to be reported is confidential, proprietary and trade secret information; non-protected information is confusing and would not be helpful to the public if disclosed without proper context

The Proposed Rule notes that CMS will be putting all non-proprietary information submitted in the survey on the internet for public consumption. Disclosing data for the sake of disclosing it does not benefit patients, states, manufacturers, or the Agency. BIO is also extremely troubled that much of the information requested by CMS in the survey is confidential proprietary and trade secret information. Despite indicating that much of this information is "likely protected under section 1927(b)(3)(D) of the Act, in addition to other privacy and confidentiality provisions, including the Trade Secrets Act[,]"[38] CMS fails to lay out any process to identify and protect confidential proprietary and trade secret information. This is especially important given that CMS intends to post non-proprietary information on the internet.

Moreover, BIO is deeply concerned that without proper context the public will not understand all that goes into pricing of a product or the vast amount of research and development that goes into bringing these drugs to market, nor will they understand the tremendous risk undertaken by biopharmaceutical manufacturers, especially since much of the data is not pertinent. For example, it is for this reason, that most of the additional data submitted to certain states as part of reporting requirements of price transparency laws is not disclosed or used by the states, and simply creates additional burden for all. At the very least, manufacturers ought to have an opportunity to review and comment on data that will be posted publicly prior to its release, so that they can see the information that will be disclosed and how it will be displayed. In this manner, they would be able to ensure appropriate context is provided as needed.

Definition of Covered Outpatient Drug (Direct Reimbursement Modification)— § 447.502

BIO strongly opposes CMS's proposed expansion of the definition of "covered outpatient drug." CMS puts forward a proposed new interpretation of the definition of "covered outpatient drug," specifically to change what is "direct reimbursement"

[38] 88 Federal Register 34273.

under the "limiting definition" of Section 1927's definition of a "covered outpatient drug." Under this proposed revised definition, CMS would depart from its longstanding historical recognition of the outer bounds of the definition of "covered outpatient drug" set forth in Section 1927, which exclude units included as part of a bundled payment. According to the proposed rule, "direct reimbursement for a drug may 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." The proposed revised definition flatly contradicts the statute.

Under § 1927k(3)'s "*Limiting Definitions*," "[t]he term "covered outpatient drug" does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (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). . ."[39] CMS's longstanding policy, consistent with § 1927k(3), is that manufacturers are not required to pay rebates when a unit of a drug is bundled with other services for payment. CMS is now inexplicably proposing to reverse its position by proposing that a unit is considered "direct reimbursement," thus falling under the definition of a "covered outpatient drug," so long as the unit and its cost are itemized, even if the unit is bundled with associated services for payment. The unit would then be subject to a rebate under the Medicaid Drug Rebate Program (MDRP). This is a gross misunderstanding of the clear statutory boundaries of the "covered outpatient drug" definition. By expanding the definition of "covered outpatient drug" as proposed, CMS would nullify the statutory exclusion of units that are paid for "as part of payment for" inpatient or other associated services. Nearly all claims for bundled payment that include a drug, identify the drug and its charge for rate setting purposes. CMS's proposal contradicts the plain statutory reading of "direct reimbursement."

Furthermore, BIO has significant concerns regarding the impact this proposal could have on hospital reimbursement and patient access to innovative cell and gene therapies (CGTs) that are administered inpatient. In the majority of states, hospitals received a bundled payment that is intended to cover the cost of the therapy as well as any ancillary services associated with providing care to the patient during the inpatient stay. Since payment to hospitals administering cell and gene therapies is often insufficient under the Diagnosis-Related Group (DRG) system, states are beginning to pay hospitals separately, outside of the bundled payment for inpatient services, for their acquisition cost of CGTs. In this scenario – when the CGT is "carved out" of the bundle and paid for separately –CMS's longstanding traditional interpretation of COD requires that manufacturers pay a rebate when the drug is administered to a Medicaid patient. Under this

[39] Section 1927(k)(3) of the Social Security Act (emphasis added).

arrangement, hospitals are paid adequately, states have the benefit of federal rebates on the utilization, and Medicaid patients in turn benefit from increased access. This also has the effect of opening up the opportunity for VBAs. However, CMS' proposed change would deem any drug that is administered inpatient and paid for as part of a bundled payment as a "covered outpatient drug" simply by the inclusion of that drug on a claim form. As a result, states would presumably be authorized to seek Medicaid rebates from manufacturers on such drugs by simply identifying the product on the claim form, and without directly reimbursing providers for the cost of the drug. Thus, we disagree with CMS' new interpretation that such action would qualify as "direct reimbursement" and classify drugs paid for as part of a bundled arrangement as "covered outpatient drugs." In so doing, CMS undermines payment arrangements that serve all stakeholders and creates an opportunity for states to merely add a line-item to an otherwise bundled payment, resulting in significant financial losses for hospitals or, may have the effect of limiting access to CGTs because hospitals will not want to provide such therapies.

The impact of this proposed policy on other programs such as 340B could be significant. The proposed COD definition would simply add more confusion with respect to the 340B Program. As noted earlier, there are well-documented cases of abuse in the 340B Program and covered entities already take significant liberties with their interpretation of HRSA's COD definition, which is clear. The proposed revision to the definition of COD could create even more inappropriate variance in its application.

Definition of Vaccine— § 447.502

BIO has strong concerns regarding the proposed approach defining "vaccine" for the purposes of the MDRP. We recommend that CMS not finalize the proposed definition of a vaccine in the draft rule. As written, the definition does not take into consideration products that are vaccine-like and intended for broad prevention of infectious diseases. Furthermore, this proposed definition: is contrary to how vaccines are defined across other federal programs, contradicts the Congressional intent on immunization decision-making authority, will create programmatic overlap and confusion, and will create barriers in patient access to life-saving preventive products used in a vaccine-like manner.

To continue to ensure broad, equitable access to immunizations, BIO suggests CMS modify its proposed definition of a vaccine for purposes of MDRP to be consistent in deferring immunization coverage requirements to ACIP, while maintaining the distinction between preventive and therapeutic vaccines.

BIO's suggested modified definition is: "a product that is administered prophylactically for active or passive antigen-specific immunity for the prevention of one or more infectious diseases, is approved or authorized by the FDA and is either recommended by ACIP for adults or is included in the Vaccines for Children (VFC) program".

Congress has repeatedly tasked the Advisory Committee on Immunization Practices (ACIP) with determining what products fall under immunization coverage requirements across markets (e.g., via the Affordable Care Act (ACA) and Inflation Reduction Act (IRA)). The ACIP makes recommendations on "vaccines and immune globulin preparations… for prevention of infectious diseases".

Most immunizations reaching Medicaid beneficiaries or uninsured and under-insured individuals are provided through the federal government at no cost to states or patients (e.g., Vaccines for Children program (VFC), purchased with Section 317 funds for adults). As a result, including products available through VFC in MDRP would not expand coverage for children, as VFC ensures access for all Medicaid children and additional children not covered by MDRP (e.g., uninsured and underinsured, AI/AN). Similarly, state Medicaid programs must cover all ACIP-recommended products for adults without cost-sharing, per the IRA. These federal programs allow states to purchase immunizations at negotiated prices with no cash outlays required by healthcare providers or patients. Therefore, CMS should ensure the MDRP definition of a vaccine reflects recent actions by Congress, and define a vaccine based on whether a product is either recommended by ACIP for adults or is included in the VFC program.

The modified definition would allow CMS to align with federal programs by deferring to ACIP and accomplish its objectives of ensuring broad and equitable access at fair prices. Cost-effectiveness is a key consideration throughout the ACIP recommendation process for both childhood and adult immunization products, and federal programs already purchase immunization products at negotiated prices. Limiting preventive vaccines to those included in the FDA vaccine list, as proposed in CMS's current definition, is too narrow as it excludes passive prophylactic products for antigen-specific immunity. Two recent innovations in the prevention of respiratory syncytial virus (RSV) highlight this need. First, nirsevimab, a monoclonal antibody for prevention of RSV in infants, was recently approved by the FDA and will have a recommendation vote at ACIP in early August 2023. Second, a vaccine given to pregnant women that gives passive immunity to infants against RSV was recommended by an FDA Advisory Committee in May and an approval decision is expected by FDA in August.

BIO recommends that CMS engage in discussions with stakeholders involved in approving and recommending vaccines, including FDA and ACIP at CDC, prior to finalization of the definition. These stakeholder groups could discuss the importance of alignment in a definition across programs.

Definition of Manufacturer—§447.502

CMS proposes to change the definition of "manufacturer" under the National Drug Rebate Agreement. It would be changed to include all affiliated entities. CMS insists that all affiliates that market a COD participate in the MDRP, or none at all. The proposed definition is as follows:

> The term "'manufacturer' means that all associated labeler entities of the manufacturer that sell prescription drugs, including, but not limited to, owned, acquired, affiliates, brother or sister corporations, operating subsidiaries, franchises, business segments, part of holding companies, divisions, or entities under common corporate ownership or control, must each maintain an effectuated rebate agreement. . ."[40]

This is an extremely broad definition of "manufacturer," and many companies have affiliates that are truly autonomous. The proposed definition would sweep in truly independent companies, even if only one affiliate were to participate in the MDRP, and even if it were to have only one product, such as a rare disease product. This might result in a product having more than one manufacturer. BIO opposes such a broad definition of "manufacturer" particularly when CMS has not fully defined the terms "affiliate" and "franchise". We are deeply troubled by the fact that CMS is undermining a cornerstone of the "grand bargain" represented by the MDRP, which is intended to be voluntary for participants. Inclusion of all associated or affiliated labelers, no matter of autonomy, is too far removed from common control to make participation truly voluntary.

Definition of Drug Product Information—§ 447.502

As part of its efforts to ensure proper classification of drugs, CMS proposes a new definition of "Drug Product Information" that includes the NDC, drug name, units per package size, drug category (S, I, or N), unit type, drug product type (prescription or OTC), base date AMP, therapeutic equivalent code, line extension indicator, 5i indicator, and route of administration, and, if applicable, FDA approval date and application number, OTC monograph citation, market date, COD status, and "any other information deemed necessary" by the agency to perform accurate

[40] 88 Federal Register 34,256.

URA calculations.[41] However, these data points have nothing to do with drug classification under the Medicaid program, and, thus, this proposed new definition is not warranted. It appears this information is more geared toward the newly proposed and unlawful drug survey than proper classification of drugs for rebate purposes. Further, BIO is deeply concerned that CMS proposes to leave open the ability of the agency to request "any other information deemed necessary." The proposed definition already includes an extensive list of information manufacturers would need to report, yet CMS proposes to reserve to itself the unilateral right to expand such list at any time, without additional rulemaking or other procedural safeguard. This is extremely disturbing given the fact that manufacturers are subject to penalties for failing to accurately report Drug Product Information. Therefore, CMS must define "Drug Product Information" with sufficient specificity to provide manufacturers with a basis on which to comment fully. BIO strenuously objects to this approach.

Further, the proposed requirement that the information be reported monthly would place an unnecessary burden on both manufacturers and the agency.

Proposed Suspension of a Manufacturer's Drug Rebate Agreement— § 447.510(i)

Regarding the possible suspension from the Medicaid program for not complying with requests for drug product information, BIO is concerned about the impact this policy would have on patients. The very act of suspending a drug manufacturer and, thus, a drug or drugs, from participation in the Medicaid program would deny patients access to medication. The suspension of a manufacturer for any length of time would have a significant impact on a patient's continuity of care. The proposed regulation indicates that Medicaid programs would have 30 days to notify prescribers and beneficiaries that the medication(s) may not be available for some period of time. This is troubling given that patients may be stable on the medication, which may have taken weeks or months to become so. Further, there is no indication as to what would happen if there were no therapeutic alternative to switch to. We strongly urge CMS to reconsider a policy with such a Draconian impact on patients.

[41] 88 Federal Register 34,291

F. Drug Classification; Oversight and Enforcement of Manufacturer's Drug Product Data Reporting Requirements—Proposals Related to the Calculation of Medicaid Drug Rebates and Requirements for Manufacturers— §447.509 and §447.510

CMS proposes two new elements to implement provisions of the Medicaid Services Investment and Accountability Act of 2019 (MSIAA), which would be used to ensure proper classification (i.e., single source—S, innovator multiple source—I, or non-innovator multiple source drug—N) of drugs under the MDRP. If a manufacturer reports and certifies a COD that is not supported by the definitions of an S, I, or N drug, it is considered "misclassified." The proposed definition of "misclassification" is:

> "(i) [r]eported and certified to the agency its drug category or drug product information related to a [COD] that is not supported by the statute and applicable regulations; or
>
> (ii) [r]eported and certified to the agency its drug category or drug product information that is supported by the statute and applicable regulations, but pays rebates to the States at a level other than that associated with that classification."[42] Further, CMS insists in the proposed rule that a "misclassification may occur without regard to whether the manufacturer knowingly made the misclassification or should have known that the misclassification was being made."[43]

We are deeply concerned that, under § 447.509(d)(2) as proposed, CMS would make a determination of a misclassification and then, within 30 days of notification, expect the manufacturer to provide "drug product and drug pricing information needed to correct the misclassification . . . and calculate rebate obligations due, if any . . ."[44] This suggests that CMS might be making a determination on a drug's classification without proper drug product and pricing information. Further, if a misclassification may occur unknowingly, the manufacturer may not know the information necessary to "correct" the error. We believe the process should be more collaborative. For example, if CMS suspects a misclassification, it should hold a meeting with the manufacturer and otherwise allow the company a reasonable opportunity to justify its classification of the drug. The proposed process automatically presumes impropriety on the part of the manufacturer.

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[42] 88 Federal Register 34293.
[43] 88 Federal Register 34262.
[44] 88 Federal Register 34293.

Time Limits on Manufacturer Audit Requests—§ 447.510(j)

CMS proposes to establish a 12-quarter time limit for manufacturers to initiate disputes, hearing requests, and audits for state-invoiced units on any currently invoiced rebates as well as on rebates that have been paid in full. Section 1927(b)(2)(B) does not impose any limitation on a manufacturer's time ability to initiate an audit or review of a state's rebate calculations. While current regulations and the Medicaid statute indicate that there is a 60-day requirement with respect to receipt of rebate invoices,[45] some BIO members have reported receiving rebate invoices related to decades-old utilization. Given these actions, BIO does not believe a time limit is appropriate, however, at a minimum, there should be equitable treatment of both parties to the rebate invoicing (i.e., CMS should not apply one set of standards to manufacturers and another to states). If CMS insists on imposing a time limit the clock should be tolled during the period which a request by the manufacturer to the state for data necessary to validate the rebates is pending.

In addition, we believe that retrospective audits by manufacturers to determine prohibited duplicate discounts in the 340B Program fall outside the scope of this proposed rule. These types of reviews can take much longer than 12-quarters. CMS should clarify this and specifically indicate that these types of audits do not fall under this proposed rule's jurisdiction to avoid any confusion.

Definition of Internal Investigation in Connection with Restatements—§ 447.502

BIO is opposed to the proposed definition of an "internal investigation," which would limit the circumstances in which a manufacturer may seek a restatement outside of the 3-year window. The proposed rule would define "internal investigation" to mean a manufacturer's investigation of its AMP, BP, customary prompt pay discounts, or nominal prices that have been previously certified under MDRP that results in a finding made by the manufacturer of fraud, abuse, or a violation of law or regulation. Manufacturers should not be required to have to admit to fraud or a legal violation to seek a restatement based on an internal investigation beyond 12-quarters, given that an investigation may find none yet still suggest that restatement would be appropriate. CMS falsely presumes that manufacturers seek to restate based on an internal investigation only where legal fault is found. For example, a manufacturer may need restatement in the case of consistency in application of a reasonable assumption. And CMS presumes manufacturers submit requests to reopen only when it is in the manufacturer's favor, which is not the case.

[45] § 1927(b)(2)(A) and § 447.511(a).

Definition of Market Date—§447.502

CMS proposes to define the term "Market Date" for purposes of establishing the base date AMP quarter, which would mean the first day a drug is sold or on the market. BIO appreciates the fact that CMS is attempting to bring some consistency to reporting practices. We support efforts to standardize this date, however, we are concerned that the definition of when a drug is "sold" is not consistent with industry convention. Some manufacturers consider the date a drug is first sold as the date it first registers on an invoice. Since CMS does not intend to eliminate the need for reasonable assumptions, we recommend that reasonable assumptions aligned with overall business practices be used.

Medicaid Managed Care Standard Contracts and New Requirements for Pharmacy ID Cards—§ 438.3(s)(7)

CMS is proposing that Medicaid managed care organizations (MCOs) that use pharmacy ID cards must include a Medicaid-specific Banking Identification Number and the Processor Control Number (BIN/PCN) and group number. This could marginally improve the capability of states and Medicaid MCOs to identify claims for drugs paid under the 340B Program, and thus avoid invoicing for rebates on those same drugs, reducing the incidence of duplicate discounts. BIO believes that the BIN/PCN and group numbers should specifically be provided to hospitals or their service providers to help avoid duplicate discounts. However, this policy alone would not be nearly sufficient to help eliminate duplicate discounts. A conservative estimate puts duplicate discounts between 3% and 5%.[46] Continued disregard and abuse by covered entities through Medicaid MCOs is unacceptable.

"Therefore, we urge CMS to require states and Medicaid MCOs to use 340B claims modifiers and to share claims-level data with manufacturers. CMS itself recommended both these methods as "Best Practices" for states to avoid duplicate discounts in January 2020.[47] We agree with CMS that inclusion of the BIN/PCN and group number on pharmacy ID cards would allow for the use of a claims modifier at the point of sale. Given CMS's stated Best Practices, and its stated position with respect to this proposed policy, CMS should require claims modifiers at the point of sale along with this proposed change in policy, in addition to other reforms that would meaningfully help prevent duplicate discounts. Because claims modifiers and non-modifiers are not used, some covered entities and pharmacies do not know at

[46]Mundra, Ashwin, "The 340B Noncompliance Data Gap Leaves Drug Manufacturers in the Dark," Drug Channels Blog, March 18, 2022. Accessed: July 24, 2023. https://www.drugchannels.net/2022/03/the-340b-noncompliance-data-gap-leaves.html
[47] "Best Practices for Avoiding 340B Duplicate Discounts in Medicaid," Calder Lynch, CMS Memo to States, January 8, 2020.

the point-of-service whether a patient or drug is 340B eligible, as such covered entities need another option to submit batch claims-level data. Accordingly, BIO believes that CMS should consider requiring the use of an independent third-party administrator or clearinghouse that could receive the claims data either through the covered entity's use of a 340B or non-340B modifier, or the submission of batch data and confirm the validity of 340B or non-340B claims. In this manner, the clearinghouse would receive the provider data and share the relevant information with manufacturers and states to prevent payment of 340B duplicate discounts. In addition, CMS should re-state that until the status of prescription is known, the provider should not bill Medicaid, i.e., providers should not bill Medicaid until 340B eligibility screening of a claim is complete. Also, BIO strongly recommends that CMS issue guidance to establish a transparent and consistent dispute resolution process. Manufacturers have no method to resolve disputes when a duplicate discount has been identified.

Another key reform to shore up 340B program integrity regarding duplicate discounts relates to manufacturer review of Medicaid MCO claims. Many times manufacturers are not given claims data to review from MCOs until it is past the 30- to 60-day cutoff, in some cases the data is never received. In these cases, manufacturers cannot pursue duplicate discounts with MCOs. Medicaid MCOs contracting with a state should be required to share data and permit correction of claims processed with 340B product until after the manufacturer receives data from the Medicaid MCO, ***NOT*** 30-60 days from the date of service. This would allow manufacturers to review this MCO claims data to help ensure accountability on duplicate discounts.

***Drug Cost Transparency in Medicaid Managed Care Contracts*—§ 438.3(s)(8)**

CMS proposes to improve transparency in Medicaid managed care by requiring Medicaid managed care organizations (MCOs) to require subcontractors (including PBMs) to itemize claims. The proposed rule seeks to limit "spread pricing," where a PBM retains the difference between what a Medicaid MCO plan pays a PBM and what the PBM pays a pharmacy for the cost of dispensing a drug. Thus, the PBM charges the Medicaid plan a higher amount than what is paid to the pharmacy. BIO supports this proposed policy. We believe third parties acting on behalf of Medicaid MCOs should not be allowed to charge the MCO more than what is paid the pharmacy, thus increasing costs to Medicaid as a whole.

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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 BIO's comments, please do not hesitate to contact me at 202-962-9200.

Sincerely,

/s/

Crystal Kuntz
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/s/

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