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Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244–1850
Attn: CMS-2434-P

Re: Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program [CMS-2434-P]

Dear Administrator Brooks-LaSure:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to submit comments on the above-referenced Medicaid proposed rule published by the Centers for Medicare & Medicaid Services (CMS).[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $1.1 trillion in the search for new treatments and cures, including $102.3 billion in 2021 alone.

CMS is proposing sweeping changes to the Medicaid Drug Rebate Program (MDRP), many of which would transform policies and practices that have been pillars of the program since its inception. As detailed below, we are also concerned that several of these proposals are not grounded in the Medicaid rebate statute and would go beyond CMS' legal authority. It is crucial that CMS rethink and reject these proposals.

Our comments on the key issues in the proposed rule can be summarized as follows:

- **Best Price Stacking Proposal.** CMS proposes to change the regulatory definition of Best Price, by requiring "stacking," or the aggregation of manufacturer price concessions available to separate entities across the pharmaceutical supply chain. CMS' proposal is inconsistent with the Best Price statute, and if adopted would also result in significant operational barriers making this proposal unworkable to implement.

- **"Covered Outpatient Drug" Definition.** CMS proposes a change in the regulatory definition of "covered outpatient drug" that would—for the first time, and in clear conflict with the language and history of the Medicaid rebate statute—allow state Medicaid programs to treat bundled inpatient drugs as "covered outpatient drugs" subject to Medicaid rebates. PhRMA opposes this proposal, which goes beyond CMS' statutory authority.

- **"Manufacturer" Definition.** PhRMA opposes CMS' proposed definition of a "manufacturer," because CMS does not have the authority to expand the statutory definition to include "all associated entities of the manufacturer that sell prescription

[1] 88 Fed. Reg. 34238 (May 26, 2023).

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." Both the statutory definition of a "manufacturer" and the legislative history are silent on corporate affiliations and thus CMS may not arbitrarily broaden the definition.

- **"Internal Investigations" Definition.** PhRMA opposes CMS' proposed "internal investigations" definition, because it will have a chilling effect on pricing revision requests, potentially leading to less accurate pricing data.

- **"Vaccine" Definition.** PhRMA opposes CMS' proposed definition of a "vaccine," because it appears that CMS has not adequately consulted with stakeholders and federal programs that have relevant expertise. If after such consultation CMS moves forward with a "vaccine" definition, it is critically important that the agency go through notice and comment rulemaking.

- **12 Quarter Audit Limit.** PhRMA opposes CMS' proposal to limit manufacturers' ability to initiate disputes, hearing requests and audits of State-invoiced utilization data to 12 quarters. No statutory authority exists for this proposal, and adopting this one-sided proposal could actually undercut CMS' ability to administer the rebate program by raising concerns about CMS' even-handedness.

- **Standard Medicaid Managed Care Contract Requirements.** PhRMA supports CMS' proposal to require states' contracted Medicaid managed care plans that provide coverage of covered outpatient drugs to assign and exclusively use unique Medicaid-specific bank identification number (BIN), processor control number (PCN), and group number identifiers for all Medicaid managed care pharmacy benefit identification cards. While PhRMA supports CMS' proposal and urges its timely implementation, this policy, by itself, will not fully address the risk of 340B duplicate discounts in Medicaid managed care. Therefore, we urge CMS to consider additional policies designed to achieve the statutory imperative of zero instances of Medicaid/340B duplicate discounts.

- **Verification Survey**. PhRMA opposes CMS' proposal for a burdensome "price verification survey," which would require that manufacturers submit a broad array of detailed data for certain drugs that has no utility in verifying the accuracy of prices reported to CMS under the Medicaid rebate statute and seeks instead to extract additional rebates without any statutory authority to do so.

- **Proposals Related to State Plan Requirements, Findings and Assurances.** PhRMA supports adequate reimbursement for pharmacies to ensure patient access to medicines.

- **Request for Information – Comments on Issues Relating to Requiring a Diagnosis on Medicaid Prescriptions as a Condition for Claims Payment.** PhRMA is concerned that this proposal could have a negative impact on patient access to medicines and would interfere with doctors' clinical judgment.

Our detailed comments follow below.

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I. MDRP Administrative and Program Integrity Changes

A. Best Price Stacking Proposal (88 Fed. Reg. at 34260-61); 34292-93)

CMS proposes prospectively to make a fundamental change in the regulatory definition of Best Price, by requiring "stacking," or the aggregation of manufacturer price concessions available to separate entities across the pharmaceutical supply chain. Specifically, CMS would modify 42 C.F.R. § 447.505(d)(3) to add that "[c]umulative discounts, rebates, or other arrangements must be stacked to determine a final price realized by the manufacturer for a covered outpatient drug, including discounts, rebates, or other arrangements provided to different best price[-]eligible entities."[2] According to CMS, pursuant to this regulatory provision, "if a manufacturer provides a discount to a wholesaler, then a rebate to the provider who dispensed the drug unit, and then another rebate to the insurer who covered that drug unit," Best Price "must include (or 'stack') all the discounts and rebates associated with the final price, even if the entity did not buy the drug directly from the manufacturer."[3] In other words, CMS proposes to transform Best Price by requiring manufacturers to track and aggregate, for each unit, all manufacturer discounts that may be given to different Best Price-eligible customers across the supply chain and then subtract the aggregated discounts from the initial sale price, to arrive at a hypothetical Best Price value that is not available to any actual customer.

Doing so would radically change Best Price, which lawmakers, oversight agencies,[4] manufacturers, and other industry stakeholders have always viewed as just what the statute says: the single lowest price available from the manufacturer to any individual Best Price-eligible customer. PhRMA opposes this proposal. CMS lacks authority to re-write the statutory definition of Best Price to reflect a hypothetical value available to no actual Best Price-eligible entity. Additionally, even if the CMS proposal were consistent with the statute (which it is not), operational barriers would make this proposal impossible (or at best, highly impractical and burdensome) to implement. For the reasons detailed below, CMS must not finalize and implement this proposal.

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[2] 88 Fed. Reg. at 34292–93.

[3] 88 Fed. Reg. at 34260 ("By stacking, best price reflects the lowest realized price at which the manufacturer made that drug unit available.").

[4] *See*, *e.g.*, Department of Health & Human Services (HHS), Office of Inspector General (OIG), *Medicaid Drug Rebates—Sales to Repackagers Excluded From Best Price Determinations*, A-06-00-00056 (Mar. 27, 2001). Here, OIG investigated the impact of manufacturers that were excluding sales to Health Maintenance Organization (HMO) repackagers from their determination of Best Price. To do so, OIG collected from manufacturers information about sales to HMO drug repackagers. "In order to determine the impact of manufacturers excluding sales to repackagers from best price, we recalculated the rebates for any sale to a repackager that was at a price below the reported best price." *Id.* at 3. OIG did not, apparently, understand Best Price to include stacked discounts to others in the supply chain on these units. Instead, OIG identified the underpayment of rebates by reference to the price available to a single, Best Price-setting customer. Without objecting to this method of determining Best Price, CMS described OIG's report in subregulatory guidance. *See* CMS, Manufacturer Release No. 68, at 3 (Apr. 1, 2005), https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/mfr68.pdf.

(1) CMS Lacks Authority to Re-Write the Statutory Definition of Best Price

PhRMA urges CMS not to adopt its proposed changes to rewrite the statutory Best Price definition to include a stacking requirement. CMS claims that its proposed regulatory definition reflects an "expansive" understanding of the statutory Best Price definition.[5] Far beyond an "expansive" interpretation, CMS' proposal would rewrite the Medicaid rebate statute to contradict its plain language and undermine Congress's express intent.

First, the Medicaid rebate statute defines Best Price as "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States."[6] This plain language indicates that Best Price is one price offered to a single entity. By contrast, CMS appears to interpret "to any" to mean the sum of the discounts to several unrelated entities subtracted from the initial sale price.[7] However, the ordinary meaning of "any" forecloses this understanding.[8] "Any" typically means a single member in a class if used with singular nouns.[9] Each of the definition's terms—"price" and the listed entities—are singular, clearly referring to the single lowest price to any specified entity. Moreover, the use of the disjunctive "or" underscores that the listed entities should be understood apart from each other. Without any other contextual indication that Best Price should aggregate discounts to different entities, the words "to any BP-eligible entity" can only mean that Best Price is the lowest price available to any one of the listed entities and not a net price realized on a unit when price concessions to multiple customers across the supply chain are combined.

Second, the statute clearly defines Best Price as the lowest price "available from the manufacturer." "Available" unambiguously means "able to be used, obtained, or selected" and "at one's disposal."[10] Thus, the statute clearly defines Best Price as the actual lowest price available from the manufacturer, not a compiled net price that no customer receives. Under the regulatory definition proposed by CMS, the stacked price is "available" to no one. This would be the net amount ultimately realized on a particular unit, but it would not be a price at which the unit could be purchased (or was purchased) by any customer. For example, CMS states that "if a manufacturer provides a discount to a wholesaler, then a rebate to the provider who dispensed the drug unit, and then another rebate to the insurer who covered that drug unit," Best Price must include all the discounts and rebates given by the manufacturer on that unit.[11]

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[5] 88 Fed. Reg. at 34260.

[6] SSA § 1927(c)(1)(C)(i) (emphasis added).

[7] 88 Fed. Reg. at 34260 ("We interpreted this section expansively as the statute refers to a manufacturer's lowest price 'available' 'to any' entity on [the] statutory list.").

[8] *U.S. v. Lopez*, 590 F.3d 1238 (11 Cir. 2009) ("[t]o ascertain ordinary meaning, courts often turn to dictionary definitions for guidance."); *Wooden v. U.S.*, 142 S. Ct. 1063 (2022) (citing the dictionary definition of "occasion" to determine the "ordinary meaning" of the term).

[9] *See Any*, Oxford English Dictionary Online, https://www-oed-com.nyli.idm.oclc.org/view/Entry/8973?redirectedFrom=any; *see also United States v. Dunford*, 148 F.3d 385, 389 (4th Cir. 1998) (noting that the word "any" may mean a single item if "used in [the] context of [a] singular noun").

[10] *See Available*, Oxford English Dictionary Online, https://www-oed-com.nyli.idm.oclc.org/view/Entry/13583?redirectedFrom=available.

[11] 88 Fed. Reg. at 34260.

Assume in this example that the wholesaler purchased the unit at a $100 Wholesale Acquisition Cost, then received a $5 discount from the manufacturer on the unit; the provider that dispensed the drug received a $15 rebate from the manufacturer on the unit; and the insurer who covered the drug received a $20 rebate from the manufacturer. In this example, under CMS' proposed stacking theory the "Best Price" on the unit (the net amount ultimately realized by the manufacturer on the unit) would equal $60 ($100 minus [$5 + $15 +$20])—but a $60 price was not available from the manufacturer to any of the three customers.

Additionally, other statutory language also supports that Best Price reflects the price associated with a single transaction. The Best Price definition refers to "the lowest price available from the manufacturer ***during the rebate period***" to any Best Price-eligible entity.[12] This language clearly does not contemplate the stringing together of multiple transactions to separate customers on a unit, which might easily span two or more reporting quarters. Instead, the statutory language refers to one price available at a single point in time. For example, under CMS' proposal, a wholesaler could purchase a unit of a drug during one quarter, but the provider may not dispense the drug until the next quarter (and the insurer would not receive the rebate on the unit until the quarter in which the unit was dispensed, or a later quarter). Depending on product expiration dating and volume of product utilization, provider and payer rebates could actually be years, not just quarters, later than the initial wholesaler sale. CMS does not explain how Best Price would be calculated in this case or how its proposed interpretation is consistent with the statutory limitation to a single "rebate period." The CMS interpretation is based on a series of transactions with a series of customers that occur over time (all of which may not occur "during a [given] rebate period") in connection with a given unit.

The Medicaid rebate statute's legislative history also confirms that Congress intended for Best Price to be the single lowest price that a manufacturer makes available to an actual Best Price-eligible customer. 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."[13] 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."[14] In other words, Congress intended to establish Medicaid rebates based on the prices available to each customer to ensure that the government was treated on par with the manufacturer's single most-favored customer.

Nowhere does the legislative history suggest an intent that a manufacturer should track and aggregate price concessions across various purchasers on a single unit to report a hypothetical Best Price that is not actually offered to any customer. In fact, throughout the debate that culminated in the original Medicaid rebate statute, Congressional discussion repeatedly refers to Best Price as the lowest price offered to an individual customer[15] (which members of Congress

[12] SSA § 1927(c)(1)(C)(i) (emphasis added).

[13] H.R. Rep. No. 101-881 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2108.

[14] H.R. Rep. No. 101-881 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2108.

[15] *See*, *e.g.*, H.R. Rep. No. 101-881 (1990), 1990 U.S.C.C.A.N. at 2108 ("[F]or single source drugs manufacturers would be limited to charging Medicaid the best price given any bulk purchaser . . . . Medicaid pays substantially more for many single-source drugs than do other large purchasers. In California, the Medi-Cal program pays $149.08 for 100 250 mg. tablets of Ceclor, used to treat certain types of respiratory infections; the Department of Veterans Affairs pays $58.77, a discount of 61 percent.

often assumed was the Department of Veterans Affairs (VA)).[16] Such statements are inconsistent with a Congressional intention that Best Price should involve aggregated discounts realized on a unit, aggregating discounts given by the manufacturer to different customers across the supply chain.

Moreover, Congress' subsequent exclusion of VA prices from Best Price also demonstrates that Congress intended for Best Price to be a price available to a single customer. Following the enactment of the original Medicaid drug rebate statute, Congress observed a spike in drug prices available to the VA.[17] Lawmakers theorized that, because the VA had historically benefitted from low prices, the VA represented the Best Price-setting customer for many manufacturers.[18] As a result, Congress enacted a version of the exclusions now codified at section 1927(c)(1)(C)(i)(I)–(II) of the Social Security Act (SSA), excluding prices charged to the VA from Best Price.[19] Similar to the legislative history supporting the original 1990 text, this subsequent debate also discussed Best Price by reference to one low price available to one customer.[20] This subsequent legislative history shows that, following the enactment of the Medicaid rebate statute, Congress affirmed the practical effect of Best Price as the single lowest price offered to one customer, and took steps to remediate the impact on a particular customer of interest, the VA.

Similarly, in the case of Tagamet, used to treat ulcers, the Medi-Cal program pays $54.77 for 100 tablets (300 mg.), while the DVA pays $27.65, or 49 percent less. . . . [L]arge private sector purchasers, including HMOs and hospital group purchasing organizations, also receive substantial discounts."); 136 Cong. Rec. E2813 (1990) (Sep. 12, 1990) (statement of Sen. Ron Wyden) ("There is simply no logical reason why the Medicaid Program . . . should have to pay prices for drugs which average 40 to 70 percent more than those prices paid by other large purchasers. . . . Another Federal department, the Department of Veterans' Affairs, pays an average of 41 percent less for drugs than the Medicaid Program. HMO's, hospitals, and other nonprofit entities regularly get discounts far below the price that Medicaid pays. Isn't Medicaid the ultimate nonprofit and shouldn't Medicaid get similar discounts?"); *see also Medicaid Prescription Drug Pricing: Hearing Before the Subcomm. On Health for Families and the Uninsured on S. 2605 and S. 3029 of the S. Comm. on Finance*, 101st Cong. 50, at 51 (Sep. 17, 1990) [hereinafter *S. 2605 and S. 3029 Hearing*] (testimony of a drug manufacturer describing that best price would be the best price given to an individual HMO customer without referencing others in the supply chain).

[16] *S.2605 and S.3029 Hearing*, *supra,* at 133 (statement of Sen. Robert A. Ingram. Executive vice-president of Glaxo Inc.) ("For most manufacturers, the 'best price' is the price provided to the Department of Veterans Affairs (DVA)."); *Id.* at 50 (opening statement of Sen. John H. Chaffe) ("[W]e would offer to the Medicaid programs our best price. Generally, that would be the VA price. . . [W]hatever [price was] sold to the VA, that would be the price in [a state] to the Medicaid program.").

[17] *See H.R. 2890 - To Establish Limits on Prices of Drugs Procured by the Department of Veterans Affairs: Hearing Before the Subcomm. on Hospitals and Health Care of the H. Comm. on Veteran's Affairs*, 102nd Cong. 1 (Sep. 11, 1991) [hereinafter *H.R. 2890 Hearing*].

[18] *See id.*; *see also S.2605 and S.3029 Hearing*, *supra,*, at 134 ("Discounts to [the VA] market segment are a historical anomaly that has evolved from World War II efforts to bolster the government's access to needed medicines. Prices in that market have remained artificially low in part because [manufacturers] have found it reasonable to give the veterans a break in a very small portion of our business.").

[19] Pub. L. No. 102-585, § 601(a), 106 Stat. 4962 (1992).

[20] *H.R. 2890 Hearing*, *supra,* at 24 (Sep. 11, 1991) ("In some cases I suspect the best price is not the VA. It's some commercial buying group that has a lot of commercial clout."); *id.* at 39 ("[J]ust to take a hypothetical HMO that has a lot of clout, . . . whatever deal they cut outside of Medicaid, that becomes a commercial best price which reflects directly into Medicaid. So Medicaid takes advantage of whatever deal HMO 'X' can cut. That automatically becomes the best price under the formula.").

In summary, both the plain language of the Medicaid rebate statute and its legislative history confirm that Best Price is the single lowest price available from a manufacturer to any individual Best Price-eligible entity. CMS' proposal exceeds the agency's authority, by rewriting the Best Price definition to include a stacking requirement not supported by the statute. PhRMA urges CMS to abandon this proposal.

(2) Operational Barriers Make This Stacking Proposal Unworkable, Creating an Impossibility of Performance by Manufacturers

Even if CMS' stacking proposal were consistent with the statute (which it is not), operational barriers would make CMS' proposal impossible, or at best, impractical to implement. The proposed rule does not address the significant challenges with this proposal.[21] Nor does CMS even discuss how a manufacturer could actually determine the lowest net amount ultimately realized on any unit (taking into account discounts to all of the manufacturer's customers on each unit) over the course of a quarter.

No system exists today that is capable of tracking the separate customers that encounter a given drug unit across the supply chain. Such a system would need to interface with and collect data from every possible Best Price-eligible entity involved in the pharmaceutical supply chain, including (among others) wholesalers, specialty distributors, retail community pharmacies, specialty pharmacies, mail-order pharmacies, physicians, hospitals, clinics, home infusion providers, home healthcare providers, hospices, long term care facilities, prisons, HMOs, and insurers. Conceivably, the system would also need to incorporate entities not eligible for Best Price in order to follow units that may leave the possession of an ineligible entity only to be purchased or reimbursed by an eligible one.

Presumably, such a system would need to communicate with all of these different stakeholders across the pharmaceutical supply chain, which alone entails a massive network of connections that may surpass the technical capabilities of any given manufacturer. CMS does not state whether it would have any role in creating the system. (As noted above, the proposed rule says nothing about how its stacking proposal could be operationalized.) What's more, the system would presumably need to link all of these independent entities by reference to a single drug unit. This could require non-manufacturer entities in the supply chain to distinguish and track each unit they purchase or reimburse, and also to consent to exchange information with each manufacturer about the entity that next purchases or reimburses the unit. It may be that these other industry stakeholders are unable or unwilling to keep track of and share all of this information, some of which they may consider proprietary or business sensitive. Moreover, connecting a unit dispensed to a patient to that patient's insurer raises health data privacy concerns, which CMS' proposal does not address. Aside from the substantial level of effort for *all* industry stakeholders (not just manufacturers) to create and participate in a network capable of following each unit of each medication, CMS should not compel manufacturers, as a condition of accurately reporting prices under the MDRP, to acquire massive amounts of data (some of which would likely be business confidential or private) from other stakeholders.

Assuming a system capable of tracking individual units throughout the pharmaceutical marketplace is even possible, PhRMA urges CMS to consider the impact that the time, effort, and expense necessary to develop this type of network could have on providers, supply chain entities, patients and the industry as a whole. The diversion of time and resources to this effort could limit participants' capacity to perform their key functions, whether that be developing new

[21] 88 Fed. Reg. 34286 ("At this time, we cannot determine cost estimates for this item.").

medicines, helping to source therapies to those who require them, or caring for patients. Despite the challenges and risks associated with such a system, the proposed rule says nothing about how manufacturers would operationalize the stacked version of Best Price, which has always been the manufacturer's lowest price to a single Best Price-eligible customer.

CMS must not adopt its proposed changes to the Best Price regulations. CMS' proposal exceeds its statutory authority and would also create operational challenges serious enough to make it infeasible.

B. Proposal to Modify the Definition of "Covered Outpatient Drug" (88 Fed. Reg. at 34242-43, 34252)

CMS proposes to expand the definition of a "covered outpatient drug" (COD) that triggers Medicaid rebates, by narrowing the "limiting definition" of a COD in SSA § 1927(k)(3), so that for the first time a COD could be an inpatient drug that is paid for as part of a bundled inpatient service instead of separately. For reasons explained below, CMS may not properly finalize and carry out this proposal. The proposal is not a valid interpretation of the Medicaid rebate statute: it contradicts the statute's language, history, and structure. Further, the proposal would make major changes to the Medicaid rebate program that are not explained or even acknowledged in the proposed rule.

Under the Medicaid rebate statute, only a "covered outpatient drug" is subject to rebates. And under the statute's "limiting definition" of a COD (in SSA § 1927(k)(3)), a COD does not include a drug "provided as part of, or as incident to and in the same setting as" certain specified services, including inpatient hospital services, "and for which payment may be made under [Medicaid] as part of payment for [hospital inpatient and other specified services] and not as direct reimbursement for the drug" (emphasis added). Therefore, a drug paid for as part of a specified service, such as a hospital inpatient service and for which payment is made "not as direct reimbursement for the drug," is not a COD that triggers Medicaid rebates. This is what takes a drug furnished as part of a bundled inpatient service out of the MDRP – i.e., what limits the MDRP to "covered outpatient drugs."

In the proposed rule, CMS makes a startling and unexplained proposal to expand the rebate program to virtually any drugs – inpatient or outpatient, bundled or unbundled – that are approved by the United States Food and Drug Administration (FDA) (or that are unapproved drugs within the COD definition). CMS states that over the years, it has received questions about when a payment is considered a "direct reimbursement" for a drug and whether identifying a drug separately on a claim for payment can amount to "direct reimbursement" for the drug. CMS states that "[i]f a drug and its cost can be separately identified on a claim for payment, it can be considered subject to direct reimbursement."[22] Armed with this novel theory, CMS proposes to revise the Medicaid rebate regulations to state that "direct reimbursement" for a drug may include both separate reimbursement for the drug (how "direct reimbursement" is interpreted today, and always has been interpreted since the beginning of the Medicaid rebate program) "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."[23] "In other words," CMS

[22] 88 Fed. Reg. at 34252.

[23] 88 Fed. Reg. at 34252, 34291 (proposed 42 C.F.R. § 447.502 (emphasis added)).

states, "the payment for the drug is not required to be a separate payment in order for such payment to be considered direct reimbursement."[24]

The proposed rule does not discuss any issues such as what the "itemized cost" of the drug represents and how it must be determined in this scenario; whether the larger service must be one in which the drug is always used; or how the "limiting definition" in SSA § 1927(k)(3) would continue to be limiting – what drugs it would exclude from the COD definition – if this new definition of "direct" reimbursement for a drug were finalized. Likewise, if bundled inpatient hospital drugs (or bundled drugs in the other settings referenced in SSA §1927(k)(3)) could be treated as "covered outpatient drugs" on which Medicaid rebates were payable, then they would also be subject to the coverage requirements in the Medicaid rebate statute (SSA § 1927(d)). Yet the proposed rule does not address any issues pertaining to how a bundled drug would need to be covered in the inpatient setting, where restrictive formularies may apply.

The new definition of "direct reimbursement" for a drug that CMS proposes is inconsistent with the text, structure, and history of the Medicaid rebate statute, and accordingly CMS must not finalize this proposal. Paying for a drug as part of a larger bundle of items and services that has the same payment rate whether the drug is furnished to the patient or not cannot reasonably be considered a "direct" payment for the drug.[25] Nor did Congress intend to allow any bundled payment for multiple items and services to be deemed a "direct" payment for the drug that would permit a drug furnished in the hospital inpatient setting (or the other settings listed in the limiting definition) to be deemed a "covered outpatient drug" triggering a Medicaid rebate. Instead, the legislative history of the Medicaid rebate statute is clear that a drug furnished in one of these listed settings can only be a covered outpatient drug when it is separately reimbursed by Medicaid – if the drug is reimbursed by Medicaid as part of a bundled payment, then the drug is not a covered outpatient drug. The statute's legislative history explains:

> A covered outpatient drug includes all prescription drugs except those for which Medicaid payment[] is made as part of payment for the following services: inpatient hospital, hospice, dental, physician office visits, outpatient hospital emergency room visits, and outpatient surgical procedures.[26]

Moreover, CMS also has long recognized that under the rebate statute's limiting definition, a drug is "directly" reimbursed – and thus falls within the definition of a COD – if and only if the drug is reimbursed separately, instead of reimbursed as part of a bundle. For example, CMS stated in its 2016 Covered Outpatient Drug final rule that:

> As discussed in the proposed rule (77 FR 5322), a drug which is billed as part of a bundled service with, and provided as part of or incident to and in the same setting as the services described in section 1927(k)(3) of the Act meets the definition of a COD if the state authorizes and provides a direct payment for the drug,

[24] 88 Fed. Reg. at 34252.

[25] According to the online Merriam-Webster dictionary, "direct" as an adjective means: proceeding from one point to another in time or space without deviation or interruption**:** STRAIGHT, a direct line, proceeding by the shortest way, the direct route, stemming immediately from a source, direct result. Here, the payment rate for a bundle of items and services – e.g., a DRG-based payment for a hospital inpatient stay—clearly does not "stem[] immediately from [the drug's itemized cost]."

[26] H.R. Rep. No. 101-881, 97 (Oct. 16, 1990) (emphasis added).

> consistent with the applicable state plan, separately from the service. ****
>
> Generally, if a state Medicaid program provides any payment for a COD that has been billed separately from a service, then in accordance with section 1927(b)(1) of the Act, the drug is subject to a manufacturer rebate under the MDR program. Alternatively, if the drug is provided as part of a bundled service and not separately reimbursed, then the drug does not qualify as a COD, in accordance with section 1927(k)(3) of the Act, and is not subject to rebates.[27]

CMS also has addressed the limiting definition of COD in the context of renal dialysis services, which are among the services specified in SSA § 1927(k)(3).[28] In connection with the end stage renal disease (ESRD) "bundle" under which Medicare pays for most ESRD services, CMS explained that bundled ESRD drugs cannot generate Medicaid rebates:

> [R]enal dialysis facilities are paid a single bundled rate for furnishing renal dialysis services, including most drugs used in the treatment of ESRD, and therefore, such bundled services can no longer be billed separately. … As a result, these bundled renal dialysis drugs and biologicals are no longer eligible for manufacturer rebates. Furthermore, the subsequent cross-over claim for the Medicaid-covered co-insurance requirement will no longer identify the drug information necessary for billing manufacturer rebates and, even if it can be derived from such a billing, should not be used to claim a Medicaid rebate….
>
> …. Since this [Medicaid cross-over co-insurance] is part of a bundled payment, manufacturers are not responsible for rebates.[29]

More recently, the Government has reiterated the principle that drugs provided and paid for as part of a bundled service listed in SSA § 1927(k)(3) are not CODs in litigation concerning the application of the limiting definition to radiopharmaceuticals. In 2018, the Government explained in the district court litigation that:

> CMS reasonably determined that because radiopharmaceuticals are approved by the FDA as prescription drugs, they are covered outpatient drugs within the meaning of the statute, unless they are provided, and paid for, as part of a bundled service.[30]

The Government went on to state that:

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[27] 81 Fed. Reg. 5170, 5187-88 (Feb. 1, 2016) (emphasis added).

[28] SSA § 1927(k)(3)(H).

[29] CMS, Medicaid Drug Rebate Program Release No. 85 for Participating Drug Manufacturers, at 3 (Oct. 26, 2012)(emphasis added).

[30] Defendants' Cross-Motion for Summary Judgment and Opposition to Plaintiff's Motion for Summary Judgment, *Council on Radionuclides and Radiopharmaceuticals, Inc. v. Azar*, No. 1:18-cv-00633-RBW, ECF No. 15, at 27 (D.D.C. 2018) (*citing* 81 Fed. Reg. 5185 and 42 U.S.C. § 1398r-8(k)(3)) *available at* 2018 WL 11580405 (emphasis added).

> [a] drug is not considered a "covered outpatient drug," however, *if* it is provided, and paid for, as part of a bundled service. 42 U.S.C. 1396r-8(k)(3) (limiting provision). The Secretary reasonably determined that because radiopharmaceuticals are approved by the FDA as prescription drugs they are covered outpatient drugs within the meaning of the Medicaid Drug Rebate statute (unless they are provided, and paid for, as part of a bundled service).[31]

On appeal, the Government again reiterated in 2021 that:

> [b]y operation of a limiting provision, drugs that are bundled together with certain services for payment are excluded from the definition of "covered outpatient drugs."[32]

Moreover, it is critical to emphasize that the limiting definition of covered outpatient drug in SSA 1927(k)(3) is what generally limits "covered outpatient drugs" to outpatient drugs, consistent with their name. If the new CMS proposal were adopted, any FDA-approved prescription drug, inpatient or outpatient, bundled or separately paid, could be treated as a COD as long as the provider's bill for bundled inpatient drugs – inpatient drugs paid for with related services "in one inclusive payment" – had a notation that it included the drug in question and listed the drug's "itemized cost." In this scenario, state Medicaid programs would presumably choose to identify the drug and its "itemized cost" on the claim for a bundled service and few drugs would fall outside the COD definition. But such a result would make the "covered outpatient drug" term nonsensical and the limiting definition meaningless. This plainly was not what Congress intended when it made Medicaid rebate statute apply only to "covered outpatient drugs" and added the limiting definition to the statute to spell out the contours of a COD.

Under a longstanding canon of construction, Congress does not engage in this type of meaningless exercise when it enacts federal statutes.[33] Congress could have skipped the whole exercise of defining a covered outpatient drug and excluding bundled inpatient drugs from that term if it wanted to make all FDA-approved prescription drugs subject to rebates: it could have called rebatable drugs "covered drugs" and finished there—but Congress did not make that choice, and this CMS cannot ignore.[34] Reversing that Congressional decision falls outside the powers of CMS. Moreover, the 340B statute also uses the term "covered outpatient drug" and defines this term by reference to SSA 1927(k).[35] Should CMS adopt its proposal to extend "covered outpatient drugs" to inpatient drugs and make the limiting definition in SSA 1927(k)(3)

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[31] Defendants' Reply to Plaintiff's Opposition to Defendants' Cross-Motion For Summary Judgment, *Council on Radionuclides and Radiopharmaceuticals, Inc. v. Azar*, ECF No. 22, No. 1:18-cv-00633-RBW, at 14 (D.D.C. 2019), *available at* 2019 WL 13388326 (italics in original) (emphasis added).

[32] Brief for Appellees, *Council on Radionuclides & Radiopharmaceuticals, Inc. v. Becerra*, No. 20-5346, ECF No. 1900665 at 10 (D.C. Cir. May 28, 2021) *available at* 2021 WL 2184514, *1.

[33] "[W]e must interpret the statutory phrase as a whole, giving effect to each word and not interpreting the provision so as to make other provisions meaningless or superfluous. *Boise Cascade Corp. v. EPA,* 942 F.2d 1427, 1432 (9th Cir.1991)*; see also United States v. Menasche,* 348 U.S. 528, 538-39 (1955).

[34] An agency's power to regulate "must always be grounded in a valid grant of authority from Congress. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000).

[35] 42 U.S.C. § 256b(b)(1).

meaningless, this step would create an unauthorized sea change in the MDRP and could create the risk of confusion and chaos in the 340B program as well.

As the statutory language and the precedents discussed above make clear, CMS states it is merely "seek[ing] greater clarity on the meaning of 'direct reimbursement,'" but CMS' proposed definition would actually be a significant shift that would dramatically increase the scope of drugs falling under the MDRP. CMS does not acknowledge that its proposal would represent a major shift, or provide any reasoned explanation for this proposed change. As detailed above, CMS has not even discussed any of the questions that naturally arise about how this proposal could work as an operational matter. Federal agencies must do much more than this to adopt such a far-reaching change in their position. As the courts have long emphasized:

> When an **agency changes** its **position**, it must (1) "display[ ] awareness that it is **changing position**," (2) show "the new policy is permissible under the statute," (3) "believe[ ]" the new policy is better, and (4) provide "good reasons" for the new policy. *Org. Vill. of Kake v. U.S. Dep't of Agric.*, 795 F.3d 956, 966 (9th Cir. 2015) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515–16, 129 S.Ct. 1800, 173 L.Ed.2d 738 (2009)).[36]

CMS has not satisfied any of these four requirements for a change in position. CMS has not displayed awareness of the far-reaching nature of its proposed changes. The proposed change is not permissible under the statute – a sticking point no CMS explanation can overcome. And finally, CMS has not stated that it believes the proposed change would be better, or explained any good reasons for its adoption.

In short, CMS may not finalize this proposal. CMS instead should stay within the boundaries of the covered outpatient drug definition and avoid the risks of creating upheaval and instability in two federal drug programs.

C. Proposal to Expand the Definition of "Manufacturer" (88 Fed. Reg. at 34254-56, 34292)

PhRMA opposes CMS' proposal to expand the definition of a "manufacturer" because the proposed definition is inconsistent with the Medicaid rebate statute and the legislative history. The Medicaid rebate statute defines a "manufacturer" as "any entity which is engaged in—(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or (B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law."[37]

The rebate statute and its legislative history are both silent on corporate affiliations. There is no statement in the Medicaid rebate statute (or even in its legislative history) suggesting that a "manufacturer" includes the manufacturer itself and additional entities that are affiliated with the manufacturer in some manner. Likewise, neither the Medicaid rebate statute nor its legislative history suggest that under SSA § 1927(a), a manufacturer's drugs may not be covered by Medicaid or Medicare Part B unless all the drugs of the manufacturer itself and of manufacturer

[36] *Center for BIO Diversity v. Haaland*, 998 F.3d 1061, 1067 (9th Cir. 2021).

[37] SSA § 1927(k)(5).

affiliates are subject to a Medicaid rebate agreement. However, CMS now proposes to adopt an open-ended definition of a "manufacturer" that would read as follows:

> For the purposes of maintaining an effectuated rebate agreement consistent with section 1927(a)(1) of the Social Security Act, the term ''manufacturer'' means that all associated 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.[38]

Similarly, CMS makes two related proposals that would: (1) require that a manufacturer with a rebate agreement that "acquires or purchases [CODs] from another labeler code, or forms a new subsidiary" must ensure that a signed rebate agreement is in effect for all of those entities or CODs; and (2) subject all of a manufacturer's labeler codes to termination if any "associated labeler code" is not covered by a rebate agreement or is terminated.[39]

PhRMA does not support this proposal to redefine a manufacturer as an entity described as such in SSA § 1927(k)(5) plus "all associated 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," as this proposal goes too far beyond the statute's language.

First, CMS lacks the authority to broaden the "manufacturer" definition so as to include the manufacturer and various undefined "associated entities." Expanding the definition of a "manufacturer" that must participate in the MDRP (or have Medicaid and Medicare Part B deny coverage for its drugs) from a manufacturer as described in SSA § 1927(k)(5) to a statutorily-described manufacturer *plus* "all associated entities …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" would give the MDRP an immense scope that Congress never intended or authorized. Had Congress meant to create such a program – with far-reaching powers to control virtually the entire pharmaceutical sector of our economy – it would have said so. As the Supreme Court has often emphasized, Congress is expected to "speak clearly when authorizing an agency to exercise powers of vast economic and political significance."[40] This is particularly true, if like here, an agency "claim[s] to discover an

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[38] 88 Fed. Reg. at 34292 (proposed 42 CFR 447.502) (emphasis added).

[39] 88 Fed. Reg. at 34294 (proposed 42 CFR 447.510(h)(2)-(3)).

[40] *Ala. Ass'n of Realtors v. U.S. Dep't of Health & Hum. Servs.*, 141 S. Ct. 2485, 2489 (2021) (citing *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000) (internal quotation marks omitted). *See also, e.g., West Virginia v. EPA,* 142 S. Ct. 2587, 2595 (2022) (citing *Utility Air Regulatory Group v. EPA*, 573 U.S. 302, 324 (2014)) (The U.S. Supreme Court held that "[u]nder . . . the major questions doctrine, given both separation of powers principles and a practical understanding of legislative intent, the agency must point to 'clear congressional authorization' for the authority it claims."); *id*. at 2608 (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000)) (in *Brown & Williamson*, the U.S. Supreme Court "rejected [the] 'expansive construction of the statute,' concluding that 'Congress could not have intended to delegate' such a sweeping and consequential authority 'in so cryptic a fashion.'"); *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 147, 157 (2000) ("Given the economic and political significance of the tobacco industry at the time, it is extremely unlikely that Congress could have intended

unheralded power representing a transformative expansion" of the statute.[41] Congress surely would not have remained silent regarding a mandate that "all associated entities" of a manufacturer participate in the MDRP or else all of the manufacturer's drugs would lose Medicaid and Medicare Part B coverage. Such a drastic change in the "manufacturer" definition would disrupt how manufacturers operate and inflate CMS' powers. And here, the idea that a "manufacturer" under the Medicaid rebate statute includes the manufacturer actually described in the statute plus "all associated entities" is not even hidden "in vague terms or ancillary provisions"[42] of the Medicaid rebate statute; it is nowhere to be found.[43]

In fact, even the Medicaid rebate statute's legislative history does not support construing "manufacturer" as the manufacturer itself plus "all corporate affiliates." This point is worth noting because CMS' case for expanding the "manufacturer" definition as proposed rests solely on CMS' understanding of the statute's legislative history (and on past guidance from CMS, which lacks the force and effect of law).[44] Specifically, the proposed rule cites "Congress' desire to maximize recipient access to medically necessary drugs while at the same time providing a more favorable drug purchasing arrangement for state Medicaid agencies" and argues that "it would be directly contrary to Congressional intent to apply the definition of a manufacturer in a manner that would permit a manufacturer (that is, by forming a subsidiary corporation) to exclude some of its drugs from the MDRP."[45] While CMS does not actually quote the cited legislative history, the legislative history does indicate that Congress wished to improve Medicaid beneficiaries' access to drugs and to reduce state Medicaid programs' drug costs[46] –

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to place tobacco within the ambit of the FDCA absent any discussion of the matter. . . . Moreover, Congress expressly pre-empted any other regulation of the labeling of tobacco products concerning their health consequences, even though the oversight of labeling is central to the FDCA's regulatory scheme. . . . Under these circumstances, we believe the appropriate inference that Congress intended to ratify the FDA's prior position that it lacks jurisdiction—is unmistakable.")

[41] *West Virginia v. EPA,* 142 S. Ct. 2587, 2595 (2022) ("EPA claimed to discover an unheralded power representing a transformative expansion of its regulatory authority in the vague language of a long-extant, but rarely used, statute designed as a gap filler. That discovery allowed it to adopt a regulatory program that Congress had conspicuously declined to enact itself. Given these circumstances, there is every reason to 'hesitate before concluding that Congress' meant to confer on EPA the authority it claims under Section 111(d).").

[42] Whitman v. Am. Trucking Ass'n, 531 U.S. 457, 468 (2001) ("Congress, we have held, does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes.").

[43] Under the *Chevron* two-step analysis, if a "statute is silent or ambiguous with respect to the specific issue" (step 1), then courts assess whether the agency's interpretation is "a permissible construction of the statute" (step 2). *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 468 U.S. 837, 842-43 (1984). Because the Medicaid rebate statute's "manufacturer" definition unambiguously does not include "all associated entities" of a manufacturer, courts would not reach the second step as to whether CMS' proposed broad definition is a permissible construction of the statute.

[44] 88 Fed. Reg. at 34255.

[45] 88 Fed. Reg. at 34256 (citing but not quoting H.R. Conf. Rept. No. 964, 101st Cong., 2d Sess. 822, 832 (1990) and H.R. Rep. No. 881, 101st Cong., 2d Sess. 996 (1990)).

[46] As noted above, the proposed rule cites H.R. Conf. Rept. No. 101-964, at 822 and 832 and H.R. Rept. No. 101-881, at 996. We note that House conference report no. 964 at 822 refers to "a" manufacturer in a singular term: "[I]n the case of **a** manufacturer which has entered into and complies with an agreement, States will cover **the** manufacturer's covered outpatient drugs." (emphasis added). Otherwise, this report

but these propositions are far afield from showing that Congress intended a "manufacturer" under the rebate statute to include entities beyond those expressly defined in the statutory text as a manufacturer. And the cited legislative history says nothing about including manufacturer affiliates in the "manufacturer" definition, requiring that affiliated entities participate in the rebate program, or anything else regarding manufacturers' affiliates or affiliations.

Second, Congress knows how to define an entity so as to include the entity's corporate affiliates – and it does so expressly when it intends that result – but it did not do so in the Medicaid rebate statute. For example, Congress explicitly defined a "manufacturer" to include specified affiliates in certain provisions of the Inflation Reduction Act (IRA) and the Internal Revenue Code (IRC). In the IRA, Congress generally adopted the definition of a "manufacturer" from the Medicaid rebate statute for purposes of the "Negotiation" Program and the new Part D Manufacturer Discount Program.[47] But in certain cases, Congress chose to include corporate affiliates in the "manufacturer" definition and did so explicitly, by referencing certain IRC provisions and providing that all persons treated as a single employer under those IRC provisions "**shall be treated as one manufacturer"** for specified purposes.[48] The referenced IRC provisions establish special tax rules regarding certain corporate associations: under subsection (a), when a parent corporation has "more than 50%" ownership of a subsidiary, then both are treated as one corporation, and under subsection (b), "all employees of trades or business . . . which are under common control [are] treated as employed by a single employer."[49]

These statutory examples illustrate two key points. First, when Congress wishes to define an entity to include affiliates, it does so expressly. Second, these examples provide even more evidence (although the text of the rebate statute's "manufacturer" definition already makes this

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generally describes Medicaid rebate agreement requirements and is completely silent on corporate affiliations. With respect to House Report no. 881, the proposed rule's reference to page 996 is an error; the report does not have a page 996 and discusses the Medicaid rebate program at pages 95-98, so we believe that CMS likely meant to cite page 96. This report states at pp. 96-97 that: "The Committee bill would . . . establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser. Because the Committee is concerned that Medicaid beneficiaries have access to the same range of drugs that the private patients of their physicians enjoy, the Committee bill would require States that elect to offer prescription drugs to cover all of the products of any manufacturer that agrees to provide price rebates." Also, page 98 of the report says that States must "cover all of the drugs of any manufacturer entering into and complying with [a Medicaid rebate agreement] with the Secretary."

[47] SSA § 1191(c)(1) (cross referencing SSA § 1847A(c)(6)(A) to define a "manufacturer," which in turn references SSA § 1927(k)(5)); SSA § 1860D-14C(g)(5) (defining a "manufacturer" as "any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.").

[48] Specifically, the "aggregation rule" in the following provisions provides that "[a]ll persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 shall be treated as one manufacturer for [specified] purposes]." SSA § 1192(d)(2)(B)(i) (small biotech drug exception), 1192(f)((1)(C) (biosimilar pause), 1860D-14C(g)(4)(B)(ii)(II)(bb) (Part D manufacturer discount phase-in for specified manufacturers); 1860D-14C(g)(4)(C)(ii)(II)(bb) (Part D manufacturer discount phase-in for specified small manufacturers).

[49] 26 U.S.C. §§ 52(a), (b).

clear) that the rebate statute's "manufacturer" definition does not extend to manufacturer affiliates; otherwise there would be no need for IRA provisions with the same manufacturer definition as the rebate statute to specify that certain affiliated entities "shall be treated as one manufacturer."

Third, Congress would not have authorized CMS to define a "manufacturer" in a way that would "pierce the corporate veil" without permitting this explicitly, as well-recognized corporate law principles generally presume that subsidiaries are regarded as distinct legal entities absent certain exceptional circumstances.[50] The Supreme Court has held that a federal statute will not be construed to upend this "fundamental principle of corporate law" unless it "speaks directly."[51] Therefore, Congress would not have presumed that by remaining silent on "piercing the veil" it was somehow granting CMS authority to pierce the veil and collapse affiliated companies into one "manufacturer" under the Medicaid rebate statute.

Fourth, CMS' proposal is inconsistent with language in the Medicaid rebate statute suggesting that corporate affiliates are not the "same" manufacturer. For example, the

[50] *See, e.g., Corrigan v. U.S. Steel Corp.*, 478 F.3d 718, 724 (6th Cir. 2007) (holding that the plaintiffs failed to show that the defendant were "fundamentally indistinguishable." The court explained that "[a] parent corporation generally is not liable for the acts of its subsidiary, even if its subsidiary is wholly owned. . . . [A] court should focus on principles of equity and whether the relationship is so dominating that respecting it would be unjust."); *Benton v. Cameco Corp.*, 375 F.3d 1070, 1081 (10th Cir. 2004) (quoting *Quarles v. Fuqua Indus., Inc.*, 504 F.2d 1358, 1362 (10th Cir. 1973)) ("[A] holding or parent company has a separate corporate existence and is treated separately from the subsidiary in the absence of circumstances justifying disregard of the corporate entity." The court explained that an overlap of one common officer between an entity and its wholly-owned subsidiary is "insufficient proof" to show that the subsidiary is the general agent or alter ego of the entity.).

[51] *United States v. Bestfoods*, 524 U.S. 51, 62-63 (1998) ("But there is an equally fundamental principle of corporate law, applicable to the parent-subsidiary relationship as well as generally, that the corporate veil may be pierced and the shareholder held liable for the corporation's conduct when, *inter alia,* the corporate form would otherwise be misused …, most notably fraud . . . Nothing in CERCLA purports to rewrite this well-settled rule, either. CERCLA is thus like many another congressional enactment in giving no indication that the entire corpus of state corporation law is to be replaced simply because a plaintiff's cause of action is based upon a federal statute, and the failure of the statute to speak to a matter as fundamental as the liability implications of corporate ownership demands application of the rule that in order to abrogate a common-law principle, the statute must speak directly to the question addressed by the common law." (internal quotations and citations omitted)). *See also, e.g.*, *In re Crescent City Estates, LLC*, 588 F.3d 822, 826 (4th Cir. 2009).("As to the general applicability of common - law principles to federal statutes, the Supreme Court has held that "in order to abrogate a common-law principle, the statute must speak directly to the question addressed by the common law. Nothing in the FLSA seeks to displace the principles of agency law"(citing *United States v. Texas*, 507 U.S. 529, 534 (1993) (internal quotations omitted).

An example of a case where Congress did pierce the veil – and did so explicitly – is the Corporate Transparency Act (CTA), which authorized the Treasury Department's Financial Crimes Enforcement Network to pierce the corporate veil to crack down on "shell companies" used in financial crimes. *See* Nation Defense Authorization Act § 6403(a); H.R. Rep. No. 227, 116th Cong, 1st Sess.10 (2019) ("No state of the United States currently requires companies (including anonymous shell companies) to disclose their beneficial owners. , , , The Corporate Transparency Act would address this omnipresent hindrance by requiring a company's beneficial owners to be disclosed to FinCEN.…); Washington Post (Oct. 12, 2022), Elizabeth Meehan, The U.S. Treasury Expects Millions of Companies to Name their Owners ("According to Treasury, the CTA will 'pierce the corporate veil' and require reporting the real person who owns a company, not just the shell company that claims ownership").

statute defines the baseline AMP for older drugs as the AMP for the quarter beginning July 1, 1990 "without regard to whether or not the drug has [later] been sold or transferred to an entity, including a division or subsidiary of the manufacturer."[52] Had Congress intended to capture "all associated entities" in the "manufacturer" definition, it would not have clarified that the baseline AMP would be inherited even if the drug has been sold to a "division or subsidiary of the manufacturer"—it would already have been understood that a drug sold to an "associated entity" would keep the same baseline AMP.

Similarly, the proposed rule's "manufacturer" definition could result in a drug having many manufacturers – the actual manufacturer plus multiple companies with various types of affiliation with the manufacturer – whereas the Medicaid rebate statute strongly suggests instead that each drug has only one manufacturer. The rebate statute's first sentence provides that "[i]n order for payment to be available under section 1903(a) [Medicaid] or under part B of title XVIII [Medicare] for covered outpatient drugs of **a** manufacturer, **the** manufacturer must have entered into and have in effect a [Medicaid] rebate agreement . . . ."[53] Similarly, SSA § 1927(b)(1)(A) provides that a rebate agreement "shall require **the** manufacturer to provide, to each State plan approved under this title, a rebate for a rebate period …for covered outpatient drugs of **the** manufacturer . . . ." (emphasis added). The statute's obligations thus apply to "a" manufacturer with respect to "the" manufacturer's drugs, making clear that the definition of a "manufacturer" under SSA § 1927(k)(5) should be read in a way that each drug has only one manufacturer.

Fifth, even if CMS had the authority to define a "manufacturer" to include corporate affiliates – and for reasons set forth above, CMS plainly lacks that authority – the proposed rule's definition of a "manufacturer" is not comprehensible or workable. Specifically, CMS' definition is too vague. CMS proposes that a manufacturer "include[s], but [is] 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."[54] CMS does not define what any of these ten terms mean. Without a definition, these broad terms could potentially sweep into the "manufacturer" definition any entity that has some sort of business relationship with the manufacturer—or at a minimum, cause confusion about which entities fall within one or more of the ten terms in CMS' proposed definition. But courts generally hold that agencies may not issue vague and non-specific regulations.[55] In fact, in 1995, CMS had proposed to define a "manufacturer" in a manner that

[52] SSA § 1927(c)(2)(A)(ii)(II) (emphasis added).

[53] SSA § 1927(a)(1) (emphasis added).

[54] 88 Fed. Reg. at 34292.

[55] *See, e.g.*, *Sentner v. Colarelli*, 145 F. Supp. 569 (E.D. Mo. 1956), *judgment aff'd* 353 U.S. 963 (1957) ("[A]dministrative regulations are subject to the same requirements of definiteness as are statutes."); *Mahoney v. U.S. Capitol Police Bd.*, 566 F. Supp. 3d 1, 20 (D.D.C. 2022) (quoting *F.C.C. v. Fox Television Stations, Inc.*, 567 U.S. 239 (2012)) ("The Due Process Clause 'requires the invalidation of laws [or regulations] that are impermissibly vague.'"); *Indep. Ins. Agents & Brokers v. N.Y. State Dep't of Fin. Servs.*, 39 N.Y.3d 56, 65-66 (N.Y. 2022) (quoting *Ulster Home Care, Inc. v. Vacco*, 96 N.Y.2d 505, 509 (2001)) ("A statute, or a regulation, is unconstitutionally vague if it fails to provide a person of ordinary intelligence with a reasonable opportunity to know what is prohibited, and it is written in a manner that permits or encourages arbitrary or discriminatory enforcement."); *Sobin v. District of Columbia*, 480 F. Supp. 3d 210, 220 (D.D.C. 2020) (quoting *Freeman United Coal Mining Co. v. Fed. Mine Safety & Health Rev. Comm'n*, 108 F.3d 358, 362 (D.C. Cir. 1997) ("[R]egulations will be found to satisfy due process so long as they are sufficiently specific that a reasonably prudent person, familiar with the conditions the

would have treated any affiliate that is owned "at least 80%" by another entity to be the same manufacturer.[56] CMS' very different proposed definition from nearly three decades ago – while also not permitted under the statute – is clearer and more specific than the current proposed definition, which further highlights the defects in this proposed definition.

Further, CMS itself would be hard-pressed to understand which entities are part of a certain "manufacturer" under its proposed definition: CMS does not have the expertise on corporate affiliation matters or the fact-finding ability that would be necessary for CMS to try to apply this proposed definition and identify who is a "manufacturer."[57] The lack of expertise is demonstrated in the way CMS arbitrarily defined the term "manufacturer" – a definition sprinkled with undefined terms describing various business relationships that generally lack a standard, commonly understood meaning, which could not readily be applied to a particular case. Manufacturers would not have fair notice of what was expected of them under the Medicaid rebate statute were this definition finalized and put into place. The inevitable result of finalizing this proposed definition (or anything even remotely resembling it) would be costly disputes reducing the efficiency of the MDRP, unfairness to manufacturers, and frustration for CMS.

Finally, we note that even if CMS had the authority to issue regulations that extended the Medicaid rebate statute's "manufacturer" definition to corporate affiliates, which it does not, CMS could not do so retroactively. In the preamble to the proposed rule, CMS repeatedly claims that its "longstanding" policy has been to include all "associated labelers" in the "manufacturer" definition.[58] CMS alludes to the proposed definition representing a clarification of what CMS "continue[s]" to believe from the inception of the MDRP, perhaps hinting that the proposed definition could not only be finalized but then applied retroactively from the beginning of the MDRP.[59] Well-established case law makes clear that CMS could not do this.[60] Federal agencies do not have the power to promulgate rules with a retroactive effect

regulations are meant to address and the objectives the regulations are meant to achieve, would have fair warning of what the regulations require.").

[56] 60 Fed. Reg. 48442, 48447-48 (Sept. 19, 1995).

[57] Courts are unlikely to find that Congress implicitly granted an agency certain important powers (and instead will require an express grant of authority) where the agency "has no expertise in crafting …policy [in the area in question]." *King v. Burwell*, 135 S. Ct. 2480, 2489 (2015). *See also, e.g.*, *Gonzales v. Oregon*, 546 U.S. 243, 266–67 (2006) (Congress would not be presumed to delegate interpretive authority to the Attorney General on an issue where he lacked expertise); *City & Cnty. of San Francisco v. Trump*, 897 F.3d 1225, 1242 (9th Cir. 2018) (an agency interpretation of an important economic and political question may not be entitled to deference and "[t]his is particularly true where the agency lacks expertise").

[58] 88 Fed. Reg. at 34254-56.

[59] 88 Fed. Reg. at 34256.

[60] *Bowen v. Georgetown Univ. Hosp*., 488 U.S. 204, 208 (1988) (holding that "[a]s a general matter, statutory grants of rulemaking authority will not be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by express terms."). *See also, e.g., United States v. Fermin*, No. 02-CR-1213 (RPP), 2010 WL 468357 (S.D.N.Y. Nov. 17, 2010) (holding that the Fair Sentencing Act does not apply retroactively because it is silent with respect to any retroactive effects); *AT & T Corp. v. Hulteen*, 556 U.S. 701, 715 (2009) (holding that the Pregnancy Discrimination Act of 1978 cannot be applied retroactively because Congress did not make the law retroactive).

absent an express delegation of authority from Congress.[61] Congress did not grant such authority to CMS under the Medicaid rebate statute.

II. Proposed "Internal Investigations" Definition (88 Fed. Reg. at 34253-54; 34291-92)

The Medicaid rebate statute requires manufacturers to report certain pricing information to CMS within specified times following the end of a rebate period.[62] CMS regulations generally limit manufacturers' ability to report revisions to AMP, best price, customary prompt pay discounts, or nominal prices to "a period not to exceed 12 quarters from the quarter in which the data were due."[63] However, because "certain circumstances will arise that may require a revision of pricing data [after 12 quarters]," CMS will consider revision requests after the 12 quarter period ends if (among other things) "[t]he change is to address specific rebate adjustments to States by manufacturers, as required by CMS or court order, or under internal investigation, or an OIG or Department of Justice (DOJ) investigation."[64] CMS has not previously defined "internal investigation" and now proposes to define this term as follows:

> A manufacturer's investigation of its AMP, best price, customary prompt pay discounts, or nominal prices that have been previously certified in the [MDRP] that results in a finding made by the manufacturer of fraud, abuse, or violation of law or regulation. A manufacturer must make data available to CMS to support its finding.[65]

PhRMA opposes this definition, which if adopted would essentially render the internal investigation exception meaningless. Price reporting revisions are complex and manufacturers do not take them lightly. A manufacturer will have no incentive to undertake the burden of requesting a pricing revision if to do so it must represent to CMS (and provide evidence) that it is seeking to revise previously reported data because its internal investigation found "fraud, abuse, or violation of law or regulation." In effect, CMS is proposing to limit the internal investigation exception to circumstances in which a manufacturer admits legal culpability and presents the government with its case against the manufacturer (or states that a previous owner of the drug that reported the data in question engaged in fraud, abuse, or violation of law or

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[61] When an agency's rule implicates actions pre-dating the rule's effective date, the rule is impermissibly retroactive where (1) the application of the rule would have a retroactive effect and (2) Congress has not authorized retroactive rulemaking. *See, e.g., Landgraf v. USI Film Prods*., 511 U.S. 224, 280 (1994) ("When a case implicates a federal statute enacted after the events in suit, the court's first task is to determine whether Congress has expressly prescribed the statute's proper reach. If Congress has done so, of course, there is no need to resort to judicial default rules. When, however, the statute contains no such express command, the court must determine whether the new statute would have retroactive effect . . . . If the statute would operate retroactively, our traditional presumption teaches that it does not govern absent clear congressional intent favoring such a result."). *See also Bowen*, 488 U.S. at 208 (applying the same two-step analysis to agency rulemaking). CMS' proposed definition, applied retroactively, would alter "the *past* legal consequences of past actions." *Bowen*, 488 U.S. at 219–20 (Scalia, J., concurring).

[62] SSA § 1927(b)(3).

[63] 42 C.F.R. 447.510(b)(1).

[64] 42 C.F.R. 447.510(b)(1)(v) (emphasis added);*see also* 81 Fed. Reg. at 5279.

[65] 88 Fed. Reg. at 34291-34292 (emphasis added).

regulation). We are concerned that this could have a chilling effect on pricing revision requests, potentially leading to less accurate pricing data. CMS would essentially nullify an exception it just created in 2016, without explaining why.[66]

A manufacturer may wish to revise previously-reported data that was calculated under a methodology that may be consistent with the law and regulations (and not the product of abuse) but not the best practice for calculating the metric in question. In many cases, several methods for handling a certain reporting issue may be reasonable and consistent with the law, but the manufacturer believes one method is better or a change is necessary, to bring practices for newly-acquired products into conformity with the company's existing practices. The idea that a manufacturer would only seek to revise previously-reported data because it has concluded that the reported data stems from "fraud, abuse, or a violation or law or regulation" is not correct, and CMS should not prevent a manufacturer from requesting a revision after 12 quarters unless the manufacturer is willing to represent to CMS that the previously-reported data stems from misconduct.

CMS appears fixated on a specific fact pattern – all of the examples in the proposed rule involve manufacturers that requested a revision following an acquisition of a product or a line of business[67] – and does not consider the various reasons why manufacturers may conduct an internal investigation. Manufacturers conduct internal investigations for many reasons, such as when looking into potential errors or discrepancies in the normal course of corporate self-governance programs, and such investigations can result in valuable recommendations for improvements in price reporting practices even if the existing practice is not a violation of law. The proposed rule does not explain why CMS now wishes to cut off manufacturer requests to revise data after 12 quarters in these circumstances. Such requests have the potential to improve the accuracy of reported Medicaid rebate metrics, which presumably was the goal of creating exceptions to the 12 quarter limit in the first place, and in certain cases also could correct underpayments to States. Moreover, the CMS proposal seems particularly puzzling and misguided because the internal investigation exception is merely a vehicle to request that CMS permit pricing revisions after 12 quarters; if CMS concludes that such revisions are unwarranted it can just deny the request. Under this proposal, however, CMS would not have the option to approve many requests, including ones that could resolve underpayments to States. Therefore, we request that CMS not finalize its proposed "internal investigation" definition. If CMS wishes to define "internal investigation" in future rulemaking, we encourage CMS to develop a proposal that maintains the viability of the internal investigation exception to the general 12 quarter rule, instead of a proposal that essentially forecloses pricing revision requests following an internal investigation.

[66] 81 Fed. Reg. 5170, 5354 (Feb. 1, 2016).

[67] CMS provides the following examples: (1) "For example, some requests from manufacturers to revise AMP or best price for drug product and drug pricing information previously reported and certified from another manufacturer were based on internal reviews that did not result in proof that the prior manufacturer misapplied the laws or regulations, or acted in a fraudulent or illegal manner"; (2) "For example, a request to restate or revise pricing outside of the 12-quarter time frame by a manufacturer to previously reported and certified data of a prior manufacturer based upon a mere disagreement with the prior manufacturer's government pricing calculations and assumptions would not be considered a valid reason to revise a prior manufacturer's pricing outside of the 12-quarter time frame. The manufacturer must make findings that include actual data as evidence that the prior manufacturer violated statute or regulation." 88 Fed. Reg. at 34254.

III. Proposed "Vaccine" Definition (88 Fed. Reg. at 34258-34260; 34292)

The MDRP statute excludes all "vaccines," without limitation, from the COD definition. In relevant part, the statute defines a "covered outpatient drug" as a "biological product, other than a vaccine." SSA § 1927(k)(2) (emphasis added). CMS has not previously defined a "vaccine" for this purpose and now proposes to define a "vaccine" as follows:

> Vaccine means a product that is administered prophylactically to induce active, antigen-specific immunity for the prevention of one or more specific infectious diseases and is included in a current or previous FDA published list of vaccines licensed for use in the United States.[68]

PhRMA opposes CMS' proposed definition of a "vaccine" and urges CMS not to finalize its proposal. Given the importance of this issue, PhRMA is concerned that CMS has not adequately consulted with groups that have expertise with vaccines. Therefore, we recommend that CMS convene relevant stakeholder groups and programs – including for example, the FDA, the Centers for Disease Control and Prevention (CDC), Advisory Committee on Immunization Practices (ACIP), and the Vaccine Injury Compensation Program (VICP) – to discuss the definition of vaccine in other programs. We also recommend that CMS consult with stakeholders to determine whether there is consensus over CMS' proposed definition, and whether CMS should seek alignment with other program definitions in defining "vaccines' under the MDRP. After such coordination and if CMS moves forward with proposing a definition, it is critically important that go through notice and comment rulemaking to ensure a transparent and deliberative process with stakeholder feedback.

Separately, we also have concerns with CMS' proposed requirement that a vaccine must "appear on a current or previous list compiled by FDA."[69] The preamble cites to FDA's *Vaccines Licensed for Use in the United States* list (Vaccine List).[70] Unlike the Purple Book, which FDA is statutorily-obligated to update,[71] the Vaccine List is an informal list on FDA's website. FDA has no obligation to keep the Vaccine List updated, define what is being included on the list, or ensure that it is comprehensive. If after consulting with relevant stakeholders CMS proposes a "vaccine" definition, we believe it would be inappropriate for CMS to require that vaccines appear on the Vaccine List.

IV. Drug Classification; Oversight and Enforcement of Manufacturer's Drug Product Data Reporting Requirements (88 Fed. Reg. at 34261-66; 34293-94)

A. Definitions of "S," "I" and "N" Drugs and Application of Narrow Exception. (42 C.F.R. § 447.509)

In the preamble discussion of the definition of "drug product information," CMS states:

> [T]he drug category for an NDC should be single source or innovator for the entire history of the NDC if it was always produced,

[68] 88 Fed. Reg. at 34292.

[69] 88 Fed. Reg. at 34259.

[70] FDA, Vaccines Listed for Use in the United States, https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states.

[71] Public Health Service Act § 351(k)(9).

> distributed, or marketed under an NDA, unless a narrow exception applies, or single source if marketed under a BLA. If a narrow exception has been granted by CMS, the drug category for that NDC should historically be reported as single source or innovator, and can be changed to noninnovator, effective April 1, 2016.[72]

Later, in the section of the preamble discussing misclassification, CMS portrays the Medicaid Services Investment and Accountability Act of 2019 (P.L. 116-16) (MSIAA) revisions to the S, I, and N definitions as mere clarifications, stating that the changes were made only "***to clarify*** the definitions for multiple source drug, single source drug and innovator multiple source drug."[73]

In both cases, CMS mischaracterizes the MSIAA. The whole point of the narrow exception process was to recognize that certain drugs approved under NDAs were more appropriately treated as noninnovator drugs, and this recognition should apply from the outset of the MDRP. CMS should specify that drugs meeting the narrow exception are non-innovator drugs under the plain language of both the pre- and post-MSIAA definitions. The U.S. District Court for the District of Columbia embraced the view that under the MDRP, the definition of "N" drugs has always been broader than just products approved via an ANDA. In *STI Pharma, LLC v. Azar*,[74] a drug manufacturer challenged a narrow exception decision by CMS that a drug approved under a "paper NDA" (i.e., a non-original NDA) must be classified as an innovator product for reporting periods prior to April 1, 2016. The court concluded that CMS' interpretation contradicted the then-current Medicaid rebate statute and thus vacated CMS' action.[75]

Furthermore, CMS is wrong to frame its 2016 rulemaking and the MSIAA's subsequent deletion of the word "original," as mere "clarifications" that apply retroactively. First, given the subsequent enactment of the MSIAA and its deletion of the word "original" in the definitions of "S" and "I" drugs, CMS' position that its 2016 final rule reflects the plain language of the Medicaid Act is suspect. Until the MSIAA's enactment, the Medicaid rebate statute defined both single source "S" and multi-source "I" drugs as products approved under "an ***original new drug application*** approved by [the FDA]."[76] The MSIAA removed references to "original" from the definitions of "S" and "I" drugs but made these changes prospective only.[77]

The *STI Pharma* Court also found that pre-MSIAA, Congress' use of the word "original" was significant and permitted certain drugs approved under NDAs to be rightly classified as non-

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[72] 88 Fed. Reg. at 34252.

[73] 88 Fed. Reg. at 34252.

[74] 613 F.Supp.3d 152 (D.D.C. 2020).

[75] *See id.* at 169–70 (("[T]he version of the MDRP statute in effect during the [pre-2016] period is best read to treat duplicate drugs approved pursuant to paper NDAs as 'noninnovator multisource drugs'[.] . . . CMS's decision . . . for the period from 2013 through 2016 must be set aside as not in accordance with law.").

[76] SSA § 1927(k)(7)(A)(ii), (iv) [42 U.S.C. § 1396r-8(k)(7)(A)(ii), (iv)] (prior to April 2019) (emphasis added). "Original" means "the first instance of a source from which a copy, reproduction, or translation is or can be made" and "not secondary, derivative, or imitative." Webster's Collegiate Dictionary, 10th Ed. (1994).

[77] *See* Pub. L. No. 116-16, § 6(e) ("The amendments made by this section shall take effect on the date of the enactment of this Act, and shall apply to covered outpatient drugs supplied by manufacturers under agreements under the [Medicaid Statute] on or after such date.").

innovator.[78] The government did not appeal the *STI* ruling, but in a 2020 preamble discussion, claimed *STI Pharma* was "wrongly decided,"[79] rejecting comments to apply the new classification standards from the MSIAA effective date forward.[80]

Agencies may not alter rules without statutory authority and apply them retroactively (potentially to the beginning of the drug rebate program) by referring to such changes as "mere clarifications." Such activity would set a troubling precedent for retroactive rulemaking if permitted—particularly in the face of significant penalties for misclassifications that CMS proposes to adopt, such as suspending Medicaid patients' access to a manufacturer's medicine, imposing a new type of civil monetary penalty (CMP), or terminating a manufacturer's participation in the MDRP. In *Bowen v. Georgetown*, the Supreme Court recognized that retroactive rulemaking is not permitted, unless that power is conveyed by Congress in express terms.[81] Accordingly, we urge CMS to reverse course in its final rule and recognize that it lacks authority to apply its definitions retroactively.

B. Remedies/Penalties for Misclassifications (§ 447.509)

At 42 C.F.R. § 447.509(d), CMS proposes new regulations to implement the additional penalty and compliance authorities outlined in Section 6 of the MSIAA. If a manufacturer "misclassifies" its drug products, CMS proposes it may take any or all of the following actions: suspend the misclassified drug from the MDRP, impose on the manufacturer a new CMP, and any other penalties available under the Medicaid rebate statute, such as referring the manufacturer to the OIG or terminating the manufacturer from the MDRP.

CMS should recognize that the MSIAA remedies included in the amendments to section 1927 are effective prospectively only. "Retroactivity is not favored in the law. Thus, congressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result."[82] Section 6 of the MSIAA does not require retroactive application. Instead, section 6 includes an effective date provision explicitly stating that: "The amendments made by this section shall take effect on the date of the enactment of this Act, and *shall apply to covered outpatient drugs supplied by manufacturers under agreements under section 1927 of the Social Security Act (42 U.S.C. 1396r–8) on or after such date.*"[83]

Before the MSIAA's enactment, CMS acknowledged that it lacked the compliance authority included in section 6 of the MSIAA. CMS stated: "CMS' authority to act if a manufacturer

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[78] *See STI Pharma LLC v. Azar,* 613 F.Supp.3d at 166–67 (CMS' contention of a bright-line NDA/ANDA rule to distinguish between innovator and non-innovator drugs was unconvincing, and did not accord with canons of statutory interpretation: "When Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (Internal citations removed).

[79] *See* 85 Fed. Reg. 87000, 87032 (Dec. 31, 2020).

[80] *Id.* In the 2020 rule preamble, CMS also failed to explain in any detail which parts of the District Court's reasoning were in error. The *STI Pharma* Court had evaluated, in exacting detail, the "text, structure, history, and purpose" of the Medicaid Rebate statute and found that the law offered a judicially discernible answer that CMS' interpretation could not stand under *Chevron.* 613 F. Supp. 3d at 164. In its 2020 preamble discussion, CMS did not address this *Chevron* analysis.

[81] *Bowen v. Georgetown Univ. Hosp*., 488 U.S. 204, 208 (1988).

[82] *Id.*

[83] § 6(e), Pub. L. 116-16 (emphasis added).

improperly classifies a drug is limited. . . . The statute does not expressly provide the Secretary of HHS with the authority to compel a manufacturer that has incorrectly reported a drug to change that classification or to issue civil monetary penalties in such a case."[84] Because section 6 of the MSIAA provides expressly that it applies only to drugs supplied after its effective date (April 18, 2019), CMS cannot apply the recovery requirements, suspensions, or other penalties of the MSIAA to drugs supplied before that date.

C. Definitions of "Misclassification" and "Drug Product Information." (42 C.F.R. §§ 447.509(d)(1) and 447.502)

CMS proposes to define "misclassification," with reference to the new "drug product information" definition stating:

> A misclassification in the MDRP has occurred when a manufacturer has: (i) Reported and certified to the agency its drug category or *drug product information* related to a covered outpatient drug that is not supported by the statute and applicable regulations; or, (ii) Reported 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 States at a level other than that associated with that classification.[85]

However, because CMS has broadly defined "drug product information" to include drug pricing information, as well as any other information CMS deems necessary to calculate unit rebate amounts, CMS' "misclassification" definition exceeds the authority of the MSIAA. Specifically, CMS cannot include as a "misclassification," errors in pricing data, such as base date AMP or other pricing information necessary to calculate the unit rebate amount, as proposed.

In the MSIAA, particularly the new authority at section 1927(c)(4) of the Act (which is the stated statutory basis for CMS' regulations at 42 C.F.R. § 447.509(d)),[86] Congress was clearly seeking to remedy misclassifications of "innovator" drugs as "non-innovator." Congress was responding to reports that companies "may have misclassified some drugs in the MDRP as innovator (brand-name), or noninnovator (generic) products."[87] CMS itself recognized this in Manufacturer

[84] HHS Office of the Inspector General, *Potential Misclassifications Reported by Drug Manufacturers May Have Led to $1 Billion in Lost Medicaid Rebates* (Dec. 2017)(CMS comments), https://oig.hhs.gov/oei/reports/oei-03-17-00100.pdf.

[85] 42 C.F.R. § 447.509(d)(1) (proposed, emphasis added).

[86] 88 Fed. Reg. at 34261 ("Specifically, section 1927(c)(4)(A) of the Act, 'Recovery of Unpaid Rebate Amounts due to Misclassification of Drugs,' was added to the statute to provide new authorities to the agency to identify and correct a manufacturer's misclassification of a drug, as well as impose other penalties on manufacturers that fail to correct their misclassifications."). Note, as well, that the Administrative Procedure Act requires agencies to cite the "legal authority under which the rule is proposed." 5 U.S.C. § 553(b)(2).

[87] HHS Office of the Inspector General, *Potential Misclassifications Reported by Drug Manufacturers May Have Led to $1 Billion in Lost Medicaid Rebates* (Dec. 2017), available at: https://oig.hhs.gov/oei/reports/oei-03-17-00100.pdf.

Release 113, characterizing the new section 1927(c)(4)(A) as addressing "manufacturers' obligation to pay unpaid rebate amounts due to misclassification of covered outpatient drugs."[88]

CMS also lacks authority for its open-ended definition of "drug product information." CMS proposes to define "drug product information" such that the term "includes but is not limited to" a list of information, including "any other information deemed necessary by the agency to perform accurate unit rebate amount (URA) calculations." 42 C.F.R. § 447.502 (proposed). Agencies cannot short circuit true notice-and-comment by promulgating "catch-all" regulations, and then interpreting said regulations in whatever manner they choose. Instead, the agency must define terms with precision, providing a true opportunity for notice and comment.

For the above reasons, CMS should delete the reference to "drug product information" entirely from 447.509(d)(1). But if it does not, it should strike the open-ended language at both the beginning and end of the "drug product information" definition. It should also remove any drug pricing references from such definition. This is for two reasons: (1) because a misclassification does not encompass drug pricing issues, as discussed above; and (2) because the Medicaid statute distinguishes drug pricing information from drug product information. By authorizing CMS to collect "drug product information," Congress clearly intended to address misclassifications, not drug pricing issues. For this reason, section 6 of the MSIAA is entitled "Preventing the Misclassification of Drugs Under the Medicaid Program." While the statute does allow HHS to collect "such drug product information as the Secretary shall require for each of the manufacturer's covered outpatient drugs," SSA § 1927(b)(3)(A)(v), elsewhere the law distinguishes between "drug pricing" and "drug product" information, treating them as separate concepts.[89]

Although CMS is not proposing to implement section 1927(b)(3)(A)(iii) of the Social Security Act, that provision authorizes CMPs "for knowingly submitting incorrect drug product information." In addition, in accordance with sections 1927(c)(4)(C) of the Social Security Act, CMS proposes in 447.509(d)(5) to publish information on covered outpatient drugs that have been misclassified – but given CMS' broad and overlapping definitions, it is not clear if such publication would include just the issue of innovator/non-innovator classifications (as we believe Congress intended) or extend to other pricing information. As such, it is important that CMS precisely and accurately define the term "drug product information."

Finally, for the reasons stated above, any revised definitions must be prospective only.

D. Dispute Resolution and Time Frame for Paying Corrected Rebate Amounts. (42 C.F.R. §§ 447.509(d) and 447.510(i))

The penalties that attach to CMS' misclassification determinations are severe, including suspension of the drug (resulting in patients potentially losing access to such drug) and CMPs. However, CMS offers no indication that a manufacturer might disagree with or dispute CMS' preliminary views that a misclassification exists, or how such a dispute process would operate. In fact, CMS proposes no procedures whatsoever for contesting an alleged misclassification.

[88] Misclassification of Drugs (Jun. 5, 2020) at 3, available at: https://www.medicaid.gov/prescription-drugs/downloads/mfr-rel-113.pdf.

[89] *See, e.g.,* SSA § 1927(b)(3)(C)(iii); 1128(b)(17), as amended by the MSIAA.

CMS should revisit its process for determining that misclassifications exist, in order to: (a) accord with principles of procedural due process – with a dispute process occurring *prior to* the agency making a final determination that a misclassification exists; (b) provide sufficient time for such process; (c) require payments of any additional rebate assessments only once the procedural due process has resulted in a final Secretarial determination that a misclassification exists; and (d) create a reasonable time period for manufacturers to pay rebate amounts to states. The new proposed amendments to the definition of "manufacturer" (which, as discussed above, are unauthorized) makes a dispute process essential, given the potential for error due to such definition. Also, the fact that a number of narrow exception requests (which were due no later than March 31, 2017)[90] remain pending with CMS demonstrates the unreasonableness of CMS' expectation that unit rebate amounts will be calculated and paid within 60 days of CMS' notification of a misclassification. In analogous situations, only "undisputed" amounts are owed to states, and are due **within 38 days** after postmark of state utilization data.[91] CMS allows up to 36 months for routine restatements, and we recommend CMS remain consistent with this timing. If there are items to be corrected, for whatever reason, time is needed to determine the payments. After the corrected AMP or BP is submitted to CMS, the adjusted payments should be made with the next invoice payment to each state/program.

Allowing for a robust dispute resolution and appeals process would accord with prior Medicaid and CHIP Payment and Access Commission (MACPAC) recommendations. In 2018, MACPAC discussed the issue of Congress providing CMS with the authority to suspend a misclassified drug, "but determined that the threat to beneficiary access outweighed the benefits of such a measure. Suspending a drug from the program carries with it the risk of harm to beneficiaries who rely on the drug, particularly if that drug is the primary course of treatment with few therapeutic alternatives." MACPAC also stated:

> The Commission maintains that HHS should ensure that manufacturers are afforded due process to present evidence that their classification of a drug is correct, such as provided under the narrow exceptions process established under the 2016 covered outpatient drug rule, and that HHS should provide a robust appeals process and establish protections for beneficiary access as part of any intermediate enforcement authority. HHS should be mindful of how its enforcement actions may affect beneficiaries; for many, access to prescription drugs is critically important and there may be only one drug that meets their needs. It is the Commission's view that any intermediate sanctions authorized by Congress be paired with appropriate protections to ensure that beneficiaries are not harmed by enforcement actions.[92]

Similarly, in the proposed 42 C.F.R. § 447.510(i), CMS must provide adequate due process prior to taking action to suspend the Medicaid drug rebate agreement. CMS has proposed that it

[90] Manufacturer Release 98 at 3, available at: https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-098.pdf.

[91] Medicaid Drug Rebate Program Release No. 11 (April 11, 1994), https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-011.pdf.

[92] Improving Operations of the Medicaid Drug Rebate Program (June 2018), https://www.macpac.gov/publication/improving-operations-of-the-medicaid-drug-rebate-program.

would merely provide written notice to the manufacturer of the failure to provide timely information. Thereafter, a manufacturer's failure to report such information within 90 calendar days of a CMS-determined deadline "shall result in suspension of the manufacturer's rebate agreement for all covered outpatient drugs furnished after the end of the 90-calendar day period for purposes of Medicaid and the MDRP only, and the rebate agreement shall remain suspended for Medicaid until such information is reported in full and certified, but not for a period of suspension of less than 30 calendar days." Here too, procedural due process requires a dispute process prior to the automatic suspension CMS proposes. A manufacturer may disagree with the CMS notice or have explanations regarding the allegedly missing information. Given the repercussions for patients, prior to imposing a suspension, CMS should engage with the manufacturer in a considered, robust dispute process.

V. Proposed CMS' 12-Quarter Audit Time Limitation (88 Fed. Reg. at 34244; 34294)

CMS proposes "to limit the time period for manufacturers to initiate disputes, hearing requests and audits of State-invoiced utilization data to 12 quarters from the last day of the quarter from the date of State invoice to the manufacturer."[93] CMS states that this proposal would help "ensure more efficient administration of the Medicaid Drug Rebate Program."[94] Although CMS does not define the start date, we assume that the proposed 12 quarter limit would begin upon a manufacturer's receipt of a state invoice that includes the disputed utilization (i.e., utilization that is reported to the manufacturer late would have a 12-quarter limit running from the last day of the late invoice). CMS contends that this limitation is necessary because HHS OIG reports indicate that manufacturers have initiated disputes "dating back many years"[95] and because certain "manufacturer requests, which could span multiple years prior to the 12-quarter timeframe . . . sometimes result in substantial recoupment of Medicaid rebates already paid to States, [and] impede the economic and efficient operation of the Medicaid program."[96]

CMS' proposal exceeds its statutory authority and cannot be implemented. The Medicaid rebate statute permits manufacturers to audit state utilization data and does not include any temporal limitation, as CMS acknowledges.[97] In relevant part, the statute states:

> A manufacturer may audit the information provided (or required to be provided) under subparagraph (A). Adjustments to rebates shall be made to the extent that information indicates that utilization was greater or less than the amount previously specified.[98]

CMS purports to derive its authority to impose a time limitation on manufacturers' audit of state utilization data under sections 1102 and 1902(a)(4) of the SSA, yet neither provision grants this authority to CMS.

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[93] 88 Fed. Reg. at 34244.

[94] 88 Fed. Reg. at 34244, 34268.

[95] 88 Fed. Reg. at 34266.

[96] 88 Fed. Reg. at 34255.

[97] *See* 88 Fed. Reg. at 34244 ("Currently, there is no time limit for a manufacturer to initiate an audit or resolve previously disputed State utilization data with respect to rebates owed, and section 1927 of the Act does not impose a specific timeframe on a manufacturer's audit authority.") (emphasis added).

[98] SSA § 1927(b)(2)(B).

SSA 1102 states, in relevant part, that:

> "[t]he Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services, respectively, shall make and publish such rules and regulations, not inconsistent with [the Social Security Act], as may be necessary to the efficient administration of the functions with which each is charged under [the Social Security Act]."[99]

Notably, this section only permits the Secretary of Health and Human Services (or a delegate like CMS) to promulgate "rules and regulations . . . as may be necessary to the efficient administration of the functions" with which the *HHS Secretary* is charged.

While CMS argues that "[h]aving an unlimited period to initiate disputes is not consistent with the proper and efficient operation of the rebate program,"[100] this rationale is misplaced given that CMS' role with respect to audits of state utilization data and disputes with states over utilization data is minimal and unrelated to CMS' administration of the MDRP. CMS' role is largely confined to encouraging voluntary dispute resolution between willing states and manufacturers. Because any regulation that is "necessary" to the Secretary's "administration" of the rebate program must bear "an actual and discernible nexus" to the program's practical management,[101] CMS may not rely on SSA 1102 given that its role regarding audits and disputes over utilization data is at best tangential. In fact, the current National Drug Rebate Agreement (NDRA) clearly illustrates the minimal, hands-off role CMS plays in audits and disputes concerning state utilization data. The NDRA provides as follows regarding these audits and disputes: "Nothing in this section [section V, on Disputes] shall preclude the right of the manufacturer to audit the state drug utilization data reported (or required to be reported) by the state. The Secretary encourages the manufacturer and the state to develop mutually beneficial audit procedures."[102]

CMS also suggests that its proposed cutoff of manufacturers' audit rights is authorized by SSA § 1902(a)(4), explaining that this provision "allows the Secretary to specify such methods necessary for the proper and efficient operation of the [State Medicaid] plan."[103] Yet this

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[99] SSA § 1102 (emphasis added).

[100] 88 Fed. Reg. at 34267.

[101] *See Merck & Co.*, 962 F.3d at 538 ("the further a regulation strays from truly facilitating the 'administration' of the Secretary's duties, the less likely it is to fall within the statutory grant of authority."); *see also* Manufacturer Release No. 105 ("As a reminder, under Section V of the NDRA (in accordance with 42 CFR § 447.253(e)) states can make a state hearing mechanism available to the manufacturer. Most manufacturers and states prefer to engage in the dispute resolution process; however, the state hearing option is available to both states and manufacturers when they have reached an impasse through the normal dispute resolution process, or when one of the parties is not being responsive to another's efforts to engage in dispute resolution. Therefore, we have issued State Release #181 to states recommending that states make manufacturers aware of what the process is to request such a hearing in the state as the processes will likely vary by state."); Medicaid Drug Rebate Program Dispute Resolution, https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/medicaid-drug-rebate-program-dispute-resolution/index.html (explaining that "Please note that either party may opt to use the state hearing process at any time; however, both parties must agree to engage in order to use the [CMS Dispute Resolution Process] process.").

[102] NDRA § V(d) (emphasis added).

[103] 88 Fed. Reg. at 34267.

provision governs regulation of *state plans*,[104] and does not convey to CMS any authority to adopt regulations concerning manufacturers' exercise of the audit rights expressly granted to them – without any temporal cutoff – by SSA 1927(b)(2)(B).

In addition, as a matter of equity and fairness, CMS does not suggest a similar temporal limitation – or any temporal limitation at all – on states' ability to bill manufacturers extra rebates for utilization from long-ago previous quarters (which is a fairly common practice, particularly with physician-administered products). Nor does CMS propose to give a manufacturer any remedy for duplicate Medicaid/340B discounts that the manufacturer only became aware of after the 12-quarter period expires, even though these duplicate discounts are prohibited by law.[105]

For all these reasons, CMS should not impose an arbitrary, one-sided limit on manufacturers' ability to initiate audits of state utilization data (and to pursue efforts to investigate and remedy potentially improper rebate billing after initiating an audit). No statutory authority exists for this proposal, and instead of promoting efficient administration of the MDRP, adopting this proposal could actually undercut CMS' ability to administer the rebate program by raising concerns about CMS' even-handedness.

VI. Standard Medicaid Managed Care Contract Requirements

A. BIN/PCN on Medicaid Managed Care Cards (88 Fed. Reg. at 34248-49; 34291)

PhRMA supports CMS' proposal to require states' contracted Medicaid managed care plans[106] that provide coverage of covered outpatient drugs to assign and exclusively use unique Medicaid-specific bank identification number (BIN), processor control number (PCN), and group number identifiers for all Medicaid managed care pharmacy benefit identification cards. This policy if finalized could more easily identify Medicaid managed care enrollees and help avoid duplicate Medicaid/340B discounts. To help all relevant stakeholders, including network pharmacies and providers, use BIN/PCN identifiers to avoid duplicate discounts, CMS should, in

[104] Specifically, SSA § 1902(a)(4) provides that a state plan shall "provide (A) such methods of administration (including methods relating to the establishment and maintenance of personnel standards on a merit basis…)… (B) for the training and effective use of paid subprofessional staff…, , (C) that each State or local officer, employee, or independent contractor who is responsible for the expenditure of substantial amounts of funds under the State plan, each individual who formerly was such an officer, employee, or contractor and each partner of such an officer or employee shall be prohibited from committing any act, in relation to any activity under the plan, the commission of which, in connection with any activity concerning the United States Government,… is prohibited by section 207 or 208 of title 18, United States Code, and (D) that each State or local officer, employee, or independent contractor who is responsible for selecting, awarding, or otherwise obtaining items and services under the State plan shall be subject to safeguards against conflicts of interest …."

[105] Public Health Service Act § 340B(a)(5)(A)(i); SSA § 1927(j)(1); SSA § 1903(m)(2)(A)(xiii). Moreover, even if this proposal were consistent with CMS' authority and the prohibitions on duplicate 340B/Medicaid discounts (which it is not), limiting the time period for manufacturers to initiate disputes, hearing requests and audits related to rebate claims for 340B drugs to 12 quarters would be particularly burdensome given that the process to resolve these 340B claims can take much more time than a dispute related to the amount of utilization in a certain quarter and in no circumstance should any limitation be considered on 340B/Medicaid duplicate discount disputes.

[106] Specifically, Medicaid managed care organizations, prepaid inpatient health plans, and prepaid ambulatory health plans (referred to herein, collectively, as "MCOs").

the final rule: (i) require that each state maintain and regularly report to CMS a current list of all Medicaid-specific BIN/PCN identifiers used by MCOs in the state; (ii) indicate that CMS will publish and regularly update a list of all such identifiers, broken down by state, on a public CMS website; and (iii) require states to monitor and take appropriate action to enforce MCOs' compliance with the new BIN/PCN identifier requirement.

While PhRMA supports CMS' proposal and urges its timely implementation, we note that this policy, by itself, will not fully address the risk of 340B duplicate discounts in Medicaid managed care. Therefore, we urge CMS in the final rule to require states to combine the use of Medicaid-specific BIN/PCN identifiers with one of the below approaches, which have been previously identified in HHS publications,[107] so as to achieve the statutory imperative of zero instances of Medicaid/340B duplicate discounts:

1. **Carve Out Approach**: States and MCOs could "carve out" Medicaid managed care enrollees from 340B using the proposed Medicaid-specific BIN/PCN identifiers. There are various 340B carve out approaches (*e.g.*, carving out 340B utilization only in the contract pharmacy setting or across additional settings). Under this approach, MCOs should be required to contractually obligate their network pharmacies and providers not to dispense 340B drugs to MCO enrollees.

2. **Claim-Level Identification Approach**: States could require network pharmacies and providers to use specified claim-level identification methods that identify 340B drugs. Under this approach, MCOs could be required to contractually obligate their network pharmacies and providers to comply with the MCO's specified claim-level identification policies to avoid Medicaid/340B duplicate discounts. CMS could effectuate this requirement by amending 42 C.F.R. § 438.3(s)(3) to require MCOs to specify in their policies and procedures that covered entities and pharmacies dispensing 340B drugs on their behalf must either: (i) include a specified 340B modifier[108] or non-340B modifier[109], as applicable, on each managed Medicaid claims at the point of drug dispensing or administration that flows through all intermediaries to the MCO without modification so the MCO can exclude 340B claims from utilization data reported to the state under § 438.3(s)(2); or (ii) directly submit to the state a file listing all managed Medicaid claims determined to be 340B-purchased so the state can exclude such claims from Medicaid rebate invoices provided to manufacturers.[110]

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[107] *See, e.g.*, CMS, Best Practices for Avoiding 340B Duplicate Discounts in Medicaid (Jan. 8, 2020), https://www.hhs.gov/guidance/document/best-practices-avoiding-340b-duplicate-discounts-medicaid; OIG, State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates (Jun. 2016), https://oig.hhs.gov/oei/reports/oei-05-14-00430.pdf.

[108] For example, the NCPDP "20" submission clarification code for retail 340B drug claims, the "UD" modifier for physician-administered 340B drug claims, and/or other widely recognized industry billing and coding standards.

[109] We urge CMS to require use of specified 340B and non-340B modifiers to provide needed certainty that a 340B eligibility determination has been made for each drug claim such that the claim is never silent as to its 340B status.

[110] These policies would be consistent with recommendations OIG made to CMS in a 2016 report. *See* OIG, State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates at 16 (Jun. 2016), https://oig.hhs.gov/oei/reports/oei-05-14-00430.pdf.

Regardless of the approach selected, CMS should also require states to provide to manufacturers, along with Medicaid rebate invoices, detailed claims-level utilization data that includes, among other fields,[111] the MCO BIN/PCN identifier. If MCOs require use of 340B/non-340B modifiers, then utilization data provided to manufacturers should include the 340B/non-340B modifier field as one of the required elements. Alternatively, if MCOs require direct submission of claims data to the state, similar elements from such data should be shared with manufacturers so they can verify that claims for 340B drugs have been appropriately excluded from Medicaid rebate invoices. Additionally, CMS should issue clear guidance describing the process states must follow to resolve all duplicate Medicaid/340B discounts – whether in FFS or managed care – identified by manufacturers. Because of challenges manufacturers have faced in determining whether the state or the covered entity is responsible for providing a manufacturer a remedy for a duplicate discount, it is critical that this guidance clarify the obligations of state Medicaid agencies, MCOs, and 340B covered entities in timely resolving such duplicate discounts.

The carve-out and claims-level identification approaches described above are near-term priorities that CMS should implement as part of the final rule. Notwithstanding these near-term approaches, we urge CMS to consider establishing a clearinghouse-type organization to identify 340B units dispensed or administered to Medicaid beneficiaries. The 340B clearinghouse would act as a claims verifier, reviewing Medicaid utilization data and data submitted by 340B covered entities (or entities acting on their behalf) to identify potential duplicate discounts. We note that clearinghouse-assisted identification of 340B units could also be useful to CMS in identifying these units for exclusion from the Medicare Part B and Part D inflation rebates enacted under the Inflation Reduction Act.

B. Drug Cost Transparency in Medicaid Managed Care Organization Contracts (88 Fed. Reg. 34247; 34291)

In the proposed rule, CMS is seeking comments on its proposal to require contracts between Medicaid MCOs, and pharmacy benefit managers (PBMs) to require that PBMs report to MCOs the cost of the covered outpatient drug and fees to pharmacies and providers for dispensing or administering the drug separately from any PBM administrative costs. Importantly, CMS indicates in the proposed rule that this requirement would allow the MCO to identify PBM costs over the cost of the prescription and dispensing fee, preventing such costs from being used to inflate the medical loss ratio. PhRMA supports this proposal, and we believe this requirement, if finalized, will assist in ensuring access to crucial medicines and will allow for increased transparency in the calculation of the medical loss ratio (MLR) to ensure that Medicaid MCO rates are actuarially sound as required by law.

Currently, PBMs control prescription medicine access for hundreds of millions of Americans, and their business practices and financial incentives may restrict patient access to medicines and increase overall costs. For example, through the practice of spread pricing, PBMs often bill their health plan clients, including Medicaid MCOs, more than what the PBMs pay to the

[111] PhRMA has previously commented on specific fields that should be included in utilization data provided to manufacturers. *See, e.g.*, PhRMA, Comments on CMS Medicaid Managed Care Proposed Rule (Jul. 27, 2015), https://www.regulations.gov/comment/CMS-2015-0068-0789; PhRMA, Comments on HRSA Proposed 340B Drug Pricing Program Omnibus Guidelines (Oct. 27, 2015), https://www.regulations.gov/comment/HRSA-2015-0002-0553.

pharmacy for medicines and keep the difference, enriching themselves instead of serving their clients or the patients.[112]

As CMS highlights in the proposed rule, the overall impact of spread pricing in Medicaid managed care may be substantial. For example, a 2020 analysis by the Congressional Budget Office found that prohibiting the use of spread pricing contracts in Medicaid alone would save approximately $929 million over 10 years.[113] In addition, an analysis of Ohio's Medicaid managed care program by the state auditor found that PBMs had used spread pricing to make over $200 million more per year from the state than they reimbursed pharmacies in addition to costing taxpayers an extra $150 million to $186 million per year by charging above average rates.[114] As a result of these findings, Ohio policymakers prohibited spread pricing contracts in Medicaid managed care plans and at least 21 states took action to limit spread pricing.[115] While Congress currently considers legislation to ban the practice of spread pricing in Medicaid,[116] PhRMA supports CMS' proposal to bring further transparency into the practice so that states can better understand whether MCOs are appropriately paying for covered outpatient drugs and Medicaid MCOs have the data needed to calculate MLRs correctly.

VII. Drug Price Verification Survey for Certain Covered Outpatient Drugs (88 Fed. Reg. 34268-34273; 34294-34295)

CMS proposes to implement a broad and burdensome survey of manufacturers and wholesalers – without any statutory authority to do so – in order to extract additional rebates by forcing manufactures to justify prices. The statute does not permit a survey of this breadth and for this purpose, and therefore it cannot be finalized.

In the proposed rule, CMS proposes to survey manufacturers and wholesalers "to assure that Medicaid payments and applicable rebates for CODs can be made, and that Medicaid payments are economical and efficient, as well as sufficient, to provide access to care." CMS would determine which drugs to survey based on data related to Medicaid spending and rebates paid to states. Specifically, CMS proposes to select drugs for annual surveys by identifying drugs

[112] Robert Langreth," Bloomberg, September 11, 2018.The Secret Drug Pricing System Middlemen Use to Rake in Millions," Bloomberg, September 11, 2018.

[113] Congressional Budget Office, Analysis of Prescription Drug Pricing Reduction Act of 2019. March 13, 2020.

https://www.cbo.gov/system/files/2020-03/PDPRA-SFC.pdf

[114] Ohio's Medicaid Managed Care Pharmacy Services, Auditor of State Report. August 2018.

https://audits.ohioauditor.gov/Reports/AuditReports/2018/Medicaid_Pharmacy_Services_2018_Franklin.pdf

[115] Tepper, Nona. "PBM clawbacks sidestep state bans on spread pricing," Modern Healthcare, October 2021.

https://www.modernhealthcare.com/payment/pbm-clawbacks-sidestep-state-bans-spread-

pricing?adobe_mc=MCMID%3D84382931027412571591411966027321820076%7CMCORGID%3D138FFF2554E6E7220A4C98C6%2540AdobeOrg%7CTS%3D1635559965&CSAuthResp=1%3A%3A1042569%3A7461%3A24%3Asuccess%3A7B2869D9F448BE6E6633CBB3379746EA.

[116] Introduced legislation includes: Rep. Earl L. "Buddy" Carter Drug Price Transparency in Medicaid Act of 2023, H.R. 1613, 118th Cong. (2023). https://www.congress.gov/bill/118th-congress/house-bill/1613?q=%7B%22search%22%3A%5B%22drug+price+transparency+in+medicaid+act%22%5D%7D&s=1&r=2.

with the highest Medicaid spending per claim, the highest total Medicaid drug spending, the highest one-year price increase among single source CODs, and the highest launch price.[117] Drugs already subject to price controls by CMS and drugs for which manufacturers provide supplemental rebates to at least half the states that results in a ratio of total rebates to total drug spend above the ratio for states that cover drugs exclusively through their fee-for-service programs would be excluded from annual surveys. CMS proposes to narrow the list of selected drugs further, if necessary, based on additional factors, such as input from states on manufacturer efforts to lower drug prices. CMS would then require surveyed manufacturers (or wholesalers), under threat of civil monetary penalties, to submit a broad range of detailed pricing, utilization, distribution, product and clinical information, and production, research, and marketing cost data to the agency, plus "any other data as determined by the Secretary to verify the price or charge of [the targeted drug]."

Following its collection of this expansive data set from manufacturers (or wholesalers) of the targeted drugs, CMS would post publicly non-proprietary information provided by the manufacturer and wholesaler in response to the "survey." Then CMS will seek comment on the posted information from the public generally and specifically from Medicaid beneficiaries, state Medicaid agencies, other governmental agencies, and other affected interested parties. The stated purpose of the public posting is "[t]o further verify the prices and charges submitted by the manufacturer [under the Medicaid rebate statute]" (even though the prices reported by manufacturers under the rebate statute are all confidential except WAC, so the public's ability to "further verify" the reported prices is unclear). CMS also may request that a manufacturer address the publicly posted information in a public forum.

PhRMA strongly opposes this. Far from being a legitimate use of the agency's authority to verify pricing data reported to CMS under the MDRP, the agency's focus on what CMS considers to be high-priced drugs and on exclusions for drugs such as those with higher "voluntary" supplemental rebates from manufacturers – and the complete lack of utility of this initiative for the purpose of actually verifying prices submitted to CMS under the Medicaid rebate statute -- makes clear that the purpose of this survey is actually an attempt to force manufacturers to lower drug prices.[118] And contrary to CMS' statements, this proposal vastly exceeds the agency's authority under both sections 1927(b)(3)(A) and 1902(a)(30)(A) of the SSA. We provide further detail on these points below.

A. The "Verification Survey" Proposal Exceeds CMS' Authority Under Section 1927(b)(3)(B)

The proposed rule cites as authority for the price verification survey SSA §§ 1927(b)(3)(B) and 1902(a)(30)(A). Neither of these provisions, however, grants CMS the authority to conduct this proposed survey. Because the proposal exceeds CMS' authority, it cannot be finalized and carried out.

[117] CMS does not state whether "highest Medicaid drug spend per claim" or the "highest total Medicaid drug spend" would be based on gross spending or be net of rebates.

[118] In addition, the proposed "verification" survey also would focus on cell and gene therapies, which despite their upfront cost may result in subsequent cost *savings* to Medicaid and transformative and long term benefits to patients. *See, e.g.*, A Transformative Therapy Value Model for Rare Blood Diseases (January 2020), http://alliancerm.org/wp-content/uploads/2020/01/ARM-Marwood-White-Paper-FINAL.pdf (total potential savings of cell and gene therapies range from 18 to 30% in annual total disease costs and productivity, which represents an aggregate potential cost savings of more than $33 billion by 2029).

SSA § 1927(b)(3)(B), titled "verification surveys of average manufacturer price and average sales price," provides in relevant part that:

> [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 cost) if required to make payment reported under subparagraph (A).[119]

CMS notes that section 1927(b)(3)(B) authorizes it to "survey wholesalers and manufacturers that directly distribute their CODs, when necessary, to verify manufacturer prices reported to us under section 1927(b)(3)(A) of the Act,"[120] and acknowledges that it has "never used the section 1927(b)(3)(B) . . . authority to survey manufacturers or wholesalers" and never "interpreted this statutory section in regulation."[121] Yet, CMS now proposes an admittedly "broad" interpretation[122] that would require the manufacturer of a targeted drug to comply with sweeping data submission requirements concerning "pricing, charges, distribution, and utilization [information]," "product and clinical information," "costs of production, research, and marketing," and "any other information" CMS deems necessary.[123] The manufacturer must submit all this information under threat of civil monetary penalties for failure to comply. [124]

CMS proposes to collect the survey information for a broad range of purposes far removed from the statutory text. Nearly all of the information that CMS proposes to collect has no connection to "verify[ing]" the prices reported to CMS under the Medicaid rebate statute, which would mean confirming the accuracy of the reported prices. Instead of seeking data that would be pertinent to verifying the prices reported under the rebate statute and proposing a process that could be used to verify these prices, CMS proposes to collect data irrelevant to price verification and then to use the data for purposes other than price verification – to "give States the ability to better negotiate supplemental rebates, and better understand the impact of the drug on its budget as supplemental rebates are negotiated."[125] Yet, the plain language of SSA 1927(b)(3)(B) does not permit a survey for this purpose (or any purpose other than to verify a manufacturer's reported prices).[126]

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[119] SSA § 1927(b)(3)(B) (emphasis added).

[120] 88 Fed. Reg. at 34268. CMS notes that the prices reported to it under the Medicaid rebate statute consist of AMP, best price, ASP, and WAC.

[121] 88 Fed. Reg. at 34279.

[122] 88 Fed. Reg. at 34268.

[123] *See* 88 Fed. Reg. at 34295 (proposed 42 C.F.R. § 447.510(k)(6) (in addition to the various listed types of information the manufacturer must provide, CMS may request "*[a]ny other information* as determined by the Secretary to verify the price or charge of the covered outpatient drug reported under section 1927(b)(3)(A) of the Act and this section") (emphasis added).

[124] SSA § 1927(b)(3)(B); 88 Fed. Reg. at 34295.

[125] 88 Fed. Reg. at 34268.

[126] Nor does the proposed rule cite any legislative history suggesting that Congress intended to give CMS broader authority than stated in the text of SSA § 1927(b)(3)(B). We found only two sentences in the legislative history concerning this provision: "The Secretary would be authorized to survey wholesalers and manufacturers that directly distribute their covered drugs to verify average manufacturer prices.

CMS' authority is limited to verifying certain prices, yet the proposed survey rests on CMS' flawed equation of the terms "verify" and "justify," which have entirely different meanings. To determine the plain meaning of a statute's words or phrases, courts often look to dictionary definitions.[127] CMS states that it relies on the Oxford English Dictionary definition of "verify"– to "make sure or demonstrate that (something) is true, accurate, or justified."[128] However, CMS appears to be quoting from the *Concise* Oxford English Dictionary, which is the only dictionary we could find that defines "verify" to include "justify." All other dictionaries that we reviewed – including the Oxford English Dictionary (as opposed to the concise version that CMS relies on) – define "verify" to mean to confirm that something is true or accurate. The Oxford English Dictionary defines "verify" as "[t]o show to be true by demonstration or evidence; to confirm the truth or authenticity of; to substantiate."[129] Merriam-Webster (the oldest dictionary publisher in the United States) similarly defines "verify" as "to establish the truth, accuracy, or reality of."[130] Likewise, Black's Law Dictionary (among the most frequently used legal dictionaries in the United States) defines "verify" as "[t]o prove to be true; to confirm or establish the truth or truthfulness of; to authenticate."[131] The American Heritage Dictionary defines "verify" as "[t]o demonstrate the truth or accuracy of, as by the presentation of evidence:"[132]

"Justify[ing]" goes far beyond "verify[ing]" that submitted information is accurate. The plain meaning of to "justify" is "to provide or show to be *just, right or reasonable*."[133] Under well-recognized statutory interpretation principles, CMS cannot expand the statutory meaning of "verify" based on an outlier definition like "to justify" found only in one dictionary. The whole point of consulting dictionaries to interpret a statute is to find evidence of *common or ordinary usage*, not obscure definitions.[134] Thus, an outlier dictionary definition cannot be used to determine a statute's meaning. As the Supreme Court has held:

> That a definition is broad enough to encompass one sense of a word does not establish that the word is *ordinarily* understood in

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Information disclosed by manufacturers or wholesalers regarding average manufacturer price or best price would be confidential and could be disclosed only as the Secretary determines necessary to carry out this provision and to permit review by the Comptroller General or Inspector General." H.R. Rep. No. 101-881, 97-98 (Oct. 16, 1990) (emphasis added).

[127] *See United States v. Lopez*, 590 F.3d 1238 (11 Cir. 2009) ("[t]o ascertain ordinary meaning, courts often turn to dictionary definitions for guidance."); see also *Wooden v. United States*, 142 S. Ct. 1063 (2022) (citing the dictionary definition of "occasion" to determine the "ordinary meaning" of the term).

[128] *See* 88 Fed. Reg. at 34268 (emphasis added).

[129] Oxford English Dictionary (most recently updated March 2023).

[130] Merriam-Webster.com. 2023, https://www.merriam-webster.com.

[131] Black's Law Dictionary (11th ed. 2019).

[132] American Heritage Dictionary of the English Language (5th ed. 2022), https://ahdictionary.com/word/search.

[133] Merriam-Webster.com. 2023, https://www.merriam-webster.com.

[134] *See*, *e.g.*, *CBS, Inc. v. PrimeTime 24 Joint Venture*, 245 F.3d 1217, 1223 (11th Cir. 2001) ("to determine the common usage or ordinary meaning of a term, courts often turn to dictionary definitions") (citing *United States v. Gonzalez*, 520 U.S. 1, 6 (1997)); *In re Hamilton Creek Metro Dist,.* 143 F.3d 1381, 1385 (10th Cir. 1998) (courts "presume the plain language of a statute expresses congressional intent" and that "such expression lies in the ordinary meaning attached to the word, which may be found by aid of commonly accepted dictionary definitions") (citations omitted).

> that sense…. The fact that the definition of "interpreter" in Webster's Third has a sense divider denoting the most common usage suggests that other usages, although acceptable, might not be common or ordinary. *It is telling that all the dictionaries cited above defined "interpreter" at the time of the statute's enactment as including persons who translate orally, but only a handful defined the word broadly enough to encompass translators of written material. …. Were the meaning of "interpreter" that respondent advocates truly common or ordinary, we would expect to see more support for that meaning*. …
>
> To be sure, the word "interpreter" can encompass persons who translate documents, *but because that is not the ordinary meaning of the word, it does not control unless the context in which the word appears indicates that it does. Nothing in the [relevant statute] however, even hints that Congress intended to go beyond the ordinary meaning of "interpreter" and to embrace the broadest possible meaning that the definition of the word can bear*.[135]

Here, CMS relies on an atypical dictionary definition of "verify" – *i.e.*, "justify" – and then builds its "survey" requirements on that atypical definition, arguing that it may require manufacturers and wholesalers to turn over detailed categories of data that are irrelevant to whether the reported prices of the targeted drug are accurate, but instead bear on whether those reported prices can be justified in various specified ways. ***Thus, instead of seeking to verify the accuracy of the prices reported under the Medicaid rebate statute, CMS seeks data to "verify" several propositions that are not mentioned in SSA 1927(b)(3)(B)***. Among other things, CMS states that:

- The proposed survey process "should provide CMS and the States a clearer understanding into a manufacturer's pricing for its covered outpatient drug to verify those prices and charges, and ensure that Medicaid payments are made in an economical and efficient, as well as sufficient manner, to provide access to care."[136]
- "We propose to collect these utilization and pricing metrics [detailed in the proposed regulatory text] from manufacturers to verify that the prices reported at section 1927(b)(3)(A) of the Act do not have the potential to negatively impact state budgets to the extent states are not able to cover the drugs, thus impairing Medicaid beneficiary access to treatment."[137]
- "[W]e propose to collect product and clinical information [detailed in the proposed regulatory text] to understand the clinical benefits and risks of the covered

[135] *Taniguchi v. Kan Pacific Saipan Ltd*,. 566 U.S. 560, 568-69 (2012). *See also*, e.g., *MCI Telecomms. Corp. v. AT&T Co*, 512 U.S. 218, 227 (1994) (rejecting definition that was only contained in one of the dictionaries consulted and that contradicted one of the meanings contained in virtually all other dictionaries).

[136] 88 Fed. Reg. at 34270.

[137] 88 Fed. Reg. at 34273.

> outpatient drug to verify that the price reported fairly represents the benefits and/or risks of the COD."[138]

Thus, the proposed rule would empower CMS to demand from manufacturers and wholesalers a broad range of pricing, utilization, distribution, product and clinical information, and production, research, and marketing cost data – all under the guise of "verifying" pricing metrics reported under the rebate statute. Most of these data points could not possibly affect the proper determination of the prices reported to CMS under the rebate statute. To take just one example, CMS would mandate the submission of "calculated average prices from the manufacturer to wholesalers and other direct purchasers for sales outside of the U.S.,"[139] which do not enter into any of the prices reported under the Medicaid rebate statute.

And these daunting powers – comparable in scope but even broader in some ways than the data submission powers CMS plans to exercise under the IRA– would all stem from a sentence on price "verification" that was enacted in 1990 and has never been used in the 33 years since its enactment. These expansive powers cannot be linked to the ordinary meaning of "verify" and are not consistent with the text or history of SSA 1927(b)(3)(B). As the Supreme Court has emphasized, where "an agency claims to discover in a long-extant statute an unheralded power to regulate a significant portion of the American economy," courts "typically greet its announcement with a measure of skepticism."[140]

Finally, the proposed rule ignores two express limitations on surveys set forth in SSA 1927(b)(3)(B):

- ***CMS does not acknowledge that SSA 1927(b)(3)(B) is limited to "manufacturers that directly distribute" their drugs.***[141] Instead, CMS states that it interprets this provision to permit surveys when "a manufacturer sells to wholesalers and/or distributes [CODs] directly on their own."[142] However, the statutory limitation to manufacturers that "directly distribute" CODs sharply curtails CMS' authority, because most manufacturers do not directly distribute their products: in fact, approximately 92% of prescription drugs in the U.S. are distributed through wholesalers.[143] CMS' proposal that it may survey any "manufacturer with a rebate agreement "[144] would ignore this express statutory restriction.

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[138] 88 Fed. Reg. at 34273.

[139] 88 Fed. Reg. 34295 (proposed 42 CFR 447.510(k)(5)(i)(B)).

[140] *Util. Air Regul. Grp. v. E.P.A.*, 573 U.S. 302, 324 (2014) (internal quotation marks and citation omitted). *See also*, *e.g.*, *Chamber of Commerce v. U.S. Dep't of Labor*, 885 F.3d 360, 380 (5th Cir. 2018) ("that it took DOL 40 years to 'discover' its novel interpretation further highlights the Rule's unreasonableness"); *American Bar Ass'n v. FTC*, 430 F.3d 457, 469 (D.C. Cir. 2005) ("we find it hard to believe that Congress . . . intended to undertake the regulation of the practice of law–a profession never before regulated by 'federal functional regulators' and never mentioned in the statute").

[141] SSA § 1927(b)(3)(B) (emphasis added).

[142] 88 Fed. Reg. 34268.

[143] Deloitte and Healthcare Distribution Alliance, The Role of Distributors in the U.S. Health Care Industry (Deloitte and HDA, 2019), https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/the-role-of-distributors-in-the-us-health-care-industry.html.

[144] 88 Fed. Reg. at 34294.

- ***The proposed rule also ignores the statute's limitation that surveys may be conducted only "when necessary."*** The rationales CMS cites for why a survey would be "necessary" are not tied to verifying reported prices (the only permitted basis for a survey in SSA 1927(b)(3)(B)), but instead extend to goals such as "leverag[ing] crowded therapeutic classes to negotiate supplemental rebates with manufacturers."[145]

Had Congress intended SSA 1927(b)(3)(B) to grant CMS powers beyond surveying a limited subset of manufacturers to verify the accuracy of certain reported prices – particularly under threat of civil monetary penalties – it could have done so. But Congress has not done so, and CMS may not exceed its statutory authority through rulemaking.

B. Section 1902(a)(30)(A) Cannot Extend CMS' Verification Survey Authority

CMS also cites an unrelated provision in SSA 1902(a)(30)(A) as a "backup" source of authority for the proposed survey.[146] Even if Section 1902(a)(30)(A) were in any way related to CMS' verification survey authority (which it is not), CMS' reliance would be entirely misplaced given the longstanding principle that where a more specific provision directly addresses a delegated authority, that provision should control.[147] Further, SSA 1902(a)(30)(A) provides no support for CMS' verification survey proposal – either standing alone or when read in conjunction with SSA 1927(b)(3)(B).

Under the heading "State plans for medical assistance," SSA 1902(a)(30)(A) states in relevant part that:

> (a) Contents
>
> *A State plan for medical assistance must—*
>
> > (30)(A) provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan … as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such

[145] 88 Fed. Reg. at 34269.

[146] *See, e.g.*, 88 Fed. Reg. at 34268 ("Viewing the authority provided under section 1927(b)(3)(B) of the Act through the lens of section 1902(a)(30)(A) of the Act obligations, we are proposing . . .").

[147] *See, e.g., Radzanower v. Touche Ross & Co.*, 426 U.S. 148, 153 (1976) ("It is a basic principle of statutory construction that a statute dealing with a narrow, precise, and specific subject is not submerged by a later enacted statute covering a more generalized spectrum. Where there is no clear intention otherwise, a specific statute will not be controlled or nullified by a general one, regardless of the priority of enactment. The reason and philosophy of the rule is, that when the mind of the legislator has been turned to the details of a subject, and he has acted upon it, a subsequent statute in general terms, or treating the subject in a general manner, and not expressly contradicting the original act*, shall not be considered as intended to affect the more particular or positive previous provisions, unless it is absolutely necessary to give the latter act such a construction, in order that its words shall have any meaning at all.*") (internal citations and quotation marks omitted) (emphasis added).

> care and services are available to the general population in the geographic area; . . . . (emphasis added).

The text and heading of this provision make clear that SSA 1902(a)(30)(A) governs the contents of state plans. It does not authorize CMS to regulate the conduct of manufacturers or wholesalers, let alone to require from them sweeping data submissions. But without explanation CMS takes out of context a requirement for state plans – that "payments [be] consistent with efficiency, economy, and quality of care"– and attempts to apply it to surveys of manufacturers and wholesalers. Such a reading is inconsistent with the statute, which relates only to payments by State Medicaid plans.[148]

Extending CMS' authority under Section 1902(a)(30)(A) to reach demands for information from wholesalers and manufacturers would grant CMS seemingly limitless authority over any entity that provides services to Medicaid beneficiaries or manufactures Medicaid-covered products. As the D.C. Circuit explained in overturning another rule exceeding the agency's authority, "the breadth of [CMS'] asserted authority [must be] measured not only by the specific application at issue, but also by the implications of the authority claimed."[149] Congress would not have granted CMS the expansive powers CMS would need to conduct the proposed survey under a provision limited to requirements for state Medicaid plans.

In adopting regulations, agencies are "bound, not only by the ultimate purposes Congress has selected, *but by the means it has deemed appropriate …for the pursuit of those purposes*."[150] Agencies must adhere to both the ends and means prescribed by Congress:

> …[T]he Commission points to . . . the Act's general declaration of policy, which it says embodies … a purpose the Commission's regulations further. But this cannot carry the Commission as far as it needs to go. We have observed before that "[a]ll questions of government are ultimately questions of ends and means." *Agencies are therefore "bound, not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes." The Commission is correct that Congress wanted to ensure the integrity of Indian*

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[148] *See Pennsylvania Pharmacists Ass'n v. Houstoun*, 283 F.3d 531, 537 (3d Cir. 2002) ("It seems clear to us that the first two required outcomes–'efficiency' and 'economy'–*relate to the state program, not providers*, i.e., Section 30(A) requires that a state program set payments at levels that make the program efficient and economical.") (emphasis added); c*f. Alaska Dep't of Health & Soc. Servs. v. Centers for Medicare & Medicaid Servs.*, 424 F.3d 931, 935-36, 939-40 (9th Cir. 2005) ("since 1997, § 30(A) has been the principal statutory authority for a series of upper payment limit ('UPL') regulations that cap state reimbursement rates to 'promote economy and efficiency.'… These regulations …respond to concerns about states' inappropriate use of intergovernmental transfers to fund their Medicaid programs.").

[149] *Merck & Co. v. United States Dep't of Health & Hum. Servs.*, 962 F.3d 531, 541 (D.C. Cir. 2020) (citing *Gonzales v. Oregon*, 546 U.S. 243, 248-249, 267-268 (2006) (rejecting the argument that Congress implicitly delegated the authority to "prohibit doctors from prescribing regulated drugs for use in physician-assisted suicide" in part because, under the Government's theory, the Attorney General would have broad power to decide "whether *any* particular drug may be used for any particular purpose," and whether "a physician who administers any controversial treatment could be" punished).

[150] *Colorado River Indian Tribes v. Nat'l Indian Gaming Commission*, 466 F.3d 134, 139-40 (D.C. Cir. 2006) (quoting *MCI Telecomms. Corp. v. AT&T*, 512 U.S. 218, 231 n.4 (1994)) (citation omitted, emphasis added).

> *gaming, but it is equally clear that Congress wanted to do this in a particular way.*[151]

Here, CMS asserts that its proposed survey would "give States the ability to better negotiate supplemental rebates." But, SSA 1902(a)(30(A) only pertains to the efficiency, economy, and sufficiency of payments under State Medicaid plans – it is not a blanket authority to pursue any means to promote Medicaid "efficiency and economy." ***And the survey proposal has nothing to do with State plans***.[152]

In short, the proposed "verification survey" exceeds the authority provided by SSA 1927(b)(3)(B) and finds no further support in SSA 1902(a)(30)(A). Because CMS lacks authority, CMS cannot finalize and carry out the proposed survey.

C. Collecting Data Proposed Under the Survey is Not Necessary for Medicaid Reimbursement

Even putting aside the fact that CMS does not have the authority under 1927(b)(3)(B) or 1902(a)(30)(A) of the SSA to collect pricing, utilization, clinical, and product data from manufacturers to "verify" prices reported to CMS under the Medicaid rebate statute, this burdensome set of data is not necessary for States to set Medicaid reimbursement rates for covered outpatient drugs under the MDRP. In fact, much of the proposed data request has nothing to do with pricing or state reimbursement.

Under current law, State Medicaid programs, not CMS, reimburse retail pharmacies for covered outpatient drugs based on a formula that includes the ingredient cost for the drug and a dispensing fee for filling the prescription.[153] States – not CMS – make these determinations. While states have flexibility in the methodologies they use to determine their payments rates to pharmacies, almost none of the data CMS proposes to obtain from manufacturers has any relevance to setting payment rates to pharmacies. As CMS acknowledges, many states already use the National Average Drug Acquisition Cost (NADAC) files to set reimbursement rates, which CMS publishes based on survey information of pharmacy invoice prices of covered outpatient drugs. In addition, wholesale acquisition cost (WAC) information is already available from public sources.

In the proposed rule, CMS indicates that drugs not traditionally dispensed through retail pharmacies, including physician-administered drug and gene therapy drugs, are not required to

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[151] 466 F.3d at 139-40 (emphasis added). See also, e.g., *Waterkeeper Alliance v. EPA*, 853 F.3d 527, 535 (D.C. Cir. 2017) ("Agencies are … bound not only by the ultimate purposes Congress has selected, but by the means it has deemed *appropriate*, and prescribed, for the pursuit of those purposes."); *Ranbaxy Laboratories Ltd v. Leavit*t, 469 F.3d 120, 176 (D.C. Cir. 2006) ("The FDA may not … change the incentive structure adopted by Congress, for the agency is bound not only by the ultimate purposes Congress has selected but by the means it has deemed appropriate/for the pursuit of those purposes") (internal quotations and citations omitted).

[152] Even beyond that, SSA § 1902(a)(30)(A) only concerns the efficiency, economy, and sufficiency of State Medicaid program "payments," which are different from their net-of-rebate drug costs. *See Iowa Dept of Human Services v Centers for Medicare and Medicaid Services* ,576 F.3d 885, 888-90 (8th Cir, 2009) (Iowa's proposed payment to pharmacies of net cost, after federal and state rebates, for multiple source brand name drugs for state Medicaid program was not "payment" comporting with CMS regulations, prohibiting multiple source drug payment from exceeding, in aggregate, federal upper limit (FUL) capping amount that states were allowed to pay for purchase of prescription drugs).

[153] 42 CFR § 447.512(b).

follow the reimbursement requirements pertaining to actual acquisition costs or professional dispensing fees. However, if CMS is concerned that State Medicaid agencies are not reimbursing pharmacies and other dispensers appropriately, the agency should consider issuing further guidelines to States to ensure that such reimbursement policies pertaining to these drugs are proper and consistent with efficiency, economy, and quality of care and sufficient to enlist Medicaid participation by enough providers rather than creating a broad intentionally burdensome "survey" requirement in a thinly-veiled attempt to further the Administration's goals of controlling drug prices without evidence that this approach would offer any meaningful benefit to beneficiaries or states themselves.

Finally, this proposal disturbs the legislative "grand bargain" that underlies the Medicaid rebate statute, and that CMS itself invokes in this proposed rule.[154] As envisioned and codified over 30 years ago, manufacturers pay statutorily-defined rebates, and in exchange, states must cover all of the manufacturer's covered outpatient drugs.[155] Yet, the proposed survey upsets this carefully designed balance by forcing manufacturers to justify their prices in order to extract from them additional rebates. Because the proposed survey lacks statutory authority and would break the Medicaid rebate statute's covenant, it cannot be finalized.

D. Surveying Drugs Approved through the Accelerated Approval Pathway Would Target Critical, Lifesaving Medicines

PhRMA is also strongly opposed to any proposals expanding the verification survey to specifically target drugs approved under the accelerated approval pathway. The accelerated approval pathway was created three decades ago at the urging of patients and has helped many of them get timely access to potentially lifesaving treatments.[156] Patients — including those fighting rare and serious conditions such as hard-to-treat cancers — rely on accelerated approval to improve or extend their lives.[157] The accelerated approval pathway allows the FDA to approve safe and effective medicines while addressing urgent and unmet medical needs. Medicines granted accelerated approval must adhere to the same standards for establishing safety and effectiveness as medicines receiving a traditional FDA approval.[158] Without the accelerated approval pathway, patients in need will have fewer treatment options. Accelerated approval is key to allowing drugs that fill an unmet need to quickly and safely reach patients with serious conditions. Adding additional and burdensome hurdles to drugs approved under this pathway could limit access to key therapies for vulnerable patients who would be harmed by arbitrary and avoidable delays. PhRMA is also concerned that targeting the accelerated

[154] *See* 88 Fed. Reg. at 34254 ("When Congress passed the drug rebate provisions in 1990, they established a framework for coverage and payment of covered outpatient drugs under Medicaid, and prescribed drugs, generally. Often referenced as the 'grand bargain' between the States, the Federal Government, and manufacturers, the MDRP made clear that if manufacturers paid rebates for the covered outpatient drugs dispensed and paid for under the State Plan, States would be required to cover their covered outpatient drugs, subject to limited permissible restrictions and exclusions.").

[155] *See generally* SSA § 1927(a); *see also* 88 Fed. Reg. at 34254; H.R. Rep. No. 101-964, at 97 (1990) (emphasis added) (explaining that "the Committee bill would require states that elect to offer prescription drugs to cover all of the products of any manufacturer that agrees to provide price rebates").

[156] https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/accelerated-approval

[157] https://rarediseases.org/wp-content/uploads/2021/06/NRD-2182-Policy-Report_Accelerated-Approval_FNL.pdf

[158] U.S.C. § 356(e)(2) (referencing 21 U.S.C. § 355(d))

approval pathway could lead to further widening health disparities — as recent research shows that a higher proportion of Black and Asian beneficiaries use accelerated approval drugs compared to all other drug utilizers.[159] This result would be inconsistent with CMS' focus on health equity for all people.[160] While CMS indicates that the proposed drug price verification survey is "not intended to limit or deny access to any of the CODs included on the survey list, assess cost effectiveness or such drugs, or supplant findings from the applicable FDA approval," it is unclear how CMS would use "survey" data on accelerated approval drugs other than to question the clinical benefits and seek additional price controls which may decrease access to these urgently-needed medicines.[161]

VIII. Proposals Related to State Plan Requirements, Findings and Assurances

Under current regulations, pharmacies are paid for drugs they dispense under the State Plan based on a formula that includes the ingredient cost (based on actual acquisition cost) and the pharmacy's professional dispensing fee. States are required to ensure that pharmacies receive adequate reimbursement for both of these components. CMS reviews each state's proposed reimbursement methodology to ensure it reflects the actual ingredient costs and actual costs of dispensing the drug. CMS notes that states recently have submitted proposed changes to the reimbursement components without adequate supporting data that reflects current drug acquisition prices or dispensing costs, and that periodic reviews of research regarding what other payers reimburse for dispensing costs is not a sufficient basis of determining actual dispensing costs. PhRMA agrees that if pharmacies are not reimbursed for covered outpatient drugs based on actual ingredient and dispensing costs, they may be unable to purchase and dispense such drugs to Medicaid beneficiaries. PhRMA agrees that it is critical that pharmacies are reimbursed a sufficient amount in order to ensure that beneficiaries have access to the medicines that they need. PhRMA supports CMS' call for states to come into compliance with the requirement to reimburse pharmacies based on actual acquisition costs and the costs of dispensing covered outpatient drugs and supports CMS' clarifications in this area.

IX. Request for Information – Comments on Issues Relating to Requiring a Diagnosis on Medicaid Prescriptions as a Condition for Claims Payment

Under the MDRP, a drug is generally covered if approved by the FDA and used "for a medically accepted indication." CMS notes that Medicaid covered outpatient drug (COD) claims currently do not require a diagnosis code as a condition for payment, and that it is difficult to determine if a drug is being used for a medically accepted indication without a diagnosis on the prescription drug claim. CMS states that there currently are no systems in place to confirm that a Medicaid beneficiary's prescription drug use is for a medically accepted indication. CMS believes there

[159] Milliman. Demographic characteristics of accelerated approval drug utilizers in Medicaid. https://www.milliman.com/en/insight/demographic-characteristics-accelerated-approval-drug-utilizers-medicaid

[160] CMS, "Health Equity," https://www.cms.gov/pillar/health-equity.

[161] As is the case with nearly all of the agency's time estimates contained in the proposed rule, CMS woefully underestimates the administrative burden that the "verification" survey would impose on manufacturers and wholesalers. Despite the multitude of wide ranging topics – most of which are entirely unrelated to prices or reimbursement and which manufacturers and wholesalers may not maintain in the ordinary course of business –CMS estimates that the survey would "tak[e] 5 hours . . . for an operations research analyst to complete." 88 Fed. Reg. at 34279. This estimate is unrealistic, and demonstrates a lack of understanding of the scope of the survey proposal and its impact on manufacturers and wholesalers.

would be benefits to adding diagnosis information on prescriptions for states, providers, and beneficiaries and solicits comments on whether to require diagnosis codes on prescription drug claims.

PhRMA is concerned that a requirement for diagnosis codes on Medicaid prescription claims has the potential to be another utilization management hoop that Medicaid beneficiaries have to jump through to obtain their medicines. PhRMA is generally supportive of policies that reduce prior authorization (PA) processes, not those that could cause additional hurdles for patients to receive their medicines. For many patients suffering from complex, life-threatening diseases, PA barriers can lead to a delay in getting the medicines and care they need. And at times PA requirements for drugs can interfere with the doctor-patient relationship and doctors' clinical judgment by preventing prescribers from being able to select the best drug for each patient's individual circumstances. Due to the often time-consuming and cumbersome nature of current PA systems, doctors may be discouraged from prescribing the most appropriate therapies. More than nine out of ten physicians say PA has a negative impact on patients' clinical outcomes and a recent Office of Inspector General Report raises concerns that Medicaid beneficiaries enrolled in managed care are not receiving all medically necessary care due to the high rate of denied PA requests and limited PA oversight by states.[162] Timely access to appropriate prescription drug therapy slows or prevents disease progression, improves health outcomes, and reduces the need for costly hospital and emergency care. PhRMA encourages the agency to be mindful about how adding diagnosis codes to prescription claims could be used in particular to restrict timely access to needed medicines.

X. Conclusion

CMS is proposing sweeping changes to the Medicaid Drug Rebate Program (MDRP), many of which would transform policies and practices that have been pillars of the program since its inception. CMS itself admits it is unable to estimate the economic impact of many of these far-reaching proposals. Many of these proposals are not grounded in the Medicaid rebate statute and would go beyond CMS' legal authority. It is crucial that CMS rethink and reject these proposals.

PhRMA appreciates your consideration of these comments. Please feel free to contact Rachel Dolan at rdolan@phrma.org or Sylvia Yu at syu@phrma.org if there is any further information we can provide or if you have any questions about our comments.

/s/	/s/
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[162] https://oig.hhs.gov/oei/reports/OEI-09-19-00350.asp