



VIA ELECTRONIC SUBMISSION

July 8, 2020

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-2482-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments to CMS-2482-P
Proposed Rule: Medicaid Program; Establishing Minimum Standards in Medicaid
State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP)
for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party
Liability (TPL) Requirements

Dear Sir or Madam:

The Center for Children and Families (CCF), part of the Health Policy Institute at the McCourt School of Public Policy at Georgetown University, is an independent, nonpartisan policy and research center that conducts research, develops strategies and offers policy solutions to improve the health of America's children and families, particularly those with low- and moderate-incomes. Thank you for this opportunity to make the following comments to the CMS proposed rule, which focus on the proposed changes to the Medicaid Drug Rebate Program (MDRP). In particular, the comments raise significant concerns about the changes to how manufacturers report best price.

In order to facilitate more widespread adoption of value-based purchasing arrangements (VBP), some drug manufacturers have proposed damaging statutory changes to the Medicaid best price requirement which would sharply increase federal and state Medicaid costs and likely lead to harmful Medicaid cuts reducing beneficiaries' access to needed care. We welcome CMS' intent to instead use rulemaking to clarify how manufacturers can report best price under VBP arrangements and protect the best price requirement. This approach is clearly preferable to amending the MDRP statute in the harmful ways that manufacturers support.

Nonetheless, we believe the rule's proposed changes to best price reporting are seriously flawed. The proposed regulatory language lacks any detail about how the changes would work in practice. And where the preamble to the proposed rule spells out the changes in some greater detail, they raise significant risks that manufacturers could end up paying considerably smaller drug rebates or significantly delaying their rebate payments, relative to current law.

Yet this potential harmful fiscal impact on state Medicaid programs is not considered or analyzed, as required by Executive Order 12866 and the Administrative Procedure Act. This is especially striking because the preamble to the proposed rule makes clear that the intent of these proposed changes to best price reporting is about facilitating the adoption of VBP arrangements in the commercial sector. States already have considerable flexibility to adopt outcome-based contracts with drug manufacturers as well as other alternative approaches, such as "subscription" models, in their Medicaid programs. Seven states have received CMS approval (without waivers) for such arrangements since July 2018. So long as these Medicaid arrangements include a supplemental rebate component, CMS has determined that best price poses no obstacle. If states want to use these arrangements for some drugs in their Medicaid programs, they can do so today.

As a result, CMS should not finalize the proposed rule's best price reporting changes until it takes considerable time to substantially revise and adequately develop these reporting changes. CMS must also fully assess whether or not these best price reporting changes may adversely affect the Medicaid program. Finally, unlike the best price reporting changes, the proposed rule's provisions related to the treatment of line extensions are sound, although they could be further strengthened.

1. Best Price Requirement is Critical Element of the Highly Effective Medicaid Drug Rebate Program

The Medicaid Drug Rebate Program is highly effective.¹ Under the Medicaid Drug Rebate Program (MDRP), all drug manufacturers must provide rebates to the federal government and states as a condition of having their drugs covered by Medicaid. In the case of brand-name drugs, manufacturers must pay a base rebate equal to 23.1 percent of the Average Manufacturer Price (AMP) or the AMP minus the "best price" provided to most other purchasers, whichever is greater. (The AMP is generally the average price paid by wholesalers for drugs distributed to retail community pharmacies.) For generic drugs, the base rebate equals 13 percent of the AMP. Manufacturers must also pay additional inflation-related rebates for both brand-name and generic drugs if their prices rise faster than general inflation. Nearly all states also negotiate directly with manufacturers and/or have managed care plans negotiate for voluntary supplemental rebates on top of these federally required rebates, with many states directly negotiating for some supplemental rebates together as part of a multi-state purchasing pool.

¹ Edwin Park, "How to Strengthen the Medicaid Drug Rebate Program to Address Rising Medicaid Prescription Drug Costs," Georgetown University Center for Children and Families, January 2019, <https://ccf.georgetown.edu/wp-content/uploads/2019/01/Medicaid-Rx-Policy-Options-v4.pdf>.

These rebates are substantial. According to the Medicaid and CHIP Payment and Access Commission (MACPAC), in federal fiscal year 2018, drug manufacturers paid \$36.2 billion in rebates to the federal government and the states, lowering Medicaid prescription drug costs by 59.5 percent.² In contrast, data from the 2020 Medicare Trustees report shows that the rebates negotiated between private insurers and drug manufacturers lowered Medicare Part D costs by only 25 percent in 2018.³ (Unlike under the MDRP, there are no mandatory rebates required in Medicare Part D. All rebates are the result of negotiation between manufacturers and Part D plans and the PBMs with which they contract.) Similarly, according to the Congressional Budget Office, in 2015, the average rebate paid by manufacturers to Medicaid on brand-name drugs was 66.9 percent of the AMP, compared to 28.9 percent in Medicare Part D.⁴ Other analysis has similarly found that the drug rebates manufacturers pay to Medicaid are far larger than what Medicare Part D plans or private insurance plans receive.⁵

The best price requirement is a critical component of the MDRP that lowers Medicaid spending on brand-name drugs significantly. The intent of the best price provision is to ensure that Medicaid obtains discounts at least as large as those available to most purchasers in the commercial sector. The Congressional Budget Office estimated that in 2015, the average base rebate (the higher of the minimum rebate of 23.1 percent of AMP or the best price discount) paid by manufacturers for brand-name drugs was 35.4 percent of AMP.⁶ In other words, because the minimum rebate is 23.1 percent of AMP, the best price requirement, on average, increased the base rebate for brand-name drugs by more than half. That translated into total federal and state Medicaid savings of up to \$5 billion (of which, roughly about \$2 billion were state savings) in 2015 alone.⁷

² Medicaid and CHIP Payment and Access Commission, “MACStats: Exhibit 28 Medicaid Gross Spending and Rebates for Drugs by Delivery System, FY 2018,” December 2019, <https://www.macpac.gov/wp-content/uploads/2015/11/EXHIBIT-28.-Medicaid-Gross-Spending-and-Rebates-for-Drugs-by-Delivery-System-FY-2018-millions.pdf>.

³ “2020 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds,” April 2020 (see Table IV.B8), <https://www.cms.gov/files/document/2020-medicare-trustees-report.pdf>.

⁴ Anna Anderson-Cook, Jared Maeda and Lyle Nelson, “Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid: An In-Depth Analysis,” Congressional Budget Office, Working Paper 2019-02, March 2019, https://www.cbo.gov/system/files/2019-03/55011-Specialty_Drugs_WP.pdf.

⁵ See, for example, Office of Inspector General, U.S. Department of Health and Human Services, “Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin,” April 2015, <https://oig.hhs.gov/oei/reports/oei-03-13-00650.pdf> and Charles Roehrig, “The Impact of Prescription Drug Rebates on Health Plans and Consumers,” Altarum, April 2018, <https://altarum.org/sites/default/files/uploaded-publication-files/Altarum-Prescription-Drug-Rebate-Report-April-2018.pdf>.

⁶ Congressional Budget Office, *op cit*.

⁷ Edwin Park and Andrea Noda, “Alternative Drug Purchasing Arrangements Do Not Justify Raising the Prices Medicaid Pays for Brand Drugs,” Health Affairs Blog, April 3, 2020, <https://www.healthaffairs.org/doi/10.1377/hblog20200325.649781/full/>.

In exchange for these substantial rebates, except for a very limited set of drug classes, state Medicaid programs cannot outright deny coverage of drugs produced by manufacturers participating in the drug rebate program. In addition, children enrolled in Medicaid receive the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit which ensures that children can obtain any drugs their practitioners determine they need as the result of a screening and diagnosis. Medicaid also limits co-payments that may be charged on each prescription to nominal amounts, and for most children on Medicaid, co-payments and other cost-sharing are prohibited entirely. Together, these protections help ensure that low-income Medicaid beneficiaries including children and families have access to the prescription drugs they need.⁸

2. Proposed Changes Could Significantly Weaken Best Price Requirement and Increase Federal and State Medicaid Drug Costs

Some drug manufacturers have pushed for legislative changes to entirely eliminate or seriously undermine the Medicaid best price requirement. They argue that Medicaid best price poses an obstacle to more widespread commercial adoption of VBP arrangements like outcomes-based contracts that vary rebates based on how patients actually fare. Manufacturers have claimed that VBP arrangements could make their new high-cost drugs more affordable to payers and consumers, even though in reality they may do little or nothing to discourage excessive launch prices and instead merely facilitate them.⁹ However, repealing best price or providing broad exemptions for such payment arrangements, as some manufacturers support, would considerably reduce the total rebates manufacturers now pay to Medicaid under current law, significantly raising Medicaid drug costs. A clearly preferable approach would be for CMS to use its authority under the MDRP, either through regulation and/or through subregulatory guidance to manufacturers, to provide detailed, narrow technical clarifications about how best price could be reasonably reported under contracts in which discounts vary based on patients' clinical outcomes, without eliminating or dramatically weakening the best price requirement.¹⁰ Unfortunately, the specific changes to best price reporting that CMS proposes in this rule raise serious concerns.

In the proposed rule, CMS would allow manufacturers using VBP arrangements to report best price in two new ways: bundled sales and variable best price. As discussed below, both the bundled price and variable price changes are seriously flawed, as is the proposed definition of value-based arrangements.

⁸ Jack Hoadley and Joan Alker, "How Medicaid and CHIP Shield Children from the Rising Costs of Prescription Drugs," Georgetown University Center for Children and Families, July 2017, <https://ccf.georgetown.edu/wp-content/uploads/2017/07/Prescription-drugs-v3-link-fix.pdf>.

⁹ Park and Noda, *op cit*.

¹⁰ Park and Noda, *op cit*.

Bundled Sale

The proposed rule would amend the definition of a “bundled sale” in 42 C.F.R. § 447.502 so that VBP arrangements may qualify as a bundled sale “if the arrangement contains a performance requirement such an outcome(s) measurement metric.” We believe the intent of this change is to allow manufacturers to report a net discount under a VBP arrangement: that is, the weighted average of the discounts actually provided based on individual patient outcomes under that specific arrangement. That is consistent with the preamble, which states: “When manufacturers recognize the VBP arrangement as a bundled sale, the manufacturer, for example, may assume that the discount that resulted from a performance requirement of a single unit is distributed proportionally to the total dollar value of the units of all the drugs sold in the bundled arrangement. This smooths out the discount over all the units sold under the arrangement in the rebate period and does not reset the manufacturer’s best price based on the ultimate price of one unit of a drug.”

Unfortunately, this change would make the best price requirement highly vulnerable to manufacturer gaming and inaccurate reporting that could substantially reduce or delay drug rebate payments. That is because neither the amended regulatory language nor the preamble limit what could be included in the bundled price. If finalized, this would appear to allow manufacturers to mix VBP and non-VBP prices under different contracts with the same purchaser. It would also appear to allow manufacturers to mix prices across multiple purchasers if they are subject to the same VBP agreements. If discounts provided under a non-VBP contract with the same purchaser or discounts provided to other purchasers would otherwise determine best price, the rule would essentially permit manufacturers to dilute those discounts, raise their best price and lower their rebate obligations. Even within a single VBP contract, the proposed rule would appear to also allow manufacturers to exclude non-outcome-based discounts that would otherwise apply under the contract (such as a formulary placement or volume discount) and be part of the total “stacked” discounts (including varying discounts based on patient outcomes) provided under the contract.

In addition, neither the proposed regulatory language nor the preamble addresses the issue of how manufacturers would report their initial best price when clinical patient outcome data that determine the discounts available under a VBP arrangement would not be available for more than three years and if no regular best price is reported because the drug is exclusively provided through VBP arrangements. This could allow manufacturers to calculate their initial best price using the smallest discounts possible under a VBP, even though the most likely net discount once actual patient outcome data is available would be far greater. In turn, that would allow manufacturers to delay paying the bulk of the rebates they otherwise owe state Medicaid program for a potentially lengthy period of time. Notably, the rule does not set a time limit on when manufacturers have to revise their best price reporting under a VBP arrangement — the current time limit is 3 years — even though state Medicaid programs would be most in need of upfront rebates to offset the costs of a new expensive drug in the first years the drug enters the market.

CMS must instead clarify that manufacturers reporting VBP arrangements as a bundled sale for purposes of the best price requirement can only do so for a single contract with a single purchaser, while incorporating the full stacking of discounts. They should not be permitted to mix prices under a VBP arrangement with those under a non-VBP arrangement. They also should not be allowed to mix prices under VBP arrangements across multiple purchasers. In addition, CMS should clarify that manufacturers would initially calculate the best price they report to the federal government by looking at the expected net price under the VBP arrangement, based on the expectations of the manufacturer and the private purchaser using available clinical data. (The expected net price should be a required element of the arrangement.) The manufacturer would then revise its best price once actual clinical data is available, with rebate amounts adjusted retroactively.¹¹ A reasonable time limit — no more than one or two additional years beyond the current three-year limit — should also be set for revising best price under bundled sales that account for discounts based on actual patient outcomes as they become available.

Variable Best Price

The proposed rule would also amend 42 C.F.R. § 447.505 to allow manufacturers to report “varying best price points for a single dosage form and strength as a result of a value based purchasing arrangement...” instead of a single best price. This would appear to permit manufacturers to report a best price range to the extent they may be determined by varying discounts under VBP arrangements, along with the regular best price under any non-VBP arrangements. Yet this variable best price reporting change is entirely unnecessary. The proposed rule already provides the bundled sale option for manufacturers that accounts for varying discounts based on patient outcomes and would ensure best price would not be determined solely by the largest possible discount for a single patient under a VBP arrangement.

In addition, the preamble appears to state that when manufacturers use this option to report a range of best prices due to VBP arrangements, best prices determined by VBP arrangements would not be factored into the calculation of rebates owed to a state Medicaid program if the state was not participating in such VBP arrangements with those manufacturers.¹² *In other words, if the state Medicaid program was not part of a VBP arrangement with the manufacturer, no VBP-related best prices, if reported as a range, would apply even if they would have the effect of increasing the rebates manufacturers owe.* If the manufacturer exclusively provides the drug through VBP arrangements, there would be no non-VBP best price. That would essentially gut best price if manufacturers then refuse to offer VBP arrangements to state Medicaid programs. Moreover, as discussed below, only a relatively small number of state Medicaid programs currently have VBP arrangements, and of those, the arrangements are only with a single or a handful of manufacturers. This would essentially force states to enter into VBP arrangements with manufacturers, with manufacturers given nearly all of the negotiating leverage as states may otherwise lose

¹¹ Park and Noda, *op cit.*

¹² 85 Fed. Reg. 37293 (June 19, 2020).

access to base rebates set by best price. Even if manufacturers were willing to negotiate VBP discounts with state Medicaid programs over time, it is likely that many states, at least initially, would face smaller rebates as they would no longer benefit from best price.

The preamble also appears to state that the best price that would apply for purposes of the MDRP, if it is based on a VBP arrangement, would be adjusted for the actual clinical outcomes of individual Medicaid beneficiaries receiving the drug in the state (not the outcomes of patients under the commercial VBP arrangement under which the manufacturer has reported a range of best prices).¹³ This means that even if the average best price discount under VBP arrangements is larger, a smaller discount would apply for purposes of best price if a Medicaid beneficiary has a clinical outcome that is better than average. This seems entirely infeasible. The proposed rule acknowledges that the Medicaid drug rebate system does not currently allow for manufacturers to report varying best prices, let alone allow for calculation of rebates based on the individual patient outcomes of Medicaid beneficiaries receiving that drug within a state Medicaid VBP arrangement. The proposed rule states there would be “operational challenges this may bring to MDRP systems” and that “it will take us time to make such system changes.” Also, it is hard to see how states could possibly track patient outcomes in this manner. States do not furnish drugs directly: they (or the managed care organizations (MCOs) with which they contract, or the pharmacy benefit managers with which those MCOs subcontract) reimburse pharmacies for dispensing drugs to beneficiaries. They lack systems to track specific patient outcomes for current beneficiaries. In addition, many beneficiaries may leave the program as they become no longer eligible due to income or other changes and states would have no programmatic connection to these individuals after disenrolling from Medicaid.

Finally, the variable best price option appears to assume that manufacturers are negotiating uniform VBP arrangements across purchasers and with state Medicaid programs. The preamble never addresses the concern of how variable prices could ever be accurately reported if there are multiple arrangements with multiple purchasers providing different discounts based on different outcomes outside and inside Medicaid. As discussed further below, this would make the ongoing issues of ensuring manufacturer compliance with MDRP requirements, including accurate price reporting, far worse, if not impossible.

CMS must therefore drop this flawed, poorly designed and risky variable best pricing option. It is entirely redundant with the availability of the proposed bundled sale option. If CMS still finalizes this provision, it must clarify that variable best prices may set base rebate amounts irrespective of whether a state Medicaid program participates in a VBP arrangement and that rebate amounts would not be affected by the actual clinical outcomes of Medicaid beneficiaries receiving the drug.

¹³ 85 Fed. Reg. 37293 (June 19, 2020).

Definitions

The proposed rule would amend 42 C.F.R. § 447.502 to add a definition of a value-based purchasing (VBP) arrangement for purposes of a bundled sale and for variable best price reporting. In paragraph (1), a VBP arrangement would include not just outcome-based measures but also “[e]vidence-based measures, which substantially link the cost of a drug to existing evidence of effectiveness and potential value for specific uses of that product.” Including evidence-based measures would make the VBP definition excessively broad, incorporating regular discounts, such as those related to formulary placement that are currently negotiated between commercial purchasers and manufacturers and which already take into account perceived value and effectiveness, including analysis from outside entities such as the Institute for Clinical and Economic Review.¹⁴ Unlike with outcome-based contracts, such discounts do not conflict at all with current best price reporting requirements as manufacturers already account for them in their best price calculations. But by incorporating such measures into the definition of VBP, it would dramatically increase the risk that the best price requirement would be undermined. For example, it would raise the likelihood that non-VBP best prices would disappear entirely and only VBP prices would factor into best price. Manufacturers would thus be able to dilute many existing discounts (based on relative value or clinical effectiveness) that currently set best price by mixing them with VBP prices, in order to minimize their rebate obligations.

Also, for both evidence-based measures and outcomes-based measures to meet the definition of VBP, the proposed rule in 42 C.F.R. § 447.502 uses the exceedingly vague phrase “substantially link.” For outcomes-based measures to meet the definition of a VBP arrangement, such measures must “substantially link payment for the drug to that of the drug’s actual performance in patient or a population, or a reduction in other medical expenses.” The preamble does not further define what “substantially link” means. This could allow manufacturers to classify existing contracts and arrangements as VBP arrangements by adding some additional outcome-based discounts, even if the bulk of the discounts remain unchanged. Combined with the above changes that result in a significant risk of gaming to reduce or delay rebate amounts, this vague definition would further facilitate the risk of gaming and inaccurate best price reporting by manufacturers and make it more likely that the proposed rule results in higher federal and state Medicaid costs.

Evidence-based measures must be dropped from the definition of a VBP arrangement. CMS should also clarify what constitutes a substantial linkage of payment to performance under an outcome-based measure for purposes of VBP. That could include specific types of contracts and other arrangements where a high, minimum percentage of discounts are tied to performance in delineated ways.

¹⁴ Peter Bach, “CMS’ Proposed Medicaid Best Price Loophole for Value-Based Purchasing of Drugs,” Health Affairs Blog, July 6, 2020, <https://www.healthaffairs.org/doi/10.1377/hblog20200701.841730/full/>.

Best Price Reporting Changes Would Dramatically Worsen Existing Rebate Enforcement Challenges

CMS still does not conduct a mandatory audit system for manufacturers in order to periodically verify the accuracy of reported price information under the MDRP.¹⁵ If finalized, these best price reporting changes would make it far more difficult for the federal government — not just CMS but also the HHS Office of Inspector General and the Department of Justice — and states to ensure manufacturer compliance with MDRP requirements including best price (and in some scenarios related to the proposed variable best price reporting, as noted above, impossible). Manufacturer failure to accurately report best price has been the subject of False Claims Act litigation for decades.¹⁶

3. Proposed Rule Includes No Analysis of the Potential Harmful Impact of the Best Price Reporting Changes on the Medicaid Program

CMS asserts without explanation that the proposed rule does not constitute a major rule with economically significant effects (\$100 million or more in any 1 year). CMS mistakenly claims it therefore does not have to prepare a regulatory impact analysis (which would otherwise be required under Executive Order 12866). But as discussed above, the best price requirement produced total Medicaid savings of up to \$5 billion (and roughly about \$2 billion in state savings) in 2015 alone and the proposed changes, if finalized as-is, could significantly weaken best price and increase Medicaid drug costs, which would also constitute a material adverse effect on state governments. As a result, the rule should constitute an “economically significant” rule under Executive Order 12866, requiring a regulatory impact analysis. It should also meet the criteria for “other significant” rule as it could materially alter the budgetary impact of the Medicaid program. This, in turn, still requires a complete assessment of the potential costs and benefits. Moreover, in order to fulfill their duties under the Administrative Procedure Act, agencies must also consider important aspects of the problem they seek to address through rulemaking (such as the potential adverse impact on the Medicaid program) and allow for meaningful public comment (including knowledge of a rule’s potential adverse impact). (This rule should also trigger review under the Regulatory Flexibility Act as the proposed best price rule changes are likely to have a significant impact on a substantial number of small providers participating in the 340B program.)

Yet inconsistent with both Executive Order 12866 and the Administrative Procedure Act, the proposed rule does not examine, let alone estimate, the potential negative fiscal impact of the rule on the Medicaid program even as the proposed rule’s best price changes are clearly intended to facilitate the more widespread adoption of VBP arrangements outside of Medicaid in the commercial sector. Moreover, as noted above, VBP arrangements may

¹⁵ Park, *op cit.*

¹⁶ See, for example, Andy Schneider, “The Role of the False Claims Act in Combatting Medicare and Medicaid Fraud by Drug Manufacturers: An Update,” Taxpayers Against Fraud Education Fund, 2007, https://97ae160d-c32b-4fb0-96cb-320cabbdfe94.filesusr.com/ugd/471b50_143174e184054d5aa6fb7b6ee5960a52.pdf.

do little or nothing to discourage excessive launch prices for new drugs and could instead facilitate them, which would also increase Medicaid drug costs over time.¹⁷ This is another indication that CMS has not taken the time needed to sufficiently consider, develop and analyze its proposed changes to best price reporting under the MDRP. A full analysis of the impact on state Medicaid programs must be conducted before these best price reporting changes are finalized.

The lack of analysis is particularly problematic because the preamble to the proposed rule makes clear that the intent of these proposed changes to best price reporting is about facilitating the adoption of VBP arrangements in the commercial sector, not in Medicaid. Notably, the preamble omits the fact that states already have considerable flexibility to adopt “subscription” models, outcome-based contracts, and pay-over-time contracts and other alternative payment arrangements in their Medicaid programs. Since July 2018, seven states — Oklahoma, Michigan, Colorado, Washington, Louisiana, Massachusetts and Alabama — have received CMS approval for state plan amendments (without waivers) adopting these approaches. (In addition, Arizona submitted a Medicaid state plan amendment but it has not yet been approved.)¹⁸ The preamble to the rule argues that without the proposed best price reporting changes, “manufacturers may be unwilling to offer VBP to Medicaid....”¹⁹ But so long as the Medicaid drug pricing arrangements include a supplemental rebate component, CMS has already determined through state plan amendment approvals and guidance to states that best price poses no obstacle to states adopting these arrangements.²⁰ If states want to use these arrangements for some drugs and determine whether they can meaningfully reduce their Medicaid prescription drug costs, particularly for new expensive drugs, they can do so today.

4. Clarifications of Treatment of Line Extensions Are Sound and Could Be Further Strengthened

In addition to the best price reporting changes, the proposed rule also includes clarifications to what constitutes a “line extension” for purposes of the MDRP. We strongly support these clarifications. The Bipartisan Budget Act of 2018 (P.L. 115-123) amended how inflation-related rebates under the MDRP would be calculated for the line extensions of a drug. Effective October 1, 2018, inflation-related rebates would be the higher of the amount determined under the regular inflation-related rebate formula or the highest

¹⁷ Bach, *op cit.*

¹⁸ Park and Noda, *op cit.*

¹⁹ 85 Fed. Reg. 37291 (June 19, 2020).

²⁰ See Centers for Medicare and Medicaid Services, “CMS Approves Louisiana State Plan Amendment for Supplemental Rebate Agreements Using a Modified Subscription Model for Hepatitis C Therapies in Medicaid,” June 26, 2019, <https://www.cms.gov/newsroom/press-releases/cms-approves-louisiana-state-plan-amendment-supplemental-rebate-agreements-using-modified> and Centers for Medicare and Medicaid Services, “Medicaid Drug Rebate Program Notice Release No. 176,” July 14, 2016, <https://www.medicare.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-176.pdf>.

inflationary-related rebate for the original drug (measured as a percentage of the original drug's AMP).²¹

In 42 C.F.R. § 447.502, the proposed rule would establish a definition for a line extension: “a new formulation of the drug, but does not include an abuse-deterrent formulation of the drug....” In turn, the proposed rule would define a new formulation as including “at least one active ingredient in common with the initial brand name listed drug” and include, but are not limited to, changes in dosage, strength, route of administration, ingredients, pharmacodynamics or pharmacokinetic properties, changes in indications and combination drugs. In 42 C.F.R. § 447.509(a)(4)(i), the proposed rule would also clarify that for purposes of a line extension, only the initial drug has to be an oral solid dosage form.

We agree with the preamble that these changes would address the concern that “manufacturers may have a financial incentive to be underinclusive in their identification of drugs as line extensions because a drug identified as a line extension may be subject to a higher rebate.” For example, requiring that only the initial drug has to be an oral solid dosage form would prevent manufacturers from switching forms to avoid higher inflation-related rebates. Similarly, delineating some of the specific changes that constitute new formulations for purposes of line extensions would help discourage manufacturers from misclassifying drugs in order to minimize their inflation-related rebates.

CMS, however, should also consider revisiting current 42 C.F.R. § 447.509(a)(4)(iii) which applies the special rebate formula for line extension drugs only to manufacturers that had also manufactured the initial drug or have a corporate relationship with the initial manufacturer. This may have the effect of encouraging manufacturers to sell off a line extension of a drug to another manufacturer in order to minimize rebate obligations. It is also inconsistent with how regular inflation-related rebates are calculated in the case of a drug sold to a different manufacturer: the base AMP for purposes of the inflation-related rebate is the same and determined no differently than if the drug had continued to be produced by the same manufacturer.

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Thank you again for the opportunity to make the above comments to the proposed rule. Please contact me at Edwin.Park@georgetown.edu if you have any questions or if we can be of further assistance.

²¹ Medicaid and CHIP Payment and Access Commission, “Improving Operations of the Medicaid Drug Rebate Program,” June 2018, <https://www.macpac.gov/wp-content/uploads/2018/06/Improving-Operations-of-the-Medicaid-Drug-Rebate-Program.pdf>.

Respectfully submitted,

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