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A New Year for Drug Pricing and Price Reporting? What's Happening Now and What's New for 2022

Introduction

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The past two years have featured a flurry of legislative action, agency rulemaking and executive orders targeting the pricing of pharmaceutical and biologic products and related price reporting obligations. The legislative and executive branches of government were especially active over the summer and the start of fall, as discussed in an August 2021 Alert. As we approach the end of 2021, this Alert takes stock of what's happened, what's been delayed, and what's likely to happen in 2022 in the key areas that have been in play. Specifically, what we're seeing is:

- *Multiple best price value-based price reporting must wait.* A delay in the implementation of the value-based arrangement exception to the "best price" rule, including related reporting requirements;
- *Payor drug price transparency still happening.* The implementation of regulations on payor drug price transparency reporting requirements, along with an exercise of enforcement discretion;
- *Another pause on PBM and pass-through rebate reforms; Part B single-use discard reform.* The Infrastructure Investment and Jobs Act's delay of the new drug discount-related safe harbors, as well as implementation of penalties for discarding portions of single-use packaged drugs reimbursed by Medicare Part B;
- *Uncertain fate of Medicare price negotiation and inflationary rebates.* The still-in-discussion Build Back Better Act's proposed provisions including the potential requirement that the government negotiate Medicare Part B and Part D drug prices, and potential inflation-based rebates in Medicare, both of which would impose new cost burdens on drug manufacturers; and
- *The covered entity-manufacturer 340B litigation continues.* The 340B contract pharmacy litigation, pitting DSH hospitals and other covered entities against manufacturers, likely will continue throughout much of 2022.

I. Executive Orders/Agency Action

a. Delays to the Medicaid Multiple Best Price VBA Exception. As we discussed in detail in a December 23, 2020 Alert, the Centers for Medicare & Medicaid Services ("CMS") promulgated a final rule on December 21, 2020 focused on Medicaid drug pricing (the "Medicaid Rule"), including the creation of a value-based arrangement ("VBA")[1] exception to the Medicaid "best price" requirement. Specifically, the Medicaid Rule enables pharmaceutical manufacturers to enter into VBAs (which include certain discounting arrangements) and then report to CMS the range of best prices provided pursuant to such VBAs. A manufacturer may elect to report multiple best prices that reflect the terms of a VBA, and the manufacturer must then offer the VBA to states, which may in turn elect whether to participate. If a state opts out, then it will receive rebates based on the manufacturer's non-value-based purchasing best price for the particular drug. The VBA exception to the best price requirement was originally scheduled to go into effect in March of 2021, but was delayed until January 1, 2022 pursuant to a May 28, 2021 proposed rule.[2] On November 19, 2021, CMS issued a final rule again delaying the implementation of the Medicaid Rule's VBA exception until July 1, 2022 (the "November Rule").[3] CMS attributes much of the ongoing delay to the operational complexity and continuing challenges presented by the COVID-19 pandemic, noting that states and manufacturers need time to address the significant change in policy and operation contemplated by the VBA exception while also addressing the pandemic.[4] Given CMS's recent focus on encouraging VBA arrangements across the health care industry, as well as the seemingly strong appetite among pharmaceutical manufacturers to avail themselves of this price reporting exception, it is reasonable to think that the VBA exception will

not be delayed indefinitely, and will indeed be implemented by the end of 2022. In the meantime, pharmaceutical manufacturers may wish to continue discussions with state Medicaid programs to evaluate potential VBA opportunities – under the Medicaid Rule and/or under best price-exempt CMS-approved outcome-based Medicaid supplemental rebate agreements that have been available for several years and continue to proliferate in the states.

b. Delay in Inclusion of Territories in Medicaid Drug Rebate Program. The November Rule also delayed until January 1, 2023 the Medicaid Rule's addition of the U.S. territories of American Samoa, Northern Mariana Islands, Guam, Puerto Rico and the Virgin Islands to the regulatory definitions of "States" and "United States" in the Medicaid Drug Rebate Program. In issuing the delay, CMS expressed its concern that the territories would not be ready to participate in the Medicaid Drug Rebate Program by the originally scheduled April 1, 2022 implementation date. Further, CMS explained that in the COVID-19 pandemic, "it is imperative that the territories prioritize the Medicaid eligibility and mandatory benefit requirements brought about by the [American Rescue Plan Act of 2021] to address beneficiary needs," which would necessarily be affected by diverting resources to prepare for participation in the Medicaid Drug Rebate Program.

c. Payor-Imposed Drug Price Transparency Reporting Requirements Go into Effect, but Enforcement Delayed. On November 17, 2021, CMS published an interim final rule entitled "Prescription Drug and Health Care Spending."[5] This rule implements parts of the Consolidated Appropriations Act, 2021 ("CAA") that address drug cost transparency, and builds on earlier rules that implement the "No Surprises Act."[6] The interim final rule's transparency provisions require insurers, employer-based health plans, and other group health plans to report prescription drug and health coverage costs to the U.S. Department of Health and Human Services ("HHS"), U.S. Department of Labor, and the U.S. Treasury Department. These departments are then required to work with the HHS Assistant Secretary for Planning and Evaluation to publish a report on prescription drug pricing trends and rebates.

Reported information will include, but will not be limited to:

- Average monthly premiums and drug spending for patients compared to employers, group health plans, or insurers;
- 50 most frequently dispensed brand prescription drugs;
- 50 costliest prescription drugs by total annual spending;
- 50 prescription drugs with the greatest increase in plan or coverage expenditures from the previous year;
- Prescription drug rebates, fees, and other remuneration paid by drug manufacturers to the plan or issuer in each therapeutic class of drugs, as well as for each of the 25 drugs that yielded the highest amount of rebates; and
- The impact of prescription drug rebates, fees, and other remuneration on premiums and out-of-pocket patient costs.

The interim final rule's regulations go into effect December 23, 2021, with the first transparency report due December 27, 2021, and the second due June 1, 2022. However, the interim final rule notes that enforcement of the first required reports will be waived so long as obligated reports provide the required 2020 and 2021 data by December 27, 2022.[7] The first HHS report is not anticipated to be published until June 2023, with such reports released biennially thereafter.

The payor drug price transparency requirements under the CAA and interim final rule are distinct from those under the Transparency in Coverage Final Rule, which calls for various, drug-specific price disclosures. It is unclear whether the drug pricing provisions of the Transparency in Coverage Final Rule ultimately will go into effect, or whether, instead, the transparency requirements under the interim final rule will become the primary ones for these categories of payers. In November 2021, HHS, the U.S. Department of Labor, the U.S. Department of Health, and the Treasury published "FAQs

About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49," which state that the agencies will, in their discretion, refrain from enforcement of the Transparency in Coverage Final Rule drug pricing provisions pending further rulemaking.[8]

II. Legislation

a. Infrastructure Investment and Jobs Act Drug Pricing Delays and Reforms. The Infrastructure Investment and Jobs Act, which President Biden signed into law on November 15, 2021 (the "Infrastructure Act"), contains two provisions affecting drug pricing.[9] The first imposes a moratorium on the implementation of the HHS OIG Final Rule "Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees," which was published on November 30, 2020.[10] We addressed the final rule in depth in a December 9, 2020 Alert, but in short, it (a) eliminates the current safe harbor for Medicare Part D rebates, (b) creates a beneficiary point-of-sale discount safe harbor, and (c) creates a PBM service fee safe harbor. While these changes were originally scheduled to go into effect on January 29, 2021, they were delayed until January 1, 2023 by a court order in a lawsuit that the PBM industry brought against HHS.[11] Now, under the Infrastructure Act, these changes will not be implemented until January 1, 2026 at the earliest, resulting in anticipated federal government savings during the interim years.

The second drug pricing provision in the Infrastructure Act requires manufacturers of certain single-dose container or single-use package drugs payable under Medicare Part B to refund Medicare for discarded Part B drugs.[12] Each quarter, beginning on or after January 1, 2023, HHS will report to each pharmaceutical manufacturer the total number of units that were discarded of each of the manufacturers' single-dose container or single-use package drug (with some limited exceptions), and the refund due for such discarded drugs. A manufacturer that fails to comply with issuing the refund may be faced with a civil monetary penalty of up to 125% of what the manufacturer would have owed for each applicable drug. Beginning on January 1, 2023, pharmaceutical manufacturers will be required to refund Medicare for discarded Part B drugs, not including (a) drugs that have been covered for less than eighteen (18) months under Part B (until such drug has been covered for eighteen (18) months), (b) radiopharmaceuticals or imaging agents, (c) drugs approved under abbreviated new drug applications or multiple source drugs, and (d) drugs that require filtration during the preparation process in accordance with a drug's label, prior to dilution and administration, and that require the unused portion of the drug after filtration to be discarded. The Secretary of HHS has authority to audit manufacturers in connection with the refunds and providers in connection with their claims.

b. Build Back Better Act Would Bulk Up Government Negotiating Power. The House of Representatives passed the Build Back Better Act ("BBB") on November 19, 2021.[13] While Senate Majority Leader Chuck Schumer has stated that his goal is to pass the bill before Christmas,[14] it is unclear whether he will achieve this goal, and, if he does, whether the Senate will pass the bill without amendments.

If enacted in its current form, the BBB contains several drug pricing proposals, including one that would allow the federal government to negotiate prices for certain high-cost Medicare Part B and Part D drugs. The BBB would also require manufacturers to pay Medicare rebates for certain Part B and nearly all Part D drugs if the prices for these drugs increase more quickly than inflation, thereby creating incentives for manufacturers to limit drug price increases.[15] Other noteworthy provisions include capping out-of-pocket spending for Medicare Part D enrollees, limiting cost sharing for insulin for patients covered by both Medicare and private insurance, eliminating cost sharing for vaccinations covered by Medicare Part D, and eliminating the Trump administration's drug rebate rule.

III. 340B Developments

a. 340B Contract Pharmacy Litigation Proceeds, May 2021 Letters Struck Down. This past fall, three federal courts weighed in on the ongoing dispute between manufacturers and the U.S. Health Resources and Services Administration ("HRSA") regarding whether manufacturers' obligation to offer discounts under the 340B Program extends to contract pharmacies. Manufacturers in each case challenged the validity of HRSA's May 2021 letters asserting that the

manufacturers' policies with respect to contract pharmacies violated the 340B statute (the "May 2021 Letters"). In all three cases, the federal courts vacated the May 2021 Letters. Nevertheless, these decisions almost certainly will not be the final word on this issue, as the courts offered different rationales for their decisions, left important questions unresolved, and made various statements that both manufacturers and HRSA will cite going forward to support their respective positions. Moreover, the manufacturer plaintiffs in two of the cases have already announced their intention to appeal, while HRSA has indicated that it "continues to evaluate its options."

In sum, the U.S. District Courts for the Southern District of Indiana and the District of New Jersey appeared sympathetic to HRSA's position that manufacturers cannot unilaterally impose restrictions on the offer and sale of 340B drugs. However, both courts vacated the May 2021 Letters because (1) according to the Indiana decision, the letters were arbitrary and capricious in violation of the Administrative Procedure Act to the extent they failed to explain the change in HRSA's position regarding its enforcement authority with respect to contract pharmacies; and (2) according to the New Jersey decision, HRSA did not adequately determine whether the 340B program permits covered entities to use multiple or an unlimited number of contract pharmacies. Both courts remanded the letters to HRSA to remedy the issues identified by the courts.

On the other hand, the U.S. District Court for the District of Columbia provided further relief for the manufacturer plaintiffs in that case. In addition to vacating the May 2021 Letters, the court declared that the manufacturers' contract pharmacy policies did not violate the 340B statute under the specific positions advanced by HRSA in the letters and during the litigation. Unlike in the other two decisions, the court here did not agree that the statute prohibits manufacturers from imposing *any* conditions on the offer of 340B drugs and, thus, held that HRSA had failed to show why the companies' specific conditions at issue were unlawful. The court, however, declined to affirmatively state whether the companies' policies are permitted. Looking ahead, the court noted that any future HRSA enforcement action would have to rest on a new statutory provision, a new legislative rule, or a better legal theory.

b. Resolution by Rulemaking? Additionally, on November 18, 2021, the Office of Management and Budget received a proposed rule titled "340B Drug Pricing Program; Administrative Dispute Resolution." The content of the proposed rule is unclear, but it purports to allow manufacturers and covered entities participating in the 340B Program to file claims for specific compliance areas "after good faith efforts have been exhausted by the parties" and to "correct procedural deficiencies in the 340B ADR process."[16]

If you have any questions about this Alert, please do not hesitate to contact one of the authors or your usual Ropes & Gray advisor.

1. The Medicaid Rule defines a value-based purchasing arrangement as "an arrangement or agreement intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in select populations and includes, but is not limited to (1) evidence-based measures, which substantially link the cost of a covered outpatient drug to existing evidence of effectiveness and potential value for specific uses of that product; and/or (2) outcomes-based measures, which substantially link payment for the covered outpatient drug to that of the drug's actual performance in a patient or a population, or a reduction in other medical expenses." 85 Fed. Reg. 37286, 37292.
2. 86 Fed. Reg. 28742.
3. 86 Fed. Reg. 64819.
4. 86 Fed. Reg. 64819, 64819.
5. 86 Fed. Reg. 66662.
6. CAA, 2021, Pub. L. No. 116-260, div. BB, tit. 1 (No Surprises Act), sec. 102, 134 Stat. 1182, 2758-2797
7. (2020); 86 Fed. Reg. at 36,877. See also discussion in an October 2021 Alert.
8. The interim final rule states that "the Departments will not initiate enforcement action against a plan or issuer that does not report the required information by the first statutory deadline for reporting on December 27, 2021 or the second statutory deadline for reporting on June 1, 2022, and that instead submits the section 204 data submissions for the 2020 and 2021 reference years by December 27, 2022." 86 Fed. Reg. 66662, 66671
9. FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49, Aug. 20, 2021, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf.
10. Infrastructure Investment and Jobs Act, Pub. L. No. 117-58, § 90006, 135 Stat. 429, 1346 (2021).
11. 85 Fed. Reg. 76666, 76701.
12. Order in Pharmaceutical Care Management Association v. U.S Dep't of Health & Human Servs., 1:21-cv-00095, available at https://s3-prod.modernhealthcare.com/2021-02/Drug%20Rebate%20Decision%20Date%20Order.pdf.
13. Infrastructure Investment and Jobs Act, Pub. L. No. 117-58, § 90006, 135 Stat. 429, 1343 (2021).
14. H.R. 5376, 117th Cong. (2021), available at https://www.congress.gov/bill/117th-congress/house-bill/5376/text.
15. Dear Colleague Letter (Dec. 6, 2021), *available at* https://www.democrats.senate.gov/imo/media/doc/Dear%20Colleague%2012.6.21.pdf.
16. H.R. 5376, 117th Cong. (2021), § 139101 et seq.
17. See https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202110&RIN=0906-AB28.