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Developments in Drug Pricing and Price Reporting as the Congressional Recess Approaches (August 2021)

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Update on Most Favored Nation Pricing Proposed Rule: On August 6, 2021, HHS issued a proposed rule to rescind the November 2020 interim final rule, citing the nationwide preliminary injunction that precluded the MFN model's implementation, stakeholder concerns about the model's start date, and issues identified by commenters. However, the agency was careful to say that it is continuing to evaluate the issue, and that the proposal to rescind the interim final rule does not reflect any judgment by HHS regarding future policy. The updated proposal can be found here, and the comment deadline is October 12, 2021.

Introduction

As the August congressional recess approaches, there have been several developments in the drug pricing/price reporting space. All branches of government have worked to tackle drug pricing in recent months, and by late August, we may have a much stronger sense of the direction the Biden Administration intends to take to address drug pricing through administrative action.

Executive approaches under consideration include further Federal Trade Commission action to improve **competition from generics and biologics**, **re-importation**, variations on **most-favored nation** price controls, and delaying a Trump-era rule on **rebates** as a pay-for for infrastructure spending. Pending legislation includes a Democratic proposal (HR 3) and a Republican proposal (HR 19)—both of which would eliminate the **Medicare Part D coverage gap**, lower the **Medicare Part D out-of-pocket threshold**, and **require manufacturers to report certain price increases** to the U.S. Department of Health and Human Services ("HHS")—as well as bipartisan proposals such as the "Ensuring Timely Access to Generics Act." Active, continued **litigation involving the 340B Program** is challenging sales to contract pharmacies, CMS's hospital rate cuts, and the required use of mail order pharmacies. Finally, international developments include a potential **World Trade Organization COVID vaccine patent waiver**.

I. Executive Orders/Agency Action

Ordering Multi-Agency Action, Including Pay-for-Delay Reform. President Biden signed an executive order on July 9 that calls on more than a dozen federal agencies to pursue over seventy initiatives in order to invigorate competition, with a focus on addressing prescription drug costs. One initiative directs HHS to craft a plan within forty-five days to combat "excessive pricing of prescription drugs and enhance domestic pharmaceutical supply chains, to reduce the prices paid by the federal government for such drugs, and to address the recurrent problem of price gouging." Additionally, Biden's order recommends that the Federal Trade Commission use its rulemaking authority to address so-called "pay-for-delay" deals—e.g., deals in which brand-name drugmakers allegedly compensate generic-drug manufacturers to postpone the market entry of copycat products with lower price tags.

Re-importation. On the issue of drug importation, the executive order directed the U.S. Food and Drug Administration ("FDA") commissioner to work with states to develop a program allowing prescription medications to be brought in from other countries, particularly Canada. A number of U.S. states, including Florida, Colorado, and several New England states, are prepared to implement drug importation and are awaiting federal action. Conversely, the Pharmaceutical Research and Manufacturers of America ("PhRMA") opposes this proposal, arguing that other countries have less stringent regulatory standards when it comes to medicine supply standards. In November 2020, PhRMA filed suit to stop drug importation from Canada.

Most Favored Nation: Office of Management and Budget ("OMB") Proposed Rule. In November 2020, the Centers for Medicare & Medicaid Services ("CMS") introduced an interim final rule with a comment period that aimed to implement

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a nationwide Most Favored Nation ("MFN") Medicare fee-for-service payment model (the "MFN Model"). According to the OMB, the MFN Model intended to test whether more closely aligning payment for Medicare Part B drugs and biologicals with international prices, thus removing incentives to use higher-cost drugs, could control unsustainable growth in Medicare Part B spending without adversely affecting quality of care for beneficiaries. In July 2021, what appeared to be a new version of the MFN drug pricing rule arrived at the OMB for review. At the time, there was speculation regarding whether this proposed rule would rescind the Trump Administration MFN proposal, or whether the Biden Administration would propose its own MFN rule. The interim final rule, and the OMB description of the pending proposed rule, contrasted with Senator Ron Wyden's proposal (discussed below), which would empower HHS to negotiate drug prices and cap the price of certain drugs based on the negotiated "maximum fair price" of each drug. On August 6, 2021, this speculation was laid to rest when HHS issued a proposed rule to rescind the November 2020 interim final rule, citing the nationwide preliminary injunction that precluded the MFN model's implementation, stakeholder concerns about the model's start date, and issues identified by commenters. However, the agency was careful to say that it is continuing to evaluate the issue, and that the proposal to rescind the interim final rule does not reflect any judgment by HHS regarding future policy.

Drug Rebate Rule Delay as Infrastructure Pay-for. Senate Democrats are considering agreeing to a GOP proposal to delay the Trump Administration's drug rebate rule to help fund infrastructure legislation. The rule would eliminate a safe harbor for Medicare Part D rebates and replace it with a new protection for discounts offered at the point of sale. The rebate rule has been estimated to be very costly to government—it is projected to increase federal spending by $177 billion through 2029—and repealing the rule could help pay for both a bipartisan infrastructure deal and Democrats' more sweeping infrastructure proposal. The Biden Administration already delayed the regulation's effective date until January 1, 2023, but the Democrats' proposal would extend this delay. The pharmaceutical industry is strongly opposed to delaying the rebate rule. A PhRMA spokesperson stated that the rebate rule provides patients with meaningful relief at the pharmacy counter.

II. Legislative Proposals: Part D Redesign and Drug Pricing Transparency Reform

Both Democrats and Republicans have introduced bills focusing on drug pricing transparency and other drug pricing reforms.

Democratic Proposals: Direct Price Negotiations and More Transparency. The Democratic proposal (HR 3), called the "Elijah E. Cummings Lower Drug Costs Now Act," was introduced in the House on April 22, 2021. HR 3 builds upon bipartisan proposals to restructure Part D that were introduced in 2019. House Democrats' draft bill would tack a sweeping drug price negotiation bill to Biden's infrastructure package; however, the bill faces long odds in the Senate. HR 3 would allow the federal government to negotiate selected drug prices in Medicare and make those same negotiated prices available to commercial health insurance plans. It also would require a drug's "maximum fair price" to be published in the Federal Register, and it would require drug manufacturers to report certain price increases to the government and pay a rebate back to the federal government if they increase the price of their prescription drugs faster than permitted. In June, Democratic Senator Ron Wyden released a framework for a related proposal to lower prescription drugs prices; his proposal would authorize the Secretary of HHS to negotiate Medicare drug prices with pharmaceutical companies, based on a determined "fair price" for each selected drug. It also would extend drug pricing reforms to other, non-Medicare insurance programs, including employer-based and commercial plans.

Republican Proposals: Less Sweeping Reforms and More Study. The Republican proposal (HR 19), called the "Lower Costs, More Cures Act of 2021," was introduced in the House on April 21, 2021. It does not contain provisions relating to international reference pricing or direct negotiation of drug prices. Rather, the proposal focuses on other changes, such as Part B reimbursement changes that include establishing a variable average sales price-based payment rate methodology for drugs and biological products. The proposal also would expand the Medicaid drug rebate program's definition of "covered outpatient drug" to include certain drugs paid for as part of a bundle. Additionally, HR 19 would create a value-based pricing agreement pathway, limit pharmacy reimbursement in connection with Medicaid managed

care dispenses to an ingredient cost plus a dispensing fee (restricting 340B covered entity profits on the "spread"), and mandate wholesale acquisition cost reporting.

Both proposals would implement sweeping changes related to Medicare Part D drug coverage and drug pricing transparency reform. Both proposals would eliminate the Part D coverage gap and lower the out-of-pocket threshold: HR 19 would lower the threshold to $3,100; HR 3 to $2,000. HR 19 would require manufacturers to report certain price increases to HHS, which would post such manufacturer reports on the HHS website. HR 3 includes drug pricing transparency requirements similar to those in HR 19, requiring manufacturers to report to HHS certain price increases, which HHS then would post on its website.

Bipartisan Proposals. In addition, there have been bipartisan legislative proposals in this space, and the issue of drug pricing seems to be a frequent bipartisan discussion topic. For example, in 2020, Republican Senator Chuck Grassley introduced a bipartisan bill, the "Prescription Drug Pricing Reduction Act," that serves as the blueprint for this session's bills. That bill focused on lowering drug prices, improving Part D, and eliminating impediments to competition. The Prescription Drug Pricing Reduction Act originally had support from Senator Wyden and others on the Finance Committee, so it suggests a potential compromise approach that could receive bipartisan support. Additionally, Senator Grassley recently met with a group of moderate House Democrats to discuss a bipartisan approach to lowering prescription drug prices. Grassley proposed to replace price negotiation and MFN with inflationary rebates, limiting drug price increases to the rate of inflation. A distinct but still potentially meaningful approach to improving generic competition is the "Ensuring Timely Access to Generics Act." Introduced in the Senate on March 3, 2021 by Senators Rubio (R), Shaheen (D), Cassidy (R), and Bennet (D), the legislation would enhance the FDA's power to reject citizen petitions if they believe that the primary purpose of the petition is to delay the approval of an application, and would set a time limit to ensure that citizen petitions are submitted in a timely manner.

III. Litigation Developments: 340B Program and Others

Challenging Sales to Contract Pharmacies. There have been a number of developments regarding contract pharmacies, and there likely will be certain changes in the 340B program's approach to contract pharmacies over the next year. Ongoing litigation regarding contract pharmacy arrangements focuses on whether manufacturers are required to extend 340B discounts to contract pharmacies. There are multiple active court cases, some of which appear likely to reach a decision by late August or early September (although there is no firm date for a decision in any case). The cases include Eli Lilly (S.D. Indiana), which held oral arguments on July 30; Sanofi (D. New Jersey), which has completed briefing and has not yet set a date for oral arguments; and AstraZeneca (D. Delaware), which is scheduled to complete briefing by August 6 and has set oral arguments for September 14. Additionally, the Novartis and United Therapeutics cases (D.D.C.) will be considered together; briefing in those matters will conclude by mid-September, with oral argument occurring sometime in October.

At issue in all of these cases is the validity of the U.S. Health Resources and Services Administration ("HRSA") May 2021 letters to specific manufacturers that mandated that the manufacturers extend 340B discounts to contract pharmacies. Those letters are at issue, as the agency has withdrawn its December 2020 general guidance document reflecting its intent to enforce the requirement that manufacturers extend 340B discounts to contract pharmacies. This withdrawal came after a federal judge denied HHS' motion to dismiss the AstraZeneca lawsuit, which alleged that the advisory opinion violated federal law. While many of these cases started as motions for preliminary injunctions, there do not appear to be any active emergency motion requests, most likely because HRSA is not currently applying the contested policy. As such, exactly when any of these courts may rule on the merits is difficult to predict, but there seems to be some momentum to reach a decision sooner rather than later.

In light of these developments, it is not clear how the Biden Administration plans to proceed, but it continues to stand by its May 2021 letters as appropriate and lawful. Those letters demanded compliance by June 1, but the manufacturers seem to have indicated that they will not comply while the litigation is still pending.

Challenging CMS Hospital Rate Cuts. In February, the Supreme Court took up an American Hospital Association ("AHA") dispute regarding Medicare hospital drug reimbursements in connection with the Medicare 340B Program. The lawsuit is challenging HHS's nearly thirty percent cut to 2018 and 2019 Medicare outpatient prospective payment system drug payments for certain hospitals participating in the 340B Drug Pricing Program. The district court sided with the AHA and found that the payment reductions were unlawful. However, in July 2020, two members of the three-judge panel on the D.C. Circuit agreed to overturn that ruling, despite a spirited dissent questioning the majority's deference to the government's position. The D.C. Circuit ruled that the decision to lower the reimbursement rate was based on a reasonable interpretation of the Medicare statute.

Challenging Required Use of Mail Order Pharmacies. Additionally, the Supreme Court agreed to review a class action lawsuit against CVS, regarding the requirement that CVS Caremark beneficiaries either receive their HIV medications via mail order or pick them up at a CVS pharmacy to receive in-network prices (they must pay out-of-network prices at other pharmacies). CVS maintains that the policy applies to all "specialty medications." The class members, who are HIV-positive, argue that the inability to access HIV medications at regular pharmacies disproportionately harms HIV-positive plan members.

IV. International Developments

Compulsory Licensing for COVID Vaccines. In the international sphere, there has been much debate over the World Trade Organization ("WTO") COVID vaccine patent waiver. The TRIPS waiver is a proposal, advanced by the governments of South Africa and India, to the WTO to waive intellectual property rights protection for technologies needed to prevent, contain, or treat COVID-19 "until widespread vaccination is in place globally, and the majority of the world's population has developed immunity." Negotiations at the WTO are ongoing: there have been eleven sessions regarding the patent waiver since it was first proposed in October. Opponents of this patent waiver claim that developing countries do not have the capacity to distribute vaccines widely, and would face barriers relating to production facilities and infrastructure. Those opponents argue that it is better to pursue voluntary mechanisms, such as Pfizer's strategy of preparing, packaging, and distributing vaccines at the Biovac Institute in South Africa for distribution across Africa.

In May, the U.S. surprisingly shifted its position to support the patent waiver; however, the U.S. action here may be mostly symbolic, given that EU members such as Germany oppose the waiver. Based on prior WTO practice, adopting any waiver of TRIPS obligations would require the unanimous support of all WTO members.

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