Summary of Trump Administration Drug Pricing Regulations

Prepared by

Stephanie A. Kennan

Senior Vice President

McGuireWoods Consulting, LLC

McGuireWoods Consulting, LLC

2001 K Street, NW, Suite 400

Washington, D.C. 20006

Most Favored Nations Rule and Drug Rebate Rule, Drug Price Transparency and Drug Importation

The Friday before Thanksgiving, the Trump Administration issued two final rules related to drug pricing.

- Finalization of the most favored nation rule and the rebate rule represent rhetorical victories for the Trump Administration.

- The rules are symbolic changes for drug pricing reform as they establish Republican support for the idea of price controls.

- However, the way in which the rules were created put their implementation into jeopardy.

- The Most Favored Nation Rule has implementation issues that if it were to survive legal challenges would make implementation highly difficult and the data used questionable.

The finalizations of these rules represent large rhetorical victories for the Trump Administration. They are important symbolic changes for drug pricing reform, as they establish Republican support for the idea of drug price controls. However, the Administration chose to finalize these rules in ways that create serious issues related to their implementation.

Most Favored Nation Rule

The Interim Final Rule (IFR) impacts the 50 drugs in Part B that account for 73 percent of Part B spending. The Administration claims that the rule will save $85 billion over 7 years in Medicare spending. Part B covers prescription drugs administered in outpatient settings (rather than those patients purchase at the pharmacy counter). Oncology is one area that is prominent in Part B.

What was proposed initially? Part B drug spending has been a target of concern by two previous administrations. The Advanced Notice of Proposed Rule Making (ANPRM) was aimed at lowering spending for Medicare Part B drugs by tying Medicare rates to the lower prices paid abroad for the same drugs. By using international reference pricing, the ANPRM aimed to import those foreign price controls and obtain lower spending for drugs provided through Medicare Part B.

Under the current payment system, known by some as “buy and bill”, physicians generally purchase Part B drugs and bill Medicare for the average sales price (ASP) of those drugs, plus 6 percent. The ANPRM built upon a private sector vendor model that had been previously been proposed under President George W. Bush, but was abandoned for lack of interest. The ANPRM’s plan was to use private sector vendors to

purchase Part B drugs, and to reimburse those vendors on the basis of the new, lower, international reference price. Last, this was to be a test of a payment model and administered through the Innovation Center.

What did the Interim Final Rule (IFR) do*?*

- **National Mandatory demonstration** for Medicare-participating providers (e.g., physicians, non-physicians practitioners, supplier groups, hospital outpatient departments (HOPDS), ambulatory surgical centers (ASCs) that receive separate Medicare Part B reimbursement for model-included drugs, with some exceptions through the model. Provider reimbursement for included drugs would shift from current 6% of average sales price (ASP) add-on, to a flat-fee add-on.

- **Drugs Included:** Top 50 Part B drugs (including biosimilars) by 2019 spend (to be updated annually). Excluding vaccines, radiopharmaceuticals, oral drugs, compounded drugs, intravenous immune globulin products, and drugs that share a HCPCS code with a generic.

- **Countries Included:** OECD countries with at least 60% of the US GDP per capita.

The IFR changed several important aspects.

- The IFR eliminated the vendor model. Instead, CMS chose to implement the IFR through the current "buy and bill" model. The providers themselves will be reimbursed for the 50 Part B drugs that are the subject of the IFR program on the most favored nation price. Eliminating the private sector vendor model removes a level of complexity, but it creates new liabilities for physicians.

- Each provider group will need to engage in its own negotiations with manufacturers or distributors in an effort to obtain prices more in line with CMS' new reimbursement rates, rather than centralizing negotiating authority through vendors. In addition, providers had no notice until the rule was released, that their practices would be responsible for these negotiations beginning on January 1, 2021.

- It is a mandatory model across the country. Formally, CMS was proposing to implement the most-favored-nation program as a model through the CMS Innovation Center, and it would have touched only half of the country. Instead.

- Third, CMS has changed the target international reference price. The ANPRM envisioned using prices from a set of sixteen countries and bringing down Part B prices closer to a target price derived from those countries, hoping to obtain a 30 percent savings in spending for the targeted drugs. The IFR goes further, choosing as its target price the lowest price—adjusted for per-capita gross

domestic product (GDP)—of any OECD country with a GDP per capita at least 60 percent of that of the United States.

- Fourth and finally, there is a major rhetorical shift buried deep in the 258-page rule. When the ANPRM was released, CMS took the strong position that the program would operate "without any restrictions on patient access." Now, the best estimate of the CMS Office of the Actuary is that as the program phases in over time, 19 percent of Part B drug utilization may be eliminated because patients can no longer access the drugs in question from their providers. If providers cannot negotiate favorable enough deals with manufacturers, they may decline to take the financial risk of acquiring particular drugs at all, meaning that their patients may no longer be able to access them. Even under the private sector vendor model, some were concerned about access.

Procedural Issues:

- CMS went from an ANPRM to the IFR stage without first issuing a notice of proposed rulemaking. This makes the regulation vulnerable to being struck by a court on procedural grounds. Agencies can bypass the standard rulemaking process if they find "good cause" for doing so. CMS argues that that pandemic and cost of drugs made this urgent. However, CMS sent an NPRM to OMB for review and it was never released. This may undermines CMS' position.

Implementation Issues:

Even if the IRF survives a legal challenge, implementation problems remain. CMS chief implementation hurdle is likely to be the need to obtain the international pricing data that would be used to identify the target most-favored-nation price. The IFR discusses at length ways in which potential sources of evidence would be ranked by quality and used in different ways to support the analysis (albeit while focusing on just one such source: IQVIA's MIDAS database).

The IFR also recognizes that getting "the data" may be just the beginning. CMS is not likely to be able to account for confidential rebates. So existing sources may overstate net prices obtained abroad. They also recognize the possibility that other countries may shift to a model of high prices and high rebates in part to disguise their true net prices, if they fear companies will be less willing to extend discounts to them going forward.

Other Policy Issues:

While the IFR applied to Part B drugs only, President Trump issues an executive order requiring the most favored nation model also apply to Part D. While CMS Administrator Sema Verma has said something will be forthcoming on Part D, nothing has been released to date.

There are ripple effects through Medicare that need to be further explored. For example, Medicare Advantage plans will not participate in the payment model, and the model is likely to lower MA payments because of lower Part B costs. This would lower Medicare expenditures used to benchmark the Medicare Advantage payment rates.

An analysis by Avalere Health suggests that the new rule will lead to few reductions in out of pocket costs for Medicare fee-for service beneficiaries, considering about 94% of Part B Medicare beneficiaries have supplemental coverage. Avalere suggests that less than 1% of Medicare beneficiaries will have reduced out of pocket costs under the most favored nation rule.

Law Suit:

PHARMA has filed suit to stop implementation as has several organizations representing cancer providers. The suits cite two reasons for striking the rule: (1) violation of the Administrative Procedures Act, and (2) that the ANPRM said this was to be a "test" and that involving 90% of Medicare beneficiaries and being nationwide stretches the parameters of a payment model test and thus is beyond CMS' statutory authority.

Conclusion:

Given the issues surrounding whether this IFR followed appropriate process and the difficulty in implementing, the Biden Administration is likely to shelve this IFR or allow the courts to rule against it.

Drug Rebate Final Rule

The Initial Proposal

In January 2019, CMS issues a proposed rule to eliminate the existing regulatory safe harbor to rebates involving pharmacy benefit managers (PBMs) in Medicare Part D. The goal was to force PBMS and insurers to pass along to patients at the point of sale the "after the fact" rebates they receive from pharmaceutical companies rather than using those rebates to lower overall premiums or provide other benefits. Eliminating the safe harbor would create legal liability under the federal anti-kickback statute for companies engaging in their existing rebate but the proposed rule aimed to replace the existing safe harbor with two narrow safe harbors.

The first safe harbor is for drug price discounts for the consumer at the pharmacy counter. The second safe harbor protects arrangements between manufacturers and pharmacy benefit managers that are fixed fee services arrangements – a practice that often occurs in government contract bids in which the services and final price are agreed upon upfront.

Many Medicare beneficiaries' cost-sharing obligations are calculated based on the artificially high list price of their drugs, rather than on the basis of the (typically lower) negotiated net price. So, patients who may need medications that are subject to large rebates (such as those where there is competition within the class) would be likely to see their cost-sharing obligations drop under this rule, perhaps significantly, as insurers pass along these negotiated rebates at the point of sale.

However, patients who take medications where there are small or no rebates (such as those where there is no competition) would not see a substantial decrease in their cost-sharing obligations. Further, overall premiums for all beneficiaries were projected to increase, as insurers could no longer use rebates to reduce overall premiums. Overall government spending was also projected to increase, as the federal government offers premium subsidies in Part D.

The CMS Office of the Actuary projected that the rebate rule would increase government spending by $196.1 billion over a decade. At the same time, pharmaceutical firms would be likely to benefit financially (by tens of billions of dollars) over the same period, as they were projected to pay smaller amounts for patients in the coverage gap portion of their benefits.

What Changed?

The rule largely finalizes provisions in the January 2019 proposed rule to eliminate the current AKS safe harbor protections for manufacturer rebates to plan sponsors and pharmacy benefit managers (PBMs) in Part D (but not Medicaid managed care) beginning on January 1, 2022 and creates 2 new safe harbors:

- **Point-of-Sale Reductions in Price for Prescription Pharmaceutical Products:** Protects point-of-sale price reductions offered by manufacturers on certain prescription pharmaceutical products that are payable under Medicare Part D if the price reduction is set in advance and passed on to beneficiaries at the point of sale

- **PBM Service Fees:** Protects fixed fees that manufacturers pay to PBMs for services rendered to manufacturers for the "benefit of the manufacturer" and are related to the PBMs' arrangements to provide pharmacy benefit management services to health plans

Additionally, the rule clarifies that point-of-sale chargebacks from pharmaceutical manufacturers to dispensing pharmacies must be at least equal to the discounted price of the drug and that any entity (including PBMs and wholesalers) may administer the chargebacks.

1) Removing Medicaid Managed Care Organizations

The NPRM would have applied not only to Medicare Part D but also to Medicaid Managed Care Organizations (MCOs). A large number of commenters objected to the inclusion of Medicaid MCOs in the rule, noting that the projected result of their inclusion would be to increase Medicaid costs (for both states and the federal government) without providing the policy benefits that might be present in the Medicare Part D program. That is, because Medicaid beneficiaries' cost-sharing obligations are highly constrained already (or are even zero in many cases), the stated goal of lowering patients' out-of-pocket costs did not fit the structure of the Medicaid program.

Based on the comments, CMS decided to remove Medicaid MCOs from the scope of the safe harbor changes in the final rebate rule. There may still be a Medicaid spending increase as a result of the relationship between the programs, but it will likely be much smaller if the MCO spending impact is removed from the projections.

2) Changing Course By Confirming That Premiums And Spending Will Not Rise

In July 2020, President Trump signed an executive order directing Health and Human Secretary Alex Azar to "complete the rulemaking process" and move this proposal forward. However, as a condition of doing so, Secretary Azar was ordered to "confirm—and make public such confirmation—that the action is not projected to increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs." As noted above, the CMS Office of the Actuary had projected that federal spending and Medicare beneficiary premiums were likely to increase as a result of the rebate rule. Additional analyses from the Congressional Budget Office and other external entities concurred.

Yet the final rule makes no structural changes in an attempt to comply with the President's executive order. To be clear, Secretary Azar did make public his required confirmation that federal spending and beneficiary premiums would not increase. His statement does not explicitly state why he believes the existing actuarial projections are incorrect, but he does assert that his long experience in both industry and government support his "projection that there will not be an increase in federal spending, patient out-of-pocket costs, or premiums for Part D beneficiaries under the Final Rule implementing the Executive Order."

Secretary Azar's perspective is likely explained by HHS' view that it "expects that manufacturers will lower list prices" in response to the rule. Lowering list prices, not just by a small amount, but significantly, is key to the actuarial projections that explain how the rebate rule could result in lower federal spending overall. CMS acknowledged the commenters who argued that manufacturers would be unlikely to lower list prices significantly in response to the rule, but "disagree[d]

that manufacturers have given no indication that they would lower drug prices if the rule were finalized.

3) **The effective date was moved to January 1, 2022.**

4) **The final rule clarifies some of the confusion around whether the safe harbors included price reductions for Part D plan sponsors or certain Medicaid managed care organizations** that require formulary placements. The new rule clarifies that these price reductions are permissible.

Procedural Issues:

Was the rule withdrawn or not?

Although the rebate NPRM was introduced in January of 2019, it was controversial in part because of the large projected increases in federal spending and smaller projected increase in beneficiaries' premiums. As a result, the White House decided not to move the proposed rule forward. A statement was issued that stated that "based on careful analysis and thorough consideration, the President has decided to withdraw the rebate rule." This statement was reflected administratively, as OMB's Unified Agenda entry for the rule listing it as "withdrawn" as of July 2019.

Ordinarily, if an agency withdraws a previous proposed rule, it cannot proceed directly to the final rule stage. If the Administration changes its mind about the withdrawal, it must start again at the NPRM stage. HHS did not do so here. As such, a challenge could be made that the rule was officially withdrawn in 2019, and therefore, the final rule could be invalidated on procedural grounds.

Supporters of the rule argue that the NPRM was not in fact withdrawn because HHS did not publish a notice of withdrawal in the Federal Register. Other argue that on balance, the administration's actions should best be understood as a withdrawal of the proposal, requiring the agency to start again; as they note, more is at stake here than administrative law arcana and the viability of this particular rule. The question is rather, "When can the public rely on a statement from the head of an agency, or from the president?"

Some are concerned about the precedent this sets in "withdrawing a rule" because of negative political consequences and then finalize a rule after the election which is what occurred in this case.

Will Secretary Azar's Confirmation Create Legal Challenges for the Rule?

Secretary Azar confirmed that the rule will not lead to an increase in federal spending or premiums. It is possible that the form of his confirmation might also create legal jeopardy for the rule. Executive orders (including the one at issue here) typically are not privately enforceable, so if Secretary Azar had made no such confirmation, it would be

difficult for stakeholders to sue on the grounds that the rule violated the executive order's requirements.

However, the specific form of Secretary Azar's confirmation could be cited to support a substantive legal challenge to the rule. Secretary Azar publicly asserted a conclusion that contradicted multiple existing projections of the rule's impact, without building a public record to support his conclusion. It does not appear that the text of the rule itself explicitly recognizes the issues surrounding its arguable earlier withdrawal or Secretary Azar's confirmation (unlike the most-favored-nation rule, which explains why the agency believes it has "good cause" to bypass the standard rulemaking process). Therefore, we do not yet know how the agency would defend itself on these matters.

Other analysis:

The rule fundamentally reshapes how payers and providers will negotiate, while requiring significant operational changes to an already complex drug supply chain. Looking ahead to 2021, the rule will also influence the future debate about changes to the Part D program, such as an out-of-pocket cap and benefit redesign."

The Biden Administration

It is not yet known how the Biden Administration will handle those rules published 60 days or less prior to his taking office. Most administrations put a hold on major rules to review them at a minimum. The rebate rule was highly controversial and opposed by significant health policy leaders on the Hill. It is likely the Biden Administration will want to address concerns of those it will want to work with on the Hill on drug pricing policy as well as other health issues.

Health Transparency and Drug Rates

On October 29, 2020, the Departments of Health and Human Services (HHS), Treasury, and Labor issued the "transparency in coverage" final rule. The rule imposes new transparency requirements on group health plans and health insurers in the individual and group markets.

Under the final rule, plans and insurers must disclose cost-sharing estimates at the request of an enrollee and publicly release negotiated rates for in-network providers, historical out-of-network allowed amounts and billed charges, and drug pricing information. The rule's goal is to enable enrollees to estimate their cost-sharing *before* receiving health care to encourage shopping and price competition amongst providers.

The Departments specifically asked for comments on what amount should be disclosed for prescription drugs (and how to account for rebates and dispensing fees). After consideration of many options for displaying drug cost information, the final rule requires plans and insurers to disclose the negotiated rate of the drug. However, in general, plans and insurers will generally not have to disclose discounts, rebates, or price concessions for a drug.

Drug Reimportation

Current law allows for the importation of certain drugs from Canada under defined, limited circumstances, and only if the Secretary of the United States Department of Health and Human Services (HHS) certifies that importation poses no threat to the health and safety of the American public. As recently as 2017, four former FDA commissioners signed a joint letter voicing concerns about the ability of HHS to assure the safety of drugs imported from other countries. Nevertheless, many federal and state lawmakers have continued to press for legislation to allow for the importation of prescription drugs from Canada and other countries. More recently, in September of 2020, HHS Secretary Alex Azar certified that importation of prescription drugs poses no risk to public health and safety and would result in significant cost savings. Also in September, the Trump Administration issued a final rule and final FDA guidance, creating two new pathways for the safe importation of drugs from Canada and other countries.

Canada Says NO

Canadian health minister Patty Hajdu in November announced new measures to protect the country's drug supply from bulk importations that could worsen drug shortages. The measures bar the distribution of certain drugs outside of Canada if that would cause or worsen a shortage.

"Our health care system is a symbol of our national identity and we are committed to defending it," Hajdu said. "The actions we are taking today will help protect Canadians' access to the medication they rely on."

PHARMA Files Suit

On November 23, 2020, the Pharmaceutical Research and Manufacturers of America (PhRMA), along with the Partnership for Safe Medicines (PSM) and the Council for Affordable Health Coverage (CAHC), filed suit in the U.S. District Court for the District of Columbia challenging a final rule issued by HHS in September. The suit challenges the Final Rule alleging it disregards key protections of the Federal Food, Drug, and Cosmetic Act (FDCA) that are designed to ensure patient safety. The complaint notes that while Section 804 of the FDCA authorizes HHS to permit both the importation of drugs by pharmacists and wholesalers for commercial distribution and the importation of drugs by individual patients, it is effective only if the HHS Secretary certifies to Congress “that the implementation of this section will—(A) pose no additional risk to the public’s health and safety; and (B) result in a significant reduction in the cost of covered products [(i.e., certain prescription drugs)] to the American consumer.”

However, to the plaintiffs, the Final Rule on importation, Secretary Azar made conclusory statements as to safety and cost savings in his “certification” with no supporting evidence and essentially put the responsibility for safety and cost savings on state governments. The complaint, therefore, alleges the Secretary’s certification is contrary to Section 804 and unsupported by the record.

The three industry groups further believe that there is no proof that the Final Rule will actually result in reduced costs to American patients. In the preamble to both the proposed and Final Rule, HHS acknowledged that it cannot quantify the savings, if any, that would result from its rule, even classifying it as “not economically significant” for purposes of review by the Office of Management and Budget. The complaint argues that HHS Secretary Azar “failed to acknowledge” whether the “economic benefits of importation are likely to prove more than a ‘gimmick’.”

The three groups also argue the Final Rule that are contrary to the FDCA, in addition to violating manufacturers’ First Amendment rights and raising serious questions under the Fifth Amendment Takings Clause.

PhRMA, PSM and CAHC are asking the Court to hold the Final Rule to be unlawful, set it aside, and permanently enjoin implementation of the Certification and Final Rule. If the groups are successful, states will not ever successfully get an importation plan approved.