
# HHS's Efforts to Reduce Prescription Drug Prices and Transition to Value-Based Care

## Part 1: CMS and OIG Issue a Series of Final Rules

**By Anjali Downs, Jennifer Michael, Victoria Sheridan, and Lesley Yeung**

**November 2020**

---

In a completely unexpected move, on November 20, 2020, the Centers for Medicare & Medicaid Services ("CMS") and the Department of Health and Human Services ("HHS") Office of the Inspector General ("OIG") published advance copies of a collection of four rules focusing on two themes: (i) reducing prescription drug prices and (ii) advancing the transition to value-based care and modernizing the regulatory framework.

This Client Alert provides a brief, high-level summary of each of the four rules and serves as the first in a series of Client Alerts. Subsequent Client Alerts will provide in-depth analyses of each of these final rules.

### Reducing Prescription Drug Prices

CMS and OIG each published advance copies of rules responding to executive orders that President Trump issued in July and September 2020 to lower costs on prescription drugs. CMS's interim final rule with comment period ("IFC") implements a "most favored nation" ("MFN") model that will test whether aligning the reimbursement for a cohort of Medicare Part B drugs with the prices certain other countries pay will reduce Medicare program expenditures while preserving quality of care. OIG's final rule excludes certain reductions in price offered from pharmaceutical manufacturers to Medicare Part D plan sponsors or the pharmacy benefit managers that contract with them and promulgates two new safe harbors.

## ***CMS's IFC Implementing the MFN Model***[1]

On September 13, 2020, President Trump issued an executive order[2] to create an MFN drug pricing system under Medicare. The executive order directed the Secretary of HHS to implement his "rulemaking plan" to create a demonstration program through which Medicare would pay no more for a drug than the lowest available price in countries in the Organization for Economic Cooperation and Development ("OECD"). The Secretary's "rulemaking plan" may have been a reference to an Advance Notice of Proposed Rulemaking ("ANPRM") CMS issued in October 2018 that proposed to establish an International Pricing Index ("IPI") model for Medicare Part B drugs. Under the IPI model, private-sector vendors would be allowed to take on the risk of obtaining drugs, distributing them to physicians and hospitals, and billing Medicare. In turn, the amount Medicare would pay the vendor would be based on an international reference price, so that payments would be comparable with prices in other countries.

Following the issuance of an ANPRM, CMS typically issues a proposed rule for notice and comment that details the proposed model. However, no such proposed rule has been issued with respect to the IPI model. Instead, CMS issued the IFC establishing a new payment methodology for Medicare Part B drugs to test whether the MFN Model, which will pay the lowest adjusted international price plus a fixed add-on amount for each dose of an MFN drug, will result in lower prescription drug costs and Medicare Part B spending. The MFN Model will replace the current Medicare Part B drug payment methodology of Average Sales Price ("ASP") plus six percent, where ASP is based on the volume-weighted average of manufacturer-reported pricing information for all drugs assigned to a Healthcare Common Procedure Coding System ("HCPCS") code.

The MFN Model will be tested in all 50 states and the U.S. territories for seven performance years, from January 1, 2021, through December 31, 2027. It requires mandatory participation by all providers and suppliers that participate in the Medicare program and submit a separately payable claim for an MFN drug (e.g., physicians, non-physician practitioners, supplier groups, such as group practices, hospital outpatient departments, and ambulatory surgical centers). For the first year, CMS has identified the MFN drugs to include a list of 50 Medicare Part B drugs that accounted for a high percentage of Medicare Part B drug spending in 2019. Excluded from the MFN model are: certain types of drugs (such as certain vaccines, oral drugs, multiple source drugs, and intravenous immune globulin products), drugs used at home, and drugs that treat patients with suspected or confirmed coronavirus disease 2019 ("COVID-19"). Additions to the list of MFN drugs will be made annually.

---

[1] This Final Rule is expected to be published in the Federal Register on November 27, 2020.
[2] Lowering Drug Prices by Putting America First, Exec. Order No. 13,948, 85 Fed. Reg. 59649 (September 23, 2020), https://www.federalregister.gov/documents/2020/09/23/2020-21129/lowering-drug-prices-by-putting-america-first.

For an MFN drug, CMS will calculate the MFN Drug Payment Amount for a calendar quarter based on a phased-in blend of the applicable ASP and the MFN Price, and the MFN Price will be phased-in over the first four years of the MFN Model. In lieu of the current 6 percent add-on to the ASP, the MFN Model will use a fixed add-on payment for MFN drugs and the per-dose add-on payment for the first quarter of 2021 will be $148.73.

CMS anticipates that it will assess the initial impacts of the MFN Model on quality of care, including access to drugs, prior to beginning Performance Year 5. CMS also plans to provide additional Medicare beneficiary protections, such as enhanced monitoring and Medicare Beneficiary Ombudsman supports, to ensure that beneficiaries retain their existing rights and are not harmed by the model test.

## ***OIG's Final Rule Removing Safe Harbor Protection for Certain Drug Rebates***[3]

On July 24, 2020, President Trump issued an executive order[4] directing the Secretary of HHS to complete the federal rulemaking process he commenced in February 2019[5] to exclude from Anti-Kickback Statute safe harbor protection certain drug rebates that are not applied at the point of sale or other remuneration that pharmaceutical manufacturers provide to health plan sponsors, pharmacies, or pharmacy benefit managers ("PBMs") operating in the Medicare Part D program. In July 2019, the Trump administration withdrew the February 2019 proposed rule due to the impact it would have had on beneficiaries' premiums and the Congressional Budget Office's projection that the proposed rule would increase federal spending by $177 billion between 2020 and 2029. President Trump's executive order required the Secretary to confirm, prior to federal rulemaking, that the action would not increase federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs.

The final rule removes from safe harbor protection reductions in price on prescription pharmaceutical products that manufacturers offer to Medicare Part D plan sponsors (either directly or through PBMs acting under contract with them) unless the reduction in price is required by law. The final rule also promulgates two new safe harbors that protect (i) reductions in price negotiated between manufacturers and plan sponsors (or PBMs acting on their behalf) that take the form of upfront discounts, as opposed to post-sale rebates, and (ii) fixed fees that manufacturers pay to PBMs for certain services the PBMs render to the manufacturers.

---

[3] This Final Rule is expected to be published in the Federal Register on November 30, 2020.
[4] Lowering Prices for Patients by Eliminating Kickbacks to Middlemen, Exec. Order No. 13,938, 85 Fed. Reg. 45759 (July 29, 2020), https://www.federalregister.gov/documents/2020/07/29/2020-16625/lowering-prices-for-patients-by-eliminating-kickbacks-to-middlemen.
[5] *See* Proposed Rule, 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, 84 Fed. Reg. 2340 (Feb. 6, 2019).

The Secretary issued a confirmation in conjunction with the final rule that stated—based on the Secretary's extensive experience in the field of pharmaceutical pricing, payment, and reimbursement—that the final rule "is not projected to increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs."[6]

**Advancing the Transition to Value-Based Care and Modernizing the Regulatory Framework**

In October 2019, CMS and OIG issued proposed rules that would make significant changes to the regulatory framework of the federal physician self-referral law (commonly referred to as the "Stark Law"), the federal health care program's Anti-Kickback Statute, and the civil monetary penalties ("CMP") law regarding beneficiary inducements.

A little over a year later, CMS and OIG published advance copies of companion final rules that are the culmination of the agencies' efforts to revise regulations to address obstacles to coordinated care in connection with HHS' Regulatory Sprint to Coordinated Care. CMS and OIG collaborated throughout the rulemaking process and sought to align the rules' terminology and conditions wherever possible; however, the agencies noted that complete alignment is not feasible because of fundamental differences between the Anti-Kickback Statute's and Stark Law's structures and sanctions, and stated that they intend for the Anti-Kickback Statute to serve as "backstop protection" against abusive arrangements.

Both the new safe harbors to the Anti-Kickback Statute and the new exception and clarifications regarding the Stark Law regulations become effective on January 19, 2021, with one exception. Specifically, the Stark Law final rule modifications related to calculation of productivity bonuses and profit shares in a group practice is to become effective January 1, 2022.

***OIG's Final Rule Revising Safe Harbors Under the Anti-Kickback Statute***[7]

OIG's Final Rule promulgates seven new safe harbors, the most expansive of which are the new safe harbors for value-based arrangements and arrangements for patient engagement and support. The three new safe harbors for value-based arrangements were finalized as proposed, with modifications; these safe harbors protect remuneration exchanged among individuals or entities participating in value-based arrangements that focus on coordinating and managing the care of a target patient population. OIG structured the value-based safe harbors using a tiered framework that provides more flexibility and imposes fewer requirements as the parties to the value-based

[6] *See* Secretary Azar Confirmation in Response to Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen, (Nov. 20, 2020), *available at* https://www.hhs.gov/about/news/2020/11/20/secretary-azar-confirmation-in-response-to-executive-order-on-lowering-prices-for-patients.html.

[7] This Final Rule is expected to be published in the Federal Register on December 2, 2020.

arrangements take on more financial risk. The safe harbor for arrangements for patient engagement and support protects remuneration provided in the form of in-kind patient engagement tools and supports to patients in a defined target patient population. This safe harbor does not include a requirement that the offeror assume any financial risk, and imposes a $500 annual, aggregate cap. Although the remuneration must be in-kind, the safe harbor is otherwise agnostic about the specific types or categories of tools and supports an offeror may provide, as long as all of the safe harbor's other requirements are satisfied.

Although all types of entities and individuals (other than patients) can be "value-based enterprise participants" as that term is used for purposes of the value-based arrangements and patient engagement and support safe harbors, the following entities are ineligible for safe harbor protection:

- pharmaceutical manufacturers, distributors, and wholesalers;
- PBMs;
- laboratory companies;
- pharmacies that primarily compound drugs or primarily dispense compounded drugs;
- manufacturers of devices or medical supplies;
- entities or individuals that sell or rent durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS") (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services); and
- medical device distributors and wholesalers.

OIG also promulgated new safe harbors for certain remuneration provided in connection with a CMS-sponsored model, and for donations of cybersecurity technology and services.

Finally, OIG modified four existing safe harbors:

- the safe harbor for electronic health records ("EHR") items and services, to add protections for certain cybersecurity technology, to update the interoperability provisions, and to remove the sunset date;
- the safe harbor for personal services and management contracts, to protect outcomes-based payments by certain individuals and entities that are tied to the achievement of legitimate and measurable outcomes;
- the warranties safe harbor, to revise the definition of "warranty" and to protect warranties for bundled items or for one or more items and related services; and
- the local transportation safe harbor, to expand the mileage limit for residents of rural areas to 75 miles and to remove any mileage limitations associated with the transportation of patients discharged from inpatient facilities to their residences.

## ***CMS's Final Rule Modernizing and Clarifying the Physician Self-Referral Regulations***[8]

In the preamble to the final rule, CMS emphasizes that the final rule is intended to focus on encouraging new value-based Medicare and Medicaid payment models and to remove regulatory barriers that traditionally have impeded care coordination. In furtherance of these objectives, CMS created three compensation exceptions for remuneration paid to a physician under a value-based arrangement. These exceptions largely align with the safe harbors OIG promulgated, as they use a similar three-tiered framework that focuses on the level of financial risk involved in the applicable value-based arrangement. The first exception is available for value-based arrangements within a value-based enterprise that assume full financial risk. The second exception applies when the physician assumes "meaningful downside financial risk" in connection with the value-based arrangement, meaning that the physician is responsible for repaying or forgoing no less than 10 percent of the total value of the remuneration the physician receives under the arrangement. The third exception is available for any value-based arrangement, including those involving compensation under a traditional fee-for-service basis, provided that certain requirements are met.

Unlike the OIG value-based safe harbors, which make certain types of persons or entities ineligible for safe harbor protection, the Stark exceptions do not exclude any individuals or entities from participating in a protected value-based arrangement. This is a significant modification made by CMS from the proposed rules, which would have excluded certain types of providers and suppliers.

In addition to the value-based exceptions, CMS took further steps to "modernize and clarify" the regulations, including:

- creating a new exception that protects "nonabusive business practices" that result in remuneration of up to $5,000 (adjusted for inflation) per calendar year paid to a physician for providing items and services, if certain requirements are met;
- establishing a new exception for the donation of cybersecurity technology and related services;
- amending certain components of the exception for EHR items and services, including making the EHR exception permanent; and
- providing amendments and clarifications to key definitions and requirements that are fundamental to the application of the regulatory exceptions, including the concepts of "fair market value," "volume and value," and "set in advance." The final rule also incorporates a definition for "commercially reasonable," which had not been previously defined by the Stark regulations and more directly addresses the permissibility of directed referrals across multiple types of arrangements.

[8] This Final Rule is expected to be published in the Federal Register on December 2, 2020.

Notably, while the final rules address multiple aspects of compliant compensation arrangements, CMS did not make any modifications or additions to the ownership exceptions aside from making clear that neither purely titular ownership nor ownership or investment in an employee stock ownership program constitutes an "ownership or investment interest" that triggers application of the Stark Law.

As noted above, subsequent Client Alerts will provide a deeper analysis of each of OIG's and CMS's final rules.

* * *

*This Client Alert was authored by* **Anjali Downs, Jennifer Michael, Victoria Sheridan,** *and* **Lesley Yeung.** *For additional information about the issues discussed in this Client Alert, please contact one of the authors or the Epstein Becker Green attorney who regularly handles your legal matters.*