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CMS PROPOSES MAJOR CHANGE TO MEDICARE PART B DRUG PAYMENT SYSTEM INTRODUCING INTERNATIONAL PRICING INDEX MODEL

The Centers for Medicare & Medicaid Services ("CMS") Center for Medicare and Medicaid Innovation proposed to lower the cost of Medicare Part B outpatient prescription drugs by establishing their prices based on lower drug prices of other advanced industrial nations as compiled in an "international price index" ("IPI") and changing the way the current drug add-on payment to providers is structured ("Proposal" or "IPI Model"). CMS announced the Proposal on October 25, 2018 as part of the Trump administration's efforts to lower drug prices. As proposed, the IPI Model would include mandatory participation from physician practices and hospital outpatient departments that supply certain drugs, initially contemplated as single-source drugs and biologics. The complete Proposal is outlined in detail in CMS's Advance Notice of Proposed Rulemaking with Comment ("ANPRM"), which is available here.[1]

CMS believes that pricing drugs based on an IPI would save Medicare roughly $17.2 billion over a five-year period and also provide out-of-pocket savings of up to $3.4 billion. Stakeholders and interested parties who wish to submit comments regarding the Proposal should do so by December 31, 2018.[2] Following this comment period, CMS is considering issuing a proposed rule on this topic in the spring of 2019 with the potential model to start in spring 2020.

DISCUSSION

Drugs covered by Medicare Part B are those that are typically administered by infusion or injection in a physician's office, clinic or in a hospital outpatient setting. Currently, Medicare pays providers for Medicare Part B drugs at the drug's average sales price ("ASP") in the U.S. market, plus an add-on fee of 4.3 percent (post-sequester) to cover the costs of drug ordering, storage and handling and payments to join group purchasing organizations. Because the dollar amount of the add-on fee is larger as drug prices increase, some argue this incentivizes physicians to prescribe higher-cost drugs for patients and in turn increases beneficiary and government spending.

Further, because drug manufacturers deeply discount these same drugs that are sold to other countries, the administration believes the U.S., including government payers such as Medicare, unfairly pay more to subsidize the drug manufacturers' research and development costs (thereby enabling other countries to enjoy the benefits of American pharmaceutical innovation without sharing a reasonable percentage of the cost). A recently released U.S. Department of Health and Human Services ("HHS") study concluded that prices charged by drug manufacturers to wholesalers and distributors in the U.S. are 1.8 times higher than in other advanced countries included in the IPI for the top drugs paid under Medicare Part B.[3] Further, for 19 of the 27 drugs reviewed in the study, prices are highest in the U.S.[4] As outlined below, employing the IPI Model to develop drug prices for the U.S. market ostensibly would correct these inequities in drug pricing.

Goals of the IPI Model

CMS has identified the following goals for the IPI Model:

1. Reduce Medicare expenditures and beneficiary cost-sharing for Part B drugs;
2. Preserve or enhance quality of care for beneficiaries;
3. Provide for drug pricing that is comparable to international markets;
4. Remove the incentive for providers to prescribe higher-cost drugs by reforming the add-on drug payment;
5. Minimize disruption to the supply chain; and
6. Reduce federal spending and taxpayer dollars and increase Medicare value and efficiency.

IPI Model - How It Would Work

1. CMS would develop an IPI for certain separately payable Part B drugs based on drug costs in other advanced industrial countries.[5] The IPI

Model initially would concentrate on those drugs that make up a high percentage of Part B drug utilization and spending. CMS would then set payment for Part B drugs at a "target price" of 126 percent of the average price other countries pay for these same drugs.

2. CMS would pay hospitals and physicians a new, larger add-on fee of 6 percent of historical drug costs that is independent of drug prices, meaning the payment would not be calculated as a percentage of ASP. This means the add-on fee would *not* rise proportionately with the cost of the drug, thereby removing any incentive to prescribe a more expensive drug in order to secure a higher add-on fee. If the IPI Model is fully implemented, payment for Medicare Part B drugs would drop by approximately 30 percent.
3. The IPI Model would be phased in over five years from 2020 to 2025.
4. The IPI Model would be rolled out in selected geographic areas covering half of the country with the possibility of expanding the IPI Model over time. IPI Model participants would include all physician practices and hospital outpatient departments that furnish the IPI Model's included drugs in the selected geographic areas. CMS is considering whether to include ambulatory surgery centers or other Part B providers that furnish the included drugs in the IPI Model.
5. Under the IPI Model, physicians would generally abandon the business of buying drugs and billing for them.[6] Instead, CMS would contract with a number of private sector vendors (e.g., GPOs, wholesalers, distributors, specialty pharmacies, individual or groups of physicians and hospitals, Part D sponsors) that would negotiate prices for drugs, take title to drugs (but not necessarily physical possession) and compete for physician and hospital business. The IPI Model vendors would take on the financial risk of acquiring the drugs and billing Medicare and would have flexibility to offer innovative delivery systems to encourage physicians and hospitals to secure drugs through the vendors' distribution arrangements (e.g., electronic ordering, frequent delivery and on site stock replacement programs).7 Physicians and hospitals could contract with multiple vendors for different drugs and change vendors if they so desired.
6. For newly approved and marketed Part B drugs included in the IPI Model, CMS would calculate an IPI Model payment amount even in the absence of international pricing information.
7. CMS is considering whether to include a data collections system for manufacturers to report to CMS their international drug sales data to support the calculation of the IPI and the target price for each included drug.
8. CMS would propose to review the IPI and IPI Model payments on a quarterly basis.
9. CMS would implement a monitoring program for the Model to ensure it meets the needs of Medicare beneficiaries, health care providers and the Medicare program.

PRACTICAL TAKEAWAYS

These proposed changes to Part B drug pricing represent another effort by the current administration to decrease drug prices. Further, the Proposal aligns with the larger effort outlined by the administration both through its Blueprint to Lower Drug Prices and other agency actions, many of which we highlighted earlier this year.[8] Health care providers, payors, pharmaceutical manufacturers, PBMs, pharmacies and others involved in the drug supply chain should expect further changes related to drug pricing as the administration, governmental agencies and legislators continue to tackle the issue of rising health care and drug costs. Interested stakeholders should work with their advocacy teams to submit electronic or written comments regarding the Proposal no later than **December 31, 2018**.

- *Uphill Battle Likely*. It is uncertain whether the Proposal will advance to the next level or ultimately be implemented. Pushback from the drug industry, members of Congress, providers and beneficiaries is expected. The Obama administration also tried to reform the Medicare Part B program and withdrew its proposal in 2016 amidst sharp criticism from stakeholders, including concerns that patients would lose access to important medications.[9] Last month, Stephen Ubl, President and CEO of Pharmaceutical Research and Manufacturers of America, the drug industry's main lobby group, remarked, "the administration is imposing foreign price controls from countries with socialized health care systems that deny their citizens access and discourage innovation . . . These proposals are to the detriment of American patients."[10] If manufacturers are not willing to reduce Part B drug prices in the U.S. to the extent required by CMS, some worry Medicare patients could lose access to life-saving and health-enhancing medications. Finalization of an IPI Model likely faces an uphill battle.
- *Is the Proposal Just Political Maneuvering*? Some lawmakers question the administration's motive for introducing this substantial Part B

drug reform Proposal two weeks before the mid-term elections.[11] Those skeptics question the administration's true commitment to pushing through the Proposal and how much political timing may have been a motivating factor. Some note that a proposal enabling Medicare to negotiate drug prices under the much larger Medicare Part D prescription drug program would be of greater assistance to Medicare beneficiaries.[12] Other commentators believe that introduction of a controversial Proposal that indexes international drug prices, primarily may be a strategy to further pressure drug manufacturers to lower drug prices voluntarily before they are subject to mandatory governmental regulation that will lower prices for them.

- *CMS Requests Extensive Stakeholder Input*. CMS is soliciting stakeholder comments on nearly all aspects of the Proposal, including what type of drugs and which providers should be included in the IPI Model. Some of CMS's additional requests for comment are set forth below, but please refer to the ANPRM for a comprehensive list of solicitations.
  - Which countries should be included in the IPI and how frequently should the IPI data be updated?
  - Should CMS introduce health care provider bonuses to incentivize reductions in cost or utilization relative to a benchmark?
  - Should CMS be a party to and regulate agreements between vendors and physicians/hospitals? Should the vendor-provider agreements specify obligations to ensure the physical safety and integrity of drugs included in the IPI Model? What IPI Model vendor payment options are there?
  - What types of entities should be permitted to be Model vendors? What potential "perverse incentives" would be introduced by permitting health care providers to be Model vendors? Should CMS require Model vendors to enroll any included health care provider? What "guardrails" should apply to manufacturers and health care providers who serve as Model vendors?

We will continue to monitor all developments related to the Proposal. If you would like additional information, please contact:

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[1] For additional resources, a policy brief on the ANPRM may be found here, and a fact sheet about the ANPRM may be found here.

[2] Comments may be submitted electronically through the CMS e-Regulation website here.

[3] *Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures*, U.S. Dep't of Health & Human Servs., Office of the Assistant Secretary for Planning and Evaluation (Oct. 25, 2018), https://aspe.hhs.gov/system/files/pdf/259996/ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf.

[4] *Id.*

[5] The countries included in the drug pricing analysis study were: U.S.A, France, Portugal, Austria, Germany, Slovakia, Belgium, Greece, Spain, Canada, Ireland, Sweden, Czech Republic, Italy, UK, Finland and Japan. However, pursuant to the ANPRM, CMS is considering using pricing data from a subset of the study countries including: Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Netherlands and the UK to develop the IPI.

[6] Under the Proposal, however, physicians would have the option of applying to become drug vendors either alone or in collaboration with hospitals.

[7] CMS-5528-ANPRM.

[8] See: Hall Render's This Week in Washington - May 11, 2018; CMS Allows Medicare Advantage Plans to Implement Step Therapy for Part B Drugs – Will It Really Lower Drug Costs or Simply Increase Administrative Burdens?; and 340B Program OPPS Payment Reductions and Legislative Limitation Proposals: What's Smoke and What's Fire?.

[9] Harris Meyer & Virgil Dickson, *New CMS Pay Model Targets Soaring Drug Prices*, Modern Healthcare, Oct. 25, 2018, https://www.modernhealthcare.com/article/20181025/NEWS/181029944; Robert Pear, *Plan to Reduce Medicare Drug Costs Is Withdrawn After Bipartisan Criticism*, NY Times, Dec. 16, 2016, https://www.nytimes.com/2016/12/16/us/politics/plan-to-reduce-medicare-drug-costs-is-withdrawn-after-bipartisan-criticism.html.

[10] The Associated Press, *Trump Says New Proposal Will Lower Some US Drug Prices*, NY Times, Oct. 25, 2018, https://www.nytimes.com/aponline/2018/10/25/us/politics/ap-us-trump-prescription-drug-prices-.html.

[11] *Id.*

[12] *Id.*