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CMS considers linking Medicare drug payment rates to international prices

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On October 25, 2018, the Centers for Medicare & Medicaid Services (CMS) issued an advance notice of proposed rulemaking (ANPRM) describing a potential mandatory model to test Medicare reimbursement based on an "International Pricing Index" (IPI).[1] Medicare would pay private sector vendors for Part B drugs at rates established using the IPI, and participating physicians and hospitals would receive an "add-on" payment. Under the IPI model, U.S. drug prices would be benchmarked against the reportedly lower drug prices in 14 other countries. The IPI model would seek to permit Medicare to more closely align its Medicare payment amount for selected Part B drugs with prices in other nations, reduce out-of-pocket costs for Medicare beneficiaries, increase access and adherence, and create greater competition in the acquisition process for Part B drugs.[2] According to the CMS, the model would save taxpayers and beneficiaries US$17.2 billion over five years (2020-2025), with Medicare's total spending on the selected drugs dropping by as much as 30 percent.[3]

The CMS will accept comments on the ANPRM until Monday, December 31, 2018. The CMS is considering issuing a proposed rule that would describe the model in more detail in spring 2019, with the goal of starting the model in spring 2020.[4]

The CMS announced the potential model in the wake of the release of a report from the Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE) that found manufacturers' prices to wholesalers and distributors for drugs with the highest spending under Medicare Part B are 1.8 times higher than those in other countries.[5] According to the report, Medicare and Medicare beneficiaries could have saved approximately US$8.1 billion in 2016 if payments were scaled by international price ratios.

Who would participate in the model?

The mandatory IPI model would include all physician practices and hospital outpatient departments (HOPDs) that furnish the model's included drugs in the model's selected geographic

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[1] CMS, "Medicare Program; International Pricing Index Model for Medicare Part B Drugs," available here (hereinafter ANPRM).
[2] *Id.* at 5-6.
[3] HHS press release: "What You Need to Know about President Trump Cutting Down on Foreign Freeloading," October 25, 2018, available here.
[4] ANPRM, at 7.
[5] U.S. Department of Health, Office of the Assistant Secretary for Planning and Evaluation (ASPE), "Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures," October 25, 2018, available here.

areas.[6] The CMS is also considering whether to include durable medical equipment (DME) suppliers, ambulatory surgical centers (ASCs), and/or other Part B providers and suppliers that furnish the included drugs.

The CMS anticipates the selected geographic areas would reflect 50 percent of Medicare Part B spending on separately payable Part B drugs.[7] In selecting geographic areas, the CMS indicates that the two main factors to consider would be the most appropriate geographic unit (e.g., ZIP code, county, core based statistical area (CBSA), state) that reflects how care is delivered, and the number of geographic units needed to generate statistically credible findings. The CMS is considering using CBSAs as the primary unit of analysis in the model.

Which drugs would be included?

This model would apply only to selected separately payable drugs and biologicals (referred to by the CMS as "drugs") administered in doctors' offices and HOPDs, including cancer treatments and injectable therapies.[8] When a drug is furnished in an HOPD, the model would apply if the drug has pass-through payment status or if the drug's Healthcare Common Procedure Coding System (HCPCS) code is assigned a distinct ambulatory payment classification (APC) group under the outpatient prospective payment system (OPPS).[9] Drugs that are not separately paid under the OPPS would not be included in the model when furnished by an HOPD, but would be included when furnished in physician's offices.

In years one and two, the IPI model would include only single source drugs, biologicals, biosimilars, and multiple source drugs with a single manufacturer that the CMS would identify from currently available, reliable sources of international pricing data.[10] In subsequent years, years three, four, and five, the CMS would broaden the scope of included drugs to incorporate more of these single source drugs and biologicals as more sources of international pricing data become available. The CMS is also considering including multiple source drugs and drugs provided in other settings. Specifically, it is considering including multiple source drugs, based on a concern that price increases among generic drugs are also contributing to the rising payments for Part B drugs. The CMS seeks comments on ways to calculate payment for newly approved drugs that do not yet have international sales.

Under the IPI model, several types of drugs would potentially be excluded, such as

- drugs that are identified by the Food and Drug Administration (FDA) to be in short supply;
- drugs paid under miscellaneous or "not otherwise classified" (NOC) codes, as well as compounded drugs, due to the operational complexity of identifying if drugs paid under the NOC codes are included model drugs;
- radiopharmaceuticals;
- end stage renal disease (ESRD) drugs paid under the ESRD Prospective Payment System (PPS); and
- drugs that are packaged under the OPPS when they are furnished by an HOPD.[11]

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[6] ANPRM, at 25.
[7] *Id.* at 27.
[8] *Id.* at 32-33.
[9] Skin substitutes that are separately payable as drugs could be included in the model under these criteria.
[10] ANPRM, at 33.
[11] *Id.* at 36-37.

How would rates of reimbursement to vendors be set under the IPI model?

Reimbursement rates would be set using pricing data from Austria, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, the Netherlands, and the United Kingdom.[12] The CMS is considering calculating an average international price for each drug in the model, and then calculating the IPI, which would be the ratio of Medicare spending using average sales price (ASP) for all drugs in the model to estimated spending using international pricing. The CMS would multiply the IPI, adjusted by a factor to "more closely alig[n] Medicare payment with international prices,"[13] by each drug's international price to establish a target price for each drug. The CMS' goal is to achieve "about a 30 percent reduction in Medicare spending"[14] for drugs under the model. The CMS would phase in the target price over the five years of the model, as a blend of ASP and the target price.

Who could be a vendor?

The model's contemplated use of private sector vendors is based on the Competitive Acquisition Program that was in effect from 2006 through 2008, but would reflect significant changes.[15] To increase competition, the IPI model would potentially allow entities such as group purchasing organizations (GPOs), wholesalers, distributors, specialty pharmacies, individual, or groups of physicians and hospitals, manufacturers, Part D sponsors, and/or other entities to perform the role of model vendor as long as they could satisfy the vendor qualification requirements.[16] The CMS is seeking input on the types of entities that would be allowed to be vendors, as well as on potential perverse incentives and guardrails. Model vendors would be identified through a competitive selection process. Ultimately, the CMS intends to select three to four model vendors but is soliciting comments on whether a different number would be appropriate.

How would the add-on payment to physicians and providers be calculated?

Model participants would be paid a set payment amount per encounter or per month (based on beneficiary panel size) for an administered drug, which would not vary based on the model payment for the drug itself.[17] The aggregate payments under this methodology would be based on the expected add-on amount for included drugs in the absence of the model, before sequestration (i.e., six percent of aggregate ASP).

The CMS is considering a set payment amount per administered drug that would be based on

- the class of drugs to which the administered drug belongs;
- the physician's specialty; or
- the physician's practice.[18]

To incentivize reduced utilization where appropriate, the CMS is also considering creating a bonus pool, where model participants would achieve bonus payments for prescribing lower-cost drugs or practicing evidence-based utilization.

What new price reporting obligations would apply to manufacturers?

The CMS is considering creating a new requirement for manufacturers to report certain international sales data to support its implementation of the IPI model.[19] The agency states that

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[12] *Id.* at 43.
[13] *Id.* at 39.
[14] *Id.*
[15] *See id.* at 10-13.
[16] *Id.* at 17.
[17] *Id.* at 30.
[18] *Id.*

one approach would be to require manufacturers to provide, on a quarterly basis, international drug sales prices and units sold – which is the type of information that manufacturers participating in the Medicaid Drug Rebate Program (MDRP) currently report to the CMS with respect to their U.S. sales. The CMS would provide reporting instructions, including information such as the unit level at which to report, the countries to include in the report, and how to account for exchange rates, as well as the use of reasonable assumptions.[20]

The agency states that it would take time to establish the requisite infrastructure and reporting instructions to enable it to collect and validate manufacturer-reported international sales data. Until such manufacturer-reported data would become available to the agency, the CMS contemplates relying on existing data sources for purposes of calculating the model payment to model vendors for included drugs.[21] The agency contemplates using the following existing data sources to support its implementation until manufacturer-reported pricing data would become available.

- Data provided by private companies or obtained through review of manufacturers' public filings in other countries
- Data from a CMS-constructed price comparison based on publicly available sources from each country[22]

The CMS seeks comment on the potential use of existing data sources and new data sources to establish the IPI and target price. The agency is also interested in better understanding the extent to which existing international sales-related data sources completely capture drug information in every international market that the CMS is considering for inclusion in the payment methodology, as well as how countries that provide drugs through public insurance account for private market drug sales in publicly available drug pricing sources.[23]

Questions to consider in evaluating this aspect of the model include:

- **Legal authority for a potential new reporting requirement**. The obligation of manufacturers enrolled in the MDRP to report Medicaid (average manufacturer price (AMP) and best price (BP)) and Medicare (ASP) pricing data is based in statute. The ANPRM does not address how the CMS would require manufacturers to report additional information, a gating item for its contemplated model.
- **What if the U.S. manufacturer does not control international pricing?** Many U.S. manufacturers partner with other entities to commercialize products outside the United States or vice versa. The ANPRM presumes that control over U.S. and international pricing resides in a single corporate entity, such that a reporting requirement imposed on the U.S. entity would pull in the international data. That may not always be the case. Such a disconnect also would mean that the U.S. entity should not be held accountable for ex-U.S. pricing.
- **Calculation mechanics.** As any manufacturer that reports Medicaid and Medicare pricing data knows, there are a host of issues that can arise when examining how a price to the market is calculated. Is the international price a straight average or a weighted average? In some markets, there may be after-the-fact price concessions provided to the government. How would those be accounted for? If there is patient cost-sharing in international markets, how is

[19] *Id*. at 41.
[20] *Id*. at 41-42.
[21] *Id*. at 40.
[22] *Id*. at 40.
[23] *Id*. at 44-45.

that treated? Such practicalities can have a material impact on the data reported and its resulting usefulness as a reimbursement metric.

- **BP, AMP, and the 340B ceiling price**. The ANPRM itself notes that, if a manufacturer offers a model vendor a price at or below the model payment rate, such a price would be included in the manufacturer's determination of best price and, accordingly, could impact the manufacturer's best price. The CMS seeks comment on "how manufacturers would respond to these factors as they relate to model vendors and Medicaid drug rebates."[24] The CMS further notes that such prices could impact the product's AMP (which the CMS presumes would be calculated using the so-called 5i AMP formula, given the types of drugs at issue), and seeks comments on that topic as well. As AMP and possibly BP impact a product's 340B ceiling price, the CMS also seeks comments on the 340B impact of the model.
- **VA/FSS pricing**. The ANPRM does not consider the potential impact of manufacturer pricing to model vendors on a product's price to the Department of Veterans Affairs (VA) and under the Federal Supply Schedule (FSS). That is another factor to evaluate.

If you have questions about the ANPRM, please contact any of the authors of this alert or the Hogan Lovells lawyer with whom you regularly work.

[24] *Id*. at 49.

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