THE
NATIONAL LAW REVIEW

CMS Requests Comment on Potential International Pricing Index Model for Part B Drugs

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On the Subject

- Health Law & Managed Care
- Biotech, Food, Drug

- All Federal

Monday, October 29, 2018

Summary

On October 25, 2018, the Centers for Medicare and Medicaid Services (CMS) announced an Advance Notice of Proposed Rulemaking with Comment (ANPRM) proposing to implement an international pricing index (IPI) model for Medicare Part B drugs and biologicals (IPI Model). Part B drugs and biologicals include many drugs and biologicals administered by physicians in physician offices and hospital outpatient departments. If implemented, the proposed model would make sweeping changes to the drug and biological supply chain for participants, and would pose a variety of expected and unknown implications for drug and biological manufacturers, distributors, group purchasing organizations (GPOs), hospitals and physician clinics, among other industry stakeholders.

CMS is accepting public comments on the ANPRM until December 31, 2018, and is considering issuing a proposed rule in spring 2019. The model would be implemented in spring 2020 and operate for five years. This *On the Subject* provides a comprehensive list of CMS's requests for comment at Appendix A.

In Depth

The backdrop for this ANPRM is the American Patients First Blueprint, a plan to lower drug prices and reduce beneficiary out-of-pocket spending on drugs in the Medicare program, released by President Trump on May 11, 2018. The Blueprint builds upon a trio of documents released earlier in 2018 that together provide the framework for a multi-faceted approach that the administration believes can reduce spending on prescription drugs in the United States while continuing to encourage growth and innovation. In the Blueprint, President Trump attempts to determine why prescription drug pricing continues to rise, and questions why the United States pays more for prescription drugs than its international allies. The Blueprint directs the US Department of Health and Human Services (HHS) to develop demonstration projects to test innovative ways to encourage value-based care and lower drug prices.

The ANPRM's proposals are preliminary, and it remains uncertain whether any will ultimately become implemented. If CMS determines to move forward with the IPI Model after reviewing public comments to the ANPRM, CMS would presumably publish a proposed rule that could modify the initially proposed IPI Model (discussed in-depth below). The proposed rule would offer the public another opportunity for comment, and CMS may ultimately determine not to finalize the proposals even after publishing a proposed rule. Alternatively, CMS could modify the proposals set forth in the proposed rule before it becomes finalized. In sum, public responses to the ANPRM and any subsequent proposed rule, as well as various political and regulatory considerations, have the potential to impact whether or how its proposals become implemented.

If the IPI Model were finalized as initially proposed, participating physicians, hospital outpatient departments and entities that CMS may decide to include following review of public comments (collectively, Participants) would no longer purchase and bill Medicare for Part B drugs and biologicals. Instead, they would enroll with "model vendors" to obtain Part B drugs and biologicals that they administer to patients. Medicare would continue to pay Participants for the administration of the drug and would pay an additional "add-on" payment for drugs and biologicals furnished to beneficiaries, but the add-on payment amount would be intended only to cover lost revenue and limited administrative costs. Model vendors would enroll with Medicare as suppliers and negotiate contracts with manufacturers to purchase drugs and biologicals to distribute to Participants, and Participants would hold distribution contracts with model vendors. Under the IPI Model, Medicare payment rates for included Part B drugs and biologicals would be adjusted using an indexing formula, such that domestic Medicare payment rates would more closely match international prices for each Part B drug or biological covered by the model.

Model Vendors

The model contemplates that commercial entities such as GPOs, wholesalers, distributors, specialty pharmacies, individual or groups of physicians and hospitals, manufacturers, Part D sponsors and/or other entities would be eligible to enroll as model vendors. These model vendors would negotiate the acquisition prices for drugs and biologicals and take title of the drugs and biologicals, but they would not

be required to take physical possession of the products. Model vendors would enroll Participants and establish mechanisms to receive compensation from Participants for their services. Model vendors would enroll in Medicare in a manner similar to other Medicare suppliers. The model vendors would submit claims to Medicare for included drugs distributed to Participants and furnished to Medicare beneficiaries. Periodically, CMS would ensure that payment to model vendors for administered drugs was substantiated by the Participant-submitted claims. CMS intends to select three or more model vendors, each of which would be required to be able to work with all Participants regardless of geographic location, so that Participants have several options and model vendors compete on the basis of customer service and cost.

Model Participants, Selected Geographies and Compensation

Model participants would include all physician practices and hospital outpatient departments that furnished the model's included drugs in the selected model geographic locations. CMS is seeking comments on whether to include in the model durable medical equipment (DME) suppliers, Ambulatory Surgical Centers (ASCs), or other Part B providers and suppliers that furnish the included drugs. Medicare anticipates that the spending on Part B drugs and biologicals in selected geographic areas would reflect 50 percent of Medicare Part B spending on separately payable Part B drugs. CMS is considering a randomized design with randomization of geographic areas to intervention and comparison groups. CMS is considering Core Based Statistical Areas (CBSAs) as the primary geographic unit of analysis in the model; however, CMS is also considering aggregations of CBSAs, such as metropolitan statistical areas or combined statistical areas, as alternative approaches.

Under the model, Participants would continue to be paid for drug administration services and receive an additional "add-on" payment to help cover the costs of drug ordering, storage and handling, and other costs associated with furnishing these drugs to Medicare beneficiaries. The add-on payment is proposed as a set amount, paid either per encounter or per month for an administered drug; the payment amount would not vary based on the payment amount for the drug itself. CMS contemplates calculating the add-on payment amount by each class of drug, physician specialty or physician practice (or hospital). The final payment amount would be calculated annually based on 6 percent of ASP revenue that model participants would have garnered without sequestration in the most recent year of claims data.

In other words, it appears that CMS is proposing to use the most recent year of available claims data to calculate the total amount of add-on payments a Participant would have received over the course of a year under the standard payment model absent sequestration (ASP plus 6 percent), and to divide that amount by 12 (if CMS moves forward with a per-month payment structure) or the anticipated number of patient encounters (if CMS moves forward with an per-encounter payment structure), to calculate a per-month or per-encounter add-on payment rate for Participants. CMS acknowledged in the ANPRM that total model payments to Participants would vary based on utilization under an encounter-based model, and CMS intends to monitor drug utilization carefully throughout the model "to ensure beneficiary access to

drugs is not compromised."

Included Drugs and Biologicals

As proposed, the model would initially cover single source drugs and biologicals (including biosimilars) administered incident to a physician's services. CMS explained that it selected these categories of drugs because they encompass most of Medicare's Part B drug spending (approximately 84 percent, or $23.6 billion, based on 2016 data). CMS provided a few examples of included drugs, such as cancer drugs and adjunct therapy for cancer and related conditions, biologicals used for the treatment of rheumatoid arthritis and other immune mediated conditions, and drugs used to treat macular degeneration. For purposes of the model, CMS stated that it would also include HCPCS codes that contain only products with a single manufacturer, even if they are multiple source drugs. Notably, CMS intends to broaden the scope of included drugs beginning in year three of the model.

CMS also stated that it is considering excluding (1) drugs that are identified by the US Food and Drug Administration (FDA) to be in short supply, and (2) drugs paid under miscellaneous or "not otherwise classified" (NOC) codes, such as J3490, because of the operational complexity of identifying whether drugs paid under the NOC codes are included model drugs.

Payment Methodology

CMS is considering testing an alternative payment rate for included drugs based on international prices, except where the ASP is lower. Medicare payment for separately payable Part B drugs is typically based on ASP of a given drug, plus 6 percent of the ASP as an add-on payment. For the IPI Model, CMS proposes to calculate the model payment to model vendors for included drugs through a multi-step process that considers the "average international price" in certain countries for each Part B drug included in the model, the volume of included drugs reimbursed by Medicare, and an unspecified "factor" that would "more closely align Medicare payment with international prices." More specifically:

- CMS would calculate an average international price for each Part B drug included in the model based on a standard unit that is comparable to that in the drug HCPCS code.
- CMS would then calculate the ratio of Medicare spending using ASP prices for all Part B drugs included in the model to estimated spending using international prices for the same number and set of drugs by multiplying Part B volumes by the ASP prices and then by the international prices. The resulting ratio of Medicare spending under ASP versus Medicare spending under the international prices holding volume and mix of drugs constant would represent the IPI.
- CMS would also establish the model target price for each drug by multiplying the IPI by a factor that would more closely align Medicare payment with international prices, and then multiplying that revised index (IPI adjusted for spending reduction) by the international price for each included drug. CMS

would calibrate the revised index to account for any drugs with ASP below the target price.

CMS proposes to phase-in the target price over the five years of the model, as a blend of ASP and the target price. For each calculation, if ASP is lower than the target price for an included drug, CMS proposes that the model would set the payment amount to the ASP for that drug. As with current Part B drug payments, CMS stated that it would plan to update the model payment amount for each drug periodically based on new ASP and international pricing data.

Interaction with Other Federal Programs

CMS described several potential interactions with other federal programs in the ANPRM and seeks comment on how to avoid unintended consequences arising from such interactions, listing potential impacts on (1) manufacturer's best price and resulting increase Medicaid rebates, (2) the average manufacturer price, and (3) the 340B program. Interestingly, CMS only acknowledges the potential for an impact on 340B ceiling price calculations and does not address the lost opportunity for 340B purchasing or the potential conflict with the group purchasing arrangement prohibition.

Analysis

Recent experience suggests that sweeping administrative changes to Part B drug reimbursement will be met with fierce public opposition that may ultimately defeat implementation. As recently as March 2016, CMS proposed a demonstration model that would have effected significant changes to Medicare reimbursement for Part B drugs. The model was withdrawn prior to finalization in response to widespread concerns relating to the model's impact on Part B drug accessibility and adverse implications for industry stakeholders, among other concerns. At this time, it is unclear whether any of the ANPRM's proposals will ultimately be implemented, considering their potential sweeping implications. However, the ANPRM and statements from President Trump and Secretary Alex Azar on October 25, 2018, suggest robust political interest in the implementation of the ANPRM's proposals.

Although the ANPRM proposes only general frameworks and solicits comments that indicate that even these basic frameworks may shift, the ANPRM raises a variety of potential implications, unintended consequences and concerns for industry stakeholders and policy makers to consider. From a general financial standpoint, a reduction in Medicare reimbursement for Part B drugs and biologicals furnished by model participants could unintentionally require a counterbalancing of prices for drugs and biologicals not purchased and furnished as part of the model. The ANPRM provides an opportunity for manufacturers, providers, GPOs and other interested parties to explain to policy makers the variety of adverse unintended consequences that could flow from the model's implementation, while at the same time signaling that industry stakeholders may need to engage in robust strategic planning to successfully navigate implementation of the IPI Model.

The model makes a number of presumptions about pricing behaviors in both domestic and international markets that are untested. While many have studied prices in the

international drug market, information about those international markets is still incomplete. For instance, it is unclear if the prices set under a single-payer system can or should be compared to prices set under a multi-payer system.

Beyond pricing implications outside of the model, the model would generate a variety of compliance considerations for manufacturers and model vendors. The ANPRM suggests drug and biological manufacturers may be required to report international drug sale information on a quarterly basis, although the specific requirements for these reports are yet to be determined. Model vendors would be required to enroll in Medicare as suppliers and presumably meet the myriad compliance requirements and risks associated with Medicare enrollment and billing Federal Health Care Programs for Designated Health Services (*e.g.*, direct liability under the federal Anti-Kickback Statute, Stark Law, False Claims Act, and other federal fraud and abuse statutes). The ANPRM indicates that CMS would regularly ensure that payment to model vendors is substantiated by physician- and hospital-submitted claims, drawing scrutiny to model vendor tracking system and record accuracy.

The IPI Model also has significant implications for the 340B Program. First, because the IPI Model removes Medicare payments to hospitals for Part B drugs subject to the IPI Model, it removes the opportunity for hospitals to generate a substantial portion of 340B revenue previously generated from purchasing and furnishing such drugs. Second, because the 340B Program statutory prohibition on group purchasing arrangements applies to "obtaining" drugs (not purchasing drugs) through any arrangement where prices are negotiated for more entities than just the 340B participating hospital, HHS could interpret the IPI Model as creating a group purchasing arrangement for Part B drugs. If this were to occur, hospitals required to participate in the IPI Model and subject to the 340B Program prohibition on obtaining covered outpatient drugs through a group purchasing arrangement could be forced to terminate participation in the 340B Program. As noted above, CMS only acknowledges the potential for an impact on 340B ceiling price calculations and does not address the lost opportunity for 340B purchasing or the potential conflict with the group purchasing arrangement prohibition.

This *On The Subject* was co-authored by John Warren, Senior Director, McDermottPlus Consulting.