Fact sheet

ANPRM International Pricing Index Model for Medicare Part B Drugs

Oct 25, 2018 Legislation, Medicare Parts A & B, Prescription drugs

ANPRM: Potential International Pricing Index Model for Medicare Part B Drugs

The Centers for Medicare & Medicaid Services (CMS) is committed to implementing President Trump's blueprint to lower drug costs and reduce out-of-pocket costs for patients. In line with the policies discussed in the President's blueprint, the CMS is soliciting public comments on potential options we may consider for testing changes to payment for certain separately payable Part B drugs and biologicals ("drugs"). Specifically, CMS intends to test whether phasing down the Medicare payment amount for selected Part B drugs to more closely align with international prices; allowing private-sector vendors to negotiate prices for drugs, take title to drugs, and compete for physician and hospital business; and changing the 4.3 percent (post-sequester) drug add-on payment in the model to reflect 6 percent of historical drug costs translated into a set payment amount, would lead to higher quality of care for beneficiaries and reduced expenditures for the Medicare program.

CMS is considering issuing a proposed rule in the spring of 2019 on the potential model, called the International Pricing Index (IPI) Model. The potential IPI Model would start in spring 2020 and operate for five years, until the spring of 2025. Over the course of the model, CMS would

monitor and evaluate the impact of the model on beneficiary access to drugs, program costs, and the quality of care for beneficiaries.

Through the advance notice of proposed rulemaking (ANPRM), CMS is seeking feedback on the potential parameters of the IPI Model. The ANPRM can be downloaded from the CMS Newsroom at: https://www.cms.gov/sites/drupal/files/2018-10/10-25-2018%20CMS-5528-ANPRM.PDF

In order to be considered, comments must be submitted by Monday, December 31, 2018.

Background

Medicare Part B drug expenditures have increased significantly over time. From 2011 to 2016, Medicare FFS drug spending increased from $17.6 billion to $28 billion under Medicare Part B, representing a compound annual growth rate (CAGR) of 9.8 percent, with per capita spending increasing 54 percent, from $532 to $818.[1] Medicare beneficiaries and the Medicare program are also paying more for Part B drugs than international comparators. Based on a HHS analysis comparing Medicare spending for separately payable Part B physician-administered drugs to the prices of those drugs in sixteen other developed economies – Austria, Belgium, Canada, Czech Republic, Finland, France, Germany, Greece, Ireland, Italy, Japan, Portugal, Slovakia, Spain, Sweden, and United Kingdom –spending in the U.S. was 1.8 times higher.[2] As a result, Medicare beneficiaries and the Medicare program are bearing unnecessary, potentially avoidable costs for Part B drugs.

Currently, Medicare payment for separately payable outpatient drugs in physician offices, hospital outpatient departments and certain other settings is based on drug manufacturers' average sales prices in the United States plus a six percent add-on payment (+6 percent), and is subject to the sequestration, which effectively reduces the add-on to +4.3 percent. The dollar amount of the add-on is larger as drug prices increase, which may encourage physicians to prescribe higher-cost drugs, and raise beneficiary and program spending.

Stakeholders have stated that the high cost of Part B drugs for treating cancer, rheumatoid arthritis, multiple sclerosis, other immune disorders, and other conditions, may pose a barrier to providers furnishing these therapies and beneficiaries receiving treatment. CMS has heard from many physicians, specialty groups and patient advocates that the high cost of drugs is a growing financial risk for beneficiaries and providers.

The Competitive Acquisition Program (CAP) for Part B drugs and biologicals, in section 1847B of the Social Security Act (the Act), is an alternative to the average sales price (ASP) methodology that was used to pay for the majority of separately payable Part B drugs. Under the CAP, which operated for a limited time (July 1, 2006 until December 31, 2008), instead of buying drugs for their offices, physicians who chose to participate in the CAP placed a patient-specific drug order with an approved CAP vendor, and the vendor provided the drug to the office and then billed Medicare and collected cost-sharing amounts from the patient.

Recently, we have heard from stakeholders, including physician and hospital groups, manufacturers, distributors, and beneficiary advocates, that a CAP-like approach with substantial improvements, particularly in regards to onsite availability of drugs, could potentially address concerns about the financial burdens associated with furnishing Part B drugs and their rising costs.

CMS seeks input on all of these considerations in this ANPRM.

Model Design

CMS seeks input through this ANPRM on an IPI Model that would aim to preserve or enhance quality of care for beneficiaries while reducing expenditures for Medicare Part B drugs to more closely reflect international comparator countries.[3]

The IPI Model would test whether increasing competition for private-sector vendors to negotiate drug prices, and aligning Medicare payments for drugs with prices that are paid in foreign countries, improves beneficiary access and quality of care while reducing expenditures. In the ANPRM issued today, CMS describes and seeks public feedback on the potential model design, which would have physicians and hospitals (and potentially other providers and suppliers) in selected geographic areas receive certain drugs from private-sector vendors. Providers in the non-model areas would continue to use the buy and bill system to administer Part B drugs to their patients and to be paid under the current Medicare payment policy.

In addition, the model would maintain beneficiaries' choice of provider and treatments and would have meaningful beneficiary protections such as enhanced monitoring and Medicare Beneficiary Ombudsman supports.

Participants

IPI Model participants would include physician practices and hospital outpatient departments (HOPDs) that furnish the model's included drugs in the selected model geographic areas. CMS is considering whether to also include durable medical equipment (DME) suppliers, Ambulatory Surgical Centers (ASCs), or other Part B providers and suppliers that furnish the included drugs. Model participation would be mandatory for the physician practices, HOPDs, and potentially other providers and suppliers, in each of the selected geographic areas.

CMS seeks comment in the ANPRM on the inclusion of providers and suppliers in the model.

Included Drugs

CMS envisions that the model would initially focus on single source drugs and biologicals, as they encompass a high percentage of Part B drug spending and are frequently used by physicians that bill under Medicare Part B. Initially, the model would include drugs and biologicals that we identify from international pricing data. The model would begin with these two broad groups of drugs – single source drugs and biologicals – but could over time include multiple source drugs and Part B drugs provided in other settings.

CMS is considering the best ways to include newly approved and marketed drugs in the model. CMS seeks comment in the ANPRM on additional drugs that could be added over time to bring the greatest value to the Medicare program and beneficiaries.

Model International Payment

The Medicare payment for separately payable Part B drugs is typically based on the average sales price (ASP) of a given Part B drug, plus 6 percent of the ASP as an add-on. For the potential IPI Model, CMS is considering testing an alternative payment for included drugs that would apply when ASP is higher than an international price. Instead of paying based on ASP, CMS would pay for the drug based on a Target Price derived from international price index and designed to draw down Part B drug prices toward international prices over the course of the model. We estimate that relying on an international price index and setting a Target Price rather than using ASP would result in roughly a 30 percent savings in total spending for the selected Part B drugs in the model.

CMS would phase-in this Target Price over five years of the model. CMS seeks comment in the ANPRM on several aspects of the model payment,

including calculation of the target and the international pricing data.

Vendor

CMS intends to utilize a number of private-sector vendors that would supply physicians, hospital outpatient departments, and other included providers and suppliers with the drugs and biologicals that CMS decides to include in the model. Similar to the CAP, the model vendors rather than the health care providers would take on the financial risk of acquiring the drugs and would also bill for the drugs. Instead of paying the model vendors based on bid amounts, as Section 1847B of the Act prescribes, under the IPI Model Medicare would pay the vendor for the included drugs based on the Target Price driven by the international pricing index, which would lower both the amount Medicare pays for included drugs and beneficiary cost-sharing.

The model vendors would have flexibility to offer innovative delivery mechanisms to encourage physicians and hospitals to obtain drugs through the vendor's distribution arrangements, such as electronic ordering, frequent delivery, onsite stock replacement programs, and other technologies. We plan to provide physicians and hospitals in the model test areas with an opportunity to select the vendors that best provide customer service and support beneficiary choice of treatments. Physicians and hospitals would be able to contract with multiple vendors for different drugs and to change vendors. Vendors would not operate formularies. CMS seeks comment in the ANPRM on whether group purchasing organizations, wholesalers, distributors, specialty pharmacies, Part D sponsors, and potentially individual or groups of physicians and hospitals and/or manufacturers could perform the more flexible role of model vendor.

Potential Alternative to ASP Add-on Payments

In addition to the Medicare drug administration payment that would still be made to physicians and hospitals, the model would pay physicians and hospitals a "drug add-on amount". The goals for the model add-on payments would be to hold health care providers harmless to current revenue to the greatest extent possible; create an incentive to encourage appropriate drug utilization; remove the incentive to prescribe higher-cost drugs; and create incentives to prescribe lower-cost drugs in order to reduce beneficiary cost sharing.

The ANPRM seeks input on potential modifications to the current +6 percent add-on payment of the included drugs' ASP. The ANPRM considers a modest increase in the alternative add-on payment – so that

total payments to physicians and hospitals for the add-on would reflect the full 6 percent rather than the 4.3 percent due to sequestration – for the model. Since Medicare payment for the drugs would be to the model vendors, model participants would no longer "buy and bill" Medicare for included Part B drugs administered to included beneficiaries. CMS is considering creating several alternatives to the add-on payment amount for model participants. The add-on could be established as a set payment amount per encounter or per month for an administered drug, which would not vary based on the price of the drug itself. CMS is considering whether to uniquely set the payment amount for each class of drugs, physician specialty, or physician practice (or hospital). The ANPRM seeks input on all these parameters.

Quality

CMS is considering collecting quality measures to better understand the impact of the potential IPI Model on beneficiary access and quality of care. CMS intends to identify quality measures to be collected as part of this model and is interested in several categories of measures, specifically: patient experience measures, medication management measures, medication adherence, and measures related to access and utilization. In the ANPRM, CMS seeks comment on ways to assess the quality of care for purposes of real-time monitoring of utilization, hospitalization, mortality, shifts in site-of-service and other important indicators of patient access and outcomes, without requiring providers or suppliers to report additional data. In addition, CMS seeks information on the categories and types of quality measures CMS can incorporate in the model that are targeted and judicious, while still capturing key indicators of patient experience, access, and medication management.

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[1] Spending and Enrollment Data from Centers for Medicare and Medicaid Services Office of Enterprise Data and Analytics.

[2] "Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures" accessed via https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-spending-medicare-part-b-drugs

[3] CMS has received substantial and substantive comments from other comment opportunities including, but not limited to: the CMS Innovation Center's New Direction Request for Information (RFI), the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, and the CY 2019 OPPS/ASC proposed rule request for information on leveraging the authority for the Competitive Acquisition Program (CAP) for Part B drugs and biologicals for a potential CMS Innovation Center model. The Innovation Center has carefully reviewed these comments and they were informative in the development of the advanced notice of proposed rulemaking.

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