

# Government Seeks Feedback on New Medicare Part B Payment Reform Options

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November 7, 2018

Stakeholders have until December 31, 2018 to comment on a significant new set of Medicare Part B payment reform options aimed at lowering drug costs for the Medicare program and its beneficiaries. An Advance Notice of Proposed Rulemaking (ANPRM), published in the *Federal Register* on October 30, 2018 and available [here](#), outlines plans for a potential International Pricing Index (IPI) Model, which would seek to ensure that the Medicare program pays for certain separately payable Part B drugs and biologicals at prices comparable to other countries. The ANPRM aligns with proposals discussed in a speech by President Trump on October 25, 2018, and with findings set forth in a report released on the same date by the White House Office of the Assistant Secretary for Planning and Evaluation (ASPE).

According to the ANPRM, the IPI Model would include the following features:

1. Phase down the Medicare payment amount for selected Part B drugs and biologicals to more closely align with international prices;
2. Allow private-sector vendors to negotiate prices for Medicare Part B drugs included in the model, take title to such drugs, and compete for physician and hospital business; and
3. Change 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.

The ANPRM states, “the IPI Model would initially focus on Part B single source drugs, biologicals, and biosimilars that encompass a high percentage of Part B drug utilization and spending.”

The ANPRM states that the testing of these proposed policies would occur through the Center for Medicare and Medicaid Innovation; it further asserts that the Department of Health and Human Services (HHS) “plan[s] to test the potential IPI Model under the authority of section 1115A of the [Social Security] Act and to waive certain Medicare program requirements as necessary solely for purposes of testing the potential model.” The ANPRM lists a number of requirements that HHS states that it plans to waive for purposes of testing the IPI Model.

The ASPE report, which is cited throughout the ANPRM, identifies certain single source drugs (based on a methodology designed to identify top Part B drugs by total expenditures, as described in the report) and compares U.S. prices of those selected drugs to the prices in 16 specified countries using data sources for international and domestic acquisition cost data. The report, titled “Comparison of U.S. and

International Prices for Top Medicare Part B Drugs by Total Expenditures,” is available [here](#). In the main analysis conducted for this report, ASPE focused on a set of 27 selected Part B drugs. ASPE found that, on average, across the 27 drugs included in the main analysis for the study, “[t]he prices charged by drug manufacturers to wholesalers and distributors . . . in the United States are 1.8 times higher than in other countries” that were included in the analysis. Notably, the report acknowledges that “there is variability across the 16 countries in the study . . . , with no one country consistently acquiring drugs at the lowest prices.” ASPE further states that the analysis did “not find any one country [that] consistently has the highest or lowest prices compared to the U.S.” The report asserts, based on the analysis of this 27-drug sample, that Medicare could achieve significant savings if U.S. prices were aligned with those of other large market-based economies.

The ASPE report also acknowledges there are “several” limitations to the study, including product presentations (meaning dosage forms and strengths) and differences in manufacturing standards. Moreover, the report notes that “the U.S. ex-manufacturer prices [used for the analysis] do not include potential rebates or after sale discounts,” and that for the prices “[i]n other countries, there may be additional rebates and value-based agreements that are not captured in the ex-manufacturer price[s]” used for the analysis. The report goes on to acknowledge that, “[t]o the extent that these impacts differ by country, [the] results [of the analysis] will be biased.”

The ANPRM solicits public comments on numerous aspects of the potential IPI Model, including which providers would participate in the model, which geographic areas would be selected for the model, and which drugs would be included or excluded from the model’s alternative payment methodologies. The ANPRM states that participants “would include all physician practices and hospital outpatient departments (HOPDs) that furnish the model’s included drugs in the selected model geographic areas”; in addition, HHS 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.” The ANPRM states that “[m]odel participation would be mandatory” for providers located in the selected geographic areas.

Drugs under consideration for exclusion from the model include those that are identified by the Food and Drug Administration (FDA) to be in short supply, as well as drugs that are paid under miscellaneous or “not otherwise classified” (NOC) codes, “due to the operational complexity of identifying if drugs paid under the NOC codes are included model drugs.” For this reason, the ANPRM states, “compounded drugs would be excluded from the model.” The ANPRM states that HHS also plans to exclude radiopharmaceuticals and End Stage Renal Disease (ESRD) drugs, as well as drugs that are packaged under the Outpatient Prospective Payment System when furnished in the HOPD setting.

HHS also solicits comments on how to include newly approved drugs in the model, particularly therapies that may not have any international sales. In addition, HHS seeks comments on the countries included in the analysis used to develop and establish the IPI Model. As stated in the ANPRM, HHS is considering using pricing data from the following countries: Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, the Netherlands, and the United Kingdom.

Additional topics for public comment include the following, among others:

- What sources of international pricing data should be included in the payment methodology?
- Are there areas of concern in data collection and reporting that could lead to inaccurate price calculations?
- How would the contemplated changes in payment policy affect incentives in the market?
- How could using international reference pricing affect innovation incentives in the biopharmaceutical market?
- What beneficiary outcomes would be appropriate to monitor under the IPI Model, and how can such outcomes, as well as patient experience, be monitored and measured in a way that minimizes burden on included healthcare providers and beneficiaries?
- How can unintended consequences be avoided with respect to the interaction of the IPI Model with other programs, such as, for example, the Medicaid Drug Rebate Program and 340B Drug Pricing Program?

HHS states in the ANPRM that it is “considering issuing a proposed rule in the Spring of 2019 with the potential model to start in Spring of 2020”; it further states that “[t]he potential model would operate for five years, from Spring 2020 to Spring 2025.” Healthcare stakeholders should review the ANPRM in detail, assess its potential implications, and take steps now to prepare for the potential proposed model, including providing feedback to HHS by no later than December 31, 2018.

For more on other breaking drug pricing related news, visit [Sidley’s Global Drug Pricing](#) page.

## CONTACTS

If you have any questions regarding this Sidley Update, please contact the Sidley lawyer with whom you usually work, or

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