

AMCP Summary: *Advanced Notice of Proposed Rulemaking for Medicare Program; International Pricing Index Model for Medicare Part B Drugs*

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Comments Due: *December 31, 2018*

On October 30, 2018, the Centers for Medicare and Medicaid Services (CMS) published an [Advanced Notice of Proposed Rulemaking \(ANPRM\)](#) for a potential International Pricing Index (IPI) Model for Medicare Part B Drugs. The potential model would be phased in over a five-year period starting in Spring 2020 and will be tested as a pilot program through the CMS Center for Medicare and Medicaid Innovation (CMMI). The impetus behind the IPI model is to lower expenditures for Part B drugs by implementing an international reference price to shift payments to a level that is comparable with prices in other countries. It also seeks to reform the current “buy and bill” system for Part B drugs and alter reimbursement methodology to eliminate existing incentives to prescribe higher-cost drugs.

For the first time in Medicare, private-sector vendors would take on the risk of obtaining drugs, distributing them to physicians and hospitals, and billing Medicare. The model would allow vendors to negotiate prices for drugs, take title to drugs, and compete for physician and hospital business. Medicare would pay the vendor based on a new international pricing concept and physicians and hospitals would receive a set payment amount for storing and handling drugs that would not be tied to drug prices. The model is projected to save taxpayers and beneficiaries \$17.2 billion over five years. Provisions in the proposed model are influenced by a previous [Competitive Acquisition Program \(CAP\)](#) for Part B drugs and biologicals that ended in 2008. CMS is seeking input on the potential parameters of the IPI Model as they consider issuing a proposed rule in Spring 2019. While some of the proposed provisions are new, such as the IPI, AMCP has commented on similar provisions intended to decrease Medicare Part B drug spending in the past.

AMCP will host a webinar on November 9 from 2-3 pm Eastern Standard time to review the advanced proposed policy provisions that are applicable to AMCP members in the ANPRM along with proposed policy provisions in the Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicare Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021. This webinar is free for members and \$69 for non-members. To register, please visit AMCP’s Calendar of Events at <http://www.amcp.org/calendar/>. A recording of the webinar will also be available to members on the AMCP website <http://www.amcp.org/webinars/>.

AMCP is seeking feedback from its members on the proposed changes to payment policies in Medicare Part B to help inform us as we consider submitting a formal response to CMS. You may provide feedback via email to Afton Wagner, Director of Regulatory Affairs, at awagner@amcp.org by December 7 on any of the provisions included in the ANPRM.

The following is a detailed summary of sections that may be of interest to AMCP members where CMS is seeking feedback on from stakeholders:

Model Concept Design

Section A: Model Vendors (pg. 54550 - 52)

The potential model would utilize private-sector vendors to supply physicians and hospitals with Part B drugs included in the model. Vendors would take on the financial risk of acquiring the drugs and billing Medicare as opposed to health care providers who currently perform these tasks.

- CMS would propose that all model vendors operate on a national basis and would be required to serve all selected geographical areas to promote competition among vendors.

- Physicians and hospitals would select the vendor(s) that offer delivery mechanisms that best meet their patients care needs, practice size and location(s), and support needs.
- Agreements would establish terms of arrangements.
- The model would allow the following entities to perform the role of model vendor: GPOs, wholesalers, distributors, specialty pharmacies, individual or groups of physicians and hospitals, manufacturers, Part D sponsors, and/or other entities.
- Vendors would be responsible for the following:
 - Negotiating with manufacturers for drug acquisition prices for included drugs.
 - Taking title to, but not necessarily physical possession of, and distributing included drugs to participants for administration to beneficiaries.
 - See pg. 54551 of the ANPRM for full list of vendor responsibilities.
- Vendors would not operate formularies.
- Physicians and hospitals would pay the vendor for distribution costs and would collect beneficiary cost-sharing.
- Vendors would submit claims to Medicare and would be paid an applicable amount for the Part B drug.
- Vendors would be prohibited from providing rebates or volume-based incentive payments to participants.
- CMS intends to operate a competitive selection process to identify model vendors.
 - At least 3 vendors would be selected.

CMS is seeking input on the following regarding model vendors:

- Whether CMS should be a party to and/or regulate agreements between physicians and vendors and if the agreements should specify obligations to ensure the physical safety and integrity of included drugs.
- Types of entities that would be allowed to be model vendors.
- Other options for model vendor payment.
- If 3 vendors in an appropriate floor.
- Additional requests from CMS for feedback and information on this section can be found on pg. 54552 of the ANPRM.

AMCP is seeking feedback on model vendors.

Section B: Model Participants, Compensation, and Selected Geographic Areas (pg. 54552 - 54)

Participants in the model would include all physician practices and hospital outpatient departments (HOPDs) that are in the selected model geographic areas as proposed in the ANPRM. The model also proposes alternatives to the current ASP-based provider add-on payment. The alternatives are intended to remove the incentive for physicians to prescribe higher cost drugs. Currently, Medicare Part B typically pays for Part B drugs at the average sales price (ASP) of a drug plus 6 percent of the ASP as an add-on (currently ASP + 4.3 percent due to sequestration that took effect in 2011.)

Model Participants

- CMS would propose to include all physician practices and HOPDs in selected geographic areas.
- CMS is also considering to include participants such as Durable Medical Equipment (DME) suppliers, Ambulatory Surgical Centers (ASCs), or other Part B providers and suppliers that administer included drugs.
- Model participants would be required to enroll with at least one model vendor
- Beneficiaries would be included in the model if they are administered an included drug by a model participant that is in one of the selected geographic areas.

Model Geographic Area

- The model would mandate participation from physician practices, HOPDs, and potentially others, in selected geographic areas.
- CMS anticipates the selected geographic areas to include 50 percent of Part B spending on Part B drugs.
 - Model would require physicians, HOPDs and potentially other providers and suppliers, to participate in selected geographic areas.

- CMS is considering a randomized design for the model with the randomization to intervention and comparison groups occurring at the geographic area.
 - Health care providers outside of the randomized geographic areas could potentially participate but would not be included in the evaluation sample.
- CMS is considering using Core Based Statistical Area (CBAs) as the primary unit of analysis in the model.

Compensation

- CMS is considering alternative methods for making the Part B drug add-on-payment a flat rate amount rather than a set percentage amount.
 - *Potential Alternative to ASP Add-On*
 - CMS would base payment calculations for the alternative compensation on 6 percent of the included Part B drugs' ASP.
 - This would more accurately reflect the entire 6 percent markup rather than the 4.3 percent markup that physicians are currently receiving due to sequestration.
 - *Potential Alternative to Payment Amount Add-on*
 - Model participants would be paid a set payment amount per encounter or per month for an administered drug.
 - CMS is considering whether to set a unique payment amount for each class of drugs, physician specialty, or physician practice (or hospital).
 - If used, specialties would be broadly defined.
 - Final payment amount would be calculated annually based on the 6 percent of ASP revenue model participants would have garnered in most recent year of claims data.
 - *Bonus Pool*
 - CMS is considering creating a bonus pool, where model participants would achieve bonus payments for prescribing lower-cost drugs or practicing evidence-based utilization.
 - CMS would monitor drug utilization throughout model to ensure beneficiary access is not compromised.

CMS is seeking input on the following regarding model participants, geographic areas, and compensation:

- Exclusion/inclusion of specific types of physician practices, HOPD's, and/or Part B providers and suppliers.
- Which alternative add-on option is preferable and how the payment methodology may be defined.
- Additional requests from CMS for feedback and information on this section can be found on pg. 54554 of the ANPRM.

AMCP is seeking feedback on model participants, compensation, and geographic areas.

Section C: Included Drugs (pg. 54554 – 55)

Selected Part B drugs would be phased in over the five-year course of the model. CMS would propose to start with single source drugs and biologics in years 1 - 2 and then add new drugs as more international pricing data becomes available in years 3 -5. As new drugs are added, CMS would prioritize single source drugs and biologics.

Potential Drugs that Would be Included in the IPI Model

- Drugs proposed to be included in Years 1 and 2: Single source drugs, biologics, biosimilars, and multiple source drugs with a single manufacturer that are identified from potential sources of international pricing data as described on pg. 54556 of the ANPRM.
- Drug to be included in Years 3 – 5: Broadened scope of drugs to include more single source drugs and biologics
- The model would begin by including most of the Healthcare Procedure Coding System (HCPCS) codes in a recent [HHS report](#) that compares U.S. Part B drug prices to international drug prices.
- CMS is also considering adding HCPCS codes for drugs and biologics that are clinically comparable, but not interchangeable.

Potential Drugs that Would be Excluded in the IPI Model

- Drugs that are identified by the Food and Drug Administration (FDA) to be in short supply.
- Drugs paid under the miscellaneous or “not otherwise classified” (NOC) codes (e.g. compounded drugs).
- Radiopharmaceuticals and ESRD drugs paid under section 1881 of the Act.
- Drugs packaged under the Outpatient Prospective Payment System (OPPS) when they are furnished by a hospital outpatient department.

CMS is seeking feedback on the following regarding potential included/excluded drugs in the IPI Model:

- Whether the data that CMS uses to determine the inclusion of drugs and biologicals should be limited to claim from the physician’s office and hospital outpatient settings. Should other settings be included?
- How to incorporate multiple source drugs.
- Whether to include Part B drugs in all settings in which they are separately payable or only in certain settings
- Whether quarterly updates for HCPCS codes included in the model are feasible.
 - Feedback from perspective of payment model participants and vendors encouraged.
- Best way to include new drugs in the model as they become available.
- Whether to determine inclusion of drugs based on on-label (FDA approved) indications only or whether CMS should consider on-label and off-label uses.
- Whether aspects of mandatory participation would require physicians and hospitals to have an agreement with a single vendor or would require them to obtain all drugs through a single vendor.

AMCP is seeking feedback on potential drugs to be included in the model.

Section D: Model Payment Methodology for Vendor Supplied Drugs (pg. 54555 - 57)

CMS is considering testing an alternative payment for Part B drugs based on international pricing except for where ASP is lower. This approach is intended to better align U.S. prices for Part B drugs with other countries.

- CMS would calculate an average international price for each Part B drug, calculate a ratio of Medicare spending using ASP prices versus Medicare spending under international prices to determine an IPI, and then set a “Target Price” based on calculations that include the IPI.
 - Detailed calculation steps are outlined on pg. 54556 of the ANPRM.
- The Target Price would be phased in the model over five years as a blend of ASP and Target Price (pg. 54556):

Year	Percentage of ASP and target price
Year 1	80 percent ASP and 20 percent Target Price.
Year 2	60 percent ASP and 40 percent Target Price.
Year 3	40 percent ASP and 60 percent Target Price.
Year 4	20 percent ASP and 80 percent Target Price.
Year 5	100 percent Target Price.

- CMS is considering including collection of international drug sales data and has evaluated several existing data sources to determine the availability of international drug pricing information.
- CMS is considering including a data collection system for manufacturers to report international drug sales data to CMS to support calculation of IPI and Target Price for each drug.
- *Requests for information and feedback from CMS for this section can be found on pg. of the 54557.*

AMCP is seeking feedback on payment methodology for vendor supplied drugs.

Section E: Potential Foreign Market Considerations (pg. 54557)

- *CMS seeks input from stakeholders on the potential considerations related to foreign markets and the potential model payment approach that would rely on international sales data.*

Section F: Beneficiary Impact and Model Monitoring (pg. 54557-58)

- CMS expects that beneficiary cost-sharing for included drugs under the potential IPI model would be the same or lower than non-model cost-sharing.
 - The 20 percent beneficiary co-pay would be reduced overall if model reduces payment for some Part B drugs.
- CMS would implement a monitoring program for the model to ensure it meets the needs of beneficiaries
 - *CMS is looking for feedback on appropriate outcomes to monitor, patient experience, and how to monitor.*

Section G: Interaction with Other Models (pg. 54558)

- CMS has begun to review other CMS Innovation Center Models such as the Oncology Care Model (OCM) that may overlap with the IPI model in same geographic areas that include Part B drug spending.
 - CMS and will address issues as the IPI model evolves.

Section H: Interaction with Other Federal Programs (pg. 54558)

- CMS seeks input on how to avoid unintended consequences on the interaction of the IPI Model with other federal programs such as Medicaid “Best Price”, Average Manufacturer Price (AMP), 340B Program, and 340B ceiling price.

Section I: Quality Measures (pg. 54559)

- CMS is considering collecting quality measures to understand the IPI Model’s impact on beneficiary access and quality of care.
 - Categories of measures that CMS is interested in include: Patient experience, medication management, medication adherence, access and utilization. Note that AMCP will comment and provide some info on where we have commented.
 - *CMS seeks information on the proposed quality measure categories and other types of quality measures that can be included in the model.*

Section J: Legal Considerations and Potential Waivers of Medicare Program Requirements for Purposes of Testing the Model (pg. 54559)

- CMS plans to waive several Medicare Program requirements as necessary for purposes of testing the model.
 - A list of waived requirements that would be proposed can be found on pg. 54559.

Section K: Model Termination (pg. 54559)

- CMS may terminate the model if it no longer has supporting funds or for other reasons as determined by CMS.

Section L: Model Evaluation (pg. 54559)

- The IPI Model through the Innovation Center is required to have an evaluation that must include analysis of the quality of care and changes in spending.
 - *CMS is seeking input on the model evaluation approach.*

Section M: Potential Impacts of Implementing the IPI Model (pg. 54560)

- CMS notes that there are many uncertainties around estimating the financial effects of this model and estimates of savings are an approximate measure that could change.
- Following is a table outlining estimated saving from the IPI for 2020 – 2025 (pg. 54560):

TABLE 2: ILLUSTRATION OF POTENTIAL FINANCIAL IMPACT (IN BILLIONS) [PHOTO]

	2020	2021	2022	2023	2024	2025	2020-2025
Part B Drug Baseline	31.2	34.2	37.4	40.8	44.3	48.2	
<i>Drug price</i>							
FFS impact	-0.3	-0.9	-1.9	-3.1	-5.3	-2.3	-13.8
Gross impact (FFS+MA)	-0.6	-1.5	-3.2	-5.3	-9.2	-4.1	-23.9
Net of premium offset	-0.4	-1.1	-2.4	-4.0	-6.9	-3.1	-17.9
Medicaid impact	0.0	-0.1	-0.2	-0.4	-0.7	-0.3	-1.8
Federal	0.0	-0.1	-0.1	-0.2	-0.4	-0.2	-1.0
State	0.0	0.0	-0.1	-0.2	-0.3	-0.1	-0.8
<i>Physician add-on payment</i>							
FFS impact	0.1	0.2	0.2	0.3	0.3	0.1	1.3
Gross impact (FFS+MA)	0.2	0.3	0.4	0.5	0.6	0.2	2.2
Net of premium offset	0.2	0.2	0.3	0.4	0.4	0.1	1.6
Medicaid impact	0.0	0.0	0.0	0.0	0.0	0.0	0.2
Federal	0.0	0.0	0.0	0.0	0.0	0.0	0.1
State	0.0	0.0	0.0	0.0	0.0	0.0	0.1
<i>Total impact</i>							
FFS impact	-0.2	-0.7	-1.6	-2.8	-4.9	-2.2	-12.5
Gross impact (FFS+MA)	-0.4	-1.2	-2.8	-4.8	-8.6	-3.9	-21.7
Net of premium offset	-0.3	-0.9	-2.1	-3.6	-6.4	-2.9	-16.3
Medicaid impact	0.0	-0.1	-0.2	-0.4	-0.6	-0.3	-1.6
Federal	0.0	-0.1	-0.1	-0.2	-0.4	-0.2	-0.9
State	0.0	0.0	-0.1	-0.2	-0.3	-0.1	-0.7

Notes: Amounts are presented by calendar year and are based on the date the service is incurred.
The model is assumed to run from April 1, 2020 through March 31, 2025.
The Part B baseline includes drugs provided by 340B hospitals