

facilities. We do not see a need for the EPA to continue investing its resources to complete this rule to develop a “more workable and sustainable regulatory framework” as originally anticipated when we proposed these ISR-specific standards, especially where current production is reduced and little or no growth is expected in the near future. The statutory authorities providing for this ongoing regulatory and licensing function remain unchanged. Thus, the appropriate regulatory authorities may decide on a case-by-case basis to revise their own pre-existing regulations based on these authorities if they deem it necessary to assist with their management of ISR facilities in a particular state or local area.

In addition, we find support for our decision to withdraw the proposed rule in the NRC’s comments on the 2017 Proposal. As explained above, the EPA developed the proposed standards partly based on its understanding, after consultation with the NRC, that the anticipated growth in the number of ISR facilities highlighted a need for standards specific to ISR facilities, rather than continuing to apply standards that were originally written to address surface disposal of uranium mill tailings.³⁵ However, the NRC expressed the following view in its public comments on the proposed rulemaking:

The NRC’s current regulations, at 10 CFR part 40, Appendix A, and those of the various Agreement States, as supplemented by site-specific license conditions, guidance documents (e.g., NRC’s “Standard Review Plan for In Situ Leach Uranium Extraction License Applications,” NUREG-1569), and the operational experience and technical expertise of the regulatory agency staff, constitute a comprehensive and effective regulatory program for uranium in situ recovery operations (ISR) facilities.³⁶

Considering the prevailing economic conditions affecting current and projected production, which leads the NRC now to expect significantly fewer future license applications, as opposed to the large increase that it expected at the time the rulemaking process was initiated (which was motivation for the proposal), we conclude that withdrawing this proposal is appropriate.

III. Statutory Authority

The statutory authority for this notice is provided by section 275 of the Atomic

Energy Act (AEA), as added by section 206 of UMTRCA (42 U.S.C. 2022) and the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*).

IV. Impact Analysis

Because the EPA is not promulgating any regulatory requirements, there are no compliance costs or impacts associated with today’s final action.

V. Statutory and Executive Order Reviews

Today’s action does not establish new regulatory requirements. Hence, the requirements of other regulatory statutes and Executive Orders that generally apply to rulemakings (e.g., the Unfunded Mandate Reform Act) do not apply to this action.

Dated: October 18, 2018.

Andrew R. Wheeler,

Acting Administrator.

[FR Doc. 2018–23583 Filed 10–29–18; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Chapter IV

[CMS–5528–ANPRM]

RIN 0938–AT91

Medicare Program; International Pricing Index Model for Medicare Part B Drugs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Advance notice of proposed rulemaking with comment.

SUMMARY: We are issuing this advance notice of proposed rulemaking (ANPRM) to solicit public comments on potential options we may consider for testing changes to payment for certain separately payable Part B drugs and biologicals (hereafter called “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 to the Medicare program.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 31, 2018.

ADDRESSES: In commenting, please refer to file code CMS–5528–ANPRM. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5528–ANPRM, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5528–ANPRM, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Hillary Cavanagh, 410–786–6574 or the IPI Model Team at IPIModel@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

³⁵ 82 FR at 7402–3; 80 FR 4164–7.

³⁶ EPA–HQ–OAR–2012–0788–0312 at 1.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Executive Summary

A. Purpose

The Medicare program and its beneficiaries currently pay more for many high-cost drugs than many other countries.¹ The Centers for Medicare & Medicaid Services' (CMS) Center for Medicare and Medicaid Innovation ("Innovation Center") is taking action on President Trump's goal to lower drug costs for Medicare beneficiaries by exploring a potential model that seeks to ensure the Medicare program pays comparable prices for Part B drugs relative to other economically-similar countries. The potential International Pricing Index (IPI) model would have several goals, including: reducing Medicare program selected expenditures and beneficiary cost-sharing for separately payable Part B drugs (for example, drug administered in physician offices and hospital outpatient departments), preserving or enhancing quality of care for beneficiaries, offering comparable pricing relative to international markets, removing providers' financial incentive to prescribe higher-cost drugs while creating revenue stability, minimizing disruption to the current supply chain, and increasing Medicare efficiency and value to reduce federal spending and taxpayer dollars. With this advance notice of proposed rulemaking (ANPRM), the CMS is soliciting public feedback on key design considerations for developing the IPI Model.

The IPI Model aims to drive better quality for Medicare beneficiaries and reduce Medicare drug spending by offering comparable pricing relative to other countries and addressing flawed incentives in the current payment system. Currently, Medicare pays substantially more than other countries for the highest-cost physician administered drugs.² In addition, the

current Medicare payment system has several features that may be causing greater utilization of higher priced drugs.³ Under the current system, Medicare pays doctors and hospitals a fee set at 6 percent of the price of the drug so that the dollar amount of the add-on increases with the price of the drug rather than a set payment reflecting the service being performed. The current buy-and-bill system also requires physicians to purchase high-cost Part B drugs and wait for Medicare reimbursement, exposing practices to financial risk and jeopardizing their ability to operate and provide care in their communities.

We are proposing to design the IPI Model to achieve the following: (1) Reduce expenditures while preserving or enhancing the quality of care for beneficiaries; (2) ensure the United States (U.S.) is paying comparable prices for Part B drugs relative to other countries by phasing in reduced Medicare payment for selected drugs based on a composite of international prices; (3) reduce out-of-pocket costs for included drugs for Medicare beneficiaries, and thereby increase access and adherence due to decreased drug costs; (4) maintain relative stability in provider revenue through an alternative drug add-on payment for furnishing drugs that removes the current percentage-based drug add-on payments, which creates incentives for higher list prices and to prescribe higher cost drugs; (5) reduce participating health care providers' burden and financial risk associated with furnishing included drugs by using private-sector vendors to purchase and take title to included drugs; and (6) introduce greater competition into the acquisition process for separately payable Part B drugs.

B. Summary of Major Provisions

In section III. of this ANPRM, we discuss the model concept design for the IPI Model. This IPI Model would focus on selected separately payable Part B drugs and biologicals (hereafter called "drugs"). Specifically, 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 Innovation Center would test this model under section 1115A of

the Social Security Act (the Act), which authorizes testing models expected to reduce program expenditures, while preserving or enhancing the quality of care furnished to beneficiaries. The model under consideration would include physicians, hospitals, and potentially other providers and suppliers in selected geographic areas. The IPI Model test would include the following components:

- Set the Medicare payment amount for selected Part B drugs to be phased down to more closely align with international prices;
- Allow private-sector vendors to negotiate prices for drugs, take title to drugs, and compete for physician and hospital business; and
- Increase the drug add-on payment in the model to reflect 6 percent of historical drug costs.
- Pay physicians and hospitals the add-on based on a set payment amount structure; CMS would calculate what CMS would have paid in the absence of the model, before sequestration, and redistribute this amount to model participants based on a set payment amount.

These and other components of the potential model are described in greater detail in this ANPRM.

We are considering issuing a proposed rule in the Spring of 2019 with the potential model to start in Spring 2020. The potential model would operate for five years, from Spring 2020 to Spring 2025. Of note, as discussed in section III.I. of this ANPRM, the IPI Model may have an impact on Medicaid drug rebates and payments, which we continue to explore.

With the release of this ANPRM, we solicit public input on our intended model design to inform our ongoing work to develop the IPI Model.

II. Background

A. Overview of Supply Chain

1. Current Distribution System

In the U.S., Part B drugs that are administered in the outpatient setting usually flow from the manufacturer through drug wholesalers (or specialty distributors) to the provider or supplier. At each step of the process, the drugs are sold to the next entity in the supply chain and that entity takes title to the drug. Distribution management systems are employed to order drugs, track sales and shipments, manage price and customer lists, record financial transactions, and support other industry processes. Figure 1 provides a high-level

¹ "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>.

² "Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures"

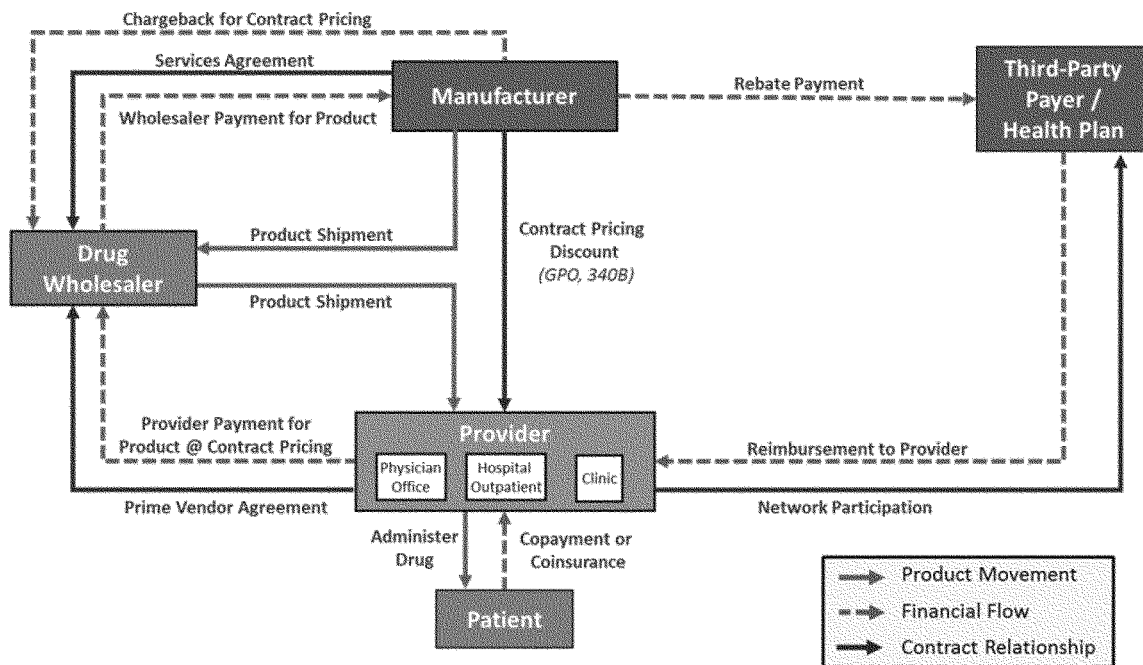
accessed via <https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-spending-medicare-part-b-drugs>.

³ "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>.

view of this “buy and bill” system⁴ and existing relationships between the various entities, including product

movement, financial flow, and contract relationships.⁵

FIGURE 1: BUY-AND-BILL SYSTEM FOR DISTRIBUTION AND REIMBURSEMENT OF PROVIDER-ADMINISTERED OUTPATIENT DRUGS



GPO = Group Purchasing Organization; 340B = 340B Drug Pricing Program. Chart illustrates flows for Provider-Administered, Outpatient Drugs. Please note that this chart is illustrative. It is not intended to be a complete representation of every type of financial, product flow, or contractual relationship in the marketplace. Source: Fein, Adam. J., *The 2016–17 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors*, Drug Channels Institute, September 2016, Exhibit 28. Available at http://drugchannelsinstitute.com/products/industry_report/wholesale/.

The role of the health care provider within the buy-and-bill system is to seek out low cost drug suppliers and purchasing mechanisms (for example, by joining a group purchasing organization (GPO)), order, buy (or use financing), receive, and store drugs, administer drugs to patients, file claims to bill insurers for payment, and collect patient cost-sharing. There are many different buying strategies that enable physicians and hospitals to obtain lower drug prices. These strategies include using GPOs, group purchasing arrangements, wholesaler/distributor price lists, the 340B Prime Vendor,⁶ and

directly negotiated agreements with manufacturers. Similarly, the current drug distribution system accommodates a variety of purchasing mechanisms and specialized distribution processes, for example, cold chain and product tracing compliance.⁷

Physicians generally purchase Part B drugs from a wholesaler, distributor, or specialty pharmacy. Hospitals generally purchase for their outpatient departments through their hospital pharmacy's arrangement with a drug wholesaler. Physicians and hospitals also have arrangements with manufacturers, individually or through

their GPOs, for discounts that are tied to prescribing, for example volume discounts based on purchases of drugs for all patients that are treated. Drug wholesalers, distributors, and specialty pharmacies negotiate with manufacturers on the price they will pay to acquire drugs. When applicable, contract pricing controls the price that the health care provider will pay to the wholesaler, distributor, or specialty pharmacy, while shipping and handling and other terms may vary. Through a process called the “chargeback process,” manufacturers reduce the final drug prices to wholesalers and other

⁴ The “buy and bill” system refers to health care providers purchasing drugs for administration to patients followed by the submission of claims to a payer.

⁵ Reprinted with permission. Drug Channels, “Follow the Vial: The Buy-and-Bill System for Distribution and Reimbursement of Provider-Administered Outpatient Drugs,” October 14 2016, accessed via: <https://www.drugchannels.net/2016/10/follow-vial-buy-and-bill-system-for.html>.

⁶ The Health Resources and Services Administration (HRSA) administers the 340B Drug Pricing Program that allows certain hospitals and other health care providers (“covered entities”) to obtain discounted prices on “covered outpatient drugs” (as defined at section 1927(k)(2) of the Act) from drug manufacturers. The 340B Prime Vendor is responsible for securing subceiling discounts on outpatient drug purchases and discounts on other pharmacy-related products and services for

participating public hospitals, community health centers, and other safety-net health care providers electing to join the 340B program.

⁷ A cold chain ensures that a product maintains a desired temperature all the way through the supply chain from manufacturing to delivery/administration. Product tracing allows a user to track every step of the supply chain.

distributors to reflect the contract prices that were applied to health care providers' drug purchases. Increasingly, specialty pharmacies are supplying oncology drugs to health care providers that have chosen to remove themselves from the buy and bill system—or private payers are mandating use of “white bagging” or “brown bagging” (that is, pharmacy dispensed drugs delivered to the practitioner by the pharmacy or patient) to control drug costs.⁸ However, Medicare does not mandate use of or encourage white bagging or brown bagging.⁹

2. Prior Competitive Acquisition Program

Under the Medicare Prescription Drug, Improvement and Modernization Act of 2003, which established section 1847B of the Act, we have authority to implement the “Competitive Acquisition Program” or “CAP” for Part B drugs that are not paid on a cost or prospective payment basis. The CAP was implemented in the mid-2000s.

The CAP was an alternative to the average sales price (ASP) methodology that is used to pay for the majority of Part B drugs, particularly drugs that are administered during a physician's office visit. Instead of buying drugs for their offices, physicians who chose to participate in the CAP would place a patient-specific drug order with an approved CAP vendor; the vendor would provide the drug to the office and then bill Medicare and collect cost-sharing amounts from the patient. Drugs were supplied in unopened containers (not pharmacy-prepared individualized doses like syringes containing a patient's prescribed dose). When the CAP was in place, most Part B drugs used in participating physicians' offices were supplied by the approved CAP vendor. Unlike the buy and bill process that is still used to obtain many Part B drugs, physicians who participated in the CAP did not buy or take title to the drug. Physician participation in the CAP was voluntary, but physicians had to elect to participate in the CAP. CAP drug claims were processed by a designated carrier.

CMS conducted bidding for CAP vendors in 2005. The first CAP contract period ran from July 1, 2006 until December 31, 2008. One drug vendor

participated in the program, providing drugs within approximately 180 Healthcare Common Procedure Coding System (HCPCS) billing codes (including heavily utilized drugs in Part B) to physicians across the United States and its territories. The parameters for the second round of the vendor contract were essentially the same as those for the first round. While CMS received several qualified bids for the subsequent contract period, shortly before the second contract period began, contractual issues with the successful bidders led to the postponement of the program, and the CAP has been suspended since January 1, 2009.

3. Challenges With the Statutory CAP

As described previously, the CAP operated for a brief time from 2006 to 2008. The Part B drug market has changed since that time. Higher cost drugs, particularly biologicals manufactured by sole sources, are driving increasing Part B drug expenditures.¹⁰ Many of the highest price drugs and biologicals available today were not contemplated when the CAP program was established. While distribution channels have remained concentrated, today's providers and suppliers have access to more sophisticated technologies such as electronic ordering systems and virtual inventory management systems.

Since 2009, physicians have faced growing financial risks under the buy and bill approach, as the prices of Part B drugs have increased. Hospitals have varying ability to negotiate discounts, so some hospitals face similar financial challenges for the outpatient drugs they provide. Further, the rising costs of prescription drugs in the Medicare Part B program strain federal resources as well as beneficiaries' wallets.

As envisioned, the CAP had the potential to reduce risk for enrolled physicians and Medicare expenditures. As implemented, the CAP was tied to the ASP payment under section 1847A of the Act and did not achieve savings.¹¹ In the aggregate, the submitted bids could not exceed a threshold that was based on “point in time” ASP data combined with historical utilization data. The submitted bids fed into the composite bid analysis and vendor

selection process. These time consuming, imprecise mechanisms, along with other features of the CAP, limited the appeal of the program for vendors. There was no guarantee for the CAP vendors that the CAP payments would cover their drug acquisition and operating costs. Participating physicians reported that CAP requirements were challenging to integrate into efficient practice patterns and treatment regimes, especially for oncologists who prescribe dosages that may change on the day of treatment, and physicians who need to administer antibiotics urgently.

Recently, we have heard from stakeholders, including physician and hospital groups, and beneficiary advocates, that a CAP-like approach with 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, and address challenges experienced in the CAP. Stakeholder feedback on the CAP has been considered in the development of the potential IPI Model described in this ANPRM. In addition, comments received on a Request for Information on a potential model to leverage the authority under the CAP for Part B drugs and biologicals that was included in the Calendar Year 2019 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule (83 FR 37046) and comments received on the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (83 FR 22692) were considered.

B. Rising Cost of Prescription Drugs

1. Medicare Spending

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 \$818.¹² The number of Medicare Part B FFS beneficiaries and the number of these beneficiaries who received a Part B drug increased over the 5-year period (2011 through 2016). However, the increase in total Medicare drug spending during this period is more fully explained by increases in the prices of drugs and mix of drugs for those beneficiaries who received them than by increases in Medicare enrollment and drug utilization. The

⁸Robinson and Howell. Specialty Pharmaceuticals: Policy Initiatives to Improve Assessment, Pricing, Prescription, and Use. *Health Affairs* 2014;33(10):1745–50.

⁹“Brown bagging” is a term used when the patient obtains the drug at a pharmacy and then brings it to the physician for administration. “White bagging” is a term used when the specialty pharmacy ships directly to the physician office or hospital outpatient department for administration.

¹⁰ Medicare Part B Drug Spending Dashboard accessed via: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartB.html>.

¹¹ Evaluation of the Competitive Acquisition Program for Part B Drugs: Final Report, December 2009, accessed via: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/CAPPARTB_Final_2010.pdf.

¹² Spending and Enrollment Data from Centers for Medicare and Medicaid Services Office of Enterprise Data and Analytics.

CAGR in number of Medicare Part B FFS beneficiaries is less than 1 percent between 2011 and 2016.

2. International Prices Relative to U.S. Prices

Drug acquisition costs in the United States exceed those in Europe, Canada, and Japan, according to a Department of Health and Human Services (HHS) analysis¹³ of drug acquisition costs for Medicare Part B physician-administered drugs. The HHS analysis compared United States drug acquisition costs for a set of Medicare Part B physician-administered drugs to acquisition costs in 16 other developed economies—Austria, Belgium, Canada, Czech Republic, Finland, France, Germany, Greece, Ireland, Italy, Japan, Portugal, Slovakia, Spain, Sweden, and the United Kingdom (UK).

Among the 27 products included in the analysis, acquisition costs in the U.S. were 1.8 times higher than in comparator countries.¹⁴ Acquisition cost ratios ranged from U.S. prices being on par with international prices for one drug, to U.S. prices being up to 7 times higher than the international prices. There is variability across the 16 countries in the study as well, with no one country consistently acquiring drugs at the lowest prices. The U.S. has the highest ex-manufacturer prices for 19 of the 27 products.

As a result, Medicare beneficiaries and the Medicare program are bearing unnecessary, potentially avoidable costs for Part B drugs.

III. Model Concept Design

The potential IPI Model would leverage and improve upon the CAP approach by paying physicians and hospitals for drug-related costs, providing more flexibility for drug ordering and distribution, and by having model vendors compete for business from physicians and hospitals. Through the potential IPI Model, we seek to test ways to remove physicians and hospitals outpatient departments from the buy and bill process, without creating undue disruption to the distribution system.

CMS is considering contracting with a number of private-sector vendors that

¹³ “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>.

¹⁴ Acquisition cost ratios ranged from U.S. prices being on par with international prices for one drug, to U.S. prices being up to 7 times higher than the international prices. There is variability across the 16 countries in the study as well, with no one country consistently acquiring drugs at the lowest prices. The U.S. has the highest acquisition costs for the vast majority of the 27 products.

would supply physicians, hospital outpatient departments, and other included providers and suppliers with the drugs and biologicals that CMS would include in the model in all of the model’s selected geographic areas. Similar to the CAP, the model vendors, rather than the health care providers, would take on the financial risk of acquiring the drugs and billing Medicare. Instead of paying the model vendors based on bid amounts, as section 1847B of the Act prescribes for the CAP, under the IPI Model Medicare would pay the vendor for the included drugs based on international prices discussed in section III.D. of this ANPRM, which would be intended to lower 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. Physicians and hospitals in the model test would select the vendors that best provide customer service and support beneficiary choice of treatments, and would be able to engage with multiple vendors for different drugs and to change vendors. 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” that would be different from the current drug add-on amount.

Outside of the designated model test areas and for drugs not included in the model, health care providers would continue to use the buy and bill approach and the current Medicare FFS payment policies would apply.

This ANPRM describes features of a potential model in more detail, such as how an international pricing index could be developed and tested. We intend to waive program requirements to the extent necessary to test the model design that we would implement through notice and comment rulemaking. We seek feedback on a number of potential model elements described in the following sections of this ANPRM. These include:

- What limitations would be in place on the entities that could participate as vendors (e.g. pharmacies, manufacturers, providers themselves)?
- Which countries should be included in calculating an international pricing index? How frequently should international data be updated?
- What should be the schedule for phasing in the spending target?

- Should we introduce health care provider bonuses to incentivize reductions in cost or utilization relative to a benchmark?

A. Model Vendors

1. Testing Alternative to CAP Requirements

As CMS develops the IPI Model, we seek to minimize disruption within the drug distribution system while increasing competition, lowering U.S. drug prices, and removing the incentive for higher list prices. Under the CAP, the CAP vendor had to acquire the CAP drug and ship the drug to the ordering physician after receiving a beneficiary-specific order. Under the IPI Model we are considering, vendors would have the flexibility to offer a variety of delivery options, including beneficiary-specific prescriptions, pre-ordering approaches such as onsite inventory management solutions, and other arrangements that would not require physicians and hospitals to purchase the drugs or face greater buying costs. Physicians and hospitals would select the vendors that offer delivery mechanisms that best meet their patient care needs, practice size and location(s), and support needs. Agreements between the vendors and physicians/hospitals would establish the terms of their arrangements and would include appropriate guardrails to protect all parties, including beneficiaries and the Medicare program. CMS seeks feedback on whether CMS should be a party to and/or regulate these agreements, and whether the agreements should specify obligations to ensure the physical safety and integrity of the included drugs until they are administered to an included beneficiary, how drug disposition would be handled, and data sharing methods, confidentiality requirements, and potentially other requirements.

2. Eligible Vendors

Under the potential IPI Model, we would intend to allow greater flexibility than under the CAP in the types of entities that could be selected as a model vendor (in accordance with applicable laws), and to minimize the impacts on drug distribution processes. Under the CAP, specialty pharmacies were the only entities that met the CAP vendor criteria, and only one such vendor participated in the program. To increase competition, the IPI Model would potentially allow entities such as 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. We are interested in ways to minimize any potential concerns that could arise by allowing a broader set of entities to be vendors, and how health care providers operating as vendors might be able to operate in all geographic areas included in the model. We seek input on the types of entities that would be allowed to be model vendors, the potential for perverse incentives that could be introduced by potentially allowing health care providers to be model vendors and/or allowing model vendors to charge health care providers for distribution-related activities, and whether there should be guardrails in place to prevent perverse incentives.

We would require that model vendors purchase and take title to the included drugs, but to allow for innovative distribution approaches, model vendors would not be required to take physical possession of the drugs. For example, if a manufacturer establishes a limited distribution program, model vendors could negotiate with the manufacturer ways to purchase the drug while the established limited distribution entity would continue to ship the drug to the physician or hospital for administration.

We would expect that all model vendors would operate on a national basis; that is, model vendors potentially would be required to serve all of the selected model geographic areas and supply all included drugs to the physicians and hospitals that enroll with the vendor. The model would promote competition among multiple national vendors; vendors would compete for agreements with physicians and hospitals and other health care providers that would be included in the model. Physicians and hospitals would not be required to use only one vendor; we would encourage model participants to obtain drugs from the most cost effective model vendors. Enrolling with more than one vendor would allow physicians and hospitals more options for obtaining drugs timely, although the minimum requirement would be that model participants maintain enrollment with at least one vendor in order to furnish included drugs to the beneficiaries they serve timely.

Model vendors would operate enrollment for physicians and hospitals and would send periodic enrollment reports and other documentation to CMS to support model operations. In addition, model vendors would be prohibited from paying rebates or volume-based incentive payments to physicians and hospitals.

3. Model Vendor Responsibilities

The model vendors' responsibilities would be based on the responsibilities of the CAP contractor under section 1847B of the Act and would be specified in a model vendor agreement. The model vendors would be responsible for such activities as—

- Negotiating with manufacturers for the vendor's drug acquisition prices for included drugs;
- Establishing mechanisms for the model vendor to take title to, but not necessarily physical possession of, included drugs, and arranging for the distribution of included drugs to participant health care providers for administration to included beneficiaries;
- Establishing mechanisms within the vendor's arrangements with manufacturers, physicians, hospitals, and other included providers and suppliers to receive compensation for vendor services;
- Implementing processes for participant health care providers to enroll with the vendor and to obtain included drugs;
- Meeting applicable licensure requirements in each State in which the vendor would supply included drugs and be enrolled in Medicare as a participating supplier, unless the model vendor distributes included drugs under contract with one or more entities, in which case the vendor must require that such entities meet applicable licensure requirements and be enrolled in Medicare as a participating supplier;
- Establishing mechanisms for physicians and hospitals to notify the vendor of the disposition of an included drug;
- Submitting claims for included drugs in accordance to model billing instructions established by CMS;
- Paying manufacturers for included drugs that were administered;
- Operating vendor-administered payment arrangements, such as indication based pricing, or outcomes-based agreements;
- Developing and implementing program integrity safeguards to ensure that all model requirements and applicable Medicare requirements are followed;
- Participating in model activities, including monitoring and evaluation activities;
- Providing support and technical assistance to participant health care providers; and
- Performing other functions and requirements as specified in the model vendor agreement, such as administrative requirements.

4. Model Vendor Payment

Physicians and hospitals would pay the model vendor for distribution costs and would collect beneficiary cost-sharing, including billing supplemental insurers.¹⁵ Informational drug claims would be submitted to the Medicare Administrative Contractor (MAC) along with claims for drug administration.

In addition, similar to how the CAP operated, under the model, vendors would submit claims to Medicare and would be paid an applicable amount for the Part B drug that was administered to an included beneficiary. The model payment amounts to vendors for included drugs would be updated quarterly. The payment amount is described in section III.D. of this ANPRM. Unlike the CAP, under the potential model CMS would not solicit bid amounts for drugs. To the extent it would be legally allowable, vendors' agreements with physicians and hospitals could include provisions for delivery fees and other vendor costs.¹⁶

On a periodic basis, for example quarterly, CMS would ensure that payment to the model vendors for administered drugs is substantiated by the physician and hospital submitted claims.

We seek feedback on other options for model vendor payment, including whether payment should include an administration fee from CMS and whether vendors' agreements with physicians and hospitals could include provisions for delivery fees and other vendor costs.

We are considering whether, given the flexibilities that model vendors and physicians and hospitals would have under the model, the model should include dispute resolution support, and if so, what such support should include.

5. Model Vendor Selection

We intend to operate a competitive selection process to identify the model vendors that would participate in the IPI Model. As we solicit applications for potential model vendors, we would encourage a variety of qualified entities to apply, including new business arrangements that could fulfill the vendor role on a national basis. We intend to select three or more model vendors so that physicians and hospitals have a number of vendors from which to obtain drugs and so that model vendors compete on the basis of

¹⁵ We envision that existing Medicare crossover claims processing steps could be leveraged to support billing supplemental insurers.

¹⁶ We envision that model vendors would compete, in part, for physicians and hospitals based on low fees.

customer service and cost, but solicit comment as to whether three vendors is an appropriate floor. The solicitation for model vendors would specify in more detail the model vendor requirements.

The model vendor solicitation would also specify the selection factors, which may include: The ability to negotiate with manufacturers; the ability to ensure product integrity; The ability to establish a customer service/grievance process; financial performance and solvency; record of integrity and the implementation of internal integrity measures; internal financial controls; maintenance of appropriate licensure to purchase drugs and biologicals; and ability to meet the model vendor agreement requirements within 6 months.

We would refuse to establish a model vendor agreement with an entity for reasons including—

- Exclusion of the entity under section 1128 of the Act from participation in Medicare or other Federal health care programs; or
- Past or present violations or misconduct related to the pricing, marketing, distribution, or handling of drugs covered under the Medicare program.

We would similarly include reasons to terminate a model vendor in the model vendor agreement. In addition, to ensure that selected model vendors would be able to perform their responsibilities under the model vendor agreement without influence from parties that have a financial interest related to included drugs or participating health care providers, we are considering including conflict of interest requirements similar to those established for the CAP in 42 CFR 414.912.

6. Requests for Feedback and Information

We are inviting public comment on the factors that would be necessary to allow CMS to identify entities that would most likely perform the responsibilities of a model vendor efficiently and effectively with minimal start up time.

- We seek information about the types of entities that could serve as national vendors for the model. Should CMS require model vendors to enroll any included health care provider? If included physicians and hospitals could be model vendors, should they be required to be a vendor for other health care providers, and should they have to operate on a national basis? Should any vendor be required to provide services on a national basis?

- We are also interested in public comment on the potential guardrails that would be appropriate if manufacturers and/or health care providers could serve as model vendors. Also should CMS receive shared savings based on the difference between a model vendor's negotiated price and CMS' payment amount? If so, how would CMS operationalize this shared savings approach?

- What should be the potential responsibilities of model vendors and model participants (included physicians, hospitals, and potentially other providers and suppliers) under the model. Specifically, are there ways that vendors and model participants could collaborate to enhance quality and reduce costs?

- What would be the ability of the potential types of entities that could be model vendors to negotiate for drug prices that would be at or below the IPI Model payment? Would certain types of entities have advantages or face additional challenges?

- Are there processes that model vendors could use to increase their price negotiation leverage with manufacturers and lower their potential loss exposure without increasing burdens on beneficiaries, physicians, and hospitals?

- Are there unsurmountable challenges related to physicians and hospitals paying for distribution costs and to continue to collect beneficiary cost-sharing, including billing supplemental insurers?

- Should physicians and hospitals receive bad debt payments if beneficiaries fail to satisfy cost-sharing obligations?

- Is there a need for the model to include billing and dispute resolution support, and if so, what should such support include?

- Should CMS pay the model vendors or should providers pay the model vendors for the responsibilities associated with taking title to drugs and distributing drugs? What incentives are established if CMS pays the model vendors?

- What should be the reasons for excluding entities from serving as a model vendor or terminating a model vendor agreement, as well as appropriate conflict of interest requirements?

- Should the role for the model vendors include entering into value-based payment arrangements (for example, indication-based pricing or outcomes-based agreements)? And if so, should there be requirements around these arrangements?

B. Model Participants, Compensation and Selected Geographic Areas

1. Model Participants

IPI Model participants would include all 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.

We intend to provide a more comprehensive list of health care providers included under the model if a proposed rulemaking moves forward.

For purposes of the potential IPI Model, beneficiaries would be included in the model if they are furnished any of the included drugs by a model participant in one of the selected geographic areas. More specifically, the following beneficiary eligibility criteria would be used based on the date that the included drug was furnished—

- The beneficiary is enrolled in Medicare Part B;
- The beneficiary is not enrolled in any group health plan or United Mine Workers of America health plan;¹⁷ and
- Medicare FFS is the primary payer.

Medicare FFS beneficiaries who are not eligible for inclusion in the model would continue to receive drugs that were obtained by their health care provider using the buy and bill approach.

Under the IPI Model, model participants in the selected geographic areas would have to enroll with at least one model vendor and obtain included drugs from a model vendor for administration to included Medicare FFS beneficiaries. Model participants would have to follow model-specific billing instructions to submit informational drug claims and the model add-on payment. To reduce beneficiary impact, model participants would continue to collect beneficiary cost-sharing. We are considering ways to ensure the reconciling of beneficiary cost-sharing that model participants

¹⁷ The United Mine Workers of America Health and Retirement Funds ("The Funds") is a Medicare Health Care Prepayment Plan (HCPP) and is the Medicare payer for non-facility Part B services. As such, providers bill the Funds for Medicare Part B services. The Funds' payment to the provider includes the Medicare amount plus the Medicare coinsurance and deductible amount, making it unnecessary for the provider to submit claims to two payers.

would be collecting. An administrative approach that deducts the cost-sharing amounts from Medicare payments made for other services to the model participants could be feasible and would be less disruptive for beneficiaries.

2. Model Geographic Areas

The model would require the participation of physician practices and HOPDs (and potentially other providers and suppliers) in selected geographic areas across the U.S. and its territories, which would allow the Innovation Center to gain experience and insight into using an alternative payment methodology for drugs included in the model. We anticipate the selected geographic areas would include 50 percent of Medicare Part B spending on separately payable Part B drugs. The mandatory participation of physician practices and HOPDs (and potentially other health care providers that furnish included drugs) in the selected geographic areas would avoid having expected financial performance in the model influence the physician practice/HOPD's decision to participate or not. It also would ensure we capture the experiences of various types of physician practices and HOPDs in different geographic areas with varying characteristics and historic utilization patterns.

For the IPI Model, we are considering a randomized design with the randomization to intervention and comparison groups occurring at the geographic unit of analysis. There are two main factors that need to be considered when selecting geographies for the model: (1) The most appropriate geographic unit (ZIP code, county, core based statistical area, state, etc.) that reflects how care is delivered in markets, and (2) the geographic scope of the model, or the number of geographic units needed to generate statistically credible findings. Typically, the more geographic units available for random assignment to the model's intervention and comparison groups the better.

However, there is a tradeoff between the size of the geographic unit and the number of units available for assignment. We are considering using CBSAs (Core Based Statistical Areas) as the primary unit of analysis in the model. CMS is further considering whether it would be necessary to use larger geographic units such as aggregations of CBSAs (metropolitan statistical areas or combined statistical areas) to avoid the potential for routine shifts in the site of care to a practice location with a different assignment under the model. Geographic areas

located outside CBSAs would not be included in the randomization to intervention or comparison groups. Health care providers outside of the randomized geographies could potentially have the opportunity to opt into the model. However, health care providers that are not part of the randomized treatment and control groups, but that opt into the model, would not be included in the evaluation sample.

3. Potential Drug Add-on Payment

Medicare Part B covers drugs administered by physicians in physician offices and hospital outpatient departments and certain drugs in other settings. In addition to payment for drug administration, Medicare Part B typically pays for separately payable Part B drugs at the average sales price (ASP) of a given drug, plus 6 percent of the ASP as an add-on (with sequestration, the actual payment allowance is ASP + 4.3 percent). This add-on payment can help to cover the costs of drug ordering, storage and handling borne by physicians and hospitals, payments to join group purchasing organizations (GPOs) or other entities with similar purchasing arrangements, as well as a portion of the drug costs themselves, in instances when the drug is acquired at a price more than ASP. However, the drug add-on payment may encourage increased utilization, particularly of higher-cost drugs, since doing so increases revenue for the physician or hospital when the add-on is higher than drug acquisition-related costs.

This section describes our thinking on alternative methods for making the drug add-on payment a set payment amount rather than as a percentage of ASP. We intend to structure the potential IPI model such that physicians and hospitals would be incentivized to seek out lower cost drugs for their beneficiaries, reduce inappropriate utilization, continue to pay for certain distribution costs, continue to bill Medicare for drug administration, albeit following model-specific instructions, and continue to collect beneficiary cost-sharing for included drugs. 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. We have considered several different structures for the set payment amount.

a. Potential Alternative to the ASP Add-On

CMS would base payment calculations for the alternative compensation on six percent (+6 percent) of the included Part B drugs' ASP, which would represent an increase from the +4.3 percent add-on that currently is paid due to sequestration, and would support appropriate drug utilization under the model structure. That is, in total the alternative compensation for model participants would approximate the expected add-on amount for included drugs in the absence of the model, before sequestration. Because the alternative compensation would not be paid in a manner that is tied directly to the ASP of an administered drug, there would not be an incentive for use of higher cost drugs when an alternative is available. As described in section III.D. of this ANPRM, Medicare payment for the drugs themselves would be to the model vendors; model participants would no longer "buy and bill" Medicare for included Part B drugs administered to included beneficiaries. Payment for drug administration services, when applicable, would continue to be separately billed by model participants to Medicare; there would be no change in the payment for drug administration services under the model. Beneficiary cost-sharing would apply to the model-specific alternative compensation payments and for model payments for included drugs.

b. Description of Alternative Add-on Payment Amount

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. We are considering whether to set a unique payment amount for each class of drugs, physician specialty, or physician practice (or hospital). That is, there would be a set payment amount per administered drug that would be based on—(1) which class of drugs the administered drug belongs to; (2) the physician's specialty; or (3) the physician's practice. If used, specialties would likely be defined broadly rather than at a subspecialty level (for example, ophthalmology rather than neuro-ophthalmology) given the difficulty of doing this through claims data, although CMS may identify an alternative approach. We would calculate the final payment amount, by drug class, physician specialty, or physician practice, annually based on

the +6 percent of ASP revenue that model participants would have garnered without sequestration in the most recent year of claims data.

Total model payments to a model participant would vary based on utilization under an encounter-based model. To incentivize reduced utilization where appropriate, CMS is considering creating a bonus pool, where model participants would achieve bonus payments for prescribing lower-cost drugs or practicing evidence-based utilization. Importantly, as described in section III.F.3. of this ANPRM, we would monitor drug utilization carefully throughout the model to ensure beneficiary access to drugs is not compromised.

4. Requests for Feedback and Information

We welcome input from stakeholders on the potential approach for defining model participants, selecting geographic areas, and calculating an alternative to the ASP add-on for the IPI Model. Specifically, we would like to receive information on which alternative add-on option is preferable and how the specific payment methodology might be designed. For example:

- The exclusion of certain types of physician practices and/or HOPDs from the model. For example, should we consider excluding small physician practices/HOPDs (for example, those with 3 or fewer physicians) from the model or establish a low-volume threshold that would exclude those physician practices and HOPDs that fall below the threshold from participating in the model? How could CMS analyze an appropriate threshold?

- The inclusion of additional Part B providers and suppliers that furnish and bill for any of the model's included drugs as well as the inclusion of providers that are paid on a cost basis, such as PPS-exempt cancer hospitals, children's hospitals, or critical access hospitals.

- The potential approach to selecting geographic areas for the intervention and comparison groups in the model. Are there particular regions of the country that would need adjustments or exclusions from the model (for example, rural areas)?

- How should we operationalize the model for large provider networks that cover some regions that are included and some that are excluded?

- Should class of drugs, physician specialty, or physician practice determine the payment amount? Are there other characteristics that should determine the alternative add-on payment amount?

- How should a per month alternative add-on payment be determined? How and how often should a beneficiary panel size be determined?

- The potential inclusion of a bonus pool. Should a bonus pool be included in the model? If so, how should the model participant bonus pool be constructed to meet the goals of the model to incentivize the use of lower-cost drugs and clinically appropriate utilization? How could a bonus pool be constructed to best protect and enhance quality under the model? How should CMS handle variable low-volume estimates and missing data values when assessing performance for purposes of a bonus pool?

- The potential phase in of an alternate provider compensation. Should CMS phase in a change from percentage-based add-on payments to set payment amounts, or should set payment amounts be implemented in Year 1 of the potential IPI Model?

- How should CMS implement an administrative process to account for beneficiary cost-sharing for drugs that is collected by model participants?

C. Included Drugs

1. Background

The Part B drug benefit includes many types of drugs and encompasses a variety of care settings and payment methodologies. Of the approximately \$28 billion per year of FFS Part B drug spending in 2016, about \$23.6 billion or 84 percent, is for drugs administered incident to a physician's services. Among the "incident to" drugs, over 90 percent of spending is for single source drugs and biologicals (including biosimilars) as defined in section 1847A of the Act.¹⁸ We plan to begin the model with these two broad groups of drugs both because they encompass most of the Part B spending, and as a result of their status as drugs with a single manufacturer, they allow for a more straightforward comparison to an international pricing metric. Examples of included drugs would be 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, we also would include HCPCS codes that contain only products with a single manufacturer, even if they are

multiple source drugs as defined in section 1847A of the Act.

2. Potential Included Drugs

In Years 1 and 2 of the potential IPI Model, we would include single source drugs, biologicals, biosimilars, and multiple source drugs with a single manufacturer that we identify from what we believe are reliable sources of international pricing data, prior to direct data collection, as discussed in section III.D. of this ANPRM. In Years 3, 4 and 5, we 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, and we are considering further increasing the number of Part B drugs included in the model as discussed later in this section. We would begin with these two broad groups of drugs—single source drugs and biologicals—as they encompass most drugs used by most physician specialties that bill under Part B. At a minimum, we believe that we could begin the model by including most of the HCPCS codes that appear in the recent HHS report;¹⁹ these drugs represent over 50 percent of Part B drug allowed charges in 2017. As we consider including more drugs over time, we would prioritize single source drugs and biologicals. We are also considering including HCPCS codes for drugs and biologicals that are clinically comparable, but not interchangeable, to those initially included in the model, particularly drugs and biologicals (including biosimilars) used incident to a physician's services, for example adding additional biologicals use to treat rheumatoid arthritis and other inflammatory diseases, including biosimilars if they are marketed.

The OPSS packages certain drugs with costs below a certain threshold and for policy reasons. This model would only include drugs that are separately paid under the OPSS, including drugs on pass-through payment status, and for which the drug's HCPCS code is assigned a distinct Ambulatory Payment Classification (APC) group for use when the drug is furnished in a HOPD. The model would include any separately payable drug or biological furnished in an HOPD, including any of the HOPD's off-campus provider-based departments (PBDs), regardless of whether those PBDs are excepted or nonexcepted under section 1833(t)(21)(B)(ii) of the

¹⁸ Office of Enterprise Data and Analytics analysis of CMS, Chronic Conditions Data Warehouse, a database with 100 percent of Medicare enrollment and fee-for-service claims data, available at: <http://cwdata.org/>.

¹⁹ "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>.

Act, as added by section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74).

For purposes of included drugs, we would remove any HCPCS codes that become inactive if they are not replaced by a successor code, and we would not include HCPCS codes for which a product becomes unavailable. If pricing data were available for other heavily utilized incident to drugs, we would consider adding them to the model.

Over the course of the model, we seek to include HCPCS codes that encompass at least 75 percent of allowed charges in Part B. We note that HCPCS codes for products that are used across multiple settings, such as clotting factors or immunoglobulin G, would be included based on overall Part B use, but the model would only include those drugs when they are administered incident to a physician’s service.

In addition, we are considering including multiple source drugs and drugs provided in other settings. Specifically, we are considering including multiple source drugs because

we are concerned that price increases among generic drugs are also contributing to the rising payments for Part B drugs. Increasing the number of drugs included in the model over time could also be accomplished by setting; however, drug acquisition and billing within Part B settings outside of the physician office and outpatient hospital may not be conducive to a CAP vendor-like approach.

We are also considering the best ways to include newly approved and marketed drugs in the model. We anticipate that international pricing data for some but not all of these drugs would be available. We include a discussion of the potential alternatives for payments for new therapies in section III.D.5. of this ANPRM.

We anticipate that newly effective HCPCS codes could be added to the model on a quarterly or annual basis. Based on experiences with the CAP, we are concerned about issues such as the lag time resulting from the provider having to obtain drugs from regular channels before the drug is available

from the vendor, the lead time for the development of vendors’ acquisition arrangements, and the potential unavailability of pricing benchmarks for new drugs immediately after a drug is marketed.

Although we are not currently able to estimate exactly what the distribution of drugs over the course of the model may look like, Table 1 presents the percentage of the total allowed Part B charges for 2017 for Part B drugs. Table 1 lists the percentage of the total spending for the following two groups of HCPCS codes: The top 50 drugs by allowed charges in the office and hospital outpatient departments for 2017 and the top 100 such drugs. Spending for biologicals (including biosimilars), single source drugs, multiple source drugs and potentially excluded drugs within each of the three groups is also shown. We believe that this information is a reasonable preliminary estimate of the potential scope of this model and its possible incorporation of additional Part B drugs during the 5-year model duration.

TABLE 1—GROUPS OF DRUGS AS A PERCENTAGE OF TOTAL PART B SPENDING

Number of drugs	Percentage of total allowed charges	Biologicals: percentage of total allowed charges	Single source drugs: ²⁰ percentage of total allowed charges	Multiple source drugs: percentage of total allowed charges	Potential excluded drugs: percentage of total allowed charges
Top 50 Drugs	81	65	12	0 – <1	4
Top 100 Drugs	94	73	15	1	6

The potential inclusion of a large subset of Part B drugs should not be interpreted to mean model participants would be required to obtain all products that are subject to inclusion from a specific model vendor. We would anticipate several model vendors to be available and that model participants could enroll with one or more model vendors.

3. Potential Excluded Drugs

We are considering excluding the following: drugs that are identified by the FDA to be in short supply (similar to the exclusion from the AMP price substitution policy for drugs in short supply (77 FR 69141)); and drugs paid under miscellaneous or “not otherwise classified” (NOC) codes, such as J3490, due to the operational complexity of identifying if drugs paid under the NOC codes are included model drugs. Thus, compounded drugs would be excluded from the model. We also plan to exclude radiopharmaceuticals and ESRD drugs

paid under the authority in section 1881 of the Act. Finally, we also would exclude drugs that are packaged under the OPDS when they are furnished by a hospital outpatient department. If these drugs met other criteria, they would be included in the model when furnished by physician offices.

4. Requests for Feedback and Information

We are seeking information on the following:

- Whether the data that CMS uses to determine the inclusion of drugs and biologicals should be limited to claims from the physician’s office and hospital outpatient department settings, or whether other settings should be included.
- The drugs to include in the model. Specifically, we are seeking information on 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 the perspective of potential model participants and vendors are especially encouraged.

- The 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 use (if supported by clinical guidelines and/or compendia).

We seek comment as to whether aspects of mandatory participation would require physicians and hospitals to have an agreement with a single vendor or would require physicians and hospitals to obtain all drugs included in the model via a single vendor.

D. Model Payment Methodology for Vendor Supplied Drugs

1. Calculating the Model’s Medicare Part B Drug Payment

The Medicare payment for separately payable Part B drugs is typically based on ASP of a given Part B drug, plus 6 percent of the ASP as an add-on payment. For the potential IPI Model,

²⁰Excluding biologicals.

CMS is considering testing an alternative payment for included drugs based on the international pricing, except where the ASP is lower. CMS would calculate the model payment to model vendors for included drugs through a multi-step process. Given current estimates of the differential between U.S. and international pricing, the model payment may be close to parity with international comparators. Additionally, Manufacturer sales through the IPI model would be included in current ASP reporting.

The potential calculation steps would include the following:

- 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. In order to do this calculation, CMS would multiply 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 International Price Index (IPI).
- CMS would also establish the model Target Price for each drug by multiplying the IPI by a factor that achieves the model goal of more closely aligning Medicare payment with international prices, which would be about a 30 percent reduction in Medicare spending for included Part B drugs over time, 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. The percentage reduction between ASP and Target Price would vary for each drug. We would monitor price changes and recalibrate as needed.
- CMS would phase-in the Target Price over the 5 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, the model would set the payment amount to ASP for that drug.

The potential phase-in would use the following blend of ASP and Target Price:

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.

• As with current Part B drug payments, we would plan to update the model payment amount for each drug periodically based on new ASP and international pricing data.

2. Data Sources on International Drug Sales

CMS is considering including collection of international drug sales data for purposes of the IPI Model. In the interim, before these data could be available, CMS is considering relying on existing data sources for calculating the model payment to model vendors for included drugs.

a. Existing Data Sources

CMS has evaluated several existing data sources to determine the availability of international drug price information. Based on our review, we believe there are appropriate sources that could be used for purposes of the potential IPI Model. These data sets include those provided by private companies or data obtained through review of publicly filed materials by manufacturers in other countries. Examples may include IQVIA's MIDAS dataset, the dataset used in the recent HHS analysis.²¹ Alternatively, CMS can try to construct price comparisons from public sources from each country. One example of a public source is the UK's Drug Tariff, which lists the National Health Service (NHS) reimbursement rates for prescription drugs.²² We believe that existing data sources may include all the information necessary to calculate the IPI and Target Prices. We are interested in better understanding the extent to which existing data sources for international sales completely capture drug information in every international market that we are considering for inclusion in our payment methodology and how private market drug sales are included in

²¹ "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>.

²² See <https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff>.

countries that provide drugs through public insurance.

b. CMS Data Collection

We are considering including a data collection system for manufacturers to report to CMS their international drug sales data to support the calculation of the IPI and the Target Price for each drug. We acknowledge that manufacturers have numerous and varying arrangements in other countries as well as in the U.S., so we are considering how we would determine the definition of manufacturer to ensure that U.S. manufacturers would robustly report this information to CMS. Under the Medicaid Drug Rebate Program in section 1927 of the Act, manufacturers are required to provide information to CMS on a quarterly basis to support the ASP calculations (as well as to support calculations for WAC and AMP²³) for Part B drugs. Using the same framework, for the purposes of the potential IPI Model, we could require manufacturers to provide international drug sales data for prices and units sold.

We envision that we would require quarterly reporting on the international sales information and CMS would provide reporting instructions. The instructions would include information such as instructions for the unit level at which the manufacturer would report the sales information, which countries to include and how to account for the exchange rate, and use of reasonable assumptions. We anticipate that the units of measure for the international drug sales data would be the same as the units in a corresponding drug product's HCPCS code. For example, products reported in milligrams of drug in the U.S. would be reported in milligrams, and products reported in international units of biological activity would be reported in the same units of corresponding biological activity.

We acknowledge that this potential approach could create situations where very large numbers of units would be reported, and we seek information on alternative units of measure to consider. We recognize that it would take some time to establish the infrastructure and reporting instructions to collect and validate international sales information directly from manufacturers for purposes of a model. In light of this, we are considering whether existing data sources could be used to establish the IPI and Target Price in the short term and transition to using manufacturer reported data when available. We seek comment on the potential use of

²³ WAC means wholesaler acquisition cost and AMP means average manufacturer price.

existing data sources and new data sources to establish the IPI and the Target Price.

3. Frequency of Data and Model Payment Updates

We are considering examining the IPI and model payments on a quarterly basis, on the same schedule and using the same quarterly sales period duration as ASP data. We believe that we could use quarterly updates of existing data sources in the short term while we set up the infrastructure to collect and validate international drug sales information from the manufacturers on a quarterly basis (the data would be reported to CMS within 30 days of the close of the quarter). We seek comment on whether to examine the international pricing data, and recalculate the IPI and Target Prices on a quarterly, annual or other basis. We also seek feedback on the mechanism for reporting of international sales, and on any additional requirements that would be needed to ensure a feasible process to collect valid international sales information for the countries that would be included in the IPI, as discussed in the following section of this ANPRM. We also seek comment on ways to ensure confidentiality of reporting of international drug pricing to CMS.

4. Potential Included Countries

We are considering using pricing data from the following countries: Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Netherlands, and the United Kingdom.

We are considering including these countries as they are either economies comparable to the United States or they are included in Germany's market basket for reference pricing for their drug prices, and existing data sources contain pricing information for these countries. Some of the countries above have far lower per-capita incomes than the U.S. However, these countries were not consistently the lowest-priced countries according to the HHS analysis.²⁴ We seek comment on the countries included in our analysis to establish the IPI, Target Price, and model payment amounts.

5. Establishing Model Payments for New Drugs Entering the Market

For newly approved and marketed Part B drugs that would be included in the model, there could be some time lag

or other issues associated with capturing international sales information. In the absence of international pricing data, CMS could still calculate a model payment amount by applying a standard factor. CMS could, for example, assume the same ratio for the new drug as the IPI, which would be the average volume-weighted payment amount across all Part B drugs included in the model. We seek comment on options for calculating the model payment for new drugs that may not yet have international sales.

6. Requests for Feedback and Information

We welcome input from stakeholders on the potential approach for establishing model payments for included drugs based on international pricing. For example:

- What sources of international pricing data capture drug information for the international markets that should be included in our payment methodology?
- Are there particular data sources to establish payment amounts based on international pricing that would best support this effort?
- How should private market drug sales included in countries that provide drugs through public insurance be included? How should CMS protect manufacturer reported international pricing information?
- What is the appropriate frequency for updating the international pricing information that we use in calculating the Part B payment under the model?
- How should manufacturers report international pricing information? Are there specific issues with data reporting processes that stakeholders would like the agency to consider, especially mechanisms that could reduce burden?
- How should we define manufacturer to ensure that all relevant entities that sell single source drug products, biologics, biosimilars and, if applicable, multiple source drugs report under the model?
- Are there areas of concern in data collection and reporting that could lead to inaccurate price calculations?
- Which countries should be included in our international price index calculations? Should the countries vary? What characteristics should CMS consider to analyze these countries?
- Are there specific considerations in the comparison of international and ASP prices that CMS should address?
- How should CMS standardize data collection and reporting? What should be the target reduction to ASP payment (that is, Target Price), and what should

be the schedule for phasing down to the target savings amount?

- How would such a change in payment policy, as described in this section, affect incentives in the market? How could using international reference pricing affect innovation incentives in the biopharmaceutical market?

E. Potential Foreign Market Considerations

Using international sales data in the potential IPI Model could raise considerations for drug prices, drug availability, and sales data in foreign markets. For example, manufacturers may seek to raise prices or limit foreign sales. However, existing, multiyear pricing relationships in foreign markets may minimize this response. There are also potential model implications in considering manufacturers' responses in foreign markets. For example, there may be a decrease or lack of international sales to serve as inputs to the model's IPI calculation, if manufacturers withdraw or do not launch included drugs in foreign markets. Similarly, manufacturers may also adjust their product launch strategies within the U.S.

Requests for feedback and information:

- CMS welcomes input from stakeholders on the potential considerations related to foreign markets and the potential model payment approach that would rely on international sales data. For example the following:
 - What foreign market considerations should CMS consider in developing the potential IPI Model?
 - How should CMS monitor for changes in foreign markets that could impact the IPI Model?
 - What are ways to address changes in foreign sales that could impact model payment calculations?

F. Beneficiary Impact and Model Monitoring

In addition to existing beneficiary protections, we would plan to actively monitor the IPI Model test to ensure it is operating effectively and meeting the needs of beneficiaries, health care providers, and the Medicare program.

1. Impact on Beneficiary Cost-Sharing

We would expect beneficiary cost-sharing for included drugs under the potential IPI Model would either be the same or lower than the non-model cost-sharing. Medicare payment policy for beneficiary cost-sharing would remain the same but since the IPI Model should reduce Medicare payment for some Part B drugs, the 20 percent beneficiary

²⁴ "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>.

coinsurance would be similarly proportionately reduced. For those beneficiaries dually eligible for Medicare and Medicaid, the coinsurance paid for by the beneficiary or state would similarly be reduced. If the Part B payment remains unchanged under the IPI Model, for example, for those drugs where Medicare payment is similar to international prices, cost-sharing would remain the same.

To minimize impact on beneficiaries, their health care provider would continue to collect cost-sharing for included drugs.

2. Medicare Ombudsman

We plan to coordinate with the Medicare Beneficiary Ombudsman to ensure that any Model-related beneficiary complaints, grievances, or requests for information submitted would be responded to in a timely manner.

3. Monitoring

Consistent with other Innovation Center Models, we would also implement a monitoring program for the IPI Model to ensure the model is meeting the needs of Medicare beneficiaries, health care providers and the Medicare program. These monitoring activities would enable CMS to access timely information about the effects of the Model on beneficiaries, providers, suppliers, and on the Medicare program and to facilitate real time identification and response to potential issues. We envision using Medicare claims and other available program data to analyze and monitor the Model's implementation, including actively looking at real-time data to identify potential impacts on beneficiaries, health care providers, model vendors, and the Medicare program. We would use these findings to inform Model oversight and the potential need for action to address findings.

As an example, CMS may conduct real-time analyses of claims and administrative data, such as monthly updates and historic comparisons of trends, including ensuring appropriate drug utilization and program spending, as well as changes in site-of-service delivery, mortality, hospital admissions, and other indicators present in claims and administrative data to identify any potential issues related to access and utilization. CMS would also consider how to best understand beneficiary experience in the model. We would consider surveys but would also be interested in other potential strategies to include beneficiary experience in our monitoring activities.

We are inviting public feedback on the appropriate beneficiary outcomes to monitor and how to monitor and measure such outcomes, as well as patient experience, in a way that minimizes burden on included health care providers and beneficiaries.

G. Interaction With Other Models

In designing each Innovation Center model, CMS considers potential overlap between a new model and other ongoing and potential models and programs. Based on the type of overlap, such as provider or beneficiary, operating rules are established for whether or not providers and beneficiaries can be part of both models as well as how to handle overlap when it is allowed to occur. These policies help to ensure that the evaluation of model impact is not compromised by issues of model overlap and that the calculation of Medicare savings is not overestimated due to double counting of beneficiaries and dollars across different models. In this vein, CMS has begun to review which models would have significant overlap with the potential IPI Model. One example is the Oncology Care Model (OCM) which runs through mid-2021. The OCM would require new policies that address model overlap due to the potential inclusion of some of OCM's initiating cancer therapies in the IPI Model and the probable overlap of some geographic areas with OCM practices included in the IPI Model. The IPI Model would potentially overlap with other Innovation Center models that operate in the same geographic areas and include Part B drug spending in the calculation of model payments, incentive payments or shared savings, and the Medicare Shared Savings Programs. We plan to carefully explore these potential overlaps and consider ways address overlap issues as we further develop the IPI Model.

H. Interaction With Other Federal Programs

With respect to single source or innovator multiple source drugs (which Medicaid recognizes to include biologics and biosimilars), the term "Medicaid Best Price" is the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, non-profit entity or governmental entity within the U.S. with certain exclusions. We seek comment on how to avoid unintended consequences on the interaction of the IPI Model with other federal programs.

1. Impact on "Best Price"

Since the model payments to model vendors for drugs is a Medicare payment and it is not a "price available from the manufacturer," the model payment amounts would not be included in the manufacturer's determination of best price. However, since the model payment amounts would drive manufacturer drug prices down, the model may impact a manufacturer's best price. In order for model vendors to purchase included drugs in the U.S. at prices that would not lead to financial loss, the prices available from the manufacturer would need to be competitive with the model payments. Therefore, such manufacturer sales to the model vendors could potentially lower best price and potentially increase Medicaid rebates. Medicaid programs could benefit.

Specifically, if the manufacturer lowers prices available to a model vendor at or below the model payment rate, such prices would be considered in the manufacturer's determination of best price and may reset the manufacturer's best price. This is particularly possible because the model payment amount includes the impact of sales outside of the U.S., which are typically lower than prices in the U.S., while a manufacturer's best price represents prices available only to purchasers in the U.S. We seek public comments on how manufacturers would respond to these factors as they relate to model vendors and Medicaid drug rebates.

2. Impact on Average Manufacturer Price (AMP)

Similarly, the model payment amounts to model vendors would not be part of the AMP determination. AMP is defined at section 1927(k)(1) of the Act. Generally, AMP is determined based on the average price paid to the manufacturer for a drug in the U.S. by wholesalers and retail community pharmacies with certain exclusions. The AMP for a Part B drug will likely be determined using the AMP computation for 5i drugs,²⁵ which would include sales that are not generally dispensed through retail community pharmacies (see 42 CFR 447.504(d)), such as sales to physicians, pharmacy benefit managers (PBMs) and hospitals. In this case, it is likely the manufacturer's sale to a model vendor (or price paid) that would be included in the AMP or 5i AMP and due to the downstream effects of the model payment approach, may lower AMP. If the AMP is lower, it may result in potentially lowering the Medicaid drug

²⁵ Inhalation, infusion, instilled, implanted or injectable drugs.

rebate paid to states (the rebate, in part, is based on a percentage of AMP), although the rebate would also be affected because “best price” may be lower as described above.

We continue to consider how the model may impact the Medicaid program. Authority for implementing innovative payment and quality models under 1115A of the Act does not completely include Title XIX waiver authority, and thus, such waiver authority does not extend to the Medicaid Drug Rebate Program, which is authorized under Title XIX at section 1927 of the Act. We welcome public feedback, including from State Medicaid programs, on this issue.

3. Interaction With 340B Program

The Health Resources and Services Administration (HRSA) administers the 340B Drug Pricing Program that allows certain hospitals and other health care providers (“covered entities”) to obtain discounted prices on “covered outpatient drugs” (as defined at 1927(k)(2) of the Act) from drug manufacturers. HRSA calculates a 340B ceiling price for each covered outpatient drug, which represents the maximum price a manufacturer can charge a covered entity for the drug. Several types of hospitals as well as clinics that receive certain federal grants from the HHS may enroll in the 340B program as covered entities. Such entities located in the selected model geographic areas would be included in the IPI Model and would be supplied included drugs for included beneficiaries through a model vendor.

4. Impact on 340B Ceiling Price

Covered entities that enroll in the 340B Program can purchase drugs at no more than a “ceiling price”, which are calculated based on a drug’s AMP net the Medicaid unit rebate amount. Since the Medicaid unit rebate amount is based partly on AMP minus best price, to the extent the potential model affects a drug’s AMP and best price, the 340B prices would be affected.

I. Quality Measures

Congress created the Innovation Center for the purpose of testing innovative payment and service delivery models that are expected to reduce program expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. In the IPI Model, we are considering collecting quality measures to help us better understand the impact of this model on beneficiary access and quality of care. We intend to identify quality measures to be collected as part of this model that

reflect national priorities for quality improvement and patient-centered care consistent with the measures described in section 1890(b)(7)(B) of the Act, to the extent feasible. To this end, we are interested in several categories of measures, specifically: patient experience measures, medication management measures, medication adherence, and measures related to access and utilization.

We are sensitive to concerns regarding adding administrative burden to model participants. Some models (for example, the Bundled Payments for Care Improvement Advanced Model) are currently structured to include quality measures that are calculated directly by CMS or collected during the evaluation and do not require the submission of additional data by providers and suppliers. We are considering following this approach, to the extent feasible, and 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.

We seek 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. We welcome recommendations for specific measures.

J. Legal Considerations and Potential Waivers of Medicare Program Requirements for Purposes of Testing the Model

We plan to test the potential IPI Model under the authority of section 1115A of the Act and to waive certain Medicare program requirements as necessary solely for purposes of testing the potential model. Under section 1115A(d)(1) of the Act, the Secretary of Health and Human Services may waive the requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii), and 1934 of the Act (other than subsections (b)(1)(A) and (c)(5) of such section) as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act.

We plan to waive requirements of the following provisions as may be necessary solely for purposes of testing the Model. The purpose of this flexibility would be to allow Medicare to test approaches described in the “Model Payment Methodology” section, with the goal of reducing Medicare expenditures while improving or

maintaining the quality of beneficiaries’ care as we implement and test this potential model.

- Section 1833(t) of the Act and 42 CFR 419.64 related to Medicare payment amounts for drugs and biologicals under the OPPS as necessary to permit testing of a modified payment amount for included drugs using the pricing approaches described in this section;

- Section 1847A of the Act and 42 CFR 414.904 and 414.802 related to use of ASP+6 percent and WAC as necessary to permit testing of a modified payment using the pricing approaches described in this paper.

- Section 1847B of the Act and 42 CFR 414.906 through 414.920 related to the Medicare Part B Drug Competitive Acquisition Program (CAP) requirements as necessary to permit testing using a CAP-like approach for the acquisition of included therapies through vendor-administered payment arrangements.

- Other requirements under title XVIII of the Act as may be necessary solely to test separate payment for included therapies furnished to included beneficiaries by participant health care providers not paid under the outpatient prospective payment system or section 1847A of the Act.

K. Model Termination

CMS may terminate the potential IPI Model for reasons including, but not limited to, the following: CMS determines that it no longer has the funds to support the Model; or CMS terminates the Model in accordance with section 1115A(b)(3)(B) of the Act.

L. Model Evaluation

Models operated under section 1115A of the Act are required to have an evaluation that must include an analysis of the quality of care furnished under the model and the changes in spending by reason of the model. The evaluation of the model would help inform the Secretary and policymakers whether this model, as designed, reduces program expenditures while maintaining or improving the quality of care furnished to Medicare beneficiaries.

Whenever feasible, a comparison group composed of entities similar to the model participants but not exposed to the model is used to determine the model impact. In this particular potential model, intervention and comparison groups would be determined through a random selection or assignment process. A randomized design helps minimize the impact of unmeasurable factors that may

contribute to providers' and suppliers' likelihood to participate in the model. Our inability to control for these unobserved differences could lead to biased or incorrect estimates in the evaluation of the model's impact on quality of care and spending. We note that to the extent that model sales affect the overall ASP calculation, we may experience evaluation challenges with the comparison group geographic areas not selected for the model.

We seek input on the evaluation approach to examine the IPI Model's impact on Medicare spending and quality of care including potential alternatives.

M. Potential Impacts of Implementing the IPI Model

1. Financial Impacts

This section outlines the potential financial impact of implementing the potential IPI Model on federal Medicare and Medicaid spending. There are many uncertainties around estimating the financial effects of this model. In addition to the various policy parameters that are either currently unspecified or subject to change throughout the policy development process, the expected change in beneficiary, provider, vendor, and manufacturer behavior would significantly affect the financial impact of the model. The current analysis of this model reflects many generalized assumptions that are likely to change pending further policy development and

additional analysis. As such, the estimates shown below should be considered an approximate measure of the potential savings of the potential model, and subsequent analyses would likely be materially different from those shown below as additional information becomes available.

a. Medicare and Dual Medicare-Medicaid Impacts

The following table presents the potential financial impact of the model. For 2020–25, federal Medicare spending is estimated to be reduced by \$16.3 billion and Medicaid spending for Medicare-Medicaid dual beneficiaries is expected to be reduced by \$1.6 billion, of which \$0.9 billion is reduced federal spending and \$0.7 billion is reduced State spending.

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

Note the following:

- No changes in utilization are assumed in this analysis.
- Medicare Advantage spending would be reduced proportionately to the reduction in FFS spending.
- Included drugs would represent 61 percent of Part B allowed drug spending in years 1 and 2, 81 percent of Part B allowed drug spending in years 3 and 4, and 94 percent of allowed drug spending in year 5.
- The Medicaid impact represents the portion of Medicare cost-sharing that is paid on behalf of dual beneficiaries. It is estimated based on the change in Medicare cost-sharing and current dual beneficiary enrollment. No assumptions are made for State price limitations that would limit the beneficiary cost-sharing paid for by Medicaid.
- Effects on private market cannot be estimated at this time and are not reflected in this analysis.

b. Medicaid Impacts

Based on a review of the Part B drugs that constituted the majority of Part B drug spending in 2017, as well as the top reported Medicaid drugs that were also covered by Part B, the affected drugs reimbursed by Medicaid spending totaled at least \$4 billion in 2017, or an estimated 6 percent of gross Medicaid drug spending. The model may impact AMP, ASP, best price, and 340B pricing for these affected drugs, reducing both reimbursements as well as rebates. CMS would seek comment on whether we should exempt prices offered under the model from AMP and Best Price calculations.

2. Potential Impacts on Medicare Providers and Suppliers Participating in the Potential IPI Model

The potential IPI Model would affect a significant number of health care providers that would furnish included drugs to included Medicare beneficiaries. The effect of the model on individual hospitals, physicians, practitioners, and other providers and suppliers would depend on individual practice patterns and the drugs that would be selected for inclusion.

IV. Collection of Information Requirements

This ANPRM is a general solicitation of comments on several options pertaining to the potential IPI Model and thereby not subject to OMB review as stated in the implementing regulations of the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 *et seq.*) at 5 CFR 1320.3(h)(4). Should the outcome of the ANPRM result in any information collection requirements or

burden that are not covered under the provisions in section 1115A(d)(3) of the Act²⁶ or otherwise covered under a PRA exemption, a detailed discussion of the requirements and burden will be submitted to OMB for approval. In accordance with the implementing regulations of the PRA at 5 CFR 1320.11, interested parties will also be provided an opportunity to comment on such information through subsequent proposed and final rulemaking documents.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will review all comments we receive by the date and time specified in the **DATES** section of this preamble, as we continue to consider the model presented in this ANPRM.

In accordance with the provisions of Executive Order 12866, this ANPRM was reviewed by the Office of Management and Budget.

Dated: October 25, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 25, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018–23688 Filed 10–25–18; 4:15 pm]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R1–ES–2007–0024; FXES1113090000C6–189–FF09E42000]

RIN 1018–AU96

Endangered and Threatened Wildlife and Plants; Removing the Hawaiian Hawk from the Federal List of Endangered and Threatened Wildlife

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; document availability and reopening of comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the

²⁶ As stated in section 1115A(d)(3) of the Act, Chapter 35 of title 44, U.S.C., shall not apply to the testing and evaluation of models under section 1115A of the Act

reopening of the public comment period on the August 6, 2008, proposed rule to remove the Hawaiian hawk or io (*Buteo solitarius*) from the List of Endangered and Threatened Wildlife (List) under the Endangered Species Act of 1973, as amended (Act). Comments submitted during the 2008 comment period, 2009 reopened comment periods, and 2014 reopened comment period do not need to be resubmitted, and will be fully considered in preparation of our final rule. We are reopening the comment period once more to present information we have received since 2014 that is relevant to our consideration of the status of the Hawaiian hawk. We encourage those who may have commented previously to submit additional comments, if appropriate, in light of this new information. In addition, we are also seeking input on considerations for post-delisting monitoring of the Hawaiian hawk. Our goal is to respond to comments and come to a final determination on the status of the Hawaiian hawk in the form of a final rule by the end of 2018.

DATES: The comment period for the proposed rule published August 6, 2008, at 73 FR 45680 is reopened. To ensure that we are able to consider your comments and information, they must be received or postmarked no later than November 29, 2018. Please note that, if you are using the Federal eRulemaking Portal (see **ADDRESSES**, below), the deadline for submitting an electronic comment is 11:59 p.m. Eastern Time on this date. We may not be able to address or incorporate information that we receive after the above requested date.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: <http://www.regulations.gov>. In the Search box, enter FWS–R1–ES–2007–0024, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rule box to locate this document. You may submit a comment by clicking on “Comment Now!” Please ensure that you have found the correct rulemaking before submitting your comment.

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R1–ES–2007–0024, U.S. Fish and Wildlife Service, MS: BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3808.

We request that you send comments only by the methods described above. We will post all comments on <http://>