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Part B International Drug Pricing Model for Medicare Part B Drugs

I. Overview:

The International Pricing Index (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 CMS 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;
- 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 it would have paid in the absence of the model, before sequestration, and redistribute this amount to model participants based on a set payment amount.

CMS is 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.

II. Background:

Among the 27 products included in the analysis, acquisition costs in the U.S. were 1.8 times higher than in comparator countries. Fourteen 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.

III. Model Concept Design:

Through the potential IPI Model, CMS seeks to test ways to remove physicians and hospitals outpatient departments from the buy and bill process, without creating undue disruption to the distribution system.

Similar to the Competitive Acquisition Program (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, under the IPI Model, Medicare would pay the vendor for the included drugs based on international prices discussed in section III.D. of the advance notice of

proposed rulemaking (ANPRM), which would be intended to lower the amount Medicare pays for included drugs and beneficiary cost-sharing.

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 fee-for-service (FFS) payment policies would apply.

A. Model Vendors:

Under the IPI Model, CMS is 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.

1. *Eligible Vendors*

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.**

CMS 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.

CMS would expect that all model vendors would operate on a national basis; that is, they 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. Physicians and hospitals would not be required to use only one vendor; CMS would encourage model participants to obtain drugs from the most cost effective model vendors.

2. *Model Vendor Responsibilities*

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.

3. ***Model Vendor Payment***

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

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.

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.

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. Model

participation would be mandatory for the physician practices, HOPDs, and potentially other providers and suppliers, in each 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; and
- **Medicare FFS is the primary payer**.

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

2. ***Model Geographic Areas***

CMS anticipates the selected geographic areas would include 50 percent of Medicare Part B spending on separately payable Part B drugs.

CMS will also randomly select the Core Based Statistical Areas **that are compelled to participate.**

3. ***Potential Drug Add-on Payment***

CMS intends 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. CMS has 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' average sales price (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. 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.

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. CMS is 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.

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. Included Drugs:

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. CMS plans 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.**

C. Potential Included Drugs:

In Years 1 and 2 of the potential IPI Model, CMS would include single source drugs, biologicals, biosimilars, and multiple source drugs with a single manufacturer that it identifies from what it believe are reliable sources of international pricing data, prior to direct data collection, as discussed in section III.D. of the ANPRM. In Years 3, 4 and 5, CMS 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 it is considering further increasing the number of Part B drugs included in the model as discussed later in this section.

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.

Over the course of the model, CMS seeks to include HCPCS codes that encompass at least 75 percent of allowed charges in Part B.

D. Model Payment Methodology for Vendor Supplied Drugs:

For the potential IPI Model, 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:

1. 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.
2. 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).

3. **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.** CMS would monitor price changes and recalibrate as needed.
4. 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

E. 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. 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.** CMS plans to carefully explore these potential overlaps and consider ways to address overlap issues as it further develops the IPI Model.

1. *Interaction with 340B Program*

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 average Manufacturer price? (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.

F. Financial Impact:

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

	2020	2021	2022	2023	2024	2025	2020-2025
Part B Drug Baseline	31.2	34.2	37.4	40.8	44.3	48.2	
Drug price							
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
Physician add-on payment							
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
Total impact							
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