340B Health Analysis

Implications for 340B Hospitals Under the International Pricing Index Model for Medicare Part B Drugs

November 13, 2018

Background

On Oct. 30, 2018, the Centers for Medicare & Medicaid Services (CMS) published in the Federal Register an Advanced Notice of Proposed Rulemaking (ANPRM) describing preliminary plans to test a new drug purchasing and payment system intended to lower costs for Medicare Part B drugs by 30 percent. Participation in the new program would be mandatory for hospital outpatient departments (HOPDs) and physician offices in selected geographic areas, responsible for half of all Part B spending. The International Pricing Index (IPI) Model is intended to be phased-in over a five-year period, beginning in the spring of 2020. CMS would first need to formally propose the model, which it suggests it may do through a proposed rule to be issued in the spring of 2019.

The IPI Model has significant implications for 340B hospitals in the selected geographic areas, as participation in the model:

- **Would remove access to 340B discounts for drugs covered under the model; and**
- **Could remove access to 340B discounts for drugs not covered under the model if the hospital is subject to the group purchasing organization (GPO) prohibition (disproportionate share hospitals, children's hospitals and cancer hospitals)**

The IPI Model may also impact 340B ceiling price calculations, which would affect 340B pricing for all 340B hospitals, including those that do not participate in the IPI Model.

Below we explain how the IPI Model would change purchasing, distribution, billing and payment of drugs under Medicare Part B, and the implications for 340B hospitals.

340B Health strongly encourages hospitals to submit comments to CMS in response to the ANPRM. We encourage hospitals to evaluate how the model could impact hospitals' ability to use 340B to assist with reaching low-income populations, affect hospital operations and patients' ability to access drugs. Comments on the ANPRM are due by 5:00 PM (EST) on Dec. 31, 2018.

Private Vendors, Not Hospitals, Buy and Bill Drugs for Hospital Patients

Under CMS's proposal, IPI Model hospitals would no longer buy drugs included in the model for Medicare Part B patients, nor bill Medicare for such drugs, and participation would be mandatory for HOPDs and physician practices in the geographic areas CMS would select to represent half of all Part B reimbursement.[1] Under the model, hospitals would contract with private vendors ("model vendors") to receive drugs for their Medicare Part B patients. These vendors would bill and receive payment from Medicare for the drugs to be used on Part B patients.

Hospital Obligations

These changes to the buy and bill system would create new tasks for hospitals included in the model, which at a minimum, would include:

- Enrolling with one or more vendors to obtain included drugs (model vendors must operate on a national basis, serving all the selected model geographic areas, but do not have to be able to process all drugs covered under the model)
- Notifying vendors of the disposition of the drug
- Paying model vendors for their services, which could potentially include delivery fees and taking title to the drug (model vendors would have agreements with providers that would establish the terms of their arrangements)
- Tracking use of Part B drugs covered by the model separately from non-model drugs
- Maintaining an account or tracking systems for model drugs that is separate from 340B, GPO, and wholesale acquisition cost (WAC) accounts
- Billing Medicare for an add-on payment to cover expenses such as overhead and handling (discussed below)
- Collecting co-payments from Medicare beneficiaries, including billing supplemental insurers
- Submitting informational bills to Medicare for drugs, including claims for drug administration

Covered Drugs

For the first two years of the model, CMS suggests that the model would include single source drugs and biologicals that are separately reimbursed by Medicare, as these products comprise the majority of Medicare Part B drug spending (approximately 84 percent of Part B drug spending, totaling $23.6 billion based on 2016 data). Cancer drugs and biologicals used to treat rheumatoid arthritis are two examples of drugs and biologicals that would likely be included in

[1] We question whether CMS intends to include CAHs in the model, given that they are not paid based on Average Sales Price (ASP), which is the payment structure that CMS intends to test changes to using the IPI Model. 340B CAHs should consider submitting comments to CMS asking that they be excluded from the IPI Model for this reason.

the model. CMS is considering expanding the scope of drugs included in the model after the initial two-year period.

Add-On Drug Payment

Currently, Medicare pays hospitals and physicians an add-on amount of 6 percent of ASP, although due to budget sequestration, the add-on is effectively reduced to 4.3%. 340B hospitals subject to the Medicare payment reduction that took effect on Jan. 1, 2018 are paid ASP minus 22.5% to cover the cost of drug acquisition and drug-related costs. CMS believes this percentage-based arrangement incentivizes providers to use more expensive drugs. To address this, the model would pay providers a flat flee to cover handling and overhead costs that CMS intends to equal revenue that providers would otherwise receive if they were not participating in the model.

Cuts to Medicare Part B Payments

CMS would like to reduce payment for Part B drugs to rates more closely aligned with international drug prices, which CMS estimates will reduce Part B drug spending by 30 percent, saving Medicare $17 billion over five years.

Under the model, Medicare would reimburse model vendors for their drug costs, rather than providers, and using an International Pricing Index (IPI), Medicare would calculate and pay vendors a “Target Price” for drugs. Pharmaceutical manufacturers would not be required to provide drugs to a model vendor at reduced prices, though, and the amount the model vendor would pay for included drugs would be based on the ability of the model vendor to successfully negotiate lower prices. The Target Price would be phased in over five years.

Beneficiary Coinsurance

CMS plans for beneficiaries to pay their coinsurance to providers and not to the model vendors. Beneficiary cost-sharing includes a coinsurance amount of 20 percent of the drug's reimbursement, covering a portion of the provider's drug acquisition costs. However, providers would ultimately not retain coinsurance payments. To help reconcile cost-sharing collection, hospitals would be required to follow model-specific billing instructions to submit informational drug claims to the Medicare Administrative Contractor along with claims for drug administration.

Vendors

Vendors would be tasked with negotiating drug prices with pharmaceutical manufacturers that presumably fall within the significant reduction in payment by Medicare. CMS envisions that commercial entities such as group purchasing organizations (GPOs), wholesalers, distributors, specialty pharmacies, individual or groups of physicians and hospitals, manufacturers, and Part D sponsors could serve as model vendors, taking title to the drugs included in the model. Model vendors would not be required to physically possess the drugs and would arrange for the distribution of the drugs to participating providers.

Potential Impact on 340B Hospitals

The IPI Model appears to have several negative implications for 340B hospitals based on what we currently know about the model, though there are several important aspects of the model that are currently unknown.

No Access to 340B Discounts for Drugs Covered Under the Model

Though not acknowledged by CMS, 340B hospitals participating in the model would lose access to 340B discounts for Part B drugs included in the model. The 340B statute requires pharmaceutical manufacturers to offer 340B discounts only to covered entities purchasing covered outpatient drugs. If a non-340B entity is purchasing the drug, the manufacturer does not have a legal obligation to provide a 340B discount on the drug. The IPI Model would prohibit hospitals from taking title to the drugs, thereby eliminating the 340B discount for drugs included in the model. This would present a significant financial impact for hospitals not subject to reduced payments, which include children's hospitals, free-standing cancer hospitals, sole community hospitals designated as rural for Medicare purposes, and critical access hospitals. The financial impact would be less for 340B hospitals that already receive reduced payments from Medicare for Part B drugs, which include disproportionate share hospitals and rural referral centers.

Interaction with the GPO Prohibition

The ANPRM does not address whether 340B hospitals subject to the 340B statute's group purchasing organization (GPO) prohibition would be able to participate in the IPI Model without violating the GPO prohibition. To be eligible to participate in the 340B program, 340B disproportionate share (DSH), children's and free-standing cancer hospitals cannot participate in a GPO or other group purchasing arrangement to purchase or obtain covered outpatient drugs. Because the proposed model vendors negotiate with drug manufacturers to provide drugs to many hospitals, there is the potential that the arrangement would be interpreted by HHS to be a group purchasing arrangement. On the other hand, model vendors may be viewed similarly to the way HRSA views the 340B Prime Vendor, as a creation of statute and not as a GPO. The model vendor, not the hospital, takes title to the drugs, which could also distinguish the model vendor from a GPO. If HHS would view model vendors negotiating pricing with manufacturers on behalf of IPI Model entities as a GPO, this would make 340B hospitals in the model ineligible to participate in the 340B program, removing their ability to access 340B discounts for drugs not covered under the model.

Impact on 340B Ceiling Price Calculations

The IPI Model may also impact 340B ceiling price calculations, which would affect 340B pricing for all 340B hospitals, including those that do not participate in the IPI Model. The 340B ceiling price is calculated using average manufacturer price (AMP) and best price data. If manufacturers were to reduce their drug prices as a result of the model, and the sales under the model were included in the calculation of best price, the lower prices could set a new best price.

A lower best price could result in a larger 340B discount and lower 340B prices. On the other hand, including reduced prices in the calculation of AMP could result in smaller 340B discounts. Ultimately, it is unclear what would be the overall impact on 340B prices.

Opportunities to Minimize Harm to 340B Hospitals

Since the release of the ANPRM, HHS Secretary Alex Azar acknowledged that the model may have negative implications for 340B hospitals and expressed interest in understanding what the impact of the model would be on hospitals that "invest significant resources into serving vulnerable populations." Such interest in supporting 340B hospitals that provide a high level of care to vulnerable patients appears similar to previous 340B policies suggested by the Administration. For example, in its fiscal year 2019 budget proposal, the Administration proposed that 340B hospitals could access higher Medicare payments if they provided a minimum level of charity care or uncompensated care. Congress has not acted on that proposal.

Impact on Pharmacy Operations and Patient Access to Care

As we noted earlier, hospitals participating in the model would have an agreement with model vendors governing the distribution and shipment of drugs to hospitals. Hospitals will want to closely evaluate how the model could change the drug distribution process and impact pharmacy operations and patients' ability to access drugs safely and effectively. For example, hospitals may want to consider what the impact would be on pharmacy operations and patient care if model vendors were to physically possess the drugs before providing them to the hospital, as some hospitals do not administer drug product to patients that is physically possessed by an external party prior to drug administration. CMS is soliciting feedback on whether CMS should be a party to and/or regulate the agreements between vendors and model participants and whether the agreements should specify obligations to ensure the physical safety of the included drugs before they are administered to beneficiaries, how drug distribution would be handled, data sharing methods, and confidentiality requirements.

The model could also create an additional burden on pharmacy operations, including 340B program systems. For example, if 340B hospitals were to place orders from vendors for Part B drugs, there may be a need to create an additional drug purchasing/distribution account, which could affect 340B accumulator programs and split billing software. 340B hospitals may want to consider providing feedback to CMS on operational concerns raised by the model, particularly those that may negatively impact patient care.

Unanswered Questions

There is uncertainty about several aspects of the IPI Model given the limited details that we have about how the model would operate. For example:

- Would the model be successful in encouraging manufacturers to agree to sell drugs to model vendors at reduced prices? What incentive would pharmaceutical manufacturers of single source drugs have to negotiate pharmaceutical prices with model vendors?

- What would happen if model vendors were unsuccessful in negotiating lower drug prices with pharmaceutical companies and could not reach an agreement? How would this impact the ability of hospitals to provide drugs to their Part B patients?
- Will the add-on payment adequately reimburse hospitals for the costs they incur when handling drugs?
- Will the model increase white bagging and brown bagging if the new distribution system does not work well?

We anticipate that CMS will provide more detail in a proposed rule that will help to answer these and other questions about how the model will work and what would be expected of participating providers, model vendors, and pharmaceutical manufacturers.

How to Submit Comments

Comments on the ANPRM are due by 5:00 PM (EST) on Dec. 31, 2018. CMS asks that stakeholders refer to "file code CMS-5528-ANPRM." Although CMS provides multiple ways to submit comments, the agency encourages submission of comments through the federal government website https://www.regulations.gov/. To do so, enter "CMS-5528-ANPRM" in the search box on the website and click "Search." The rule will appear in the search results. Click the "Comment Now!" button in the upper right-hand corner and provide the requested information. Electronic submission will help ensure comments are received by CMS before the deadline.

Comments can be sent by regular mail to the following address: Centers for Medicare & Medicaid Services, Department of Health & Human Services, Attention: CMS-5528-ANPRM, P.O. Box 8013, Baltimore, MD 21244-1850. For additional information about submission options, see page 54546 of the ANPRM.

Comments & Questions

340B Health plans to submit detailed comments and encourages our member hospitals to do the same. We will provide members with a template to help them prepare comments on 340B and other related issues raised by the model. 340B Health will be hosting a webinar to discuss the IPI model and preparing hospital comments on Thursday, Nov. 15. Click here to register for the webinar.

Please consult 340B Health's IPI Model Resource Center for additional information on the model.

Contact: 340B Health Legal Counsel, Amanda Nagrotsky at amanda.nagrotsky@340bhealth.org or 202-552-5866.