Part B Payment Model Proposed Rule

Written by Brian P. Carey, Erik L. Schulwolf

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Centers for Medicare & Medicaid Services

Overview

On March 8, 2016, the Centers for Medicare & Medicaid Services (CMS) released a Proposed Rule that would provide the agency with expansive and unprecedented authority to alter the statutory payment methodology for Part B drugs and biologics established in Section 1847A of the Social Security Act.[1] The Proposed Rule would establish a Part B Drug Payment Model (the "Model") in select regions of the country to test new payment methodologies for drugs and biologics covered under Medicare Part B in two phases. The first phase would involve reducing the 6 percent add-on to Average Sales Price (ASP) under Part B to 2.5 percent, plus a flat fee (in a budget neutral manner,). The second phase is intended to achieve savings and would implement "value-based purchasing tools" including reference pricing, indication-based pricing, and risk sharing agreements for selected drugs. CMS is implementing the Model using its statutory authority through the Center for Medicare and Medicaid Innovation (CMMI). With some limited exceptions (such as drugs billed by end stage renal disease (ESRD) facilities), CMS is proposing to include all Part B drugs in the Model.

Phase I of the Model will go into effect within 60 days of the release of the Final Rule. Phase II would begin no sooner than January 1, 2017 and CMS expects that phase II could take several years to fully implement. CMS is proposing that the Model will last for five years and that both phases will jointly be in effect in the last three years. In addition to the Proposed Rule, the HHS Assistant Secretary for Planning and Evaluation (ASPE) released two issue briefs entitled "Observations on Trends in Prescription Drug Spending" and "Medicare Part B Drugs: Pricing and Incentives."[2] Comments on the Proposed Rule are due on May 9, 2016.

Part B Drugs Included in Model

Most Part B drugs that appear on the quarterly ASP Drug Pricing Files would be included in the Model. The Model would include nationally priced drugs with ASP, WAC, and AMP-based payment amounts that are on the quarterly ASP Drug Pricing Files. CMS would overlay payment amounts for Part B drugs on the quarterly ASP Drug Pricing Files. The following drugs would be included in the Model:

- Drugs and biologicals (including biosimilars) paid under section 1847A;
- Drugs paid separately in the hospital outpatient department, including pass-through drugs;
- Non-infused drugs furnished by DME suppliers (such as immunosuppressives, oral chemotherapy, inhalation drugs used with DME, and clotting factors); and
- Intravenously and subcutaneously administered immunoglobulin G (IgG) including products administered in the office as well as intravenous products administered in the home to patients with primary immunodeficiency.

Importantly, the agency does not believe that all Part B drugs are appropriate candidates for inclusion in Phase I of the model, and CMS propose to exclude the following categories of drugs:

- Contractor-priced drugs, including drugs that do not appear on the quarterly national ASP price file;
- Influenza, pneumococcal pneumonia and hepatitis B vaccines paid under the benefit described in section 1861(s)(10) of the Social Security Act;

- Drugs infused with a covered item of DME in Phase I; drugs is made based on the average wholesale price (AWP) in effect on October 1, 2003;
- ESRD drugs paid under the authority in section 1881 of the Social Security Act (i.e., those Part B drugs that are included in the dialysis PPS bundled payment); and
- Blood and blood products.

Additionally, for drugs that are reported by the FDA to be in short supply at the time that the Model payment amounts are being finalized for the next quarter, CMS will continue to pay for those drugs using the existing statutory methodology in section 1847A.

Phase I: Modification to ASP Add-On Percentage

CMS is proposing to utilize a similar approach to a proposal in the June 2015 Medicare Payment Advisory Commission (MedPAC) report: a fixed percentage with a flat fee. MedPAC evaluated an approach based on a 2.5 percent add-on plus a $14 flat fee per day administered. The Model would maintain the same fixed percentage of ASP but set the flat fee initially at $16.80 per day administered. For 2016, the alternative ASP pricing is established so that the total spending for Part B drugs included in the Model is equal to the aggregate spending for the same set of drugs in the CY 2014 claims data. CMS may refine the flat fee in the Final Rule based on more recent claims data. CMS plans to keep the 2.5 percent add-on constant through the duration of the Model but will update the flat fee for January 2017 using the CPI MC and annually thereafter.

CMS considered but declined to propose other alternatives such as a higher starting percentage like 3 percent or 3.5 percent, a flat fee without a percentage add-on in lower quartiles, or a tiered approach in which CMS would vary the percentage or flat fee add-on across several tiers of drugs defined based on annual costs per beneficiary. While CMS declined to propose these approaches, the agency seeks comments on an alternative to the ASP add-on payment in Phase I.

Phase I would implement the variation to the add-on component of ASP payment methodology in different geographic areas of the country. All providers and suppliers in a select geographic - 3 - region would receive alternative ASP payments. Providers in geographic areas assigned to this alternative approach would bill using a G-code for the flat fee portion of the payment.

The Phase I Model is intended to be a "budget neutral" approach to isolate the impact of changes to the ASP add-on amount without introducing additional savings. CMS does not expect a "sizable" overall reduction in Part B drug spending associated with Phase I. In the agency's analysis of the economic effects of the Model, CMS concludes that the overall effect will "modestly" shift dollars from hospitals and specialties that use higher cost drugs, such as ophthalmology, to specialties that use lower cost drugs, including primary care, pain management, and orthopedic specialties. Overall, CMS estimates that Medicare spending on drugs furnished in the office setting will increase while spending on drugs furnished in the hospital setting will decrease. CMS notes that because sequestration is independent of Medicare payment policy, sequestration will continue to apply to payments made under the Model. The application of the sequestration requires the reduction of Medicare payments by two percent.

Phase II: Value Based Purchasing Tools

In Phase II, CMS is proposing to implement a value-based purchasing (VBP) model in conjunction with the variation of the ASP add-on payment amount for drugs paid under Part B. CMS states that the agency will consider tools currently employed by commercial health plans, pharmacy benefit managers (PBMs), hospitals, and other entities that manage health benefits and drug utilization. CMS is proposing to apply one or more tools, such as indication-based pricing, reference pricing, risk sharing agreements and clinical decision support tools for selected Part B drugs. This Phase is not intended to be budget neutral and the agency plans to achieve savings.

Phase II would begin no sooner than January 1, 2017. When Phase II begins, providers and suppliers selected to participate in the VBP arms would begin receiving VBP-based payments for certain drugs and would participate in other VBP activities, such as feedback on prescribing patterns. Providers and suppliers in geographic areas selected for one arm of the model will be subject to both Phase I pricing and Phase II VBP pricing.

CMS expects that Phase II could take several years to fully implement. The agency's goal is to have both phases of the Model in full operation during the last three years of the proposed five-year duration to fully evaluate changes and collect sufficient data.

As discussed by CMS, examples of value-based pricing strategies could include:

- "Reference pricing" with a standard payment for therapeutically similar products;
- "Indications-based pricing" with varying payment for a drug based on its clinical effectiveness for different indications;
- Voluntary risk-sharing agreements with manufacturers to link health care outcomes with payment (CMS is proposing that any outcomes-based agreements would require a clearly defined outcome goal);
- Discounting or eliminating patient coinsurance amounts for services that are determined to be high in value in an attempt to tailor incentives; and
- Clinical decision support tools including best practices in prescribing or information on a clinician's prescribing patterns relative to geographic or national trends.

This group of tools would serve as a framework for interventions for selected Part B drugs. CMS would gather additional information on the proposed tools, including which specific Part B drugs are suitable candidates for the application of specific tools within the group.

Under Phase II, CMS said it does not intend to apply these tools to all Part B drugs; rather, the agency plans to implement the use of the tools in a limited manner for certain drug HCPCS codes after considering these tools' appropriateness to specific Part B drugs within those codes. CMS would finalize the implementation of specific tools for specific HCPCS codes after soliciting public input on each proposal by posting on the CMS website, and would allow 30 days for public comment. CMS would provide a minimum of 45 days public notice before implementation.

Additionally, CMS proposes a two component clinical decision support (CDS) tool that consists of an online tool that supports clinical decisions through education and provides feedback based on drug utilization in Medicare claims. The educational tool would be developed by CMS with support from the VBP contractor and would be available to physicians in the VBP arms of the model. In addition to developing an evidence-based component for the tool, CMS would create an online source of data under the section 1115A authority that would provide feedback to physicians in the VBP arms of the Model.

At a minimum, and in addition to sources such as evidence-based literature and best practices, CMS proposes that manufacturers provide all competent and reliable scientific evidence to create an accurate picture regarding clinical value for a specific drug, and the agency also proposes that manufacturers provide outcome measures for an outcome-based risk-sharing agreement.

Geographic Selection and Mandatory Participation

To eliminate selection bias, CMS is proposing to require participation from all providers and suppliers furnishing any Part B drugs included in the Model who are located in the geographic areas that are selected for inclusion in the Model. The geographic areas would be established based on Primary Care Service Areas (PCSAs. CMS proposes to use random assignment of all PCSAs to one of four groups: the three test arms (paying a modified ASP add-on amount, implementation of VBP tools, and both modified ASP add-on and VBP tools at the same time) or a fourth control group.

CMS is proposing to determine a provider or supplier's specific geographic location based on the service location ZIP code for physician drug claims, the beneficiary ZIP code for DME supply claims, and the ZIP code for the address associated with the CMS certification number (CCN) for hospital outpatient claims.

Interactions with Other Alternate Payment Models

CMS notes that there are possibilities of overlap between the Part B Drug Payment Model and the Medicare Shared Savings Program, Oncology Care Model (OCM), and other CMMI payment models.

The agency does not intend to exclude beneficiaries, physicians, or providers in the Part B Drug Payment Model from other Innovation Center models or CMS programs, such as the Medicare Shared Savings Program. CMS said that it acknowledges that there is potentially greater overlap between this proposed Model and the OCM than other models. Drug claims under the OCM would be paid under the ASP methodology. As a result, CMS is proposing to include OCM practices in the Part B Drug Payment Model, but the agency also requests comment on the best approach for handling that overlap and on whether CMS should exclude OCM practices and their comparison practices from the Part B Drug Payment Model.

CMS is also soliciting comments on how to create VBP programs directly with manufacturers such as voluntary rebates, whether the agency should consider implementing a updated Competitive Acquisition Program (CAP) as an alternative to the physician buy and bill

model, and whether it should pursue a bundled or episode-based payment approach such as for groups of similar drugs.

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1. See here.

2. See here and here.

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