

AMCP Summary: Medicare Program; Part B Drug Payment Model

Released: March 8, 2016

Comments Due: May 9, 2016

On March 8, 2016, the Centers for Medicare and Medicaid Services (CMS) released a [proposed rule](#) titled “*Medicare Program; Part B Drug Payment Model*”¹ under the authority of section 1115A of the Social Security Act and the Centers for Medicare and Medicaid Innovation (CMMI). CMS proposes the Part B payment model as a two-phase model that would test whether alternative drug² payment designs will lead to a reduction in Medicare expenditures, while preserving or enhancing the quality of care provided to Medicare beneficiaries. Phase I would involve understanding the impact of changing the current payment methodology for Part B drugs from Average Sales Price (ASP) + 6% to ASP + 2.5% + a flat fee. Phase II would involve understanding the impact of implementing value-based purchasing (VBP) tools similar to those currently employed in the commercial market and Medicare Part D, such as reference pricing and indication-based pricing.

Detailed information on each phase of the payment model, as well as the value-based purchasing tools being considered, is outlined in the summary below.

Considerations for Providing Recommendations for Comment to AMCP

Comments on this proposal must be submitted to CMS by May 9, 2016. AMCP seeks feedback and input to develop comments to CMS to ensure the perspective of managed care pharmacy is voiced as changes to payment policies in Medicare Part B are considered. To guide you on areas of input, AMCP has developed the following questions and issue areas. These issues correspond to the sections of the proposed rule summarized below.

Please provide feedback via email to Soumi Saha, Assistant Director of Pharmacy & Regulatory Affairs, at ssaha@amcp.org by Monday, May 2nd. Please include the specific section and question in your feedback. AMCP’s final comments to CMS will be available on the AMCP website and also included in the Legislative-Regulatory Briefing Newsletter that is sent to all AMCP members.

General Feedback

- Many of these proposals have been implemented by health plans and pharmacy benefit management (PBM) companies. CMS has not identified the contractor to implement these demonstrations, but if it is not specifically a health plan or PBM, will any of the proposed options as described below (reference pricing; indications-based

¹ Available at: <https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-05459.pdf>. Accessed March 31, 2016.

² For the purposes of the proposed rule, CMS utilizes the term “drug” to refer to both small-molecule medications and biologics (including biosimilars) paid under the Part B program which fall into three general categories: (1) drugs furnished incident to a physician’s services (typically injectable drugs that are administered); (2) drugs administered via a covered item of durable medical equipment (DME) (such as drugs that are administered with an intravenous pump or inhalation drugs administered through a nebulizer); and (3) other drugs specified by statute (such as immunosuppressive drugs, hemophilia blood clotting factors, certain oral anti-cancer drugs, certain vaccines, etc).

pricing; risk-sharing; and elimination of patient cost sharing) be more or less difficult to implement without the use of managed care entities? What is the best type of contracted entity for CMS to use to execute these demonstrations? Please explain.

- What are the impacts on specialty pharmacy versus health plans or PBMs?

Background & Overview

- What is the impact of beginning these demonstrations, particularly the ASP reductions on January 1, 2017? Identify and explain any challenges.
- What should CMS evaluate to determine if a demonstration is not successful and should not continue to operate?
- CMS seeks feedback on how to handle drugs, services, or suppliers that may be involved with multiple demonstration models. How should CMS handle these cases?

Drugs Included in Payment Model

- Please provide feedback on the methodology CMS proposes to include drugs.
- Please provide feedback or recommendations to remove classes of medications or include excluded classes.
- Does CMS sufficiently ensure access to drugs in short supply based on its proposal to exclude and pay for these products using the current payment model?

Participants & Geographic Areas Included in Payment Model

- What are the implications of mandatory participation, particularly on patient access to medications?
- Would geographic areas have an impact on success or failure of a particular demonstration? Please be specific regarding the rationale for your answer.
- What is the implication of randomly assigning models to different geographic areas?
- What impact does the use of Primary Care Service Areas (PCSAs) with cut points compared to other methods identified, Core Based Statistical Areas (CBSA), Dartmouth Atlas of Health Care's Hospital Referral Regions (HRR), and ZIP codes have on success or failure of the program?

Proposed Modifications to the ASP Add-on for Part B Drugs

- What is the impact of the ASP percent reduction? Will access to patient care be impacted? Please provide concrete examples if available.
- Does any data exist that examines the ability to purchase medications for ASP? Are there differences in purchasing by specialty pharmacies or physician offices or clinics?
- What is the impact of the additional flat fee to the overall payment changes?
- Do drugs requiring cold chain or other special handling as described by CMS require higher payments? In what other cases should drugs be considered for higher reimbursement?

Applying Value-Based Purchasing (VBP) Tools

- What type of evidence is necessary to determine whether certain interventions are clinically sound? (CMS identifies Incremental Comparative Effectiveness Reviews but other evidence might be available).
- What tools, other than cost sharing waivers, would be effective in ensuring the use of high value medications?
- Should cost-sharing waivers or reductions be added to specific types of medications, such as biosimilars?
- Are there any medications or conditions that would benefit from certain test models? Does evidence suggest that any medication or condition be specifically excluded from certain test models? Please provide specific examples.

Clinical Decision Support Tool

- Please provide any recommendations to improve or change clinical decision support tools described by CMS.
- What medications should CMS consider for this support tool?

Additional VBP Tools Being Considered

- Please provide comments on the pros and cons of the additional VBP tools being considered: direct value-based purchasing agreements with pharmaceutical manufacturers; competitive acquisition program; and bundled or episodic payment.

Provider, Supplier, and Beneficiary Protections

- Please provide comments on the protections described by CMS and provide feedback for improvement.

Evaluation Methods

- Are the methods described by CMS sufficient, should any changes be made, and are there any additional methods that should be examined?

In addition, AMCP will host a webinar on April 27th (2-3PM EST) to discuss the options outlined in the CMS proposal and the implications to managed care pharmacy. This webinar is free for members and \$69 for non-members. To register, please visit AMCP’s Calendar of Events at <http://www.amcp.org/calendar/>.

Background & Overview (page 8)

Based on CMS claims data, it is estimated that Part B payments for drugs have doubled since 2007, with an annual increase of 8.6% and \$22 billion in payments in 2015. Given the significant growth in Part B drug expenditures and concerns from CMS that the current reimbursement methodology of ASP + 6% does not provide a clear incentive for providing high value care, the two phase model was developed to test whether alternative payment approaches for Part B drugs improve value, improve outcomes, and reduce expenditures for Part B drugs.

CMS proposes the model run for five (5) years with phase I beginning sixty (60) days after publication of the final rule and phase II beginning no earlier than January 2017. CMS proposes the model be administered geographically based upon Primary Care Service Areas (PCSAs) and that all providers, suppliers, hospitals, and pharmacies be required to participate in the model if furnishing Part B drugs included in the model and located in a geographic area that is chosen for participation in the model. CMS proposes to include nearly all drugs paid under Part B in the model, with the exception of certain categories such as drugs separately billed by End-Stage Renal Disease (ESRD) facilities. CMS acknowledges that there may be overlap between the Part B payment model and other CMMI test models, most notably the Oncology Care Model (OCM), and proposes to not exclude dual participation in test models but seeks comment on the best approach for handling overlap and whether exclusions should be considered. Finally, CMS anticipates phase I of the payment model to be budget neutral whereas phase II would not be budget neutral and is anticipated to generate savings.

TABLE 1: Summary of the Proposed Model

Phase 1 – ASP+X (no earlier than 60 days after display of final rule, Fall 2016)	Phase 2 – VBP (no earlier than January 2017)
ASP+6% (control)	ASP+6% (control)
	ASP+6% with VBP Tools
ASP+2.5% and Flat Fee Drug Payment	ASP+2.5% and Flat Fee Drug Payment
	ASP+2.5% + Flat Fee Drug Payment with VBP Tools

Note: Primary Care Service Areas (which are clusters of ZIP codes that reflect primary care service delivery) would be randomly assigned to each model test arm and the control group. The assigned PCSAs would not include ZIP codes in the state of Maryland where hospital outpatient departments operate under an all-payer model.

Drugs Included in Payment Model (page 19)

Aside from the limited exceptions outlined below, CMS proposes to include the majority of drugs covered under Part B in the model. CMS recognizes that while a vast majority of Part B drugs are paid using the ASP methodology, some medications are paid using Wholesale Acquisition Cost (WAC), Average Manufacturer Price (AMP), or Average Wholesale Price (AWP). CMS proposes to overlay payment amounts for Part B drugs (which are also referred to as payment allowance limits) on the quarterly ASP Drug Pricing and the quarterly update to Addendum B of the Outpatient Prospective Payment System (OPPS) with model derived payment amounts in the geographic areas that are being evaluated.

CMS proposes that the following drugs (and certain associated fees) also be included in the model:

- Drugs and biologicals (including biosimilars) with HCPCS codes that are nationally priced, including ASP and WAC based payment amounts, and drugs (and biologicals) paid separately under OPPS.
 - CMS proposes including all OPPS pass-through drugs in the model because OPPS pass-through drugs are paid at ASP + 6% which is the same payment as separately paid drugs under the OPPS. In phase I, for drugs paid based on ASP and WAC, the 6% add-on will be replaced with the updated add-on amount. In phase I, for HCPCS codes with AMP-based payments, the lower of the quarter's AMP-based payment amount (that is, the AMP-based amount on the quarterly ASP files) or the model payment amount would be used.
- Non-infused drugs furnished by DME suppliers (including the limited number of Part B drugs dispensed by pharmacies), such as immunosuppressives, oral chemotherapy, oral antiemetics, inhalation drugs used with DME, and clotting factors.
 - CMS proposes including this category of drugs in the payment model as it believes it is important to include drugs that are used outside of the incident-to setting. CMS also believes it is important to understand the impact of other payment-related financial incentives that are associated with the drug payment, and therefore proposes that phase II of the model may incorporate changes to the furnishing, supplying, and dispensing fees that are associated with these drugs.
- Intravenously and subcutaneously administered immunoglobulin (IgG).
 - CMS proposes including both products administered in the office as well as intravenous products administered in the home to patients with primary immunodeficiency. Payment for intravenously administered IgG would typically be based on the ASP whereas subcutaneously administered IgG would depend on who furnishes the drug.

CMS proposes to exclude the following categories of drugs from the model:

- Contractor-priced drugs, including drugs that do not appear on the quarterly national ASP price file, such as certain radiopharmaceuticals that are furnished in the physician's office.
 - CMS proposes this exclusion because pricing for contractor-priced drugs may vary and the model is being limited to drugs that are nationally priced by CMS.
 - However, in situations where the Medicare Claims Processing Manual 100-04, Chapter 17, Section 20.1.3 either permits contractors to contact CMS to obtain payment limits for drugs not included in the quarterly ASP or Not Otherwise Classified (NOC) drug file, or when contractors have the authority to independently determine a payment amount, CMS proposes that contractors would be permitted to utilize reductions to the add-on percentage that they calculate. This would be implemented through subregulatory instructions and CMS seeks comments on this approach.
- Influenza, pneumococcal pneumonia, and hepatitis B vaccines.
 - CMS proposes this exclusion because these products are typically considered preventive services and provided at no cost to beneficiaries.
- Drugs infused with a covered item of DME in phase I.
 - CMS proposes this exclusion from phase I of the model so that DME policy can focus on issues related to DME and so that the model does not interfere with decisions related to the inclusion or exclusion of

these drugs in DME competitive bidding. Please note, CMS does not propose to exclude DME infusion drugs from the entire model, just phase I.

- End-Stage Renal Disease (ESRD) drugs separately billed by ESRD facilities.
 - CMS proposes this exclusion given the majority of ESRD drugs are bundled with services and very few are separately billed.
- Blood and blood products.
 - CMS proposes this exclusion because of the varied distribution channels of blood and blood products in comparison to drugs, and that pricing information is typically not available for these products.

CMS is also concerned about access to drugs that are subject to short supplies and has proposed safeguards to ensure access. For drugs covered under a demonstration model that the Food and Drug Administration (FDA) have deemed to be in short supply at the time that model payment amounts are being finalized for the next quarter, CMS proposes to continue paying for these drugs using the existing statutory methodology. CMS also notes that it considered various methods for addressing drugs in short supply and seeks comments on whether paying the greater of the applicable arm's model payment amount or the current quarter's statutory payment amount has a significant potential benefit.

Participants & Geographic Areas Included in Payment Model (page 25)

Participation would be *mandatory* for all providers, suppliers, hospitals, and pharmacies that furnish Part B drugs included in the model and that are located in a geographic area chosen. CMS believes mandatory participation is necessary to eliminate selection bias, to observe overall changes in prescribing patterns by practitioners for all Part B drugs, and to assess the full impact of proposed payment changes on Part B expenditures. There will be no specific enrollment activities for providers, suppliers, hospitals, pharmacies, or beneficiaries in this model; the furnishing of Part B drugs in a particular geographic area will determine participation.

CMS considered five options (states, Core Based Statistical Areas (CBSA), Dartmouth Atlas of Health Care's Hospital Referral Regions (HRR), ZIP codes, and Primary Care Service Areas (PCSAs)) in determining the most appropriate geographic unit for the model and outlines in detail the advantages and disadvantages to each option. After careful consideration, CMS proposes using PCSAs³ as the geographical unit because the providers and suppliers in these areas generally do not have multiple practice locations; PCSAs would be sufficient in number to ensure adequate statistical power for the evaluation of the model; and these areas have characteristics that are relatively more similar when comparing one another so that observed changes at the area level can be more clearly attributed to the intervention and not to other factors. PCSAs were defined based upon patterns of Medicare Part B primary care services and each ZIP code in the United States is linked to a PCSA. Therefore, CMS proposes to associate claims with a PCSA on the basis of the ZIP code of the appropriate performing or billing NPI or beneficiary recorded on the claim in the following manner:

- The service location ZIP code linked to the performing NPI will be used for practitioner claims.
- The ZIP code in the CMS certification number (CCN) address associated with a hospital will be used for hospital outpatient department claims.
- The residence ZIP code of the beneficiary receiving a Part B drug will be used for DME claims.

CMS notes there are 7,144 PCSAs in the United States covering all 50 states. However, CMS recommends excluding the 96 PCSAs located in Maryland from the model because of concerns that the waiver for Medicare hospital payment rules in the Maryland All-Payer Model may create unobservable bias in the prescribing patterns or payments for the Part B drugs in the model test. Therefore, CMS proposes to assign each of the remaining 7,048 PCSAs to one of the three test arms or the control arm of the model test (outlined in Table 1) using a stratified random approach resulting in approximately 1,700 PCSAs per arm. The proposed strata are defined by the number of Medicare beneficiaries being furnished Part B drugs in each PCSA and the mean Part B drug expenditures per beneficiary. CMS proposes to use a

³ Additional information on PCSAs is available at: <http://datawarehouse.hrsa.gov/data/dataDownload/pcsas2010download.aspx>. Accessed March 31, 2016.

single cut point of Part B drug beneficiary counts per PCSA at 1,500 and two cut points for the distribution of mean dollars expended for Part B drugs per beneficiary per PCSA of \$500 and \$3,000. These three cut points in two factors result in six strata from which the PCSAs will be assigned to one of the four arms of the model in equal numbers by simple randomization. CMS seeks feedback on whether additional factors or cut points are necessary to achieve balance across the four arms of the model.

Phase I – Proposed Modifications to the ASP Add-On Percentage for Drugs Paid Under Part B (page 37)

Phase I of the payment model would involve understanding the impact of changing the current payment methodology for Part B drugs from ASP + 6% to ASP + 2.5% + a flat fee. CMS proposes to derive the flat fee from the difference in total payment between total payments with a 6% add-on percentage across Part B drugs in the most recently available calendar year claims, which is 2014, and total estimated payment for Part B drugs in the same set of claims with a 2.5% add-on percentage to the flat fee. CMS proposes to divide this difference by the total number of encounters per day per drug in the CY 2014 claims data resulting in a flat fee of \$16.80 for CY 2016. CMS proposes to update the flat fee amount each year by the percentage increase in the consumer price index (CPI) for medical care for the most 12-month period. CMS also notes that the flat fee of \$16.80 for CY 2016 may be updated as additional claims data from CY 2014 is made available prior to finalization of the proposed rule.

CMS notes that completely eliminating the percentage add-on was not a reasonable approach because it recognizes that all providers and suppliers are not able to purchase drugs at ASP. CMS chose 2.5% as a starting point for the add-on percentage because it believes it should be sufficient to cover markups from wholesalers, such as prompt pay discounts that are not passed on to purchasers. CMS intends to maintain the 2.5% add-on throughout the course of the payment model and only adjust the flat fee, but seeks comment on whether alternate budget neutral variations such as a higher starting percentage, a flat fee without a percentage add-on in lower quartiles, or a tiered approach in which the percentage or flat fee add-on would be varied across several tiers of drugs based upon cost would be warranted and sufficiently different to justify testing them. Finally, CMS seeks comment on whether certain characteristics of groups of drugs justify higher payment such as special packaging, cold chain handling, or other contributors to cost. CMS notes, however, that adding arms to the model will likely impact the statistical power of the model.

CMS notes that phase I is intended to be a budget neutral approach focused on testing redistribution of the add-on payment on Part B drugs expenditures and outcomes. CMS also notes that it believes phase I of the model will not change how Part B drugs are acquired by providers or suppliers, or how drug manufacturers sell their products to providers, suppliers, or intermediaries such as wholesalers.

Based upon the method outlined above for randomly assigning PCSAs into the four arms of the model, roughly half of the providers and suppliers nationwide would be subject to the ASP + 2.5% + a flat fee payment methodology. CMS proposes using a G-code that would be used by impacted providers and suppliers to bill for the flat fee portion of the payment. CMS also proposes to continue the standard practice of updating the weighted average portion of drug payment amount (ASP+0) on a quarterly basis using manufacturers' sales data and the weighted average calculations that are currently used.

Phase II – Applying Value-Based Purchasing Tools (page 47)

Phase II of the payment model would involve understanding the impact of implementing one or more value-based purchasing (VBP) tools for Part B drugs. CMS notes that these tools have been used effectively by Medicare Part D plans and the commercial insurance sector for years to manage health benefits and drug utilization and therefore it believes that these approaches, when appropriately structured, may be adaptable to Part B to improve patient care and manage drug spending. CMS notes that in adapting and using VBP tools in the Part B payment model, one of their goals is to ensure the model promotes integrity, transparency, and accountability. Finally, CMS notes they intend to implement the proposed VBP tools through a contractor, as they do with many Medicare programs, but would retain final review and authority over the final version of any VBP tools implemented under phase II.

Value-Based Pricing Strategies (page 50)

CMS is considering four specific VBP tools that would serve as a framework for interventions for selected Part B drugs:

- **Reference pricing (page 50):** This proposed tool would test the practice of setting a standard payment rate - a benchmark - for a group of therapeutically similar drug products. CMS notes this benchmark may be set based on the payment for the average price for drugs in a group of therapeutically similar drug products, the most clinically effective drug in the group, or another threshold that is specifically developed for such drug products (like a specified percentile of the current drug price distribution). CMS notes reference pricing eliminates the direct link between the purchase prices paid by suppliers and providers for Part B drugs and payment rates for those drugs from insurers, thereby providing stronger incentives to evaluate outcomes and cost together when determining treatment regimens. CMS also proposes that any version of reference pricing implemented would not allow for balance billing of the beneficiary for any differences in pricing between the prescribed drug and the benchmark set for the group of therapeutically similar drugs.
- **Indications-based pricing (page 52):** This proposed tool would vary the payment for a drug based on its clinical effectiveness for different indications. For example, a medication might be used to treat one condition with high levels of success but an unrelated condition with less effectiveness. CMS proposes to use indications-based pricing where appropriately supported by published studies and reviews or evidence-based clinical practice guidelines, such as reports from The Institute for Clinical and Economic Review (ICER), to more closely align drug payment with outcomes for a particular clinical indication.
- **Risk-sharing agreements based on outcomes (page 53):** This proposed tool would allow CMS to enter into voluntary agreements with drug manufacturers to link health care outcomes with payment. CMS notes this method is sometimes used in the private sector when relatively few published studies or other pieces of evidence are available to establish a drug's long-term value with regard to the magnitude of patient health outcomes. These agreements tie the final price of a drug to results achieved by specific patients rather than using a predetermined price based on historical population data. Manufacturers agree to provide rebates, refunds, or price adjustments if the drug does not meet targeted outcomes.

CMS proposes that any outcomes-based risk-sharing agreements that it enters into would require a clearly defined outcome goal and it seeks comments on methods to collect and measure outcomes, including parameters around standardizing value metrics based on differences in drug treatments and their targeted patient subpopulations. At minimum, CMS proposes manufacturers provide all competent and reliable scientific evidence to create an accurate picture regarding clinical value for a specific drug, and also provide outcomes measures for any outcome-based risk-sharing pricing agreement. CMS also seeks comments on the level of transparency that would be required or desired under this tool while recognizing the need to protect proprietary information, as well as comments on methods for establishing patient-specific pricing contingent on response to therapy.

- **Discounting or eliminating patient cost-sharing (page 54):** This proposed tool would decrease or eliminate patient cost for services that are determined to be high in value in an attempt to tailor incentives. CMS proposes to decrease (below 20%) or eliminate cost-sharing entirely for certain products to encourage the use of high-value drugs. CMS, however, does not propose to increase cost-sharing beyond 20% for low-value drugs. The cost-sharing changes would be applied at the HCPCS level to all NDCs in a HCPCS code. Providers or suppliers would not have flexibility to change or waive cost-sharing amounts. In using this tool, CMS proposes to increase Medicare's payment percentage while maintaining the total allowed charges for the drug. However, CMS seeks comments on whether more targeted cost-sharing modifications should be considered and how such modifications would avoid creating unintended competitive advantages for drugs within the same HCPCS code or other similar drugs that are paid under other HCPCS codes.

Under phase II, CMS does not intend to apply the VBP tools to all Part B drugs, but instead plans to implement the use of the tools in a limited manner for certain drug HCPCS codes after considering the tools' appropriateness to specific Part B drugs within the identified HCPCS codes and seeks public comment. CMS proposes to solicit public feedback on specific pricing proposals for use of all VBP tools and that any CMS approved pricing changes under phase II would allow for a public feedback period and be published 45 days in advance of implementation. CMS also proposes to engage in educational activities to support implementation and testing of the VBP strategies and seeks comments to help define the parameters of these educational activities. CMS also seeks comments on any additional types of VBP tools that could be considered for future rule-making and potential safeguards that could be implemented with each of the tools to make certain that the intent of the payment model is not undermined. Finally, CMS proposes a pre-appeals process for certain VBP tools to protect beneficiaries and to allow for the consideration of special circumstances that may warrant the use of non-model payments in certain situations.

Clinical Decision Support Tool (page 56)

CMS notes that another potential component of VBP is the support of accurate clinical decision-making that is based on up-to-date scientific and medical evidence, such as well-designed and conducted clinical trials, updated information on drug safety, and practice guidelines. Clinical decision support (CDS) tools enable physicians to improve patient safety and quality of care by improving patient-specific drug dosing, reducing the risk of toxic drug levels, reducing the time to achieve therapeutic drug levels, decreasing medication errors, and changing prescribing patterns in accordance with evidence-based clinical guidelines recommendations.

CMS proposes a two component CDS tool that consists of an online tool to support 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 providers in the VBP arms of the model. Use of the CDS tool would be voluntary and is not intended to replace a provider's professional judgment for the treatment of patient-specific clinical conditions. Rather, it is intended to provide information on prescribing for specific indications that reflects up-to-date literature and consensus guidelines. CMS anticipates information in the CDS tool would be listed and indexed to correspond to drugs and disease states or conditions that are commonly treated in Part B, but seeks comment on alternative approaches to organizing the information.

CMS envisions the second component of the CDS tool to provide information on Part B claim payment patterns for specific drugs and/or indications. This component of the tool could be used nationally or within specific geographic areas and could provide feedback on how an individual provider's drug claim patterns compare with local or national data or even recommended guidelines. CMS notes that this information would be used solely for feedback and to support a physician's interest in mindful prescribing.

CMS proposes that the public would be able to provide feedback on the evidence basis proposed for information that is included in the CDS tool before CMS finalizes the information. CMS also proposes to implement the CDS tool incrementally by beginning with a limited number of drugs and/or disease states. CMS seeks feedback on which Part B drugs and conditions it should consider for initial inclusion with the CDS tool as well as general feedback on the CDS tool proposal.

Additional VBP Tools Being Considered (page 62)

In addition to the VBP tools outlined above, CMS is also considering three additional options that it is seeking comment on to determine if any or all are appropriate to pursue as part of the Part B payment model or in the near future:

- **Creating Value-Based Purchasing Arrangements Directly with Manufacturers (page 62):** This proposed tool would consider new approaches to pay for medications under Part B that are not accommodated within the current payment system, such as outcomes-based rebates. CMS seeks comment on several issues related to this potential VBP model including whether rebate distributions could legally be returned to the Medicare Part B

Trust Fund, the beneficiary, the provider or supplier, or a combination of the three. To help minimize the risk of abuse, CMS also seeks comment on the appropriate amount for any rebate sharing and other potential safeguards that could be implemented to make certain that the intent of the payment model is not undermined. Finally, CMS seeks comment on industry examples of outcomes-based rebates that have been successfully implemented and how that success could be translated to Part B drugs.

- **Part B Competitive Acquisition Program (CAP) (page 64):** This proposed tool would consider possibly reinstating the CAP that was suspended in 2009. Instead of buying drugs for office use, physicians who chose to voluntarily participate in CAP would place patient-specific drug orders with an approved CAP vendor that would provide the drug to the office for administration, bill Medicare, and collect cost sharing amounts from the patient. CMS notes a potential renewed interest in CAP given the evolution of the Part B drug market over the past decade which now includes high-cost medications such as specialty drugs and biologics. CMS seeks comment on whether sufficient interest in reinstating the CAP is present to warrant considering developing and testing such an alternative as part of a future model.
- **Episode-Based or Bundled Pricing Approach (page 67):** This proposed tool would consider an episode-based or bundled approach for Part B drugs in both physician offices and hospital outpatient settings to promote greater incentives for improved patient outcomes and financial accountability for episodes of care surrounding particular courses of treatment using particular Part B drugs. CMS seeks comment on a variety of issues related to this proposed tool including how to identify groups of similar drugs for inclusion in an episode and the care settings and disease states that should be considered for this type of pricing model.

Provider, Supplier, and Beneficiary Protections (page 74)

To protect beneficiaries and to allow for the consideration of special circumstances that may warrant the use of non-model payments in certain situations, CMS is proposing a Pre-Appeals Payment Exceptions Review process for certain VBP strategies that is intended to precede, not replace, the Medicare claims appeals process that is currently in place. CMS notes that providers, suppliers, and beneficiaries who are included in phase II of the model will have access to the existing claims appeals process, as well as a proposed Pre-Appeals Payment Exceptions Review process, to resolve disputes arising from the policies implemented by the model. The process would allow the provider, supplier, or beneficiary to contact the VBP contractor, before submitting a claim, and explain the need for exception to Medicare's pricing policy under the model is warranted in the beneficiary's situation, and explain why the pricing policy under the model does not provide adequate compensation for the prescribed drug. Payment exceptions decisions would be issued, in writing, within five (5) business days of receipt. CMS notes that while a payment exceptions decision would not confer appeal rights, a provider, supplier, or beneficiary dissatisfied with a payment exception decision or pricing decision may still use the current appeals process following submission of a claim. To avoid abuse of the appeals process, CMS seeks comment on potential safeguards that could be implemented to make certain that the intent of the model is not undermined.

Proposed Waivers of Medicare Program Rules (Page 77)

CMS proposes to use the waiver authority granted under Section 1115A(d)(1) of the Social Security Act to waive several provisions of statute in order to proceed with the Part B payment model as proposed. CMS notes use of the waiver provision is necessary to allow Medicare to test the approaches described in the proposed rule with the goal of increasing the value of drug therapy that is paid under Part B while improving, or maintaining, the quality of beneficiaries' care as the test model is implemented. CMS proposes to waive the following:

- **6% Add-On (page 77):** Portions of section 1847A(b) (1) of the Act which specify the 6% add-on percentage for payments determined under section 1847A of the Act.

- **Definitions (page 78):** The definitions of single source drug or biological, multiple source drug, and biosimilar biological product in section 1847A(c)(6) of the Act to determine payment for Part B drugs, which are grouped in a way that is different from how they are grouped in the statute. Further, alternative payment amounts proposed in the model may involve assigning a HCPCS code payment value with a different payment amount than what would be determined under section 1847A of the Act.
- **NDC Assignment to HCPCS Codes (page 78):** Provisions in section 1847A(b) of the Act that require the assignment of NDCs to HCPCS codes based on whether a drug meets the definition of single source drug or biological, multiple source drug, or biosimilar, which this section defines, and requires CMS to base the determination of the ASP (ASP + 0%) on the NDCs from this assignment.
- **Volume-Weighted ASP (page 79):** Section 1847A(b)(6) of the Act, which specifies how the volume-weighted ASP is to be used in the calculation of ASP, so that CMS can test alternatives to the ASP+6 percent methodology in the model, irrespective of the volume-weighted average payment amount determination. This subsection provides the formula for using volume as a factor for determining the ASP. CMS notes that waiving this provision is necessary to test changes to the payment determination methodology that is described in section 1847A of the Act.
- **OPPS Payment Policies (page 80):** Section 1833(t)(14) of the Act in its entirety, which specifies that the OPPS pays for certain outpatient drugs at acquisition cost plus an adjustment for overhead and handling; this payment is currently set to ASP + 6%.

CMS notes that providers and suppliers participating in the model must comply with all applicable laws and regulations not explicitly waived. CMS seeks comment on whether any additional areas of law and regulation should be waived to effectively test the payment model.

Evaluation Methods (page 81)

CMS proposes to evaluate the Part B payment model in a manner similar to other models developed and tested by CMMI with the intent to inform the Secretary and policymakers about the impact of the alternatives tested relative to payment under the traditional Part B drug payment system in the absence of such alternatives. CMS proposes to apply the model interventions based upon PCSAs and evaluate separately the impacts of the test interventions by comparing Part B drug use, program costs, and the quality of care for providers, suppliers, and beneficiaries in the areas assigned to each model test arm to those in areas assigned to the control arm. CMS proposes to include a range of analytic methods in its evaluation, including regression and other multivariate analyses, and details its proposed approach at length. CMS notes that its key evaluation questions would include, but are not limited to the following:

- **Payment:** Is there a reduction in Part B drug spending, as well as total Part B and total Medicare program expenditures, in absolute terms or for subcategories of providers and suppliers (for example, physician office vs hospital outpatient department, or rural vs urban settings)?
- **Prescribing Patterns:** Are there any observed changes in utilization (measure number of doses/refill patterns) and prescribing patterns overall and for specific types of providers and suppliers? How do these patterns compare to the control or historic patterns, potentially including longitudinal patterns and, if data permit, before and after the budget sequester that began in 2013? How are these patterns of changing utilization associated with the different Medicare payment alternatives?
- **Prescriber Acquisition Prices:** Is there any change in the prices at which providers and suppliers are able to obtain Part B drugs depending upon the payment environment that applies in a particular area?

- **Outcomes/Quality:** What is the impact on quality of care, access to care, timeliness of care, and the patient experience of care?
- **Unintended Consequences:** Did the model result in any observable unintended consequences? If so, how, to what extent, under which conditions, and for which beneficiaries, or providers and suppliers?
- **Variable Model Effects:** Was each intervention tested in the model more or less successful under some conditions compared to others, for example, in certain types of markets, geographic areas, or for certain categories of drugs?

CMS seeks comment on other potential questions for inclusion in the evaluation of the Part B drug payment model.

Economic Impact Analysis (page 84)

As noted previously, current Part B drug payments is estimated at \$22 billion for CY 2015. CMS intends phase I of the model to be budget neutral, but anticipates phase II could trigger saving the United States economy \$100 million or more annually. CMS notes the changes in the proposed rule will affect all categories of outpatient providers, physicians, practitioners, and other suppliers who furnish Part B drugs. CMS estimates that the effect of the model on physician specialties will vary, depending on what drugs they furnish and their clinical patterns, but for most would result in changes in drug payments in the range of -3.3 to 50.2% and -2.9 to 3.2% for overall Medicare payments. CMS estimates that most classes of hospitals paid under the OPDS will experience a minimal decrease in overall payment related to the model, which for most hospital categories would result in decreases in payments for separately paid drugs in the range of -2.5 to -2.0% and -0.9 to -0.1% for overall Medicare payments. CMS notes the effect of the model on an individual hospital, physician, practitioner, or other supplier will depend on its individual practice patterns.