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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 511

[CMS-1670-P]

RIN 0938-AS85

Medicare Program; Part B Drug Payment Model

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

ACTION: Proposed rule.

SUMMARY: This proposed rule discusses the implementation of a new Medicare payment model under section 1115A of the Social Security Act (the Act). We propose the Part B Drug Payment Model as a two-phase model that would test whether alternative drug payment designs will lead to a reduction in Medicare expenditures, while preserving or enhancing the quality of care provided to Medicare beneficiaries. The first phase would involve changing the 6 percent add-on to Average Sales Price (ASP) that we use to make drug payments under Part B to 2.5 percent plus a flat fee (in a budget neutral manner). The second phase would implement value-based purchasing tools similar to those employed by commercial health plans, pharmacy benefit managers, hospitals, and other entities that manage health benefits and drug utilization. We believe this model will further our goals of smarter, that is, more efficient spending on quality care for Medicare beneficiaries.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on May 9, 2016.

ADDRESSES: In commenting, please refer to file code CMS-1670-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four 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-1670-P,
P.O. Box 8016,
Baltimore, MD 21244-8016.

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-1670-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:
 - a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW.,
Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

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

FOR FURTHER INFORMATION CONTACT:

Susan Janeczko (410) 786-4529 or Jasmine McKenzie (410) 786-8102.

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.

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.

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Regulation Text

Acronyms

Because of the many terms to which we refer by acronym in this proposed rule, we are listing these abbreviations and their corresponding terms in alphabetical order below:

AHRQ Agency for Healthcare Research and Quality

AMP Average Manufacturer Price

ASP Average Sales Price

AWP Average Wholesale Price

BBA	Balanced Budget Act of 1997, Pub. L. 105–33
BPCI	Bundled Payments for Care Improvement
CAP	Competitive Acquisition Program
CDS	Clinical Decision Support
CCN	CMS Certification Number
CJR	Comprehensive Joint Replacement
CMS	Centers for Medicare & Medicaid Services
CPI	Consumer Price Index
CY	Calendar Year
DME	Durable Medical Equipment
ESRD	End Stage Renal Disease
FFS	Fee-for-Service
GAO	U.S. Government Accountability Office
IgG	Immunoglobulin G
IVIG	Intravenous Immune Globulin
HCPCS	Healthcare Common Procedure Coding System
MAC	Medicare Administrative Contractor
MedPAC	Medicare Payment Advisory Commission
NDC	National Drug Code
NOC	Not Otherwise Classified
NPI	National Provider Identifier
OIG	Department of Health and Human Services' Office of the Inspector General
OCM	Oncology Care Model
OPPS	Outpatient Prospective Payment System

OPD	Outpatient Department
PBM	Pharmacy Benefit Manager
PBPM	Per-beneficiary-per-month
PCSA	Primary Care Service Area
PFS	Physician Fee Schedule
TIN	Taxpayer identification number
VBP	Value-Based Purchasing
WAC	Wholesale Acquisition Cost

I. Executive Summary

A. Purpose

Part B includes a limited drug benefit that encompasses drugs and biologicals described in section 1861(t) of the Act. For the purposes of this proposed rule, the term “drugs” refers to drugs and biologicals paid under the Part B program, as well as biosimilars. Currently covered Part B drugs fall into three general categories: drugs furnished incident to a physician’s services, drugs administered via a covered item of durable medical equipment (DME), and other drugs specified by statute. Based on our claims data, we estimate total Part B payments for separately paid drugs in 2015 were \$22 billion (this includes cost sharing). In 2007, the total payments were \$11 billion; the average annual increase since 2007 has been 8.6 percent.¹ This significant growth has largely been driven by spending on separately paid drugs in the hospital outpatient setting, which more than doubled between 2007 and 2015, from \$3 billion to \$8 billion respectively.

¹ GAO Report MEDICARE PART B Expenditures for New Drugs Concentrated among a Few Drugs, and Most Were Costly for Beneficiaries (GAO-16-12) October 2015. <http://www.gao.gov/products/GAO-16-12>

The purpose of this proposed rule is to test a new payment model called the Part B Drug Payment Model under the authority of the Center for Medicare and Medicaid Innovation (Innovation Center). Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. We propose to exercise this authority to test whether the alternative drug payment designs discussed in this proposed rule will lead to spending our dollars more wisely for drugs paid under Part B, that is, a reduction in Medicare expenditures, while preserving or enhancing the quality of care provided to Medicare beneficiaries.

Many Part B drugs, including drugs furnished in the hospital outpatient setting, are paid using the methodology in section 1847A of the Act. In most cases, this means payment is based on the Average Sales Price (ASP) plus a statutorily mandated 6 percent add-on. Under this methodology, expensive drugs receive higher add-on payment amounts than inexpensive drugs while there are no clear incentives for providing high value care, including drug therapy. We propose a two phase model to test whether alternative payment approaches for Part B drugs improve value (relative to current drug payment approaches under Part B), improve outcomes and reduce expenditures for Part B drugs. This model's goals are also consistent with the Administration's broader strategy to encourage better care, smarter spending, and healthier people by paying providers and suppliers for what works, unlocking health care data, and finding new ways to coordinate and integrate care to improve quality.

(<http://www.hhs.gov/about/news/2015/01/26/better-smarter-healthier-in-historic-announcement-hhs-sets-clear-goals-and-timeline-for-shifting-medicare-reimbursements-from-volume-to-value.html#>).

B. Summary of Major Provisions

1. Model Overview

Medicare pays for most drugs that are administered in a physician's office or the hospital outpatient department at ASP+ 6 percent as described in section 1847A of the Act. The payment for these drugs does not include costs for administering the drug to a patient (for example by injection or infusion); payments for these physician and hospital services are made separately, and payment amounts are determined under the physician fee schedule (PFS) (<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html>) and the Hospital Outpatient Prospective Payment System (OPPS) (<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>). The ASP payment amount determined under section 1847A of the Act reflects a weighted average sales price for all National Drug Codes (NDCs) that are assigned to a Healthcare Common Procedure Coding System (HCPCS) code. The ASP payment amount does not vary based on the price an individual provider or supplier pays to acquire the drug. Payment determinations under the methodology in section 1847A of the Act also do not take into account the effectiveness of a particular drug. The payment determinations also do not consider the cost of clinically comparable drugs that may be priced exclusively in other HCPCS codes. The ASP methodology may encourage the use of more expensive drugs because the 6 percent add-on generates more revenue for more expensive drugs (see MedPAC Report to the Congress: Medicare and the Health Care Delivery System June 2015, pages 65-72). The ASP is calculated quarterly using manufacturer-submitted data on sales to all purchasers (with limited exceptions as articulated in section 1847A(c)(2) of the Act, such as sales at nominal charge and sales exempt from best price) with manufacturers' rebates, discounts, and price concessions included in the ASP calculation. The statute does not identify a reason for the additional 6 percent add-on above ASP. As noted in the MedPAC report (and by

sources cited in the report), the add-on is needed to account for handling and overhead costs and/or to account for additional mark-up in distribution channels that are not captured in the manufacturer reported ASP.

The following paragraphs present a brief summary of our proposals. Additional details are discussed later in this proposed rule. We propose two phases for the Part B Drug Payment Model. In phase I of the model, we propose implementing a variation to the add-on component of Part B drug payment methodology in different geographic areas of the country. We would test whether the proposed alternative approach for the ASP add-on payment, which is discussed later in this proposed rule, would strengthen the financial incentive for physicians to choose higher value drugs. To eliminate selection bias, we are proposing to require participation for all providers and suppliers furnishing any Part B drugs included in the Part B Drug Payment Model who are located in the geographic areas that are selected for inclusion in the model. We propose to implement this first phase of the overall model no earlier than 60 days following display of the final rule. While this approach addresses the add-on to the manufacturer's ASP, it does not directly address the manufacturer's ASP, which is a more significant driver of drug expenditures than the add-on payment amount for Part B drugs. For a given HCPCS code, the add-on represents about 6 percent of an ASP-based Part B drug payment; the remaining 94 percent of the payment is calculated from the manufacturers' reported ASP data.

In phase II of this model, we propose to implement value-based purchasing (VBP) in conjunction with the phase I variation of the ASP add-on payment amount for drugs paid under Part B. Phase II would use tools currently employed by commercial health plans, pharmacy benefit managers (PBMs), hospitals, and other entities that manage health benefits and drug utilization. These tools have been used for years with positive results, and we believe that some of these successful approaches may be adaptable to Part B. We propose to apply one or more

tools, such as indication-based pricing, reference pricing, and clinical decision support tools to Part B drugs. We will test whether the implementation of the tools affects expenditures and outcomes.

In addition to the proposals and comment solicitations associated with phase I and phase II, we also solicit comments on how to create value-based purchasing arrangements with manufacturers under Medicare fee-for-service (FFS) payment for drugs; on whether we should consider implementing an updated version of the Competitive Acquisition Program (CAP); and whether we should pursue a more bundled or episode-based approach that moves beyond an FFS payment structure. We would consider all comments on these two solicitations for future rulemaking.

2. Model Scope

Under the model, we propose that providers and suppliers, in a selected geographic area, who are furnishing a covered and separately paid Part B drug that is included in this model, would receive alternative Part B drug payments. Within such selected areas, examples of providers and suppliers that Medicare commonly pays for Part B drugs include: physicians, durable medical equipment (DME) suppliers (including certain pharmacies that furnish Part B drugs), and hospital outpatient departments that furnish and bill for Part B drugs. There will be no specific enrollment activities for providers, suppliers, or beneficiaries in this model; the furnishing of Part B drugs in a particular geographic area will determine participation. We propose to require all providers and suppliers 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. We propose 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. We propose to use Primary Care Service Areas (PCSAs) as the geographic area. We propose 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. We propose to include the majority of drugs paid under Part B in the model; in general, this means drugs that appear on the quarterly ASP Price Files. We propose to exclude some categories of drugs, including drugs separately billed by End-Stage Renal Disease (ESRD) facilities from the proposed Part B Drug Payment Model.

We propose that the model would run for five years; phase I would begin in the fall of 2016 (no earlier than 60 days after the rule is finalized). During phase I, providers and suppliers that participate in the model would receive payments with either the existing statutory add-on amount or payments with the modified add-on amount. 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 experience both phase I pricing and phase II VBP pricing. We expect that phase II could take several years to fully implement. Our 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.

3. Model Payment

In section III of this proposed rule, we propose to test an alternative to the ASP add-on payment in phase I of the model. We would assign providers and suppliers to the alternative ASP add-on approach or to the control group. We propose to use ASP+2.5 percent plus a flat fee as the alternative add-on amount; however, we also discuss and solicit comments on whether an

additional approach, such as ASP + a tiered percentage add-on amount should be tested. We invite comment on whether these two approaches are sufficiently different to warrant separate arms under this model. The aggregate value of the phase I add-on that is paid each year is proposed to be budget neutral meaning that the initial total payments under the model will be based on the most recently available calendar year claim's total Part B drug payment amount for separately paid drugs and then updated annually. In other words, we are not proposing a reduction to total spending for Part B drugs. Instead, we propose to test redistribution of the add-on payment on Part B drugs expenditure and outcomes. Additional detail about phase I appears in section III.A. of this proposed rule.

In phase II of the model, we propose to test the application of a group of value-based purchasing tools that commercial and Medicare Part D plans use to improve patient outcomes and manage drug cost. We review several different tools, including value-based pricing, clinical decision support tools, and we discuss the potential applicability to the Part B drug and hospital outpatient benefits. Additional detail about phase II appears in section III.B. of this proposed rule. Table 1 summarizes the phases and arms of the model.

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.

We also solicit comment on creating value-based purchasing arrangements directly with manufacturers, taking an episode-based or bundled pricing approach, and applicability of the Part B Drug CAP.

4. Overlap with Ongoing CMS Efforts

We note that there are possibilities of overlap between the Part B Drug Payment Model and the Medicare Shared Savings Program, the Medicare Intravenous Immune Globulin (IVIG) Demonstration, and other Innovation Center payment models, such as the Oncology Care Model (OCM) and the Bundled Payments for Care Improvement (BPCI) initiative. In general, we propose not to exclude beneficiaries, suppliers (including 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, as detailed in section III.E. of this proposed rule. We acknowledge that there is potentially greater overlap between this proposed model and OCM than other models. We propose to include OCM practices in the Part B Drug Payment Model, but we request comment on the best approach for handling that overlap and on whether we should exclude OCM practices and their comparison practices from the Part B Drug Payment Model.

C. Economic Effects

Under phase I we propose to modify the ASP add-on amount to be 2.5 percent plus a flat fee of \$16.80. We propose to establish the amount of the flat fee to ensure total estimated

payments under this model are budget neutral to aggregate Part B spending, using the most recent year of available claims data. For phase I of this model, budget neutrality calculations were done using CY 2014 claims processed through June 30, 2015. We present the redistributive impacts among practitioners and hospitals in section IX. of this proposed rule. In general, phase I has the overall effect of modestly shifting money 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. In aggregate, rural practitioners are estimated to experience a net benefit and rural hospitals are estimated to experience smaller reductions than urban hospitals. Overall, spending on drugs furnished in the office setting increases while spending on drugs furnished in the hospital setting decreases.

We intend to achieve savings through behavioral responses to the revised pricing, as we hope that the revised pricing will remove any excess financial incentive to prescribe high cost drugs over lower cost ones when comparable low cost drugs are available. In other words, we believe that removing the financial incentive that may be associated with higher add-on payments will lead to some reduction in expenditures during phase I of the proposed model. An exact estimate of the amount of savings that might be achieved through behavioral responses is not readily available. Prior research on behavioral changes following modifications to drug margins suggests that the modifications we propose to the 6 percent add-on are likely to change prescribing behavior.

In phase II, we propose applying VBP tools including value-pricing and clinical decision support tools. The pricing under this phase would not be budget neutral, and we intend to achieve savings. We invite extensive comment throughout this proposed rule on the applicability of various value-based purchasing tools to the Part B and hospital outpatient drug benefit. We do not believe that we have enough detail on the structure of the final VBP component to quantify

potential savings at this time. As with phase I, we believe that implementation of these tools will result in some reduction in expenditures. We invite comment on the extent of savings that might be achieved based on experience with these VBP tools.

II. Participation

A. Background

This section describes the drugs that are furnished and paid under Part B; the providers and suppliers that furnish them; and the drugs, participants, and geographic areas that would be included in the model.

1. Drugs and Biologicals Paid Under Part B

Part B currently covers and pays for a limited number of prescription drugs. As stated earlier, for the purposes of this proposed rule, the term “drugs” will refer to drugs and biologicals paid under Part B and also includes biosimilars. Drugs paid under Part B generally fall into three categories: drugs furnished incident to a physician’s service in the physician office or hospital outpatient settings, drugs administered via a covered item of DME, and other categories of drugs specified by statute (generally in section 1861(s)(2) of the Act).

The majority of Part B drug expenditures are for drugs furnished incident to a physician’s service. Drugs furnished incident to a physician’s service are typically injectable drugs that are administered in a non-facility setting (covered under section 1861(s)(2)(A) of the Act) or in a hospital outpatient setting (covered under section 1861(s)(2)(B) of the Act). Examples of “incident to” drugs include injectable drugs used to treat macular degeneration, intravenously administered drugs used to treat cancer, injectable drugs used in connection with the treatment of cancer, and injectable biologicals used to treat rheumatoid arthritis. The statute (sections 1861(s)(2)(A) and 1861(s)(2)(B) of the Act) limits “incident to” services to drugs that are not usually self-administered; self-administered drugs, such as orally administered tablets and

capsules are not paid for under the “incident to” provision. Payment for drugs furnished incident to a physician’s service falls under section 1842(o) of the Act. In accordance with section 1842(o)(1)(C) of the Act, most “incident to” drugs are paid under the methodology in section 1847A of the Act.

Part B also pays for drugs that are infused through a covered item of DME, such as drugs administered with an intravenous pump and inhalation drugs administered through a nebulizer. Medicare payments for these drugs are described in section 1842(o)(1)(D) of the Act for DME infusion drugs and section 1842(o)(1)(G) of the Act for inhalation drugs.

Finally, Part B covers and pays for a number of drugs with specific benefit categories defined under section 1861(s) of the Act including—immunosuppressive drugs; hemophilia blood clotting factors; certain oral anti-cancer drugs; certain oral antiemetic drugs; pneumococcal pneumonia, influenza and hepatitis B vaccines; erythropoietin for trained home dialysis patients; certain other drugs separately billed by ESRD facilities; and certain osteoporosis drugs. Payment for many of these drugs falls under section 1842(o) of the Act, and in accordance with section 1842(o)(1)(C) of the Act, most, but not all, drugs with specific benefit categories are paid under the methodology in section 1847A of the Act. As discussed below, we propose to include the majority of Part B drugs in this model.

2. Types of Providers and Suppliers Furnishing Part B Drugs

Types of providers and suppliers that are paid for all or some of the Medicare covered Part B drugs that they furnish include physicians, pharmacies, DME suppliers, hospital outpatient departments, and ESRD facilities. We propose to include the majority of Part B drugs in the Part B Drug Payment Model and therefore we anticipate that few providers, and physicians and other suppliers that currently furnish Part B drugs would be excluded. However, some may experience limited impact from participation if they prescribe or furnish a low volume of drugs

paid under the Part B benefit. Based on payment data for Part B drugs, among the providers, physician, and DME suppliers that furnish Part B drugs, we anticipate that physicians and outpatient hospitals will see the greatest impact from this proposed model.

In section IX, Regulatory Impact Analysis, we discuss the potential effects of this model on suppliers and providers, including rural hospitals. Although the impact on rural hospitals is expected to be minimal (see Table 2) and the impact on rural physician specialties is generally favorable (when compared to urban specialties) (see Table 1), we are soliciting comments on the potential effect that this model may have on rural practices, how rural practices may differ from non-rural practices and whether rural practices should be considered separately from other practice locations. On a similar note, we are also soliciting comments on the potential effect that this model may have on small practices, how small practices (for example, solo practices and practices with two to nine eligible professionals) may differ from large practices and whether small practices should be considered separately from other practices.

B. Proposed Drugs Paid under Part B to be Included in the Model

Although the Part B drug benefit is generally considered to be limited in scope, the Part B drug benefit includes many categories of drugs, and encompasses a variety of care settings, and payment methodologies. In accordance with section 1842(o)(1)(C) of the Act, most Part B drugs are paid based on the ASP methodology described in section 1847A of the Act. However, at times Part B drugs are paid based on Wholesale Acquisition Cost (WAC), as authorized under section 1847A(c)(4) of the Act (see 75 FR 73465-6, the section titled Partial Quarter ASP data), or average manufacturer price (AMP)-based price substitutions, as authorized under section 1847A(d) of the Act (see 77 FR 69140). Also, in accordance with section 1842(o) of the Act, other payment methodologies may also be applied to Part B drugs: average wholesale price (AWP)-based payments (using the AWP in effect in October 1, 2003) are made for certain drugs

infused with covered DME; and AWP-based payments (using current AWP) are made for influenza, pneumococcal pneumonia and hepatitis B vaccines (section 1842(o)(1)(A)(iv) of the Act). We also use current AWP to make payment for very new drugs without ASP under the OPPS (80 FR 70426 and 80 FR 70442-3; Medicare Claims Processing Manual 100-04, Chapter 17, Section 20.1.3). With the exception of the following: influenza vaccine payment amounts, which are updated annually near the beginning of each flu season (<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/VaccinesPricing.html>), certain new drugs under the OPPS, and DME infusion drug payments which are based on November 2003 AWP values (section 1842(o)(1)(D) of the Act), payment amounts for drugs paid under the methodology in section 1847A of the Act (which means most Part B drugs) are updated quarterly by CMS. Contractors then use these quarterly updates to make payment determinations. Examples of the quarterly ASP price file updates for 2016 are available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2016ASPFiles.html>. Contractors may also make independent payment amount determinations in situations where a national price is not available for physician and other supplier claims and for drugs that are specifically excluded from payment based on section 1847A of the Act (for example, radiopharmaceuticals as noted in section 303(h) of the Medicare Modernization Act). In such cases, pricing may be determined based on compendia or invoices (Medicare Claims Processing Manual 100-04, Chapter 17, Section 20.1.3).

With limited exceptions that are discussed in this section below, we propose to include all Part B drugs in this model. We would overlay payment amounts for Part B drugs (which are also referred to as payment allowance limits) on the quarterly ASP Drug Pricing Files (see <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B->

Drugs/McrPartBDrugAvgSalesPrice/2016ASPFiles.html) and the quarterly update to Addendum B of the OPSS (<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html>) with model-derived payment amounts in the geographic areas that are being evaluated. Therefore, we would include nationally priced drugs with ASP, WAC, and AMP-based payment amounts that are on the quarterly price file; we note that based on recent claims data, nationally priced drugs with ASP-based payments account for the vast majority of this group. This means that the following drugs (and certain associated fees) would also be included in the model:

- Drugs and biologicals (including biosimilars) with HCPCS codes that are nationally priced under the methodology described in section 1847A of the Act, including ASP and WAC-based payment amounts, and drugs (and biologicals) paid separately under OPSS. Because OPSS pass-through drugs described in section 1833(t)(6) of the Act are paid ASP+6 percent, which is the same payment as separately paid drugs under the OPSS, we propose including all OPSS pass-through drugs in the model. In phase I, for drugs paid based on ASP and WAC, the 6 percent add-on will be replaced with the updated add-on amount (discussed in section III.A. of this proposed rule). 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; in other words, if the model-based payment is lower than the AMP-substitution-based payment determined under the authority in section 1847A(d) of the Act, the model-based payment amount will 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. Payment for these drugs is typically based on the ASP, but additional fees are also paid by Medicare for dispensing,

supplying, or furnishing some of these drugs in accordance with section 1842(o) of the Act. We believe that it is important for the model to include drugs that are used outside of the incident-to setting. Also, we believe that it is important to understand the impact of other payment-related financial incentives that are associated with the drug payment, therefore we propose that phase II of this model may incorporate changes to the furnishing, supplying and dispensing fees that are associated with these drugs. (Note that this subset of drugs that are furnished by DME suppliers does not include drugs that are infused with covered DME. DME infusion drugs are discussed later in this section.)

- Intravenously and subcutaneously administered immunoglobulin G (IgG). This includes products administered in the office as well as intravenous products administered in the home to patients with primary immunodeficiency under the benefit described in section 1861(s)(2)(Z) of the Act. Payment for intravenously administered IgG used in these situations is typically based on the ASP (section 1842(o)(1)(E)), while payment for subcutaneously infused IgG will depend on who furnishes the drug. For example, physicians would typically be paid an ASP-based amount while DME suppliers would be paid an amount based on the AWP.

We do not believe that all Part B drugs are appropriate candidates for inclusion in this phase of the model, and we propose to exclude the following categories of drugs:

- Contractor-priced drugs, including drugs that do not appear on the quarterly national ASP price file. Because pricing for contractor-priced drugs may vary, we are limiting the model to drugs that are nationally priced by CMS. Contractor-priced drugs (which are not nationally priced) would continue to be priced by contractors as described in the Medicare Claims Processing Manual 100-04, Chapter 17, Section 20.1.3. However, in situations where the previous manual citation either permits contractors to contact us 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, we propose that contractors would be permitted to utilize reductions to the add-on percentage that they calculate. For example if a contractor currently uses a WAC-based payment amount and adds a 6 percent add-on under existing authority, the add-on percentage could be decreased to correspond to the model arm that is being evaluated in that area. We propose to implement this approach by issuing subregulatory instructions to contractors that would allow them to utilize the modified add-on percentage for contractor-based claims. We seek comments on whether we should permit contractors to alter the add-on percentage for drug payment amounts that are determined by contractors during this model. Contractor-priced drugs include certain radiopharmaceuticals that are furnished in the physician's office (therapeutic radiopharmaceuticals paid separately under the OPSS for hospital outpatients are discussed later in this rule).

- Influenza, pneumococcal pneumonia and hepatitis B vaccines paid under the benefit described in section 1861(s)(10) of the Act. Payment amounts for these vaccines are not determined using the methodology in section 1847A. We consider these items to be preventive services (for more information about preventive services, see <https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/index.html?redirect=/Prevntiongeninfo/>), and preventive services, such as these vaccines, are typically provided at no cost to beneficiaries. We propose to exclude vaccines in section 1861(s)(10) of the Act that are preventive services from this model.

- Drugs infused with a covered item of DME in phase I. Payment for this subset of DME drugs is made based on the AWP in effect on October 1, 2003. We propose to exclude this category of drugs 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. However, OIG has pointed out concerns related to

mismatch between acquisition costs and payment for this group of drugs (OEI-12-12-00310, February 2013. See <http://oig.hhs.gov/oei/reports/oei-12-12-00310.asp>). We do not propose to exclude DME infusion drugs from the entire model, just phase I.

- ESRD drugs paid under the authority in section 1881 of the Act. Many ESRD drugs are bundled with services, and relatively few drugs are still paid separately. Given adoption of bundled payments for renal dialysis services and the diminishing number of drugs that are paid separately in this setting, we do not believe that including ESRD drugs in the proposed Part B Drug Payment Model is prudent.

- Blood and blood products. Blood and blood products are prepared in blood banks (rather than drug manufacturing facilities), and have different distribution channels than drugs that are paid under Part B. ASP sales data and compendia pricing for many of these products are not available.

We are also concerned about how to treat drugs that are in short supply. Due to access concerns related to drug shortages, under current Part B drug payment, we exclude drugs that are in short supply from AMP-based price substitution and, instead, we utilize the ASP+6 percent payment amount. The exclusion criteria for the AMP price substitution and the process for determining whether a drug is in short supply are described in the CY 2013 Medicare PFS rule with comment (77 FR 69141). To maintain access to drugs that are in short supply, we believe that incorporating a safeguard is prudent. Thus, for drugs that are included in the model and are reported by the FDA to be in short supply (for example on the FDA Current Drug Shortage list at <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm>) at the time that model payment amounts are being finalized for the next quarter, we propose to continue paying for these drugs using the existing statutory methodology in section 1847A of the Act. This safeguard

will prevent the use of a payment amount that is lower than that determined using the existing statutory methodology if a drug is in short supply.

We considered proposing to pay the greater of the following: the applicable arm's model payment amount, or the current quarter's statutory payment amount (which is often ASP+6 percent). We believe that this approach could increase payment compared to the model intervention for many drugs that are in short supply; however, we have no evidence that leads us to believe that this approach would have any meaningful positive effect on the resolution of a drug shortage. We are also concerned that incorporating this approach in this model would not provide us reliable information on how pricing impacts the focus, size, and duration of drug shortages. We are seeking comment 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 that would persuade us to reconsider our position.

The new proposed §511.200, found in subpart C of this proposed rule, reflects the drugs that we propose to include in the model. Section 511.300(c)(1) addresses drugs that are in short supply.

C. Proposed Participants, Selected Geographic Areas, and Sampling

We propose that providers and suppliers in selected geographic areas furnishing covered and separately paid Part B drugs that are included in this model, under phase I, would receive an alternative add-on to the ASP for Part B drug payments. Under phase II of the proposed model, providers and suppliers in other distinct and/or overlapping geographic areas would receive VBP payments (see sections III.A and B. of this proposed rule for a description of the proposed alternative Part B drug payments; note that one arm combines an alternative ASP add-on payment and VBP). We are interested in testing and evaluating the impact of an alternative ASP payment for Part B drugs alone in phase I of the proposed model, and in phase II, we are

interested in testing and evaluating the impact of VBP tools alone and simultaneously in combination with alternative ASP payments (see Table 1 in section I).

The Part B Drug Payment Model requires the participation of all providers and suppliers furnishing covered and separately paid Part B drugs that are included in this model. We believe a model in which participation is required of all providers and suppliers furnishing included Part B drugs in the selected geographic areas is appropriate to ensure that observed outcomes in each arm of the model do not suffer from selection bias inherent in a voluntary participation model and that observed outcomes can be generalized to all providers and suppliers billing Part B drugs. The voluntary structure of some 1115A model initiatives has facilitated testing new payment methodologies that differ significantly from current payment structures, such as BPCI. Voluntary participation can limit the generalizability of model results as voluntary model participants may not be broadly representative of all entities who could be affected by the model. Before BPCI models were scheduled to end, CMS launched the Comprehensive Joint Replacement (CJR) initiative after realizing that the full potential of new payment models requires the engagement of an even broader set of providers and suppliers than have participated to date, including those who may only be reached when new payment models are applied to an entire class of providers of a service. Requiring participation in the Part B Drug Payment Model ensures that the broadest set of providers and suppliers are included in the model from the start. Mandatory participation allows us to observe the experiences of an entire class of providers and suppliers with various characteristics, such as different geographies, patient populations, and specialty mixes, and to examine whether these characteristics impact the effect of the model on prescribing patterns and Medicare Part B drug expenditures.

In determining which providers and suppliers to include in the model, we considered whether the model should be limited to specific specialties that prescribe (or furnish) a

significant portion of high cost drugs only or to any entity prescribing drugs for certain indications. Limiting the model to specific specialties that are associated with high cost drug payments would not allow us to observe overall changes in prescribing patterns by practitioners for all Part B drugs. Many types of providers and suppliers furnish Part B drugs that are of low or medium cost in addition to high cost drugs. Medium and low-cost drugs may also be affected by statutory pricing, and CMS believes that understanding their prescribing patterns may be as important as understanding high cost drug prescribing patterns.

Similarly, limiting the model to drugs that only treat a specific indication also would not allow us to assess the full impact of proposed payment changes on Part B expenditures and outcomes as drugs that treat a specific indication rarely represent the full range of drug treatment options that are typically available in Part B, and could miss attributes such as the presence of substitutable therapies and a wide range of pricing. Therefore, given the authority in section 1115A(a)(5) of the Act, which allows the Secretary to elect to limit testing of a model to certain geographic areas, we propose to require all providers and suppliers in selected geographic areas furnishing and receiving separate payment for the drugs separately paid under Part B that are included in this proposed model to take part in the model. We discuss our consideration of geographic area selection and random assignment methodology in more detail below.

1. Overview and Options for Geographic Area Selection

In determining the most appropriate geographic unit for this model, we considered five options: (1) states; (2) Core Based Statistical Areas (CBSA)²; (3) Dartmouth Atlas of Health Care's Hospital Referral Regions (HRR)³; (4) ZIP codes⁴ and (5) PCSA⁵.

² <http://www.census.gov/population/metro/>

³ <http://www.dartmouthatlas.org/downloads/methods/geogappdx.pdf>

⁴ <http://www.census.gov/geo/reference/zctas.html>

⁵ <http://bhpr.hrsa.gov/healthworkforce/data/primarycareserviceareas/index.html>

For phase I of the model, we are proposing an alternative ASP payment method to be tested against the current ASP+6 percent method (see section III of this proposed rule), that creates three requirements for the selection of geographic areas. First, the areas need to be sufficiently large so that most providers and suppliers do not have practice locations in multiple areas. A provider or supplier with practice locations in multiple areas may be subject to multiple payment changes. This situation could create an unnecessary administrative burden for the provider or supplier. It may also create an opportunity for a provider or supplier to attempt to influence a patient to receive a medically appropriate drug paid under Part B at the practice location that provides higher payment to the provider or supplier. Moreover, we want to test the alternative payment methods in circumstances that most closely resemble how Part B drug payment policy currently is implemented, with only one payment methodology applicable to a particular provider or supplier for a particular Part B drug. Under all of these circumstances, a larger unit of analysis is preferred.

Second, the areas need to be sufficient in number to ensure adequate statistical power for the evaluation of the model. In general, the larger the number of geographic units available for assignment to the intervention and comparison groups, the greater our ability to determine whether measured differences between the intervention and comparison groups are attributable to the effects of the model or to random chance. Thus, in choosing a unit of analysis, a choice that creates more independent geographic units is preferred.

Third, the areas need to have characteristics that are relatively more similar when comparing one to another so that observed changes at the area level can be more clearly attributed to the intervention and not to other factors. If two groups of areas are exactly alike in all relevant aspects before an intervention is applied, then after the intervention is applied to one group of areas and not the other, we can conclude that any differences that we observed between

the two groups are a result of the intervention. In practice, while it is possible to select intervention and comparison areas in a way that ensures that the intervention and comparison groups are similar with respect to a set of observed characteristics (an approach known as “stratification”), it is generally impossible to construct groups that are identical in all respects because not all relevant differences can be observed. Instead, the standard approach to evaluating the effects of an intervention is to select a sufficiently large number of intervention and comparison areas to ensure that any unobserved differences between the two groups are likely to be small (on average), which permits the differences between the groups to be attributed to the intervention with reasonable confidence. The less variation there is among the areas being studied (after accounting for any reduction in variation due to stratification), the smaller the number of intervention and comparison areas required to reliably detect an effect of a given size (or, equivalently, the smaller the effect that can reliably be detected for any given number of intervention and comparison areas).

In general, with geographic areas as the unit of analysis, larger areas are likely to exhibit more substantial cross-area variation with respect to relevant characteristics such as the total number of beneficiaries as well as variations in the number of beneficiaries per square mile, or beneficiary population density. While, as noted above, stratification can help reduce the differences between the intervention and comparison areas with respect to observed characteristics, when areas vary widely and there are relatively few potential areas to test, stratification may have a limited ability to ensure balance with respect to observed characteristics and thereby increase the power of a test.

In selecting the most appropriate geographic unit for the model, the first option that we considered for a unit of analysis was entire states. States represent a sufficiently large area so as to prevent most individual providers or suppliers from experiencing multiple interventions under

the model simultaneously. However, states as a unit of analysis also would greatly limit the number of independent geographic areas subject to selection under the model and, therefore, would decrease the statistical power of the model test to the extent that none of the anticipated changes in Part B drug use or expenditures due to the model interventions could be measured with statistical confidence.

For the second option, we considered CBSAs, a Census-defined core area containing a substantial population nucleus together with adjacent communities that have a high degree of economic and social integration. There are 929 CBSAs, which include 388 Metropolitan Statistical Areas (MSAs), with an urban core population of at least 50,000, and 541 Micropolitan Statistical Areas (μ SA), with an urban core population of at least 10,000 but less than 50,000. All remaining areas within a state that are not included in CBSAs are lumped into one area designated as Outside Core Based Statistical Areas.⁶ The choice of a geographical unit based on CBSA status could mean an MSA, or a Combined Statistical Area (CSA) that consists of adjacent MSAs or μ SAs or both. Unlike CJR, where the providers and suppliers of services included in the model tend to be concentrated in high population density regions captured by CBSAs, in this proposed model, the practice locations of Part B drug providers and suppliers are distributed more often in less population dense areas. Therefore, the choice of a CBSA unit for the model would not include all providers and suppliers eligible for the model in regions that are fully representative of the entire country. To address this issue, we would anticipate designating the non-CBSA portions of each state (if any) as additional units of analysis to ensure the model addresses all eligible providers and suppliers. These non-CBSA areas could either be considered

⁶ On July 15, 2015, OMB issued OMB Bulletin No. 15-01, which established revised delineations for MSAs, μ SAs, and CSAs, and provided guidance on the use of the delineations of these statistical areas. A copy of this bulletin may be obtained at <https://www.whitehouse.gov/sites/default/files/omb/bulletins/2015/15-01.pdf>. The Standards for Delineating Metropolitan and Micropolitan Statistical Areas Notice upon which the 2015 revisions are based was published June 28, 2010 and corrected July 7, 2010.

a single large unit or could be divided into counties. If CBSAs were adopted as the unit of analysis for the model test, they are sufficiently large to prevent most individual providers or suppliers from experiencing two intervention arms simultaneously. The 929 CBSAs divided equally among the three proposed model test arms and the fourth control arm would result in approximately 232 CBSAs per arm. This could provide minimally sufficient statistical power to detect moderate changes in Part B drug expenditures or utilization, provided that appropriate stratification or analytic adjustments are made to address the wide variation across CBSAs in size and population density. However, having only minimally sufficient power may reduce the opportunities to conduct deeper analyses, such as examining whether specific aspects of the VBP intervention have a greater impact compared with smaller and more uniform areas.⁷ The differences in sizes and population densities of CBSA subunits may require additional stratification or analytic adjustments to be able to generalize results.

For the third option, we considered HRRs, which represent regional health care markets for tertiary medical care. There are 306 HRRs, which include at least one city where both major cardiovascular surgical procedures and neurosurgery are performed⁸. The number of HRRs is an improvement relative to states, but would not provide sufficient statistical power for an effective evaluation of this model. Therefore, the HRR is not the most appropriate unit of analysis for this model.

Fourth, we considered the smallest geographic unit directly linkable to Medicare Part B claims, the U.S. Postal Service's five digit ZIP codes.⁹ ZIP codes are assigned by the U.S. Postal Service to every address in the country. They represent a system of 5-digit codes that geographically identifies individual Post Offices or metropolitan area delivery stations associated

⁷ Murray, D. M., Varnell, S. P., & Blitstein, J. L. (2004). Design and Analysis of Group-Randomized Trials: A Review of Recent Methodological Developments. *American Journal of Public Health*, 94(3), 423-432.

⁸ <http://www.dartmouthatlas.org/downloads/methods/geogappdx.pdf> pp.294-5. Accessed Jan 13, 2016

⁹ <http://faq.usps.com/#Zone> Accessed Jan 13, 2016

with every mailing address. There are more than 42,000 five digit ZIP codes.¹⁰ The number of ZIP codes would provide sufficient statistical power for the model evaluation analyses. However, we are concerned that ZIP codes are very small geographic areas. While hospital outpatient departments bill as part of the hospital from a single location with a single ZIP code, large physician practices can span multiple ZIP codes. Supplier claims include a service location ZIP code that determines the geographic adjustment, and the physician must bill based upon the ZIP code of the location where services were rendered. While sampling by ZIP code would improve the power of the model's evaluation, it could expose physicians to multiple payment methods during the model test, which as we discussed above, is an unnecessary burden and has no analog in current policy.

In seeking an area definition that is sufficiently large to minimize the potential for exposing providers or suppliers to multiple test payment alternatives, while sufficiently small to ensure a sufficient numbers of areas, and to limit cluster effects due to differences that cannot be balanced using stratification, we considered aggregations of contiguous ZIP codes. Random aggregations of contiguous ZIP codes can be developed to optimize the characteristics required for a robust test of the model. Developing a unit of analysis tailored to the model test has merit, but the goal of this model is not to develop a new unit of analysis, and the process for doing so would require considerable resources for definition and validation. We would prefer to adopt an existing geographic unit of analysis that meets the requirements for testing the model.

Finally, we considered PCSAs, which were defined and updated under contract to the Health Resources and Services Administration (HRSA) by The Dartmouth Institute.¹¹ With the goal of representing service areas for office based primary health care services, PCSAs were

¹⁰ <http://faq.usps.com/?articleId=219334> Accessed Jan 13, 2016

¹¹ <http://datawarehouse.hrsa.gov/data/dataDownload/pcsa2010download.aspx> Accessed Jan 13, 2016

defined based upon patterns of Medicare Part B primary care services (specifically, patterns linking the residence of Medicare Part B beneficiaries with the practice locations for evaluation and management visits to Medicare participating physicians in primary care specialties¹²). While the service areas for evaluation and management visits may not directly match Part B drug-service areas, they are likely to be a closer match than randomly aggregated ZIP codes. CMS analyzed CY 2014 claims data, including provider and supplier practice locations for those delivering Part B drugs relative to PCSA boundaries using the practice location of the performing National Provider Identifier (NPI) or the billing location of the organizational NPI for hospital outpatient departments, and observed that almost all claims for an individual provider or supplier were billed within a single PCSA. It is possible, however, that large practices may have practice locations in more than one PCSA. As a result, there could be situations during the model test in which those large practices are exposed to multiple arms, and thus to different payment methods simultaneously.

Nevertheless, we believe that of all existing units of analysis, PCSAs are the most appropriate unit for testing this model in that they exhibit a desirable mix of size, internal homogeneity relative to differences between areas, and number. This preference is based on the specifics of this model, including the types of services involved, the national scope, and the simultaneous testing of multiple payment alternatives, and is not meant to imply that other units of analysis would not be appropriate in a different model (for example, the MSA used in the CJR model¹³).

We propose to require all providers and suppliers furnishing Part B drugs that are included in the model to participate in the Part B Drug Payment Model. Participation means that

¹² Goodman, DC, et al. Primary Care Service Areas: A New Tool for the Evaluation of Primary Care Services. *Health Services Research* 2003;38:287---309.

¹³ <https://www.federalregister.gov/articles/2015/11/24/2015-29438/medicare-program-comprehensive-care-for-joint-replacement-payment-model-for-acute-care-hospitals#h-32> Accessed Jan 13, 2016

any claim submitted for a Part B drug in the model will be paid according to the payment applicable for the control group, ASP+6 percent, or one of the proposed test alternatives (see Table 1). We propose the payment method used will be determined by the PCSA associated with the claim. We propose 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. The service location ZIP code linked to the performing NPI (recorded in item 32) will be used for practitioner claims (CMS-1500). The ZIP code in the 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-1490S). Each five digit ZIP code identified in U.S. Postal Service ZIP code files is linked to a PCSA. The PCSA associated with the claim in the manner above will be assigned to one of the three test arms or the control arm of this model test (see below for PCSA assignment method). We include a summary table of the proposed model under section I.B.3. of this proposed rule.

2. PCSA Selection

There are 7,144 PCSAs in the United States, covering all 50 states.¹⁴ Because the waiver for Medicare hospital payment rules in the Maryland All-Payer Model¹⁵ may create unobservable bias in the prescribing patterns or payments for the Part B drugs in this model test, we propose to exclude Part B drug claims from providers and suppliers associated with the 96 PCSAs located in Maryland from the Part B Drug Payment Model. This exclusion leaves a total of 7,048 PCSAs in the model test.

To test the impact of the model's intervention arms compared to the control (discussed in section III. of this proposed rule and also see summary table in section I.B.3.), we propose to

¹⁴ http://datawarehouse.hrsa.gov/DataDownload/PCSA/2010/p_103113_1.dbf, Accessed Jan 13, 2016.

¹⁵ This initiative will update Maryland's 36-year-old Medicare waiver to allow the state to adopt new policies that reduce per capita hospital expenditures and improve health outcomes as encouraged by the Affordable Care Act. <https://innovation.cms.gov/initiatives/Maryland-All-Payer-Model/> accessed Jan 13, 2016.

assign all 7,048 PCSAs to an arm of the model test, approximately 1,700 PCSAs to each of the control and three test arms. Under the control arm, we propose a provider or supplier would receive payment for a Part B drug claim according to the current ASP+6 percent methodology. Under the arms with an ASP payment alternative, we propose a provider or supplier would receive payment for a Part B drug claim according to the assigned alternative method, ASP+2.5 percent + flat fee. Under the two model arms with the VBP tools in phase II, we propose a provider or supplier would receive payment for a Part B drug claim according to the assigned payment method, either the current ASP+6 percent methodology or the ASP payment alternative (ASP+2.5 percent + flat fee), but with one or more of the VBP tools discussed in section III.B. The model is designed to allow the simultaneous testing of the ASP payment alternative separately compared to the control without VBP, and with the ASP payment alternative interactively with the VBP tools.

The assignment of each PCSA to an arm of the study will be based on a stratified random approach. We consider a randomized design to be the best method for achieving balance in unobserved confounding factors that otherwise could bias the test results. Randomized designs can be made better with stratification prior to random assignment to assure representation of population subgroups in the sample. Simple random assignment will ensure that each stratum contains the same proportion of PCSAs in each treatment arm. Strata are mutually exclusive temporarily defined groups of PCSAs proposed to be randomly assigned in equal proportions to the control and three model test arms.

The current strata proposed 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. These two factors drive the differences among PCSAs for the purpose of this model test and both factors have a significant number of outliers that must be evenly distributed to each arm.

Stratification gains are obtained with six or fewer strata within each factor. In this proposed rule, based upon an analysis of the CY 2014 claims for Part B drugs included in this model, we propose to use a 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 the one control and three test arms of the model in equal numbers by simple randomization. We solicit comment from the public regarding additional factors or cut points that may be necessary to achieve balance across the three test arms and the control arm in this model test.

Because we propose to randomly assign PCSAs within each stratum in equal proportion to the one control and three model test arms, the randomized assignment should account for unobservable confounding factors that may affect outcomes of interest while simultaneously assuring that population subgroups are equally represented within each arm of the model. After randomization of the PCSAs, we can adjust our analyses of the model test results to account for any imbalance across the arms of the model in observable characteristics that were not the basis of stratification, such as the beneficiary population's average socio-economic status in a PCSA.

The stratified random sample design cannot support analyses of all potential sub-groups of providers and suppliers, patients, and drugs at the same level of precision or with the same statistical power as it supports the primary analysis of a model test. However, we believe stakeholders will be interested in impacts of the model's interventions on these subgroups. We expect the model evaluation will employ a range of appropriate analytic methods to address questions of interest to stakeholders and to provide additional support to the overall model test analyses. We seek information on which sub-group analyses might be of more interest and which

additional analytic methods may be most appropriate. New section 511.105 reflects our proposed definition of geographic areas.

III. Payment Methodology

CMS is required to reduce Medicare payments for Part B drugs under the Balanced Budget and Emergency Deficit Control Act of 1985 (BBEDCA), as amended by the Budget Control Act of 2011. The application of the sequestration requires the reduction of Medicare payments by two percent for many Medicare FFS claims with dates-of-service on or after April 1, 2013. The discussion in this proposed rule does not consider reductions applied to Medicare payment under sequestration, which is independent of Medicare payment policy.

A. Phase I: Proposed Modifications to the ASP Add-On Percentage for Drugs Paid under Part B

In general, payment for drugs paid under Part B varies over a wide range; drugs may be paid between several dollars per dose to thousands of dollars per dose. Drug therapy may require one or a few doses, or it may require many doses over a long time period, sometimes indefinitely. As we developed potential approaches for evaluating changes to the add-on percentage, we considered the effect of a proposal on the drug price points (that is, high, medium and low cost Part B drugs), as well as the types of drugs that are paid for under Part B. We also considered the effects on entities within the drug supply chain (for example, manufacturers and wholesalers), beneficiaries, providers, suppliers, and the Medicare program. Overall, we believe that phase I of this 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. As discussed in the paragraphs below, phase I would establish payment at ASP plus a 2.5 percent add-on percentage and a flat fee per administration day as a budget neutral test. We propose to derive the flat fee from the difference in total payment between total payments with a 6 percent add-on percentage across Part B drugs in the most recently available

calendar year claims', which is CY 2014, and total estimated payment for Part B drugs in the same set of claims with a 2.5 percent add-on percentage to the flat fee. We propose to divide this difference by the total number of encounters per day per drug in the CY 2014 claims data. Because total payments made under this phase are not expected to change considerably, we anticipate that providers or suppliers will continue to buy and bill for Part B drugs that they furnish to their patients. Having established the flat fee for the initial year in 2016, we propose to update the flat fee amount each year by the percentage increase in the consumer price index (CPI) for medical care for the most recent 12-month period. The dollar value of the 2.5 percent add-on percentage would automatically adjust to changes in price levels as ASP changes. The modeling methodology is discussed in section 1 below.

We are proposing a budget neutral approach to isolate the impact of changes to the ASP add-on amount without introducing additional savings as a second potential source of behavioral adjustments. We do not expect a sizable overall reduction in Part B drug spending associated with phase I of this model, but we do anticipate an incentive to use higher value drugs.

In sections 2 and 3, we describe the proposed approaches for modifying the ASP add-on amount. The approaches discussed below are intended to minimize the risk of excessively large or small add-on payments for individual Part B drugs across the range of Part B drug prices. At the same time, our goal is to minimize providers' and suppliers' (including physicians') financial incentives to prescribe more expensive drugs. This phase of the model would not affect other payments that are associated with furnishing a drug such as the clotting factor furnishing fee, or supplying and dispensing fees that are authorized under section 1842(o) of the Act.

1. Methodology for Creating Modeling Data Set.

To determine the initial aggregate Part B drug annual spending for the implementation of phase I in 2016, we are proposing to use CY 2014 utilization for drugs paid under Part B to

calculate the amount of payments that were associated with the 6 percent ASP add-on percentage. For a detailed discussion of those drugs, please see section II.B. of this proposed rule. The data set includes drugs that are in the model.

We begin with CY 2014 Part B institutional hospital outpatient claims and Part B supplier claims data processed through June 30, 2015. We note that the payment amounts on the CY 2014 claims include the effect of sequestration. Therefore, to establish baseline payment at ASP+6 percent within the Part B Drug Payment model, we first calculate ASP+0 percent by dividing the line payments by 1.043 and then the full ASP+6 payment by multiplying by 1.06.

We propose the following approach to develop the supplier and outpatient hospital claims dataset for modeling purposes; this approach is intended to remove unusable data, errors and inconsistencies in the data set. We propose to exclude all claims billed by providers and suppliers in the state of Maryland as hospital outpatient services are paid under the Maryland All-Payer Model and not at ASP+6 percent. We also propose to exclude claims from American Samoa, Virgin Islands, and Guam because hospitals in these locations are paid at reasonable cost. We propose to remove Medicare secondary payer claims from the modeling dataset because the payment amounts in situations where Medicare is secondary may not reflect the Medicare payment amounts that are determined under statutory authority, such as the methodology in section 1847A of the Act, and used when Medicare is the primary payer. We propose to remove individual lines with units three standard deviations outside the geometric mean units billed by HCPCS, specific to the applicable portion of the dataset (supplier or hospital claims) because we believe that payments deviating from the mean by this amount are likely errors and they do not represent payment amounts that are determined and published in our price files. Additionally, we propose to remove claim lines that were rejected or denied by the claims systems for not meeting

the Medicare requirements for payment and restrict the dataset to drugs that we are proposing to include in phase I of the model.

OPPS claims will be handled in a manner that is similar to what we apply in the OPPS rates setting process; the process was established in 2000 and has been updated annually (<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html>). We propose to include hospital bill types 12X (Hospital Inpatient (Medicare Part B only)), 13X (Hospital Outpatient), 14X (Hospital—Laboratory Services Provided to Nonpatients), which are paid under the OPPS. We propose to exclude claims not paid under the OPPS based on provider type, similar to the standard OPPS rate setting process, including those from all-inclusive hospitals, Religious Nonmedical Health Care Institutions, and critical access hospitals. We are proposing to exclude certain OPPS claims: claims with more than 100,000 units on a service line, claims with condition codes '04' (HMO enrollee - information only bill), '20' (beneficiary requested billing), '21' (billing for denial notice), and '77' (payer fully paid claims), claims with more than 30 related condition codes, claims with more than 300 revenue lines on the claim, and claims where the revenue center payment is equal to the charge amount. Those claims are either not paid or may contain aberrant data. We also would exclude claim lines for hospitals with erroneous cost-to-care ratios (CCRs) (greater than 90 or less than 0.0001) on their cost reports. We propose to exclude all claim lines for packaged drugs in the hospital outpatient setting because such items are not paid separately and are not subject to the 6 percent add-on.

We propose a number of exclusions that would apply specifically to supplier claims. We propose to exclude claims with the following facility place of service codes because these places of service are not typically associated with the use of “incident to” drugs: '21' (Inpatient Hospital), '22' (Outpatient Hospital), '23' (Emergency Room-Hospital), '24' (Medicare-

participating Ambulatory Surgical Center (ASC) for a HCPCS code included on the ASC approved list of procedures), '26' (Military Treatment Facility), '31' (Skilled Nursing Facility (SNF) for a Part A resident), '34' (Hospice – for inpatient care), '41' (Ambulance – Land), '42' (Ambulance – Air or Water), '51' (Inpatient Psychiatric Facility), '52' (Psychiatric Facility -- Partial Hospitalization), '53' (Community Mental Health Center), '56' (Psychiatric Residential Treatment Center), and '61' (Comprehensive Inpatient Rehabilitation Facility) because the proposed Part B Drug Payment Model would not apply. We propose to remove claims with Carrier number “00882” which are those associated with the Railroad Retirement Board benefit since they are paid under a separate payment methodology.

We propose to exclude DME MAC claims for drugs infused through a covered item of DME from our modeling dataset. As discussed in section II.B. of this proposed rule, we propose to exclude drugs infused with a covered item of DME from phase I of the Part B Drug Payment Model. Therefore, we also propose to remove claim lines for these codes from the set of DME MAC claims to establish the flat fee amount.

In addition to soliciting comment on our proposal to exclude the data that is described above, we are interested in stakeholder comments on whether the CY 2015 claims updated as of March might be appropriate as an alternative dataset to establish the CY 2016 flat fee amount in the final rule. We note that for the final rule, more CY 2014 claims data would be available due to additional claims processing, which we would include in modeling the final rule.

We provide a summary file containing the Part B drug model payment and utilization data used to calculate the flat fee amount on the CMS website with display of this proposed rule. The summary file contains no personally identifiable information and we exclude drug codes with low beneficiary volume from the summary file.

2. Add-on Proposal: Percentage Plus a Flat Fee

As discussed previously, a flat percentage, like the current 6 percent add-on percentage to ASP, may create an incentive for using more expensive drugs because the add-on portion of the payment amount is higher for more expensive products (MedPAC Report to the Congress Medicare and the Health Care Delivery System June 2015, page 68). A flat add-on fee alone, for example \$30 per prescribed dose, that does not vary with the cost of the drug may potentially increase the risk of having payments fall below acquisition costs for expensive drugs, particularly for providers and suppliers whose acquisition costs are near or above a drug's ASP. Also, without any sort of limits or constraints, a flat add-on fee that is large (relative to the cost of an inexpensive drug) may also promote the overuse of inexpensive drugs like intravenous fluids and antihistamine injections by creating a profit incentive for overprescribing inexpensive drugs that may be associated with little risk of audits or claim denials.

Changing the add-on amount from a percentage that applies in all circumstances to a lower percentage plus a flat fee that is limited could minimize the potential for underpayment or overpayment across the entire range of prices for Part B drugs. For example, the add-on payment for high cost drugs could be lowered by decreasing the add-on percentage to an amount that minimizes the risk for providers and suppliers losing money on expensive drugs, and the add-on payment for inexpensive drugs could be preserved through the use of a flat fee that covers expected price variations among inexpensive drugs and decreases the risk for underpayment. For inexpensive drugs, inappropriate incentives that could lead to over utilization could also be mitigated by a limit on the flat fee to decrease the motivation for profit-oriented overprescribing of very inexpensive drugs that are not typically subject to medical review.

A specific approach for the use of an add-on percentage with a flat fee was described by the MedPAC in a recent report (MedPAC Report to the Congress Medicare and the Health Care Delivery System June 2015, pages 65-72). MedPAC modeled this add-on approach as budget

neutral in aggregate, meaning that it would not change total Medicare Part B spending. MedPAC evaluated changing the add-on to 2.5 percent of ASP plus a budget neutral flat fee per dose of \$14. The result redistributed add-on payments by decreasing payments for expensive drugs in favor of drugs that are paid at lower amounts. Redistribution under this approach favors the provider specialties and suppliers that utilize relatively inexpensive drugs. The June 2015 MedPAC report determined that under this approach physician specialties that heavily utilize drug therapy would see a decrease in drug revenues while specialties that utilize fewer drugs like primary care would see an increase in drug revenue.

We propose to utilize the same basic approach that was described in the June 2015 MedPAC report: a fixed percentage with a flat fee, specifically, a fixed percentage of 2.5 percent and a flat fee of \$16.80 per drug per day administered (an example of the approach appears at the end of this paragraph). We propose to update the flat fee amount annually. The flat fee amount of \$16.80 was determined using the data set described in section III.A.1. We agree with MedPAC that this approach limits financial incentives for overuse across the range of Part B drugs and the values that we are proposing are similar to those in the MedPAC report. We have chosen a 2.5 percent starting point because we agree with MedPAC's assessment that this value should be sufficient to cover markups from wholesalers, such as prompt pay discounts that are not passed on to purchasers. In the June 2015 report that is cited in this proposed rule, MedPAC stated that there is anecdotal evidence that such markups are between 1 and 2 percent, but MedPAC was not aware of data that could verify this estimate. We are not aware of information that conflicts with the assessment. The proposed add-on fee of \$16.80 is also comparable to the MedPAC determined value of \$14. In the Part B Drug Payment Model, application of the flat fee would result in the following: a primary care provider would receive \$33.60 (\$16.80 per drug) for two model drugs given during an office visit in addition to 2.5 percent of the ASP for each of

the drugs. If another practitioner, such as a rheumatologist, saw the patient later in the day, and administered one model drug, that practitioner would receive \$16.80 in addition to 2.5 percent of the ASP for the prescribed drug.

We propose to keep the 2.5 percent add-on constant over the duration of the model, but propose to update the flat fee each year based on the percentage increase in the CPI Medical Care (MC) for the most recent 12-month period. This update method is stipulated in section 1842(o)(5)(C) of the Act for use with the blood clotting factor furnishing fee. We considered several potential updates including the producer price index for Pharmaceuticals for Human Use (Prescription) or an inflation factor derived from changes in ASP for Part B drugs. We propose the CPI MC because we believe that the flat fee addresses many different services included in drug acquisition activities similar to the services including in furnishing clotting factors. The CPI MC is both widely available and based on an accepted methodology. We solicit comment on whether a different update factor would be more appropriate.

For 2016, we would establish alternative ASP pricing under phase I of the model so that total spending for Part B drugs included in the model under phase I would be equal to aggregate spending for the same set of drugs in our CY 2014 claims data. The dollar value of the flat fee of \$16.80 is proposed, but we may refine this figure for the final rule if we use more recent versions of the claims data, which would include additional utilization and payment information. We would plan to update the flat fee for January 2017 using the CPI MC and annually thereafter. We anticipate using a G-code, that providers and suppliers billing in geographic areas assigned to this approach (ASP+2.5 percent + flat fee) would use to bill for the flat fee portion of the payment. We propose to continue our standard practice of updating the weighted average portion of drug payment amount (that is, the ASP+0 portion of the payment) on a quarterly basis using

the manufacturers' sales data and the weighted average calculations that are used when determining payment amounts that are set forth in section 1847A(c)(5) of the Act.

We believe that the per drug per day administered limit will mitigate profit-oriented overprescribing of inexpensive drugs, but we are concerned that an add-on that is roughly equal to or slightly more than the cost of a drug may still leave some incentive for overusing some inexpensive drugs. While we expect that contractors will continue to examine claims (as well as patterns of claims) for potentially unnecessary use (that is use that is not reasonable or necessary), we also seek comment on whether additional measures should be taken to limit add-on amounts, especially for very low cost drugs, or whether an alternative approach to calculating the percent and flat fee should be considered, such as an additional one to three tiers of decreasing flat dollar amounts that would provide lower flat fees for very inexpensive drugs, while still maintaining overall budget neutrality.

3. Comment Solicitation: Additional Tests of Add-on Modifications

In addition to MedPAC's discussion for pairing a reduced percentage add-on with a flat fee per drug per day administered, we considered whether it would be helpful to test additional variations of the ASP add-on. As proposed, the model would have four arms: a control and three test arms including, modified ASP add-on only, VBP only, and modified ASP add-on and VBP. However, we are concerned that adding another variation in phase I would increase the number of arms in the model which may negatively impact the statistical power of this model.

We also considered whether other variations of the ASP add-on percentage would be a useful complement to the proposed ASP+2.5 percent + flat fee, such as a higher starting percentage, (instead of 2.5 percent, using 3 percent or 3.5 percent), a flat fee without a percentage add-on in lower quartiles, or a tiered approach in which we would vary the percentage or flat fee add-on across several tiers of drugs defined based on cost.

We considered defining tiers for an alternative approach based on quartiles because they create several steps between the highest and lowest add-on values; however, we also considered whether a different number of steps, such as deciles, or a gradient approach would result in more consistent payments for groups of similar drugs. One method that we considered to create the quartiles was to array the annual payment per beneficiary for each drug from lowest to highest annual payment and then divide the distribution into quartiles based on relatively even number of doses. We established quartiles for drugs with annual per beneficiary payment of greater than \$1,000, \$50.01 to \$1,000, \$10.01 to \$50, and less than or equal to \$10 and distributed the aggregate add-on amount among the tiered quartiles. Like the percentage plus flat fee option, a tiered add-on could redistribute the add-on payments toward less expensive drugs based on quartiles developed from annual per beneficiary spending for each drug. However, a budget neutral redistribution across quartiles also resulted in very high add-ons for inexpensive drugs (for example, under an approach in which a different add-on percentage was set for each tier, add-on percentages for drugs with as ASP of less than \$10 exceeded 200 percent).

Ultimately, we were concerned that testing another variation of the add-on percentage modification in phase I would not provide us with significant additional information. We are requesting comments from the public on whether the tiered approach described above, a variation (such as using deciles or a gradient) or another approach for modifying the add-on would be a useful complement to the percentage and flat fee approach that is proposed in section III.A.2. We are interested in gaining perspective on whether the approaches are sufficiently different to justify testing them, noting that adding arms to the study will likely impact the statistical power of this model and other overlapping models, especially the OCM.

We are also interested in understanding whether any advantages from testing these approaches are sufficient to overcome the potentially significant disadvantages of these

approaches. In particular, we are concerned that tiered approaches could set a very different add on amounts for each of the four quartiles. This could create large changes (“cliffs”) in payment amounts at the boundaries between quartiles. In addition, tiered approaches that specify varying percentage add-ons by quartile could generate very high percentage add-ons for the bottom three quartiles. This could create incentives for manufacturers and suppliers to vary prices of drugs near the quartile boundaries in order to increase Medicare’s payment rate. We are also concerned about the potentially high add-on payments for inexpensive drugs, their impact on providers, suppliers, and patients, and if such an approach were tested, whether additional steps to limit such payments should be considered.

Finally, we are also interested in receiving comment on whether there are any common elements within groups of drugs that might provide a basis for varying the flat fee across groups of drugs that would justify higher payments, such as requirements for cold handling, special packaging, or other contributors to costs. If such factors could be identified, we could also use this information to vary the flat fee appropriately under the ASP+2.5 percent + flat fee proposal.

B. Phase II: Applying Value-Based Purchasing Tools

1. Introduction

In the second phase of this model, we propose to implement VBP tools for Part B drugs using value-based pricing and clinical decision support tools--tools often used collectively to manage a prescription drug benefit by commercial health plans, PBMs, hospitals, and other entities that manage health benefits and drug utilization. Medicare Part D plans and the commercial insurance sector have used these tools for years to successfully manage health benefits and drug utilization, and we believe that the approaches, when appropriately structured, may be adaptable to Part B to improve patient care and manage drug spending. The revision to the 6 percent ASP add-on percentage proposed for phase I of this model broadly addresses

financial incentives that may affect prescribing. However, these revisions do not directly address differences in payment when there is a group of therapeutically similar drugs, nor are they able to test the benefits of using alternative incentives to improve the effectiveness, safety, and quality of physician prescribing patterns for Part B drugs.

Medicare Part D plans, PBMs, other third party payers, and entities like hospitals use a variety of VBP tools, such as value-based pricing, clinical decision support tools, and rebates and discounts, to improve patient outcomes and manage drug costs.¹⁶ The VBP tools vary in commercial implementation by scope and intensity; however, many of the tools, particularly those used by PBMs, are applied primarily in the retail pharmacy setting. PBMs and third party payers also agree on discounts and rebates for placement of drugs on a tiered formulary or for volume of business provided to a specific manufacturer. The application of these tools to drugs that are typically paid for under a medical benefit, such as physician administered drugs, has the potential to result in significant savings.¹⁷ Based on background work done on this model, we believe private payers are currently using these tools to manage drugs under a medical benefit.

Below, we propose the types of VBP tools that potentially could be used in the Part B Drug Payment Model to improve patient outcomes and manage drug costs. We propose to implement one or more of the following value-based pricing strategies, including reference pricing, pricing based on safety and cost-effectiveness for different indications, outcomes-based risk-sharing agreements, and discounting or elimination of patient coinsurance amounts. We also propose to implement a tool to support clinical decisions for appropriate drug use and safe prescribing. The tool would provide education and data on the use of certain Part B drugs to prescribers; such information would not be meant to interfere or substitute for medical decision

¹⁶ Hoadley J. Adapting Tools from Other Nations to Slow U.S. Prescription Drug Spending. NIHCR Policy Analysis No. 10. Aug. 2012. National Institute for Health Care Reform. http://www.nihcr.org/Drug_Spending

¹⁷ Dorholt M. Advancing Drug Trend Management in the Medical Benefit. Managed Care. June 2014. <http://managedcaremag.com/archives/2014/6/advancing-drug-trend-management-medical-benefit>

making. New section 511.305 reflects our proposed VBP model requirements. We are mindful that, in particular circumstances, the arrangements discussed here, if not properly structured and operated, could pose a risk of abuse. In adapting and using VBP tools in the Part B Drug Payment Model, one of our goals is to ensure that the model promotes integrity, transparency, and accountability. Finally, we note that we would implement these proposed tools through a contractor, as we do with many Medicare programs. We would retain final review and authority over the final version of any VBP tools implemented under phase II.

2. Value-Based Pricing Strategies

The application of the value-based pricing strategies discussed in this section would be limited. We are proposing value-based pricing strategies that include one or more of the following specific tools: reference pricing, indications-based pricing, outcomes-based risk-sharing agreements, and discounting or eliminating patient coinsurance amount. This group of tools would serve as a framework for interventions for selected Part B drugs. We 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. We 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 we would allow 30 days for public comment. We would provide a minimum of 45 days public notice before implementation. Under phase II, we do not intend to apply these tools to all Part B drugs; we plan 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.

Value-based pricing for pharmaceuticals involves linking payment for a medicine to patient outcomes and cost-effectiveness rather than solely the volume of sales.¹⁸ Under phase II of this model, we seek to test approaches for transitioning from a volume-based payment system into one that encourages or even rewards providers and suppliers who maintain or achieve better patient outcomes while lowering Part B drug expenditures. The market today uses the term “value-based” to encompass a wide variety of different options designed to improve clinical results, quality of care provided, and reduce costs.¹⁹ The following examples highlight the range of value-based pricing tools currently in use, and we propose the testing of one or more of these tools during phase II of the model.

First, providing equal payment for therapeutically similar drug products²⁰ is one form of value-based pricing that we propose to implement as part of phase II of the model. The private market capitalizes on this concept through reference pricing, which refers to a standard payment rate—a benchmark—set for a group of drugs.²¹ A benchmark is set based on the payment rate for the average price²² for drugs in a group of therapeutically similar drug products, the most clinically effective drug in the group²³, or another threshold that is specifically developed for

¹⁸ Deloitte. Issue Brief: Value-Based Pricing for Pharmaceuticals: Implications of the Shift from Volume to Value. 2012. Web. 17 Dec. 2015. http://www.converge-health.com/sites/default/files/uploads/resources/white-papers/valuebasedpricingpharma_060412.pdf.

¹⁹ Pharmacy Benefit Management Institute. 2013-2014 Prescription Drug Benefit Cost and Plan Design Report. 2013. Web. 17 Dec. 2015. <http://reports.pbmi.com/report.php?id=4>.

²⁰ Therapeutically similar drug products are generally members of the same drug class that work on the same biochemical processes but have different chemical structures. For example, the HMG-CoA reductase inhibitors, also known as statins, include the drugs atorvastatin and simvastatin. Both of these drugs lower cholesterol by inhibiting the same enzyme, but they are unique chemical entities. While these therapeutically similar drug products are not automatically interchangeable, the therapeutic effects achieved are generally similar from one member of the drug class to another.

²¹ Partnership for Sustainable Health Care. Strengthening affordability and quality in America’s health care system. Apr. 2013. Web. 17 Dec. 2015. <http://www.rwjf.org/content/dam/farm/reports/reports/2013/rwjf405432>.

²² Boynton A, Robinson JC. Appropriate Use of Reference Pricing Can Increase Value. Health Affairs. 7 July 2015. <http://healthaffairs.org/blog/2015/07/07/appropriate-use-of-reference-pricing-can-increase-value/>

²³ A determination of clinical effectiveness would be based on published studies and reviews, such as those produced by ICER as described below, and evidence-based clinical practice guidelines located at AHRQ’s National Guideline Clearinghouse: www.guideline.gov.

such drug products, like a specified percentile of the current price distribution; and all drugs from the group are then paid based on this amount. For example, if sodium hyaluronates used for intra-articular injection were chosen as candidates for reference pricing, each of the HCPCS codes determined to fall into this group would be paid a benchmark rate based on the current payment rate for a product or products in this group. Based on a review of the evidence, we may determine that the specific benchmark for this group should be the current payment rate for the HCPCS code including the most effective drug in the group. Individual characteristics of each group of drugs considered for reference pricing, such as relative effectiveness demonstrated in competent and reliable scientific evidence, would be taken into account before selecting a benchmark rate. 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. When multiple drugs in a group have varying levels of effectiveness, the payment for the most clinically effective drug in the group could be paid based on a benchmark while the payment for the remaining products could be adjusted downward based on their effectiveness in relation to the most clinically effective drug. We propose to include reference pricing in phase II.

We understand that some insurance plans allow providers and suppliers to hold the patient responsible for paying the difference between their prescribed drug and the benchmark set for the group of therapeutically similar drugs. We propose that any version of reference pricing implemented would not allow for balance billing of the beneficiary for any differences in pricing. For example, if reference pricing was implemented for the sodium hyaluronates mentioned previously and the particular sodium hyaluronate product selected by the prescriber had a cost above the reference price defined by CMS for the sodium hyaluronates included in the

reference pricing arrangement, the patient could not be held responsible for paying the difference between the reference price and either the statutory payment amount or the cost for the selected drug. By grouping similar drugs into a single payment rate, we give prescribers incentives to use the drug product that provides the most value for the patient.

Second, we propose using value-based pricing to vary prices for a given drug based on its varying clinical effectiveness for different indications that are covered under existing Medicare authority, specifically section 1861(t) of the Act, and existing national and local coverage determinations. This is often called “indications-based pricing.” Drugs are often indicated for more than one condition and may be more effective when used in one condition than another. For example, if a new drug is introduced with indications for treating two types of cancer and this drug did no better in clinical trials than existing treatments for the first type of cancer and significantly better than existing treatments for the second, our use of indications-based pricing might result in lower payments when the drug is used to treat the first type of cancer and higher payments when the drug is used to treat the second type. The Institute for Clinical and Economic Review (ICER) is currently producing reports on high-impact drugs that analyze comparative effectiveness and cost-effectiveness before calculating a benchmark price for each drug.²⁴ ICER’s reports reflect the dependence of the value of medications on evidence available for certain target populations.²⁵

We propose to use indications-based pricing where appropriately supported by published studies and reviews or evidenced-based clinical practice guidelines, such as the ICER reports, to more closely align drug payment with outcomes for a particular clinical indication. Indications-

²⁴ Institute for Clinical and Economic Review. Emerging Therapy Assessment and Pricing: Transforming the Market for New Drugs. Web. 17 Dec. 2015. <http://www.icer-review.org/etap/>.

²⁵ Institute for Clinical and Economic Review. 17 Dec. 2015. http://ctaf.org/sites/default/files/u148/CHF_Final_Report_120115.pdf and <http://cepac.icer-review.org/wp-content/uploads/2015/04/Final-Report-for-Posting-11-24-15.pdf>.

based pricing decisions would reflect the clinical evidence available and strive to rely on competent and reliable scientific evidence from neutral and/or independent sources. We understand that the quality of available evidence can vary for any given drug or indication. High quality evidence is comprehensive, relies on randomized trial designs where possible, and measures outcomes. Research findings should be valid, competent, reliable, and generalizable to the Medicare population.

Third, we propose to allow CMS to enter into voluntary agreements with manufacturers to link health care outcomes with payment. 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. Payers and pharmaceutical manufacturers contract in outcomes-based risk-sharing agreements to link payment for drugs to patient health outcomes.²⁶ 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.²⁷ Manufacturers agree to provide rebates, refunds, or price adjustments if the product does not meet targeted outcomes.²⁸ The University of Washington's School of Pharmacy maintains the Performance Based Risk Sharing Database, which currently lists detailed information on 311 risk-sharing arrangements subject to participation fees and licensing

²⁶ Neumann PJ, et al. Risk-Sharing Arrangements That Link Payment For Medications To Health Outcomes Are Proving Hard To Implement. *Health Affairs*. 2011;30(12):2329–2337.

²⁷ Garrison L, Carlson J. Performance-Based Risk-Sharing Arrangements for Drugs and Other Medical Products. Web. 12 Jan. 2016. https://depts.washington.edu/pbrs/PBRS_slides.pdf

²⁸ Garrison LP, et al. Private Sector Risk-Sharing Agreements in the United States: Trends, Barriers, and Prospects. *Am J Manag Care*. 2015;21(9):632-640. Web. 17 Dec. 2015. <http://www.ajmc.com/journals/issue/2015/2015-vol21-n9/private-sector-risk-sharing-agreements-in-the-united-states-trends-barriers-and-prospects>.

agreements.²⁹ VBP arrangements with manufacturers are discussed in more detail in a later section.

We propose that any outcomes-based risk-sharing agreements that we enter into would require a clearly defined outcome goal. We seek comment 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 a minimum, and in addition to sources such as evidence-based literature and best practices, we propose manufacturers provide all competent and reliable scientific evidence to create an accurate picture regarding clinical value for a specific drug; and we also propose that manufacturers provide outcome measures for any outcome-based risk-sharing pricing agreement.³⁰ We set forth our thinking on competent and reliable scientific evidence for the purpose of establishing value-based pricing and the clinical decision support (CDS) tool in the next section. We are seeking comments on the level of transparency that would be required or desired for outcomes-based risk-sharing agreements while recognizing the need to protect proprietary information. Finally, we seek comment on methods for establishing patient-specific pricing contingent on response to therapy.

In addition to proposals specifically aimed at improving quality and outcomes and reducing the costs of purchasing for the payer, we also propose a value-based pricing strategy that involves discounting or eliminating patient coinsurance amounts for services that are determined to be high in value in an attempt to tailor incentives. Although many Medicare beneficiaries have wrap-around coverage (which reduces or eliminates cost sharing), reducing cost sharing for certain products can still provide an effective incentive for a subset of the population to encourage use of high-value drug products. Therefore, we propose to waive

²⁹ University of Washington School of Pharmacy. Performance-Based Risk-Sharing Database. Web. 17 Dec. 2015. <https://depts.washington.edu/pbrs/index.php#sthash.g3bTvMFA.dpuf>.

³⁰ We discuss evidence further in section III.B.3 (Development of a Clinical Decision Support Tool) of this proposed rule

beneficiary cost sharing from the current 20 percent, meaning that the copayment that is associated with a HCPCS code in phase II of the model could be reduced by CMS to a value that is less than 20 percent and could be waived completely. In addition, consistent with cost sharing approaches for Part B drugs, we propose that beneficiary cost sharing will not exceed 20 percent of the total model-based payment amount for the Part B drug. In other words, this model does not seek to increase cost sharing percentages beyond 20 percent for low-value drugs. We would also like to make clear that cost sharing changes will be applied at the HCPCS level to all drugs NDCs in a HCPCS code; we are not proposing manufacturer-specific or NDC-specific cost sharing amounts, nor are we proposing that providers or suppliers would have flexibility to change or waive cost sharing amounts. By itself, value-based pricing that involves discounting or eliminating patient coinsurance would not be expected to change the overall payment amount. In other words, we are proposing to increase Medicare's payment percentage while maintaining the total allowed charges for the drug using this tool. However, we seek comments on whether more targeted modifications of cost sharing 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.

We propose to solicit public feedback on specific pricing proposals for use of all VBP tools. We propose that any CMS approved pricing changes under phase II would allow for the public to provide feedback and would be made public 45 days ahead of implementation .

Proposed new §511.305 reflects these proposals.

We would also engage in educational activities to support implementation and testing of the value-based pricing strategies. We seek comment to define the parameters of these educational activities.

While all proposed Part B drugs would be potentially subject to the value-based pricing strategies outlined here, we seek comment on the potential groups of Part B drugs most suitable for each of the proposed approaches to value-based pricing. We also seek comment on any additional types of value-based pricing that could be considered for future rulemaking for the Medicare Part B Drug Payment Model.

To protect beneficiaries and to allow for the consideration of special circumstances that may warrant the use of non-model payments in certain situations, we are proposing a Pre-Appeals process for certain value-based pricing strategies. The process is discussed in section IV. of this proposed rule.

As noted, we are aware that the value-based pricing tools discussed here could pose a risk of abuse if not properly structured and operated. It is our goal that the Medicare Part B Drug Payment Model promotes integrity, transparency, and accountability. We seek comment on potential safeguards that could be implemented with each of these tools to make certain that the intent of the policy is not undermined.

3. Development of a Clinical Decision Support Tool

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) can assist physicians and other health professionals with clinical decision-making tasks, including prescribing. Information that is delivered to the clinician can include general clinical knowledge and guidance (such as updated guidelines for the clinical use of drugs, updated safety information, etc.), processed patient data, or a mixture of both. The Agency for Healthcare Research and Quality (AHRQ) defines CDS tools as a system that ensures timely clinical information at the point of care by focusing on patient-specific information in real time

to help physician and clinical care teams proactively identify early warnings of potential problems, or providing suggestions for the clinical team and patient to consider.³¹ Other examples of CDS tools include standardized drug and test orders that are developed from evidence-based medical guidelines when prescribing for particular conditions or types of patients; preventive care reminders; and alerts about potentially dangerous situations such as adverse drug events.³²

We are aware of reports that CDS tools can be effective in changing practice patterns to better align with evidence-based developments and best practices.^{33,34,35} 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 guideline recommendations.³⁶ For example, one study showed that CDS activity supporting the use of an injectable antibiotic altered prescribing of the drug such that prescribing better matched appropriate use guidelines from the Centers for Disease Control and

³¹ Clinical Decision Support. June 2015. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/professionals/prevention-chronic-care/decision/clinical/index.html>.

³² Ibid.

³³ Moxey, A., Robertson, J., Newby, D., Hains, I., Williamson, M., & Pearson, S.-A. (2010). Computerized clinical decision support for prescribing: provision does not guarantee uptake. *Journal of the American Medical Informatics Association : JAMIA*, 17(1), 25–33. <http://doi.org/10.1197/jamia.M3170>.

³⁴ Bates, D. W., Kuperman, G. J., Wang, S., Gandhi, T., Kittler, A., Volk, L., ... Middleton, B. (2003). Ten Commandments for Effective Clinical Decision Support: Making the Practice of Evidence-based Medicine a Reality. *Journal of the American Medical Informatics Association : JAMIA*, 10(6), 523–530. <http://doi.org/10.1197/jamia.M1370>.

³⁵ Kevin M. Terrell DO, MS, Anthony J. Perkins MS, Paul R. Dexter MD, Siu L. Hui PhD, Christopher M. Callahan MD and Douglas K. Miller MD. Computerized Decision Support to Reduce Potentially Inappropriate Prescribing to Older Emergency Department Patients: A Randomized, Controlled Trial. *J Am Geriatr Soc*. 2009 Aug;57(8):1388-94.

³⁶ Moxey, A., Robertson, J., Newby, D., Hains, I., Williamson, M., & Pearson, S.-A. (2010). Computerized clinical decision support for prescribing: provision does not guarantee uptake. *Journal of the American Medical Informatics Association : JAMIA*, 17(1), 25–33. <http://doi.org/10.1197/jamia.M3170>.

Prevention.³⁷ Similarly, CDS tools could help guide physicians to more efficiently utilize companion diagnostic tests such as testing for HER2 expression in certain tumors prior to beginning chemotherapy. We are also aware that CDS feedback on practice patterns can encourage physicians to improve their practice patterns.³⁸

We propose a two component 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 (see Table 1). Physicians participating in the model would voluntarily access the education tool, meaning that they would have a choice about whether to use the tool and how they would apply information from the tool to their practice. This tool is not intended to act as or replace, in any way, the physician's medical judgment for the treatment of patient-specific clinical conditions nor is the tool intended to replace a practitioner's ability to order reasonable and necessary Part B drugs as appropriate. Rather, the tool is intended to provide information on prescribing for specific indications that reflects up-to-date literature and consensus guidelines. We believe that the availability of this tool could provide physicians with better access to up-to-date information such as guidelines for effective treatments as well as safe and appropriate drug use for specific diagnoses. We anticipate that information would be listed and indexed to correspond to drugs and disease states or conditions that are commonly treated in Part B. However, we would consider alternative approaches for presenting the data, such as the use of a decision-tree format. We seek comment on how to format the educational information. We also envision that the tool would provide

³⁷ Shojania, K. G., Yokoe, D., Platt, R., Fiskio, J., Ma'luf, N., & Bates, D. W. (1998). Reducing Vancomycin Use Utilizing a Computer Guideline: Results of a Randomized Controlled Trial. *Journal of the American Medical Informatics Association* : JAMIA, 5(6), 554–562.

³⁸ Stammen LA, Stalmeijer RE, Paternotte E, et al. Training Physicians to Provide High-Value, Cost-Conscious Care: A Systematic Review. *JAMA*. 2015;314(22):2384-2400. doi:10.1001/jama.2015.16353.

information on Part B claim payment patterns for specific drugs and/or indications. This part of the tool could be utilized nationally or within specific geographic areas and could provide feedback on how an individual physician's drug claim patterns compare with local or national data or even recommended guidelines. This information would be solely for feedback and to support a physician's interest in mindful prescribing. We believe that the concept of this tool is consistent with the proposed model's aim as discussed in the introduction to the preamble, to achieve high quality and smarter spending on drugs and biologicals paid under Part B.

We propose the evidence-based part of the CDS tool would encompass specific drugs, groups of similar drugs, or diagnoses that are typically encountered in Part B. The tool would be available online and readily available to participants in the VBP arm of the model and would provide pertinent up-to-date information on drug therapies and treatments for a specific condition. The tool would provide information such as links to evidence-based guidelines for appropriate drug use and updated information on drug safety.

A CDS tool is more likely to be effective in improving the value of payment for prescribed drugs if it adequately reflects the clinical evidence available and strives to rely on objective, high quality evidence from neutral and/or independent sources. We understand that the quality of available evidence can vary for any given drug or indication. High quality evidence is comprehensive, relies on randomized trial designs where possible, and measures outcomes. Research findings should be valid, reliable, and generalizable to the Medicare population. To incorporate information in the CDS tool, we propose that we would follow a hierarchy of evidence review similar to that followed by our Medicare Coverage Advisory Committee, the AHRQ, or the United States Preventive Services Task Force, as well as numerous private bodies

such as the National Comprehensive Cancer Network.^{39,40,41} These entities and others favor peer reviewed scientific literature and randomized control trial research designs over other types of evidence, but provide a process that allows for consideration of many types of evidence.

In addition to prioritizing review of high quality evidence, CMS would post the evidence base that supports information that is included in the online CDS, and consider feedback from the public on that evidence basis for 30 days before finalizing a CDS tool for a specific indication. We propose 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. We plan to implement the CDS tool incrementally, that is, to begin with a limited number of drugs and/or disease states. We seek comment on which Part B drugs and conditions that are commonly treated by drug therapy would be good candidates for inclusion. We also would allow for feedback on any substantial refinements to an online tool.

In addition to developing an evidence-based component for the tool, we propose creating an online source of data under our section 1115A authority that would provide feedback to physicians in the VBP arms of the model. We propose to use a process similar to that already established for reporting programs such as the Quality and Resource Use Reports (QRURs) that physician group practices and solo practitioners receive nationwide. At this time, we make QRURs available to groups and solo practitioners that participate in the Medicare Shared Savings Program, the Pioneer Accountable Care Organization (ACO) Model, or the Comprehensive Primary Care Initiative. We propose that this online tool under the Part B Drug Payment Model would allow providers and suppliers to access reports on their Medicare Part B

³⁹ Medicare Coverage Advisory Committee; Operations and Methodology Subcommittee. *Process for Evaluation of Effectiveness and Committee Operations*. July 21, 2005

⁴⁰ Agency for Healthcare Research and Quality. *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*. January 2014.

⁴¹ National Comprehensive Cancer Network (NCCN). NCCN Categories of Evidence and Consensus. http://www.nccn.org/professionals/physician_gls/categories_of_consensus.asp

drug claims as well as claims patterns in their geographic area and national patterns. We intend for this feedback to allow providers and suppliers to better understand Part B claim payment patterns and identify opportunities for individual improvement. We also believe that this activity will align with our efforts to provide regularly updated feedback to providers and suppliers on metrics such as cost and quality measures. We propose that the CDS tool will be available to physicians (that is, internal use only and non-publicly available) for informational purposes only and will not impact participating physician group practices and solo practitioners' Part B drug payments.

In summary, we are proposing a two-component CDS tool for physicians in the VBP arms of the model. The tool will use high quality evidence to educate physicians on best practices. The tool also would rely on regularly updated claims data reports to provide feedback on prescribing patterns. We seek comments on our proposed approach for identifying high-quality evidence and allowing for public feedback on the evidence basis; the online format of this proposed support tool; the most effective method for physicians to access their reports on prescribing patterns, identifying what content should be included (for example, claim payment/prescribing patterns, resource use, clinical and cost domains, patient clinical and demographic information, information about drug-drug and drug-disease interactions and clinical support guidelines for these interactions, among other factors). We also solicit comment on the level of feedback, and whether personalized reports are necessary. To the extent that such feedback includes personally identifiable information, we would provide such information through the proposed support tool consistent with applicable privacy laws, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. We solicit comment concerning privacy issues with respect to the proposed support tool.

C. Comment Solicitation

We are considering the three approaches discussed below: creating value-based purchasing arrangements for Part B drugs directly with manufacturers, the Part B Drug CAP, and an episode-based or bundled pricing approach for Part B drugs, as potential areas of interest in furthering value for Part B drugs. We solicit comments to determine if any or all are appropriate to pursue as part of the Part B Drug Payment Model or in the near future.

1. Creating Value-Based Purchasing Arrangements Directly with Manufacturers: Solicitation of Comments

We have received inquiries from manufacturers interested in testing new approaches to paying for medications under Part B that are not accommodated within the current payment system. These approaches are generally built around achievement of clinical outcomes and a new payment flow between CMS and the manufacturer, using a mechanism such as a rebate.

Outcomes-based rebates, for example, appear to be used by industry to measure and reward quality and clinical effectiveness for new drug products. Ideally, outcomes-based rebates lead to payers realizing a reduction in the uncertainty that is associated with a new drug's clinical value, performance, and financial impact, while manufacturers are able to better differentiate and demonstrate the value and effectiveness of their product.⁴² Value is measured through data collection likely, though not necessarily, provided by the prescriber and intended to address factors such as long-term safety and outcomes, effect on an individual patient, patient adherence, or impact on utilization and costs. The product's final price or rebate amount is linked to its actual effect on these measured outcomes.

One example of a potential structure would be a "try before you buy" arrangement. For example, for a product that works for some but not all beneficiaries, a manufacturer might offer

⁴² Garrison, Louis, et al. Private Sector Risk-Sharing Agreements in the United States: Trends, Barriers, and Prospects. *Am J Manag Care*. 21(9) Sep. 2015: 632-640. Web. 16 Dec. 2015. <http://www.ajmc.com/journals/issue/2015/2015-vol21-n9/private-sector-risk-sharing-agreements-in-the-united-states-trends-barriers-and-prospects>.

to provide a partial or full rebate to CMS for the costs of product purchased for patients that do not ultimately benefit from therapy. Because of the time lag involved in assessing response to therapy from claims data sources, a rebate might be the most efficient way to implement such a purchasing agreement.

We solicit comment on the approach described above and on implementing a program to incorporate VBP arrangements created with manufacturers as a part of the VBP tools that will be tested in this model. We also seek comment on a number of specific issues, discussed below, surrounding rebate-based payment structures.

CMS is currently considering whether rebate distributions could be returned to the Medicare Part B Trust Fund, the beneficiary, the provider or supplier, or a combination of the three. Any rebate arrangement would have to conform to the requirements of the Act and federal appropriations law. Comments regarding the construction of these rebate arrangements are especially welcome. We seek comment on the value of and potential approaches for sharing rebates by providing incentive payments to beneficiaries and prescribers. We solicit comments on how to incorporate rebates into claims payment for prescribers or potentially the use of payments made outside of the claims processing system. Additionally, we seek comment on the value and potential methods for sharing rebates with beneficiaries through reduced cost sharing or other incentives. As we are aware that the incentives discussed here could pose a risk of abuse if not properly structured and operated, we also seek 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 policy is not undermined. It is our goal that the Medicare Part B Drug Payment Model promotes integrity, transparency, and accountability. Further, we seek comment on the basis for potential voluntary rebates other than the proposed value-based pricing, CDS tool, or other educational activities as discussed earlier in this proposed rule for future rulemaking. We

are particularly interested in whether and to what extent other payers base rebates on tools other than those we have listed here. We are interested in specific examples of rebate agreements appropriate for this proposed model that manufacturers might be interested in creating. We recognize that manufacturers are much more likely to offer rebates for drugs where potential therapeutically similar drug alternatives are available. We also seek comments that identify examples of groups of therapeutically similar Part B drugs that are potential candidates for rebate arrangements, as well as industry examples of rebates for drugs paid for by Medicare Part B, including drugs that are used in physicians' offices and outpatient hospital settings. We are particularly interested in how significant an effort might be required to establish and execute risk sharing for outcomes-based rebates compared to volume-based rebates.

Finally, we seek comment on specific approaches that could be used to define rebates, details on how these arrangements could be created, mechanisms that could be used to calculate and distribute rebate amounts, the amount of transparency in any arrangement, how the rebates should be accounted for in manufacturers' ASP reports, other applicable pricing information reported to CMS (for example, for Medicaid purposes), and how we might monitor the prices paid by suppliers and providers for Part B drugs under the proposed model.

2. The Part B Drug Competitive Acquisition Program (CAP): Solicitation of Public Comments

Section 1847B of the Act required the implementation of the CAP for drugs that are not paid on a cost or prospective payment basis. The CAP was an alternative to the ASP method 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). Most Part B drugs used in 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.

We 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 that included approximately 180 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 we 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. Details are available in the links at the end of this section.

After the CAP was suspended, we sought additional input from physicians and interested parties about further improvements to the program. For example, we held Open Door Forums, met with stakeholders and encouraged correspondence from stakeholders and physicians who participated in the CAP. Although we received some useful suggestions, several significant concerns could not be addressed under the existing statutory requirements. These concerns included uncertainty about the participation of non-pharmacy entities like wholesalers as approved CAP vendors, and the requirement for a beneficiary-specific order which impacts the use of a consignment model to facilitate emergency deliveries and to manage inventory through automated dispensing systems in the office. Many commenters were also concerned about the complexity of the program and the level of financial risk, particularly for vendors. Also, an

evaluation of the program found that it was not associated with savings (<https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Research-Reports-Items/CMS1234237.html>).

More detailed information about the CAP is available on the following CMS webpage and links within the webpage: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/CompetitiveAcquisforBios/index.html>. The downloads section of the following CMS webpage includes information about CAP vendor bidding, physician participation, and drugs provided under the CAP: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/CompetitiveAcquisforBios/vendorbackground.html>.

The Part B drug market has evolved significantly since the CAP was suspended in 2009. For example, there has been enormous growth in specialty drugs, both by the number of drugs available and the cost of the products; acquisition of specialty drugs may utilize restricted distribution channels (like specialty distributors or pharmacies as opposed to buying drugs from wholesalers and the manufacturer); and health information technology also has changed the way physicians and distributors manage many drug products.

Although we are not proposing to include a CAP-like alternative in this model at this time, we are interested in receiving comments that would help us determine whether sufficient interest in such a program is present for us to consider developing and testing such an alternative as a part of a future model. We are specifically interested in comments on whether there is a role for a CAP-like alternative to the ASP (buy and bill) process for obtaining drugs that are billed under Part B in the physician's office. Given the length of time that has elapsed since the last solicitation for comments about the CAP in 2010, we are also interested in updated perspectives on issues such as smaller geographic areas, smaller scope of drugs included in the program, the role of wholesalers and consignment in the program, the drug ordering process, risk sharing,

impact on physician negotiated volume discounts when CAP would be used for Medicare patients, and how these issues could be addressed if we were to consider developing and testing a phase of this model in the future that is based on the CAP.

3. Episode-Based or Bundled Pricing Approach: Solicitation of Public Comments

Under the current FFS structure, Medicare makes separate payments for drugs based primarily on the manufacturer's pricing. Medicare also makes separate payments for the administration of these drugs to hospital outpatient settings and physician offices. This payment approach may not encourage practitioners in the physician office or in outpatient hospital settings to consider the total cost of care for treating a beneficiary. Instead, the current FFS drug payment structure may provide an incentive to increase the volume of drugs furnished to beneficiaries and to prescribe more expensive drugs without considering the total cost of care for treating a beneficiary with a particular drug regimen across the episode of care. MedPAC, in its June 2015 report, discussed bundled payments for Part B drugs as a potential approach to obtain better pricing for Part B drugs for beneficiaries compared to current pricing under the FFS system.

In the absence of an episode-based or bundled pricing model for Part B drugs, provider and practitioner prescribing patterns for a given drug treatment regimen under the current FFS payment system may unintentionally de-emphasize the value of drug regimens beyond the immediate care setting and throughout the course of drug therapy. For instance, in situations where drugs represent a small portion of the total cost of the patient's overall treatment therapy across multiple settings, particular attention may not be given to the financial impact of the cost of the drugs relative to the total cost of a patient's care or to the interaction of drug therapy with other aspects of the patient's care.

As part of this proposed rule, we are soliciting comments and suggestions to consider in future rulemaking related to an episode-based or bundled pricing approach for Part B drugs in both physician offices and hospital outpatient settings. The intent of this comment solicitation is to explore an initial framework that could 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 is pursuing bundled and episode payments through models such as the BPCI initiatives⁴³, the OCM⁴⁴, and CJR⁴⁵. As evidenced by the BPCI initiative and the OCM, we have demonstrated interest in developing models that utilize aligned financial incentives, including performance-based payments, to improve care coordination, appropriateness of care, and access for beneficiaries. As part of this proposed rule, we are specifically seeking comment on issues related to an episode-based or bundled pricing approach for Part B drugs, including, but not limited to:

- How CMS could identify groups of similar drugs for inclusion in an episode (for example, are drugs used to treat certain types of arthritis suitable candidates for inclusion in an episode-based or bundled payment model).
- The care settings (for example physician office, outpatient hospital) and disease states that we should consider for an episode-based or bundled pricing model.

⁴³ The BPCI initiative comprises four broadly defined models of care, which link payments for the multiple services beneficiaries receive during an episode of care. Under the initiative, organizations enter into payment arrangements that include financial and performance accountability for episodes of care. These models may lead to higher quality and more coordinated care at a lower cost to Medicare. More information on the four models can be accessed at the CMS Innovation Center: <https://innovation.cms.gov/initiatives/Bundled-Payments/>

⁴⁴ OCM is an innovative multi-payer model in which practices enter into payment arrangements that include financial and performance accountability for episodes of care surrounding chemotherapy administration to cancer patients. This model aims to provide higher quality, more highly coordinated oncology care at a lower cost. OCM is a 5-year model and will begin in spring 2016. More information on the four models can be accessed at the CMS Innovation Center: <https://innovation.cms.gov/initiatives/Oncology-Care/>

⁴⁵ The Comprehensive Care for Joint Replacement (CJR) model aims to support better and more efficient care for beneficiaries undergoing hip and knee replacements. This model tests bundled payment and quality measurement for an episode of care associated with hip and knee replacements to encourage hospitals, physicians, and post-acute care providers to improve the quality and coordination of care from the initial hospitalization through recovery. <https://innovation.cms.gov/initiatives/cjr>

- What types of entities/providers and suppliers would be responsible for care under the program and the types of financial relationships would there be if shared savings were considered.

- Measuring and setting outcomes, including parameters around standardizing value metrics based on differences in drug treatments and their targeted patient subpopulations, as well as measures of total cost of care and adjustments for case-mix.

- The scope of the bundle or episode of care, if not considering total cost of care.
- The provider or entity that is responsible for the bundle.
- The length of time the episode should cover.
- The best way to establish pricing for a bundle and whether sharing risk and savings should be considered.

- Whether the bundles should be established prospectively or calculated retrospectively.

D. Interactions with Other Payment Provisions

1. Overview

We acknowledge that there may be circumstances where a Medicare beneficiary whose Part B drug therapy is paid under the Part B Drug Payment Model may also be assigned to or otherwise accounted for in other payment models, demonstrations, programs, or other initiatives that are being tested by the Innovation Center. In this proposed rule, the term shared savings refers to models in which the payment structure includes a calculation of total savings with CMS and the model participants each retaining a particular percentage of that savings. We note that there is a potential for overlap between the Part B Drug Payment Model and the Medicare Shared Savings Program, the IVIG Demonstration, Innovation Center shared savings models, and other Innovation Center payment models, such as the OCM and the BPCI initiative. For other models tested by the Innovation Center, we have worked to prevent duplication and to monitor

arrangements that minimize duplication of effort. We anticipate undertaking similar efforts for the Part B Drug Payment Model.

2. Most Shared Savings Programs and Models

Unlike the Medicare Shared Savings Program and shared savings models such as the Next Generation ACO model or the Comprehensive ESRD Initiative where performance is measured using expansive measures that examine many facets of a patient's care, the Part B Drug Payment Model is limited to payments for drug therapy. Also, the Part B Drug Payment Model as it is proposed does not define episodes of care and instead makes payments for specific drug claims that are submitted by provider or supplier to the Medicare Administrative Contractors (MACs) that typically process their current drug claims. We believe that the adjustments made to the ASP add-on and other Part B payment amounts will typically represent a small proportion of the beneficiary's total payments for care, and thus we propose not to exclude beneficiaries assigned to ACOs in the Medicare Shared Savings Program or otherwise accounted for in shared savings models from inclusion in the Part B Drug Payment Model. Also, we do not propose a separate reconciliation process or modification to the reconciliation process for these beneficiaries. This means that with the exception of the OCM discussed in the next section, we do not plan to exclude or apply reconciliation processes to other shared savings programs or models.

3. Oncology Care Model

OCM evaluates the impact of appropriately aligned financial incentives to improve care coordination, appropriateness of care, and access to care for beneficiaries undergoing chemotherapy. Under OCM, practices will enter into payment arrangements that include financial and performance accountability for episodes of care surrounding chemotherapy

administration to cancer patients. The OCM is one of our [key](#) initiatives on alternative payment models, and we are preparing for implementation later this year.

OCM incorporates a two-part payment system for participating practices, creating incentives to improve the quality of care and furnish enhanced services for beneficiaries who undergo chemotherapy treatment for a cancer diagnosis. The two forms of payment include a monthly per-beneficiary-per-month (PBPM) payment for the duration of the episode and the potential for a performance-based payment for episodes of chemotherapy care. The monthly PBPM care management payment supports infrastructure and organizational change to meet the OCM requirements, such as 24/7 access to care, and assists participating practices in effectively managing and coordinating care for oncology patients during episodes of care, while the potential for performance-based payment will give practices incentives to lower the total cost of care and improve care for beneficiaries during treatment episodes.

There will be overlap between the Part B Drug Payment Model presented in this proposed rule and OCM in that both models will affect providers' and suppliers' incentives for the use of oncology drugs, but in different ways. Oncology drugs represent a significant portion of Part B claims and include many high cost drugs. Drug claims under the OCM are paid under the ASP methodology and costs associated with therapy (including drugs) are evaluated periodically. In the impact section to this proposed rule, section IX, we note the percent of total spending attributable to Part B drugs by specialty. Almost 80 percent of oncology practice Medicare FFS revenue is from Part B drugs.

We plan to proceed with both models, and we propose to include OCM practices in all arms of the Part B Drug Payment Model. That is, we would not alter the sampling plan discussed in section II of this proposed rule to exclude practices choosing to participate in OCM or practices that we might identify as the comparison group for OCM. In particular, as described

above, the Part B Drug Payment Model is proposed as a national mandatory model so that all practices in selected PCSAs will participate in the Part B Drug Payment Model whether or not they elect to participate in any voluntary models. Selected OCM practices and matched comparison group practices could account for up to almost 40 percent of total Part B drug spending and for 70 percent of Part B spending on oncology drugs depending upon the actual enrollment of number and type of practices in the model. For this reason, we also believe that the remaining oncology spending would not be representative of Part B spending overall and Part B oncology spending in particular. Therefore we are proposing to include all OCM practices, both intervention and comparison group practices, in this model.

We believe that including OCM practices in the Part B Drug Payment Model will not compromise our ability to evaluate effectively the effects of either model. In particular, the stratified random assignment approach used to allocate PCSAs to the treatment and control arms of the Part B Drug Payment Model will ensure that each arm of the Part B Drug Payment Model contains an approximately equal number of OCM participating practices. Since the number of OCM participants will be approximately the same in all arms of the Part B Drug Payment Model, the existence of the OCM should not bias comparisons of outcomes across arms of the Part B Drug Payment Model; thus, the existence of the OCM should not affect our ability to identify the independent effect of the Part B Drug Payment Model (that is, the effect of the Part B Drug Payment Model holding the level of OCM participation constant). Similarly, the stratified random assignment approach used in the Part B Drug Payment Model will ensure that OCM participant and comparison practices are each allocated approximately evenly across the arms of the Part B Drug Payment Model. Since the share of practices allocated to each Part B Drug Payment Model treatment arm will be approximately the same across both the OCM participant and comparison groups, the existence of the Part B Drug Payment Model should not bias

comparisons between OCM participants and non-participants and thus should not affect our ability to identify the independent effect of the OCM (that is, the effect of the OCM holding Part B Drug Payment Model activities constant). We seek comment on these conclusions.

The agency continues to assess best methods for addressing the overlap between the two models. We solicit comments on why practices choosing to participate in the OCM should or should not be included in the Part B Drug Payment Model. Should OCM practices be included in this Part B Drug Payment Model as we propose, we solicit comment on the best mechanism to account for the overlap between these two models. We also solicit comments on the generalizability of the results of the Part B Drug Payment Model if the OCM practices and their matched comparison practices are excluded; specifically, on whether the model will produce usable information without the OCM practices and their comparison practices. As we move forward to implement OCM, we will work closely with OCM practices within the context of that voluntary model to adapt to the Part B Drug Payment Model if necessary, for example through modifications to the financial reconciliation methodology.

4. Intravenous Immune Globulin (IVIG) Demonstration

The Medicare IVIG Demonstration evaluates the benefits of providing payment and items for services needed for the in-home administration of intravenous immune globulin for the treatment of primary immune deficiency disease (PIDD).

Services and items covered under the demonstration are provided and billed by the suppliers that provide the IVIG, which is already covered under Medicare Part B. The demonstration-covered services and items are paid as a single bundle and will be subject to coinsurance and deductible in the same manner as other Part B services. Home health agencies are not eligible to bill for services covered under the demonstration but may still bill for services

related to the administration of IVIG that are covered under the payment for a home health episode of care.

This IVIG demonstration encompasses only the items and services that are needed for the in-home administration of IVIG; payments for IVIG are not changed. We therefore propose not to exclude patients in the IVIG demonstration from inclusion in this model. We seek comment on our proposed approach and the potential interactions with existing models and payment provisions.

IV. Provider, Supplier, and Beneficiary Protections

Providers, suppliers, and beneficiaries who are included in 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 this model. The process will be developed and finalized by CMS. The phase II contractor's scope of work will also include day-to-day operation of this process. The Payment Exceptions Review process will precede the formal Part B claims appeals process in existing 42 CFR part 405 subpart I and will allow a provider, supplier, or beneficiary to raise issues regarding payment that are included in the VBP tools under phase II before submitting a claim. We anticipate the Payment Exceptions Review process will give providers, suppliers, or beneficiaries the opportunity to preempt potential disputes regarding a model payment, prior to filing a Medicare Appeal under 42 CFR part 405 subpart I.

A. Pre-Appeals Payment Exceptions Review Process

We propose to establish this Pre-Appeals Payment Exceptions Review process for pricing established under the value-based pricing section of phase II of this model only in order to allow the provider, supplier, or beneficiary an opportunity to dispute payments made under phase II. This process would be in addition to, not in lieu of, the current appeals process, and would be

available to any providers, suppliers, or beneficiaries receiving services in PCSAs assigned to one of the VBP arms. Providers, suppliers, and beneficiaries would have the opportunity to appeal any payment determination via the appeals mechanism that currently exist outside of this model.

We propose that the Payment Exceptions Review process would be applicable to phase II payments, described in section III.B of this proposed rule, and would not include modifications to the ASP add-on, described in section III.A of this proposed rule. The Pre-Appeals Payment Exception Review process would allow the provider, supplier, or beneficiary to contact the contractor, before submitting a claim, and explain why an exception to Medicare's pricing policy, as described in section II.B, is warranted in the beneficiary's situation, and explain why the price provided under the phase II pricing policy does not provide accurate compensation for the prescribed drug. The Payment Exceptions decisions would be issued, in writing, within 5 business days of receipt of the request for a payment exception. While a payment exception decision would not confer appeal rights, a provider, supplier, or beneficiary dissatisfied with a payment exception decision or a pricing decision, may still utilize the current appeals process in 42 CFR part 405 subpart I following submission of a claim. Throughout this process, providers and suppliers would be prohibited from charging a beneficiary more than the applicable cost sharing as explained in Section III.B.2, above, even if a payment exceptions request is not approved by the contractor or the payment amount determined by the contractor remains unchanged as a result of the appeals process.

All of the current claims appeals rights will remain in place regardless of participation in this model or the choice to utilize the Pre-Appeals process. We discuss the current appeals process below.

B. Current Appeals Procedure

As stated above, the Pre-Appeals process is intended as an option that would precede, not replace, the Medicare claims appeals process that is currently in place. The Pre-Appeals process is voluntary and intended to resolve payment disputes before the appeals process is needed, to minimize the number of formal Medicare appeals. Utilizing, or bypassing, the Pre-Appeals process will not affect the right of a provider, supplier, or beneficiary to access the current appeals process, following submission of a claim. In either the situation where the provider, supplier, or beneficiary submits a request for a Payment Exception, and that request is denied, or where the provider, supplier, or beneficiary does not choose to go through the Pre-Appeals process, the amount that will be paid on a submitted claim is that amount established through phase II pricing policy. The provider, supplier, or beneficiary may choose to appeal the payment amount, under 42 CFR part 405 subpart I, after the phase II price has been paid for a drug.

Under 42 CFR part 405 subpart I, MACs make an initial determination in response to a claim for benefits submitted by a provider, supplier, or beneficiary. We propose that the phase II pricing policy established by Medicare, which is proposed in §511.305 of this proposed rule, and discussed in section III.B of this proposed rule, and any pricing determination rendered through the Pre-Appeals process will be given substantial deference, but will not be binding on any appeals adjudicator, regardless of whether the party requesting an appeal first utilized the Pre-Appeals process. If the provider, supplier, or beneficiary is dissatisfied with the MAC's initial determination, they may request that the MAC perform a redetermination under 42 CFR 405.940. If the provider, supplier, or beneficiary is dissatisfied with the redetermination, they may then request a reconsideration by the Qualified Independent Contractor (QIC) under 42 CFR 405.960. A provider, supplier, or beneficiary may then request a hearing before an Administrative Law Judge (ALJ) under 42 CFR 405.1000, if the claim(s) at issue meet the amount in controversy requirement (\$150 for CY2016). Finally, a provider, supplier or

beneficiary may request Appeals Council review under 42 CFR 405.1100, *et seq.*, and then, in certain circumstances, request judicial review in Federal district court under 42 CFR 405.1132, if the amount in controversy requirement is satisfied (\$1,500 for CY 2016).

V. Proposed Waivers of Medicare Program Rules

Section 1115A(d)(1) of the Act provides the Secretary with broad authority to waive the statutory requirements titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii) of the Act 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. To test alternative approaches for Part B drug payments, we propose to use the waiver authority provided to the Secretary under section 1115A of the Act. The purpose of this flexibility would be to allow Medicare to test approaches described in this proposed rule with the goal of increasing the value of drug therapy that is paid under Medicare Part B while improving, or maintaining, the quality of beneficiaries' care as we implement and test this model. We believe that these waivers are necessary and appropriate to test whether the alternative drug payment designs discussed in this proposed rule will lead to better value for drugs paid under Part B, that is, a reduction in Medicare expenditures, while preserving or enhancing quality of care provided to Medicare beneficiaries.

First, we propose to waive portions of section 1847A(b) (1) of the Act which specify the 6 percent add-on percentage for payments determined under section 1847A of the Act. Waiving the fixed add-on percentage will allow the agency to modify the add-on percentage for payment determinations made under section 1847A of the Act to test whether modifying the add-on percentage improves provider and supplier financial incentives associated with Part B drug payment. The waiver for the add-on encompasses single source drugs, biologicals, multiple source drugs and biosimilars as described in section 1847A of the Act. The 6 percent add-on is

typically used for payments based on the manufacturer's ASP, but as discussed in the CY 2011 PFS rule, the ASP price files also include payments that use 106 percent of WAC. This percentage is consistent with sections 1847A(c)(4)(A) and 1847A(b) of the Act.

We also propose to waive 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. We propose to waive these definitions to test whether paying these types of drugs and biologicals using the pricing approaches described in this proposed rule will reduce expenditures while maintaining or improving quality of care. Alternative payment amounts proposed in this 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. For example, under value-based pricing (Section II.B.2), equal or benchmarked payment for therapeutically similar drug products that are used for a given indication like osteoarthritis is unlikely to be consistent with the statutory definitions of single source drug or biological, multiple source drug, and biosimilar biologicals.

We also propose to waive 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 the agency to base the determination of the ASP (that is, the ASP+0 percent) on the NDCs from this assignment. We are proposing to waive this statutory requirement for the required approach of assigning NDC's to HCPCS to test changes in these payment limits. As stated in the preceding paragraph, the determination of the model's payment amounts may not be consistent with the statutory definitions of single source drug or biological, multiple source drug, and biosimilar biologicals.

Furthermore, we propose to waive section 1847A(b)(6) of the Act, which specifies how the volume-weighted average sales price is to be used in the calculation of average sales price, so that we can test alternatives to the ASP+6 percent methodology in this model, irrespective of the volume-weighted average payment amount determination. This subsection provides the formula for using volume as a factor for determining the average sales price. Waiving this provision is necessary to test changes to the payment determination methodology that is described in section 1847A of the Act. Consistent with the statutory provisions discussed above, we also propose to waive applicable portions of §414.904-906 which define and implement payment provisions associated with section 1847A of the Act.

The waiver should also encompass other Part B drug payment methodologies that are used to pay for Part B drugs which are described in section 1842(o) of the Act. Section 1842(o)(1)(D) of the Act requires that infusion drugs furnished through an item of DME be paid at 95 percent of the AWP in effect on October 1, 2003. We are proposing to waive this section to include infusion drugs that are furnished through covered DME items in the model. Immunosuppressive drug supplying fees, inhalation drug dispensing fees and the clotting factor furnishing fees are described in sections 1842(o)(2), 1842(o)(5), 1842(o)(6) of the Act. We propose to waive these provisions to include modifications to the fees in the model. Section 1842(o)(2) of the Act allows Medicare to pay a dispensing fee (less the applicable deductible and coinsurance amounts) to the supplier for certain drugs that are dispensed and then paid under Part B. Section 1842(o)(5) of the Act requires the Secretary to provide a separate payment for items and services related to the furnishing of blood clotting factors. Finally, section 1842(o)(6) of the Act requires the Secretary to pay a supplying fee to pharmacies for certain immunosuppressive, oral anticancer and oral antiemetic drugs (less the applicable deductible and coinsurance amounts).

Further, we propose to waive portions of section 1833 of the Act. Specifically, we propose to waive section 1833(t)(14) of the Act in its entirety, which specifies that the OPSS pays for certain outpatient drugs at acquisition cost plus an adjustment for overhead and handling; this payment is currently set to ASP+6 percent. We propose to waive this provision to test the proposed changes to the ASP+6 percent methodology calculation for drugs and biologicals in the hospital outpatient department setting. Some drugs and biologicals, including certain diagnostic radiopharmaceuticals receive packaged payment. We would not revise our policy for packaging drugs and biologicals with per day costs below a certain threshold at this time for those drugs and biologicals that meet OPSS packaging criteria (we discuss episodes of care in this proposed rule, but do not propose to include episodes or other bundles at this time). We also propose to waive section 1833(t)(6) of the Act, which requires the Secretary to furnish additional pass through payments for certain drugs that are covered under the OPD service or group of services described under this section. This includes orphan drugs, cancer therapy drugs and brachytherapy, radiopharmaceuticals, and certain new drugs. We would waive the requirement that drugs and biologicals with pass-through status receive payment at ASP+6 percent to test changes with either alternative under either phase of the model. We propose to waive these sections of section 1833 of the Act, as well as related regulation text at §419.64, which provides definitions of terms used in the statute, including cancer therapy drugs, orphan drugs, and radiopharmaceutical drugs. We are waiving these regulatory definitions of terms described in section 1833 of the Act to achieve a waiver of the statutory requirement for pass through payment.

We further propose to waive section 1847B of the Act and portions of §414.906 through §414.920 which implement the Part B drug CAP. This section requires the establishment of a CAP and sets forth detailed requirements for the program. We have discussed an alternative to

the CAP in this rule and solicited comments about how a similar program may be implemented, but we are not proposing the implementation of the CAP as described in section 1847B of the Act at this time.

Providers and suppliers who participate in this model must comply with all applicable laws and regulations not explicitly waived in this document. We also seek comment on any additional Medicare program rules that it may be necessary to waive using our authority under section 1115A of the Act to effectively test the payment changes, described in this model, as it has been proposed, which we could consider in the context of our early model implementation experience to inform any future proposals we may make.

VI. Evaluation

Our evaluation of the Part B Drug Payment Model would test the proposed innovative health care payment model in this proposed rule to examine its potential to lower program expenditures while maintaining or improving the quality of care furnished to Medicare Program beneficiaries. Under this proposal, the Innovation Center would exercise its authority under section 1115A of the Act to test alternative payment designs for Part B drugs. The evaluation would collect and analyze data primarily to test the hypothesis that these alternative payment designs would lead to both higher quality and more affordable care for Part B Medicare enrollees and reduced Medicare expenditures. Our evaluation of the Part B Drug Payment Model would be used 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. We propose to evaluate this model in a manner similar to other models developed and tested under the Innovation Center authority.

Obtaining information that is representative of a wide and diverse group of providers, suppliers, and beneficiaries will best inform us on about how such a payment model might

function were it to be more fully integrated within the Medicare program. Our evaluation approach will compare historic patterns of Part B drug use and Medicare program costs for providers and suppliers, and health outcomes for beneficiaries in response to the alternative interventions proposed in this model (see section III. of this proposed rule).

We propose to apply the model interventions based upon a stratified random assignment of PCSAs, the unit of analysis for the model test (see section II.C. of this proposed rule). Researchers would 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. The evaluation will include a range of analytic methods, including regression and other multivariate analyses.

In our design, we primarily examine the impact of the proposed model interventions at the PCSA level. However, to address a broader variety of stakeholders and topics, we also propose to examine the model impact at the provider and supplier level and at the beneficiary level. We anticipate using various statistical methods to address observable factors that could confound or bias our results. We also plan, to the extent possible, to examine and account for the interactions of this model with other ongoing interventions such as the OCM, BPCI, the Pioneer ACO Models, and the Medicare Shared Savings Program. For example, the evaluation of this model may require excluding areas, providers, suppliers, or beneficiaries if including them has the potential to seriously bias the results of an existing model. Alternatively, statistical and other data analytic techniques could help to adjust for the effects of adding the Part B drug model in areas where providers, suppliers, or patients are participating in these other interventions.

Although, we expect to base many of our analyses on secondary data sources such as Medicare FFS claims, we may consider a survey of beneficiaries, suppliers, and providers to

provide insight on beneficiaries' experience under the model and additional information on any strategies undertaken by those providing drugs included under this model.

Our evaluation will focus upon whether the intervention reduces costs while improving quality of care. It also could include assessments of patient experience of care, prescribing and utilization patterns, health outcomes, Medicare expenditures, provider and supplier costs, and other potential impacts of interest to stakeholders. Our 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?

In addition, we seek comments on other potential questions for inclusion in the evaluation of the Part B Drug Payment Model.

VII. Collection of Information Requirements

As stated in section 1115A(d)(3) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of models under section 1115A of the Act. As a result, the information collection requirements contained in this proposed rule need not be reviewed by the Office of Management and Budget. However, costs incurred through information collections are included in the Regulatory Impact Analysis.

VIII. 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 consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IX. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this proposed rule, as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995,

Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Contract with America Advancement Act of 1996 (Pub. L. 104-121) (5 U.S.C. 804(2)). This section of the proposed rule contains the impact and other economic analyses for the provisions that we are proposing.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated as an economically significant rule under section 3(f)(1) of Executive Order 12866 and a major rule under the Contract with America Advancement Act of 1996 (Pub. L. 104-121). Accordingly, this proposed rule has been reviewed by the Office of Management and Budget. We have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of this proposed rule. We solicit comments on the regulatory impact analysis in the proposed rule.

B. Statement of Need

This proposed rule is necessary to implement and test a new payment and service delivery model under the authority of section 1115A of the Act, which allows the Innovation Center to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to individuals. The underlying issue addressed by the Part B Drug Payment Model is whether the FFS payment amount for drugs furnished in physician offices and hospital outpatient departments at ASP+6 percent encourages the use of more expensive drugs because the 6 percent add-on generates more revenue for more expensive drugs (see MedPAC Report to the Congress: Medicare and the Health Care Delivery

System June 2015, pages 65-72). Medicare pays this price regardless of the price a provider pays to acquire the drug. The ASP methodology does not take into account the effectiveness of a particular drug, nor the cost of comparable drugs, when determining the Medicare payment amount.

This proposed rule creates and tests one alternative payment approach to the ASP add-on amount and whether a combination of value-pricing and clinical decision support tools can change physician and hospital outpatient prescribing patterns. With minor exclusions, we propose to include the vast majority of Part B drugs in this proposed model, and we are requiring all providers and suppliers that furnish those Medicare Part B drugs to beneficiaries in selected geographic areas to participate. Some providers and suppliers will be included in the control group continuing to receive payment at ASP+6 percent. Testing the model in this manner will allow us to learn more about how best to structure FFS incentives for Part B drug payment and whether managing aspects of the Part B drug benefit can improve the value of Medicare spending on drugs. This learning could inform future Medicare payment policy.

C. Overall Impacts for the Proposed Part B Drug Payment Model

As detailed in section III of this proposed rule, we are proposing to establish the CY 2016 alternative ASP add-on amount in phase I as budget neutral to Part B spending using CY 2014 claims data. We propose to update the flat fee amount each year based on the CPI MC. We intend to achieve savings through behavioral responses to the revised pricing, as we hope that the revised pricing removes any excess financial incentive to prescribe high cost drugs over lower cost ones when comparable low cost drugs are available. In other words, we believe that removing the financial incentive that may be associated with higher add-on payments may lead to some savings during phase I of the proposed model. We do not have an exact estimate of the amount of savings that might be achieved through behavioral responses. However, prior research

suggests that changes in the 6 percent add-on percentage can change prescribing behavior. For example, in one study, the implementation of ASP+6 percent resulted in providers shifting patients to newer, more expensive drugs which had a higher profit margin under the ASP+6 percent methodology.⁴⁶ For urologists, rheumatologists, infectious disease specialists, and medical oncologists, Medicare billing decreased for Part B drugs but increased for other services (for example, drug administration and testing) between 2004 and 2005, when ASP+6 percent went into effect.⁴⁷

In phase II, we are proposing that the VBP component of the model would not be budget neutral. We intend to achieve savings in phase II through the use of value-pricing tools. We invite extensive comment throughout this proposed rule on the applicability of various VBP tools to the Part B and hospital outpatient drug benefit. We do not believe that we have enough detail on the structure of the final value-based purchasing component to quantify potential savings. As with phase I, we note evidence that changes in drug margin and the +6 percent add-on amount have correlated with changes in prescribing patterns. We cannot gauge the magnitude of savings for either proposed phase of the model at this time but we expect both to produce savings. We invite comment on the extent of savings that might be achieved based on commenter experience.

Part B and hospital outpatient spending for separately paid drugs and biologicals is estimated at \$21 billion for CY 2016. We propose to assign through the stratified random sample one-half of the PCSAs to the phase I model arms testing payment at ASP+2.5 percent plus a flat fee and that should include roughly one-half of that estimated spending amount within those arms. We estimate that the flat fee would account for roughly \$675 million of total Part B drug spending if calculated nationally. In addition to any changes in spending introduced through

⁴⁶ Medicare Payment Advisory Commission. (2006). Report to the Congress: Effects of Medicare payment changes on oncology. Washington, DC: MedPAC.

⁴⁷ Medicare Payment Advisory Commission. (2007). Report to the Congress: Impact of changes in Medicare payments for Part B drugs. Washington, DC: MedPAC.

phase II, we believe that the model's effects will trigger the threshold of "an annual effect on the economy of \$100 million or more" under E.O. 12866.

D. Detailed Economic Analyses

1. Estimated Effect of Part B Drug Payment Model Changes in This Proposed Rule

a. Limitations of Our Analysis

The distributional impacts presented here are the projected effects of phase I of the proposed Part B Drug Payment Model implementing alternative ASP add-on amounts to drug payment by various hospital categories and physician specialties, where applicable. We estimate the effects of the policy changes by categorizing drug payment and other factors from the provider and supplier claims into the appropriate categories and then recalculating payment based on the characteristics of proposed pricing under the Part B Drug Payment Model. In developing the budget neutral Part B Drug Payment Model and the corresponding impact tables, we use the best data available, but do not attempt to predict behavioral responses to our policy changes. In addition, we have not made adjustments for future changes in variables such as service volume, service-mix, or number of encounters. The impact tables included in this proposed rule display the estimated effects if the Part B Drug Payment Model were to apply to all providers. Since we propose to randomly assign PCSAs to one of three model test arms or a control group, we believe that including all providers is a fair representation of the impact. We also note that we included all providers and suppliers in our calculation of the proposed flat fee amount. In this proposed rule, we are soliciting public comment and information about the anticipated effects of our proposed changes on providers and suppliers and the methodologies used to develop the Part B Drug Payment Model. Any public comments that we receive will be addressed in the applicable section(s) of the final rule with comment period.

For phase II of this model we do not present distributional impacts. This phase of the proposed model is not budget neutral, and as discussed in section II.B.1., evidence generally suggests that utilizing approaches employed by commercial and Part D plans to contain drug costs and improve value should lead to savings in Part B drug spending. However, the proposed rule invites extensive comment on which VBP tools are appropriately applied to the Part B and hospital outpatient drug benefit. We cannot yet quantify the overall impact of VBP. We invite comment on the extent of savings that might be achieved based on commenter experience, and we anticipate being able to better estimate the probability and magnitude of savings from those comments.

b. Estimated Effects of Phase I

i. Estimated Effects of Phase I: Changes to ASP Add-on Amount on Physicians, Practitioners, and other Suppliers

Table 2 shows the estimated impact of this proposed rule on physicians, practitioners, and other suppliers. Table 2 does not show specialties with less than \$10 million in total drug spending and includes outpatient hospital spending as a specialty to demonstrate budget neutrality. Overall, Part B drug payment to practitioners, pharmacies, and hospitals by specialty in phase I of this proposed model will not change, as the ASP add-on revision is proposed to be budget neutral.

- Column 1: Physician Specialty Descriptor: Column 1 displays the physician specialty categories in the Part B drug claims. We do not show specialties with aggregate drug spending less than \$10 million.

- Column 2: Total Medicare Payment for Specialty (in millions): Column 2 displays total Medicare payment (in millions) for physician/supplier specialties in the model, including both the Medicare program and beneficiary share, based on CY 2014 claims with proposed trims

and exclusions as discussed in the proposed rule. These payment values are included to provide context for the Part B Drug Payment Model changes in the broader context of overall payment. The first line in Column 2 in Table 3 shows the total Medicare payment for all hospital and physician/supplier specialties (approximately \$127 billion). The second line in Column 2 shows the total Medicare payment for all hospitals. The third line in Column 2 shows the total Medicare payment for all specialties with drugs included in the proposed Part B drug payment model.

- Column 3: Total Medicare Payment-Physician Specialty Percent Change: Column 3 displays the estimated impact of the ASP+2.5 percent and flat fee model within the context of overall Medicare payment to physician/supplier specialties. Under the proposed rule the estimated overall percent change for specialties ranges from -2.9 percent to 3.2 percent.

- Column 4: Total Medicare Payment-Urban Area Percent Change: Column 4 displays the estimated impact of the ASP+2.5 percent and flat fee model within the context of overall Medicare payment to urban geographic areas. Under the proposed rule the estimated overall percent change for physician/supplier specialties ranges from -2.9 percent to 3.4 percent.

- Column 5: Total Medicare Payment-Rural Area Percent Change: Column 5 displays the estimated impact of the ASP+2.5 percent and flat fee model within the context of overall Medicare payment in rural geographic areas. Under the proposed rule the estimated overall percent change for physician/supplier specialties in rural areas ranges from -2.4 percent to 2.6 percent.

- Column 6: Total Drug Payment at ASP+6 percent for Specialty (in millions): Column 6 displays total drug payment at the full ASP+6 percent based on CY 2014 claims, with proposed trims and exclusions as discussed in the proposed rule.

- Column 7: ASP+2.5 percent plus Flat Fee - Physician Specialty Percent Change in Drug Payment: Column 7 displays the estimated impact of the ASP+2.5 percent + flat fee

model within the context of drug payment to physician/supplier specialties, from ASP+6 percent to ASP+2.5 percent + flat fee. The proposed flat fee amount is calculated as \$16.80, and applies per drug per day administered. Under the proposed rule, Part B drug payments to physician/supplier specialties are expected to decrease and increase in the range of -3.3 to 50.2 percent. We note that the specialty impacts will vary based on the share that Part B drug payment represents as a portion of overall practice revenue for that category. We note that the proposed changes are budget neutral across Part B drug spending hospitals and physician offices.

- Column 8: ASP+2.5 percent + Flat Fee – Urban Area Percent Change in Drug

Payment: Column 8 displays the estimated impact of the ASP +2.5 percent and flat fee model within the context of Medicare payment in urban geographic areas. Under the proposed rule the estimated overall percent change for Part B drug payments to physician/supplier specialties in urban areas ranges from -3.3 percent to 50.2 percent.

- Column 9: ASP+2.5 percent + Flat Fee – Rural Area Percent Change in Drug

Payment: Column 9 displays the estimated impact of the ASP+2.5 percent + flat fee model within the context of Medicare payment in rural geographic areas. Under the proposed rule the estimated overall percent change for Part B drug payments to physician/supplier specialties in rural areas ranges from -3.2 percent to 82.1 percent.

TABLE 2: Impact of Part B Drug Payment Model on Hospitals, Practitioners, and Pharmacies by Specialty *

Rows	Specialty	Physician Specialty Descriptor	Total Medicare Payment				Total Drug Payment			
			Total Medicare Payment for Specialty (in millions)	Physician Specialty % Change	Urban % Change	Rural % Change	Total Drug Payment at ASP+6 percent for Specialty (in millions)	Physician Specialty % Change	Urban % Change	Rural % Change
1	All	Hospital OPPS and MPFS	\$127,417	0.0%	0.0%	0.3%	\$20,391	0.0%	-0.3%	2.1%
2	Hospital	Hospital	\$50,043	-0.3%	-0.3%	-0.3%	\$7,209	-2.3%	-2.3%	-2.2%
3	Total **	All Specialties	\$77,374	0.2%	0.2%	0.6%	\$13,181	1.3%	0.9%	4.8%
4	83	Hematology/Oncology	\$5,150	-0.4%	-0.5%	-0.2%	\$4,059	-0.6%	-0.6%	-0.2%
5	18	Ophthalmology	\$6,234	-0.6%	-0.7%	-0.4%	\$2,387	-1.7%	-1.7%	-1.4%
6	A5	Pharmacy	\$3,316	1.8%	1.5%	2.6%	\$1,432	4.2%	3.4%	6.2%
7	66	Rheumatology	\$1,699	-1.1%	-1.1%	-1.0%	\$1,205	-1.5%	-1.5%	-1.5%
8	90	Medical Oncology	\$1,499	-0.5%	-0.5%	-0.4%	\$1,193	-0.7%	-0.7%	-0.5%
9	87	Other	\$486	-2.9%	-2.9%	-2.4%	\$429	-3.3%	-3.3%	-3.2%
10	11	Internal Medicine	\$6,266	0.6%	0.5%	1.0%	\$412	9.1%	8.1%	17.5%
11	34	Urology	\$1,619	0.1%	0.1%	0.2%	\$349	0.4%	0.4%	0.7%
12	13	Neurology	\$1,162	-0.3%	-0.3%	-0.1%	\$231	-1.4%	-1.4%	-0.5%
13	20	Orthopedic Surgery	\$1,792	1.9%	1.9%	2.0%	\$223	15.0%	14.9%	16.2%
14	82	Hematology	\$206	-0.5%	-0.5%	-0.3%	\$164	-0.6%	-0.6%	-0.4%
15	50	Nurse Practitioner	\$1,444	0.8%	0.5%	2.1%	\$136	8.7%	5.2%	27.1%
16	08	Family Practice	\$4,825	1.1%	0.9%	1.6%	\$119	43.6%	38.2%	62.1%
17	06	Cardiovascular Disease (Cardiology)	\$3,850	0.3%	0.3%	0.2%	\$113	9.3%	9.3%	8.6%
18	97	Physician Assistant	\$879	1.1%	1.0%	1.4%	\$79	12.3%	11.5%	15.9%
19	10	Gastroenterology	\$658	-0.2%	-0.2%	0.0%	\$76	-1.5%	-1.6%	-0.5%
20	44	Infectious Disease	\$177	3.2%	3.4%	-0.2%	\$71	8.1%	8.3%	-0.6%
21	03	Allergy/Immunology	\$270	-0.3%	-0.3%	-0.3%	\$66	-1.4%	-1.4%	-1.3%
22	25	Physical Medicine And Rehabilitation	\$589	1.0%	1.0%	1.1%	\$57	10.3%	10.0%	16.0%
23	98	Gynecological/Oncology	\$85	0.6%	0.6%	0.6%	\$51	1.0%	1.0%	2.1%

Rows	Specialty	Physician Specialty Descriptor	Total Medicare Payment				Total Drug Payment			
			Total Medicare Payment for Specialty (in millions)	Physician Specialty % Change	Urban % Change	Rural % Change	Total Drug Payment at ASP+6 percent for Specialty (in millions)	Physician Specialty % Change	Urban % Change	Rural % Change
24	39	Nephrology	\$1,357	0.2%	0.2%	0.1%	\$50	4.7%	4.9%	3.3%
25	07	Dermatology	\$3,036	0.0%	0.0%	0.1%	\$30	4.5%	4.4%	4.7%
26	29	Pulmonary Disease	\$665	0.3%	0.2%	0.3%	\$28	5.9%	6.0%	5.4%
27	46	Endocrinology	\$410	0.1%	0.1%	0.1%	\$25	1.7%	1.7%	1.1%
28	37	Pediatric Medicine	\$58	-0.4%	-0.6%	1.5%	\$21	-1.1%	-1.5%	81.0%
29	92	Radiation Oncology	\$1,489	0.0%	0.0%	0.0%	\$18	-1.2%	-1.3%	-0.5%
30	16	Obstetrics/Gynecology	\$419	0.3%	0.3%	0.3%	\$17	6.4%	6.8%	4.5%
31	09	Interventional Pain Management	\$390	2.0%	2.0%	1.8%	\$16	46.9%	45.2%	82.1%
32	72	Pain Management	\$253	1.7%	1.7%	1.5%	\$13	33.7%	32.6%	58.9%
33	05	Anesthesiology	\$343	1.7%	1.7%	1.6%	\$12	50.2%	50.2%	47.4%
34	01	General Practice	\$404	1.2%	1.0%	1.9%	\$11	44.5%	42.1%	51.9%

* Table does not display specialties with less than \$10 million in total drug spending. Identification of geographic location was based on the performing NPI's ZIP code for the line item. We note that this represented approximately 0.2% of NPI's included in this table and an estimated \$2.5 million in total drug spending.

** This row includes all specialty information for drugs included in the proposed Part B drug payment model

ii. Changes to ASP Add-on amount on Hospitals

Table 3 shows the estimated impact of this proposed rule on hospitals. The table includes cancer and children's hospitals, which are held harmless to their amount prior to the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33). These providers are part of OPSS budget neutrality but would not be affected by the proposed Part B Drug Payment Model due to their hold harmless status. Overall, Part B drug payment to hospitals in the ASP+X phase of the Part B Drug Payment Model, phase 1, will decrease by an estimated 2.3 percent within the context of ASP based drug payment, and by an estimated 0.3 percent in overall hospital spending.

As discussed in section III.B. of this proposed rule, payment to hospitals for low cost drugs is included in the OPSS payment for primary services. We likely overestimate the cost of these drugs in our OPSS rate setting methodology due to our use of an average CCR in our cost estimation methodology. It is important to note that hospitals already receive robust payment for low cost drugs under a different payment methodology in light of the Table 3 conclusion demonstrating an overall -0.3 distribution away from hospitals.

- Column 1: Total Number of Hospitals: The first line in Column 1 in Table 3 shows the total number of hospitals in the Part B Drug Payment Model (3,204), including designated cancer and children's hospitals, for which we were able to use CY 2014 hospital outpatient claims data to extract actual CY 2014 ASP based drug payments. We excluded hospitals and entities that are not paid under the OPSS. The latter entities include CAHs, all-inclusive hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. At this time, we are unable to calculate a disproportionate share hospital (DSH) variable for hospitals that are not also paid under the IPPS, since DSH payments are only made to hospitals paid under the IPPS. Hospitals for which we do not have a DSH variable are grouped separately and generally include freestanding

psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals. We included cancer and children's hospitals because they are considered in OPPS budget neutrality. However, section 1833(t)(7)(D) of the Act permanently holds harmless cancer hospitals and children's hospitals to their "pre-BBA amount" as specified under the terms of the statute, and therefore, they would not be affected by these proposed models.

- Column 2: Total Drug Payment at ASP+6 percent (in millions): Column 2 shows the total drug payment for separately payable drugs included in the model, calculated at the full ASP+6 percent for each category based on CY 2014 claims with trimming and exclusions as discussed in the proposed rule.

- Column 3: Total Medicare Payment (in millions): Column 3 displays Medicare payment for hospitals in the model, including both the Medicare program and beneficiary share, based on CY 2014 claims with proposed trims and exclusions. These payment numbers are included to provide context for the Part B Drug Payment Model changes in the broader context of overall payment to classes of hospitals.

- Column 4: ASP+2.5 percent + Flat Fee - Revised Payment (in millions): Column 4 displays total estimated revised payment under the ASP+2.5 percent and flat fee model. The proposed flat fee amount is calculated as \$16.80, and applies per drug per day administered.

- Column 5: ASP+2.5 percent + Flat Fee - Percent Change: Column 5 column displays the estimated impact of the model within the context of drug payment, from ASP+6 percent to ASP+2.5 percent + flat fee of \$16.80. Part B drug payments to hospitals based on the various categories are estimated to experience decreases in the range of -2.5 to -2.0 percent, under this proposed ASP+2.5 percent + flat fee model. We note that the proposed changes are budget neutral across Part B drug spending hospitals and physician offices.

- Column 6: ASP+2.5 percent + Flat Fee -Estimated Percent Change in Overall

Spending: Column 6 displays the estimated impact of the model within the context of overall Medicare payment to hospitals. Under the proposed rule the estimated overall percent change for overall Medicare payments to outpatient hospitals ranges from -0.9 percent to -0.1 percent.

TABLE 3: Outpatient Impact Analysis of the Part B Drug Payment Model

Row		(1)	(2)	(3)	(4)	(5)	(6)
		Number of Hospitals	Total Drug Payment at ASP+6 percent (in millions)	Total Medicare Payment (in millions)	ASP+2.5 percent + Flat Fee		
					Revised Payment (in millions)	% Change in Drug Spending	Estimated Overall % Change
1	ALL PROVIDERS *	3,204	\$7,209	\$50,043	\$7,044	-2.3%	-0.3%
2	URBAN HOSPITALS	2,412	\$6,390	\$43,887	\$6,242	-2.3%	-0.3%
3	LARGE URBAN (GT 1 MILL.)	1,324	\$3,564	\$23,730	\$3,481	-2.3%	-0.4%
4	OTHER URBAN (LE 1 MILL.)	1,088	\$2,826	\$20,157	\$2,761	-2.3%	-0.3%
5	RURAL HOSPITALS	792	\$819	\$6,156	\$801	-2.2%	-0.3%
6	SOLE COMMUNITY	371	\$491	\$3,310	\$480	-2.2%	-0.3%
7	OTHER RURAL	421	\$328	\$2,845	\$322	-2.1%	-0.2%
	BEDS (URBAN)						
8	0 - 99 BEDS	592	\$434	\$3,668	\$424	-2.3%	-0.3%
9	100-199 BEDS	737	\$915	\$8,078	\$894	-2.2%	-0.3%
10	200-299 BEDS	450	\$1,066	\$8,248	\$1,042	-2.2%	-0.3%
11	300-499 BEDS	416	\$1,716	\$12,002	\$1,677	-2.3%	-0.3%
12	500 + BEDS	217	\$2,260	\$11,891	\$2,206	-2.4%	-0.5%
	BEDS (RURAL)						
13	0 - 49 BEDS	289	\$98	\$906	\$96	-2.1%	-0.2%

Row			(1)	(2)	(3)	(4)	(5)	(6)
			Number of Hospitals	Total Drug Payment at ASP+6 percent (in millions)	Total Medicare Payment (in millions)	ASP+2.5 percent + Flat Fee		
						Revised Payment (in millions)	% Change in Drug Spending	Estimated Overall % Change
14		50- 100 BEDS	305	\$285	\$2,196	\$279	-2.1%	-0.3%
15		101- 149 BEDS	111	\$157	\$1,180	\$153	-2.1%	-0.3%
16		150- 199 BEDS	48	\$111	\$879	\$109	-2.1%	-0.3%
17		200 + BEDS	39	\$168	\$995	\$164	-2.3%	-0.4%
		REGION (URBAN)						
18		NEW ENGLAND	131	\$542	\$3,362	\$529	-2.3%	-0.4%
19		MIDDLE ATLANTIC	308	\$981	\$5,924	\$958	-2.4%	-0.4%
20		SOUTH ATLANTIC	407	\$1,116	\$8,069	\$1,091	-2.3%	-0.3%
21		EAST NORTH CENT.	393	\$1,106	\$7,616	\$1,081	-2.3%	-0.3%
22		EAST SOUTH CENT.	147	\$456	\$2,739	\$446	-2.3%	-0.4%
23		WEST NORTH CENT.	165	\$541	\$3,471	\$529	-2.3%	-0.4%
24		WEST SOUTH CENT.	349	\$539	\$4,694	\$527	-2.3%	-0.3%
25		MOUNTAIN	158	\$356	\$2,466	\$347	-2.4%	-0.3%
26		PACIFIC	330	\$751	\$5,516	\$733	-2.3%	-0.3%
27		PUERTO RICO	24	\$2	\$30	\$2	-2.5%	-0.2%
		REGION (RURAL)						
28		NEW ENGLAND	21	\$75	\$401	\$74	-2.4%	-0.4%
29		MIDDLE ATLANTIC	56	\$60	\$450	\$58	-2.2%	-0.3%
30		SOUTH ATLANTIC	123	\$117	\$946	\$114	-2.1%	-0.3%
31		EAST NORTH CENT.	114	\$143	\$1,168	\$140	-2.1%	-0.3%
32		EAST SOUTH CENT.	149	\$121	\$959	\$118	-2.2%	-0.3%
33		WEST NORTH CENT.	95	\$145	\$897	\$142	-2.1%	-0.3%

Row		(1) Number of Hospitals	(2) Total Drug Payment at ASP+6 percent (in millions)	(3) Total Medicare Payment (in millions)	(4) ASP+2.5 percent + Flat Fee			(5)	(6)
					Revised Payment (in millions)	% Change in Drug Spending	Estimated Overall % Change		
34	WEST SOUTH CENT.	152	\$41	\$676	\$40	-2.0%	-0.1%		
35	MOUNTAIN	58	\$70	\$366	\$68	-2.3%	-0.4%		
36	PACIFIC	24	\$47	\$293	\$46	-2.3%	-0.4%		
	TEACHING STATUS								
37	NON-TEACHING	2,130	\$2,371	\$21,298	\$2,318	-2.2%	-0.2%		
38	MINOR	712	\$2,162	\$15,739	\$2,112	-2.3%	-0.3%		
39	MAJOR	362	\$2,677	\$13,006	\$2,613	-2.4%	-0.5%		
	DSH PATIENT PERCENT								
40	0	9	\$3	\$33	\$3	-2.2%	-0.2%		
41	GT 0 - 0.10	283	\$347	\$3,326	\$340	-2.3%	-0.2%		
42	0.10 - 0.16	288	\$419	\$4,178	\$410	-2.2%	-0.2%		
43	0.16 - 0.23	639	\$1,063	\$9,929	\$1,039	-2.3%	-0.2%		
44	0.23 - 0.35	1,096	\$2,863	\$19,051	\$2,798	-2.3%	-0.3%		
45	GE 0.35	774	\$2,055	\$12,308	\$2,007	-2.3%	-0.4%		
46	DSH NOT AVAILABLE *	115	\$459	\$1,218	\$448	-2.4%	-0.9%		
	TYPE OF OWNERSHIP								
47	VOLUNTARY	1,934	\$5,535	\$36,228	\$5,407	-2.3%	-0.4%		
48	PROPRIETARY	799	\$428	\$6,753	\$419	-2.1%	-0.1%		
49	GOVERNMENT	471	\$1,246	\$7,062	\$1,217	-2.3%	-0.4%		

Row		(1)	(2)	(3)	(4)	(5)	(6)
		Number of Hospitals	Total Drug Payment at ASP+6 percent (in millions)	Total Medicare Payment (in millions)	ASP+2.5 percent + Flat Fee		
					Revised Payment (in millions)	% Change in Drug Spending	Estimated Overall % Change

* Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

c. Estimated Effect of Part B Drug Payment Model Changes on Beneficiaries

For phase I of this model, we estimate that the aggregate beneficiary share within the context of the model will remain unchanged as we are establishing the alternative ASP add-on amounts to be budget neutral. Coinsurance for most separately payable drugs is set at 20 percent of the payment rates, while payment for new drugs would also be set at 20 percent of payment based on the OPPS and Part B drug coinsurance requirements. As noted above, we intend to achieve savings through anticipated behavioral response to price changes, although we cannot quantify the amount. To the extent that prescribing patterns do shift toward lower cost drugs under phase I, in aggregate, beneficiaries would benefit along with the Medicare program. We note that individual beneficiaries may see increases or decreases in their cost-sharing responsibility consistent with any redistribution in payment.

For phase II of this model, commercial experience suggests that some savings could be achieved, but we cannot anticipate the magnitude of changes in spending as already discussed. To the extent that savings ultimately are realized, both the beneficiary and Medicare program would benefit. Further, we have proposed in our value-based pricing discussion in section III.A. of this proposed rule, consistent with cost sharing approaches for Part B drugs, that beneficiary cost sharing will not exceed 20 percent of the total model-based payment amount for the Part B drug.

d. Alternative Part B Drug Payment Proposed Policies Considered

Alternatives to the Part B Drug Payment Model changes that we are proposing and the reasons for our selected alternatives are discussed throughout this proposed rule. In this section, we discuss some of the significant issues and the alternatives considered.

In the context of phase I, we considered several alternative structures for the ASP add-on amount. We first considered proposing a flat fee with no percent add-on. MedPAC discussed this alternative among several in their June 2015 report on Part B drug payment (MedPAC Report to the Congress: Medicare and the Health Care Delivery System June 2015, pages 65-72). Under such an approach, we would pay for an individual drug using baseline ASP amount and redistribute the entire +6 percent add-on amount in the form of a flat fee divided equally among doses of all drugs. This would shift an even greater portion of payments from the high cost drugs to the lower cost drugs even more aggressively than the proposed redistribution of ASP+2.5 percent plus a flat fee of \$16.80. Like MedPAC, we believe that some amount of percentage add-on is required to address distribution channel costs associated with wholesalers and others between the manufacturer sales price and the physician purchase of a drug. Converting the ASP add-on payment to a complete flat fee might limit providers' ability to purchase expensive drugs as well as overly incentivize payment for the low cost drugs. We chose not to propose such a payment structure. We also have discussed additional tests of add-on modifications in section III.A.3 of this proposed rule. However, we believe that these approaches are not sufficiently different from the proposed approach to warrant proposal. We also were concerned that additional arms in the model could reduce statistical power. We invited comments on the decision to test one approach, ASP+2.5 percent + flat fee of \$16.80.

Regarding the proposed Part B VBP model and its component tools, an alternative that we had considered was establishing episode of care based payments, potentially focused on specific drug treatments. There are a variety of ways to remove financial incentives from the prescribing decision. Clearly embedding decisions about prescribing within a model that pays for care management or rewards changes in total cost of care could create incentives for better

quality and lower cost care. We are testing such an approach under the OCM, which we discuss in greater detail under section III. E. of this proposed rule. We chose not to explore an episode of care approach under this proposed Part B Drug Payment Model because of our immediate interest in addressing current incentives in Part B payment for the full range of Part B drugs. Rather than proposing an episode of care based payment built upon drug treatments, we are soliciting comments on an episode approach in section III.D. of this proposed rule for future consideration. We also plan to monitor experiences under the OCM closely to identify other opportunities for similar models that include drug therapies.

e. Accounting Statements and Table

As required by OMB Circular A-4 (available on the Office of Management and Budget Web Site at http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf), we have prepared an accounting statement to illustrate the estimated impact of this proposed rule. The accounting statement, Table 4, illustrates the classification of expenditures for providers and suppliers paid under the OPFS or MPFS, based on the estimated impacts in this proposed rule. Table 4 classifies most estimated impacts as transfers.

TABLE 4: Accounting Statement: CY 2016 Estimated Hospital OPFS and MPFS Transfers as a Result of Changes in this Proposed Rule

Category	Transfers
Annualized Monetized Transfers	\$0 million
From Whom to Whom	Federal Government to outpatient providers, physicians, other practitioners and providers and suppliers who receive OPFS or MPFS payment.
Total	\$0 million

E. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, most hospitals, practitioners, and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. For details, see the Small Business Administration's "Table of Small Business Size Standards" at <http://www.sba.gov/content/table-smallbusiness-size-standards>.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this proposed rule may have a significant impact on small rural hospitals selected for the model. Therefore, we have prepared a regulatory impact analysis that includes the effects of the proposed rule on small rural hospitals.

F. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$144 million. This proposed rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

G. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, preempts state law, or otherwise has Federalism implications. We have examined the OPPS and MPFS provisions in the Part B Drug Payment Model included in this proposed rule in accordance with Executive Order 13132, Federalism, and have determined that they will not have a substantial direct effect on state, local or tribal governments, preempt state law, or otherwise have a Federalism implication. As reflected in Table 3 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including state and local governmental hospitals) would decrease payment by 0.4 percent under this proposed rule. While we do not know the number of physician offices with government ownership, we anticipate that it is small. The analyses we have provided in this section of this proposed rule, in conjunction with the remainder of this document, demonstrate that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

H. Conclusion

The changes we are proposing to make in this proposed rule will affect all categories of outpatient providers, physicians, practitioners, and other suppliers who furnish drugs that we are proposing to include in the Part B Drug Payment Model. We estimate that the effect of this proposal on physician specialties changes will vary, depending on what drugs they furnish and their clinical patterns. Table 2 demonstrates the estimated impact of the proposal on physician and supplier specialties, which for most would result in changes in drug payments in the range of -3.3 to 50.2 percent and -2.9 to 3.2 percent for overall Medicare payments. We estimate that most classes of hospitals paid under the OPPS will experience a minimal decrease in overall

payment related to the proposed Part B Drug Payment Model. Table 3 demonstrates the estimated impact of the proposal, which for most hospital categories would result in decreases in payments for separately paid drugs in the range of -2.5 to -2.0 percent and -0.9 to -0.1 percent for overall Medicare payments. The effect of this proposal on an individual hospital, physician, practitioner, or other supplier will depend on its individual practice patterns.

List of Subjects in 42 CFR Part 511

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, under the authority at section 1115A of the Social Security Act, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR Chapter IV by adding Part 511 to Subchapter H to read as follows:

PART 511—PART B DRUG PAYMENT MODEL

Sec.

Subpart A—General Provisions

- 511.1 Basis and scope.
- 511.2 Abbreviations and definitions.

Subpart B—Part B Drug Payment Model Participants

- 511.100 Included providers and suppliers.
- 511.105 Geographic areas.

Subpart C—Scope

- 511.200 Part B drugs and related fees included in the model.
- 511.205 Model structure and duration.

Subpart D—Pricing and Payment

- 511.300 Determination of model-based ASP payment (Phase I).
- 511.305 Determination of VBP tools (Phase II).
- 511.315 Pre-appeals Payment Exceptions Review Process.

Subpart E—Waivers

- 511.400 Waiver of certain ASP payment methodologies, requirements, and definitions for certain Medicare Part B drugs.
- 511.405 Waiver of other Part B drug payment methodologies.
- 511.410 Waiver of CAP.

Authority: Secs. 1102, 1115A, and 1871 of the Social Security Act (42 U.S.C. 1302, 1315(a), and 1395hh).

Subpart A—General Provisions

§511.1 Basis and scope.

(a) Basis. This part implements the test of the Part B Drug Payment Model under section 1115A of the Act. Except as specifically noted in this part, the regulations under this part must not be construed to affect the payment, coverage, program integrity, and other requirements

(such as those in parts 412 and 482 of this chapter) that apply to providers and suppliers under this chapter.

(b) Scope. This part sets forth the following:

- (1) The participants in the model.
- (2) The drugs being tested in the model.
- (3) The methodologies for pricing and payment under the model.
- (4) Safeguards to ensure preservation of beneficiary choice and beneficiary notification.

§511.2 Abbreviations and definitions.

For the purposes of this part, the following definitions are applicable:

AMP stands for Average Manufacturer Price.

ASP stands for Average Sales Price.

ASP drug pricing files means the drug pricing files that contain the payment amounts that contractors use to pay for Part B covered drugs. They are updated quarterly and each year's files are available to the public through links at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html>.

AWP stands for Average Wholesale Price.

CAP stands for Competitive Acquisition Program.

CCN stands for CMS certification number.

DME stands for Durable Medical Equipment.

FFS stands for fee for service.

Hospital means a hospital as specified in section 1861(e) of the Act.

MAC stands for Medicare Administrative Contractor.

Maryland All-Payer Model means the CMS initiative to modernize Maryland's unique all-payer rate-setting system for hospital services that will improve patient health and reduce costs.

NCD which stands for National Coverage Determination.

NPI stands for National Provider Identifier.

OIG stands for the Department of Health and Human Services', Office of the Inspector General.

OPPS stands for Outpatient Prospective Payment System under section 42 CFR part 419.

OPD which means outpatient department.

Participant means any provider or supplier operating in an identified geographic area.

PBM stands for pharmacy benefit manager.

PBPM stands for per-beneficiary-per-month.

PCSA stands for primary care service area as defined and updated under contract to the Health Resources and Services Administration (HRSA) by the Dartmouth Institute.

Provider has the same meaning as a "provider of services" under section 1861(u) of the Act and includes a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, or hospice program.

Supplier has the same meaning as defined in section 1861(e) of the Act and unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title.

TIN stands for Taxpayer Identification Number.

United States means the fifty states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands (42 CFR 400.200).

VBP stands for value-based purchasing, which refers to a suite of tools emphasizing beneficiary outcomes, education and feedback, and price used to manage a prescription drug benefit.

VBP contractor means the entity with which CMS will contract to assist in implementation of the tools included in phase II of the Part B Drug Payment Model

WAC stands for wholesale acquisition cost.

Subpart B— Part B Drug Payment Model Program Participants

§511.100 Included providers and suppliers.

General. This model requires mandatory participation for the providers and suppliers (including physicians) who furnish Part B drugs that are included in the model if the provider or supplier is located (or services are billed) in the geographic areas that are selected for inclusion in the model. This includes physicians, DME suppliers (including certain pharmacies that furnish Part B drugs), and hospital outpatient departments that furnish and bill for Part B drugs.

§511.105 Geographic areas.

(a) General. The geographic areas for inclusion in the Part B Drug Payment Model are obtained through stratified random assignment of PCSAs to each model arm.

(b) Exclusions. PCSAs with any ZIP code located in the state of Maryland are excluded from this model.

Subpart C—Scope

§511.200 Part B drugs and related fees included in the model.

(a) General: The model includes separately paid drugs and biologicals under Medicare Part B including those with ASP and WAC based payment amounts, AMP-based substitutions of ASP payment amounts, and certain drug-related fees.

(b) Drugs, biologicals, and fees subject to inclusion. (1) Single source drugs, biologicals, multiple source drugs, and biosimilars receiving distinct and separate payments in accordance with section 1842(o) of the Act, including drugs and biologicals paid under sections 1847A, 1847B or 1833(t) of the Act,.

(2) Specified fees paid in accordance with section 1842(o) of the Act, including those paid for immunosuppressive drugs, inhalation drugs and clotting factors under sections 1842(o)(6), 1842(o)(2), 1842(o)(5) of the Act.

(c) Drugs and biologicals subject to exclusion. (1) MAC/Contractor priced drugs and biologicals that do not appear on the quarterly national ASP Drug Pricing Files.

(2) ESRD drugs paid under the authority in section 1881 of the Act.

(3) Influenza, pneumococcal pneumonia and Hepatitis B vaccines paid under the benefit described in section 1862(s)(10) of the Act.

(4) OPPS drugs that receive packaged payment.

(5) Blood and blood products.

§511.205 Model structure and duration.

(a) General. There will be 3 different arms and one control in this model.

(b) Random assignment. Geographic areas are randomly assigned within six strata to one of three model arms or control.

(c) Model arms defined. The model arms contain the following ASP payment for separately paid drugs under the Part B benefit or hospital outpatient prospective payment system and application of a suite of value-based purchasing tools.

- (1) ASP+6 percent [control].
- (2) ASP+2.5 percent plus a flat fee.
- (3) Value-based purchasing.
- (4) ASP+2.5 plus a flat fee and value-based purchasing.

(d) Duration and phased in implementation. (1) The duration of the model is 5 years from implementation. Implementation will be on or after August 1, 2016.

(2) ASP add-on will be tested in phases I and II and will be implemented no sooner than 60 days after the rule is finalized. VBP arms are tested in conjunction with ASP add-on in phase II. Phase II will be implemented on or after January 1, 2017.

(e) Use of contractor. One or more contractors will be utilized to implement CMS approved VBP tools described in §511.305(b).

Subpart D—Pricing and payment

§511.300 Determination of model-based ASP payment (Phase I).

(a) General. The ASP portion of the model encompasses testing of modifications to the 6 percent add-on for Part B drug payments. ASP model based payment rates are determined based upon values published in the quarterly ASP Drug Pricing Files per § 414.904 of this chapter, except the 6 percent add-on is replaced with a fixed percentage of 2.5 percent and a flat fee. The add-on is based on the total add-on payment for all Part B drugs that are included in the model for the most recently available complete set of Part B calendar year claims. For 2016, alternative

ASP pricing add-on under phase I of the model will be equal to aggregate add-on spending in a model CY 2014 claims data set.

(b) Payment updates. (1) The flat fee will be updated every calendar year based on the percentage increase in the consumer price index for medical care.

(2) The ASP+0 portion of the model payment rates are updated quarterly concurrently with determinations made under §414.904 of this chapter.

(c) Special circumstances — (1) Shortages. For drugs that are reported by the FDA to be in short supply at the time that ASP payment amounts are being finalized for the next quarter, payments are made using the amount determined under section 1847A of the Act.

(2) AMP-based price substitutions: For HCPCS codes with AMP-based substitutions determined under § 414.904(d)(3) of this chapter, the lower of the quarter's AMP-based substitution or the model ASP amount as determined under § 511.300 will be used.

§511.305 Determination of VBP tools (phase II).

(a) General. The model includes a VBP program which uses the tools approved for applicable Part B drugs as noted in paragraph (b) of this section.

(b) Approved tools. The following tools will be available to implement VBP:

(1) Value-based pricing strategies. Value-based pricing strategies include:

(i) Reference pricing. Reference pricing sets a benchmark rate based on the current payment rate for a drug or drugs in a class that may be used as the basis of payment for all other therapeutically similar drug products in a group. Medicare providers and suppliers may not bill the beneficiary for any difference in pricing between the benchmark rate and the statutory payment rate or the provider or supplier's charge for the drug prescribed.

(ii) Indications-based pricing. A drug's price may be adjusted based on the product's safety and cost-effectiveness for a specific indication as evidenced by published studies and reviews or evidence-based clinical practice guidelines that are competent and reliable.

(iii) Outcomes-based risk-sharing agreements. CMS may enter into outcomes-based risk-sharing contracts with pharmaceutical manufacturers to link price adjustments for a drug or drugs to clearly defined patient health outcome goals. CMS may base these goals on outcome measures submitted as part of a package of competent and reliable scientific evidence regarding the clinical value of a drug by the manufacturer.

(iv) Discounting or eliminating patient coinsurance amounts. Beneficiary cost-sharing may be reduced for Part B drugs deemed to be high in value. Any reductions in beneficiary cost-sharing may not change the overall payment amount.

(2) Clinical decision support. Clinical decision support policies are developed based on one or more of the following: competent and reliable scientific evidence, clinical guidelines, and Part B claims data.

(c) Beneficiary cost-sharing. Beneficiary cost-sharing must not exceed 20 percent of the total model-based payment amount for the applicable Part B drug.

(d) Public feedback. CMS will solicit public input for 30 days on the specific application of a proposed VBP tool.

(e) Public notification. CMS will notify the public by posting on the CMS website of application of any VBP tools 45 days before implementation.

§511.315 Pre-appeals Payment Exceptions Review Process.

(a) General. This process precedes the current appeals process in 42 CFR part 405 subpart I, and allows providers, suppliers, and beneficiaries the option to dispute pricing decisions, made under §511.305 (phase II of the model) before the claim is submitted.

(b) Payment Exceptions Review Process. This process will be conducted by the VBP contractor. A provider, supplier, or beneficiary may file a payment exception request regarding a pricing policy for a drug furnished to a beneficiary.

(c) Requirements of the Payment Exceptions Review Process. The provider, supplier, or beneficiary may submit pertinent information to the VBP contractor with the exceptions request to explain why a payment exception is appropriate, given the beneficiary's circumstances.

(d) Rendering a decision. A decision regarding a request for a payment exception shall be issued by the VBP contractor within 5 business days of receipt of the request.

(e) Current appeals process. The provider, supplier, or beneficiary retain their right to utilize the current appeals process, regardless of whether they first utilize the Pre-Appeals process, once they have submitted a claim.

Subpart E—Waivers

§511.400 Waiver of certain ASP payment methodologies, requirements, and definitions for certain Medicare Part B drugs.

(a) Waiver of 6 percent add-on percentage for certain Medicare Part B drugs. We waive portions of section 1847A (b) (1) of the Act which specify the 6 percent add-on percentage for payments determined under section 1847A of the Act.

(b) Waiver of how the volume-weighted ASP is to be used in the calculation of average sales price. We waive portions of section 1847A(b)(6) of the Act, which specifies how the volume-weighted average sales price is to be used in the calculation of ASP.

(c) Waiver of definitions of single source drug or biological, multiple source drug and biosimilar. We waive definitions of single source drug or biological, multiple source drug and biosimilar in section 1847A (c) of the Act

(d) Waiver of the NDC assignment requirement. We waive 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, multiple source drug, biological or biosimilar and to base the determination of the ASP (that is, the ASP+0 percent) on the NDCs from this assignment.

(e) Waiver of OPSS requirement to pay for drugs acquisition cost plus an overhead adjustment or by default, to ASP+6 percent. We waive section 1833 (t)(14) of the Act which specifies that the Outpatient Prospective Payment System pays for certain outpatient drugs at acquisition cost plus an adjustment for overhead and handling, or by default, to ASP+6 percent.

(f) Waiver of OPSS pass through payment for outpatient drugs. We waive section 1833(t)(6) of the Act, which requires the Secretary to furnish additional pass through payments for certain drugs that are covered under the OPD service (group of services).

§ 511.405 Waiver of other Part B drug payment methodologies.

(a) Waiver of specified payment methodology for certain infusion drugs. We propose to waive section 1842 (o)(1)(D) of the Act, which requires that infusion drugs furnished through an item of DME be paid at 95 percent of the AWP in effect on October 1, 2003.

(b) Waiver of specified fees for immunosuppressive drugs, inhalation drugs and clotting factors. We waive sections 1842(o)(6), 1842(o)(2), 1842(o)(5) of the Act that state the immunosuppressive drug supplying fees, inhalation drug dispensing fees and the clotting factor furnishing fees.

§ 511.410 Waiver of CAP.

We waive section 1847B of the Act and portions of §§414.906 through 414.920 of this chapter which implement the Part B drug competitive acquisition program (CAP).

CMS-1670-P

Dated: February 24, 2016.

Andrew M. Slavitt,
Acting Administrator,
Centers for Medicare & Medicaid Services.

Dated: February 26, 2016.

Sylvia M. Burwell,
Secretary,
Department of Health and Human Services.

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