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Medicare Program; Part B Drug Payment Model
Summary of Proposed Rule

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[CMS-1670-P]

Summary of Proposed Rule.

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I. Executive Summary (pages 13231-13233)

On March 8, 2016, the Centers for Medicare and Medicaid Services (CMS) placed on public display a proposed rule that discusses CMS' proposal to test a new payment model called the Part B Drug Payment Model under authority of the Center for Medicare and Medicaid Innovation (CMMI). Specifically, CMS notes its authority under Section 1115A of the Social Security Act (the "Act"). This proposed rule was published in the March 11, 2016 issue of the *Federal Register* (81 FR 13230-13261). Page references given in this summary are to this published document.

As way of background, Medicare Part B includes a limited drug benefit that encompasses drugs and biologicals that fall into three general categories: drugs furnished incident to a physician's service, drugs administered via a covered item of durable medical equipment (DME), and other drugs specified by statute. In most cases, Medicare pays for drugs that are administered in a physician's office or the hospital outpatient department at Average Sales Price (ASP) plus a statutorily mandated 6 percent add-on (as specified in section 1847A of the Act). CMS notes that the ASP methodology may encourage the use of more expensive drugs because the 6 percent add-on generates more revenue for more expensive drugs.[1]

CMS proposes two phases for the Medicare Part B Drug Payment model. In phase one, CMS proposes implementing a variation to the add-on component of the Part B drug payment

[1] See MedPAC Report to the Congress: Medicare and the Health Care Delivery System June 2015, pages 65-72

methodology in different geographic areas of the country. Specifically, CMS proposes using ASP+2.5 percent plus a flat fee of $16.80 (flat fee is added to maintain budget neutrality).

In phase two, CMS proposes 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. Specifically, CMS proposes applying one or more tools, such as indication-based pricing, reference pricing, and clinical decision support tools to Part B drugs, and testing whether this affects expenditures and outcomes. Table 1 in the proposed rule (recreated here) summarizes CMS' proposed 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

With respect to the scope of the model, CMS proposes 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. Providers and suppliers will include, for example, physicians, DME suppliers (including certain pharmacies that furnish Part B drugs), and hospital outpatient departments that furnish and bill for Part B drugs.

CMS proposes that the Part B Drug Payment 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), and that Phase II would begin no sooner than January 1, 2017. CMS states that its 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.

CMS estimates that total estimated payments under this model are budget neutral to aggregate Part B spending. In general, phase I has the overall effect of 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. (Table 2 reproduced at the end of this summary shows the estimated impact of the proposed rule on physicians, practitioners, and other suppliers.) CMS also notes that Phase II is not budget neutral and that it anticipates achieving savings. However, CMS states that it does not have enough detail on the structure of the final VBP component to quantify potential savings at this time.

The public comment period on the proposed rule will close on May 9, 2016.

II. Participation (pages 13233-13239)

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.

A. Proposed Drugs Paid Under Part B to be Included in the Model (pages13234-13236)

With limited exceptions, CMS proposes to include all Part B drugs in this model. CMS would include nationally priced drugs with ASP, Wholesale Acquisition Cost (WAC), and Average Manufacturer Price (AMP) based payment amounts that are on the quarterly price file; 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, including ASP and WAC based payment amounts, and drugs (and biologicals) paid separately under OPPS. CMS proposes including all OPPS pass-through drugs in the model. 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. In phase I, for HCPCS codes with AMP-based payments, the lower of the quarter's AMP-based payment amount (that is, the AMP-based amount on the quarterly ASP files) or the model payment amount would be used.

- Non-infused drugs furnished by DME suppliers (including the limited number of Part B drugs dispensed by pharmacies), such as immunosuppressives, oral chemotherapy, oral antiemetics, inhalation drugs used with DME, and clotting factors. CMS notes that payment for these drugs is typically based on the ASP. CMS proposes that phase II of this model may incorporate changes to the additional fees Medicare pays for furnishing, supplying and dispensing these drugs.

- 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, 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.

CMS proposes to <u>exclude</u> the following categories of drugs:

- Contractor-priced drugs, including drugs that do not appear on the quarterly national ASP price file. CMS proposes, however, that contractors would be permitted to utilize reductions to the add-on percentage that they calculate. CMS proposes to implement this approach by

issuing subregulatory instructions to contractors. CMS notes that contractor-priced drugs include certain radiopharmaceuticals that are furnished in the physician's office.

- Influenza, pneumococcal pneumonia and hepatitis B vaccines paid under the benefit described in section 1861(s)(10) of the Act.

- 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. This proposed exclusion only applies to phase I.

- ESRD drugs paid under the authority in section 1881 of the Act. Many ESRD drugs are bundled with services, and relatively few are still paid separately.

- 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.

CMS notes that under current Part B drug payment, CMS excludes drugs that are in short supply from AMP-based price substitution and, instead, utilize the ASP+6 percent payment amount. To maintain access to drugs that are in short supply,[2] CMS believes that incorporating a safeguard is prudent for these drugs, and thus propose to continue paying for these drugs using the existing statutory methodology in section 1847A of the Act.

B. Proposed Participants, Selected Geographic Areas, and Sampling (pages 13236-13239)

CMS notes its perspective that the Part B Drug Payment Model requires the participation of all providers and suppliers furnishing covered and separately paid Part B drugs.

1. Overview and Options for Geographic Area Selection

CMS considered five options to determine the most appropriate geographic unit for this model: (1) states; (2) Core Based Statistical Areas (CBSA)[3]; (3) Dartmouth Atlas of Health Care's Hospital Referral Regions (HRR)[4]; (4) ZIP codes[5] and (5) PCSA[6]. In determining the most appropriate geographic unit for this model, CMS considered three requirements for these areas: (1) need to be sufficiently large so that most providers and suppliers do not have practice locations in multiple areas; (2) need to be sufficient in number to ensure adequate statistical power for the evaluation of the model, and (3) 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.

[2] See FDA Current Drug Shortage list: http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm)
[3] http://www.census.gov/population/metro/
[4] http://www.dartmouthatlas.org/downloads/methods/geogappdx.pdf
[5] http://www.census.gov/geo/reference/zctas.html
[6] http://bhpr.hrsa.gov/healthworkforce/data/primarycareserviceareas/index.html

CMS proposes using PCSAs as CMS believes they exhibit a desirable mix of size, internal homogeneity relative to differences between areas, and number. PCSAs were 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 specialties[7]). Using CY 2014 claims data, CMS analysis showed that almost all claims for an individual provider or supplier were billed within a single PCSA, which limits situations, but does not eliminate, where practices are exposed to multiple payment interventions. This issue could be particularly problematic for large practices that span more than one PCSA.

CMS proposes to associate claims with a PCSA on the basis of the ZIP code of the appropriate performing or billing NPI or beneficiary recorded on the claim as follows:

- ZIP code linked to the performing NPI (recorded in item 32) will be used for practitioner claims (CMS-1500);
- ZIP code in the CCN address associated with a hospital will be used for hospital outpatient department claims; and
- Residence ZIP code of the beneficiary receiving a Part B drug will be used for DME claims (CMS-1490S).

2. PCSA Selection

CMS proposes to use 7,048 of the 7,144 PCSAs in the United States to test the impact of the model's interventions. CMS excluded 96 PCSAs located in Maryland from the Part B Drug Payment Model because of the Maryland All-Payer Model. Each of the control and three test arms of the model would be assigned approximately 1,700 PCSAs. Under the control arm, CMS proposes that 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, CMS proposes 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, CMS proposes 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 (See Table 1).

III. Payment Methodology (pages 13239-13250)

A. Phase I: Proposed Modifications to the ASP Add-On Percentage for Drugs Paid under Part B (pages 13239-13242)

1. Methodology for Creating Modeling Data Set.

CMS describes the methodology it proposes to use for creating a modeling data set to determine the initial aggregate Part B drug annual spending for the implementation of phase I in 2016. This data set will be used to help establish the flat fee amount for purposes of maintaining budget

[7] 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.

neutrality in Phase I. CMS proposes 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.

CMS plans to begin with CY 2014 Part B institutional hospital outpatient claims and Part B supplier claims data processed through June 30, 2015. CMS plan to make an adjustment to these payment amounts in the claims data because of the effect of sequestration, which reduces Medicare payments by 2 percent for many Medicare FFS claims.

To develop the supplier and outpatient hospital claims dataset, CMS proposes to make the following adjustment to remove unusable data, errors, or inconsistencies.

- 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.
- Exclude claims from American Samoa, Virgin Islands, and Guam because hospitals in these locations are paid at reasonable cost.
- Remove Medicare secondary payer claims from the modeling dataset because the payment amounts in these situations may not be consistent with ASP+6 percent methodology.
- Remove individual lines with units three standard deviations outside the geometric mean units billed by HCPCS, because these are likely errors in CMS' payment files.
- Remove claim lines that were rejected or denied by the claims systems for not meeting the Medicare requirements for payment.
- Restrict the dataset to drugs that CMS proposes to include in phase I of the model.

OPPS claims will be handled in a manner that is similar to the approach CMS uses in the OPPS rates setting process.[8] CMS proposes to include hospital bill types paid under the OPPS: 12X (Hospital Inpatient (Medicare Part B only)), 13X (Hospital Outpatient), 14X (Hospital—Laboratory Services Provided to Nonpatients). CMS proposes to make the following exclusions:

- Exclude claims not paid under the OPPS based on provider type, similar to the standard OPPS rate setting process. This includes, for example, all critical access hospitals.
- Exclude certain OPPS claims that are either not paid or may contain aberrant data. This includes, for example, claims with more than 100,000 units on a service line, claims with condition codes '04' (HMO enrollee - information only bill), or claims with more than 300 revenue lines on the claim.
- Exclude claim lines for hospitals with erroneous cost-to-charge ratios (greater than 90 or less than 0.0001) on their cost reports.
- 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.

With respect to supplier claims, CMS proposes a number of exclusions that would apply. In particular, CMS proposes excluding claims with facility place of service codes not typically associated with the use of "incident to" drugs. This includes 14 locations including inpatient hospital, outpatient hospital, emergency-room hospital, ambulance, and community mental

[8] 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).

health centers. In addition, CMS proposes to remove claims associated with the Railroad Retirement Board benefit since they are paid under a separate payment methodology. For DME MAC claims, CMS proposes to exclude drugs infused through a covered item of DME from its modeling dataset, as CMS proposes to exclude these drugs from Phase I.

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

CMS discusses the merits of using a percentage plus flat fee. CMS notes that a specific approach for the use of an add-on percentage with a flat fee was described by MedPAC in its June 2015 report. MedPAC modeled this add-on approach as budget neutral in aggregate, meaning that it would not change total Medicare Part B spending.

CMS proposes 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. CMS proposes to update the flat fee amount annually based on the percentage increase in the CPI Medical Care (MC) for the most recent 12-month period. 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.

For 2016, CMS notes that it would, under its proposal, 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 its CY 2014 claims data. CMS notes that the flat fee of $16.80 may be refined based on more recent claims data in the final rule.

CMS plans to update the flat fee for January 2017 using the CPI MC and annually thereafter. Further, CMS anticipates 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. CMS proposes to continue its 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.

B. Phase II: Applying Value-Based Purchasing Tools (pages 13242-13246)

1. Introduction

In phase II of the model, CMS proposes to implement VBP tools for Part B drugs using tools that are often used by commercial health plans, Medicare Part D plan sponsors, Pharmacy Benefit Managers (PBMs), hospitals and other entities that manage health benefits (both drugs insured under the medical benefit as well as those paid for under a prescription drug benefit) and drug utilization because. The proposed payment changes above for phase I of the model broadly address financial incentives that may affect prescribing but they do not directly address differences in payment when there is a group of therapeutically similar drugs. Also, they cannot test the benefits of using alternative incentives to improve the effectiveness, safety, and quality of physician prescribing patterns for Part B drugs.

For phase II, CMS proposes: (1) specific value-based pricing (VPB) strategies (one or more of which it may adopt) and (2) a tool to support clinical decisions for appropriate drug use and safe prescribing that would provide education and data on the use of certain Part B drugs to prescribers.

2. Value-Based Pricing (VPB) Strategies

VBP strategies for phase II would include one or more of the following:

a. Providing equal payment for therapeutically similar drug products (reference pricing). In the private market, this concept is applied through reference pricing. CMS proposes to define reference pricing in §511.305(b)(1)(i) as setting "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." Unlike what happens in the commercial plan context where patients may be held responsible for paying the difference between their prescribed drug and the benchmark set for therapeutically similar drugs, CMS proposes to prohibit Medicare providers and suppliers from billing the beneficiary. Specifically, they could 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."

CMS might determine for the group of drugs that the benchmark price should be the current payment rate for the HCPCS code that includes the most effective drug in the group. Factors such as relative effectiveness demonstrated in competent and reliable scientific evidence would be taken into account. 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.

b. Indication-based pricing. Drugs are often indicated for more than one condition and may be more effective when used in one condition than another. CMS proposes 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. CMS would define this approach as adjusting a drug's price "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." CMS provides the example of evidenced-based clinical practice guidelines, such as those issued by the Institute for Clinical and Economic Review. In describing the evidence basis for evidence-based pricing, CMS recognizes that the quality of available evidence can vary for any given drug or indication. High quality evidence would be comprehensive, relied on randomized trial designs where possible, and measured outcomes. Research findings should be valid, competent, reliable, and generalizable to the Medicare population.

c. Voluntary agreements with manufacturers to link health care outcomes with payment. CMS would be able to 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."

According to CMS, this tool 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. The outcome based agreements tie the final price of a drug to results achieved by specific patients rather than using a predetermined price based on historical population data. Manufacturers agree to provide rebates, refunds, or price adjustments if the product does not meet targeted outcomes.

d. Discounting or eliminating patient coinsurance amounts. Beneficiary cost-sharing could be reduced for Part B drugs "deemed to be high in value." Any reductions in beneficiary cost sharing would not change the overall payment amount for the drug, however.

In an elaboration of its proposed use of this tool, CMS says that cost sharing associated with a HCPCS code in phase II could be reduced to a value less than the current 20 percent coinsurance or could be eliminated altogether. However, beneficiary cost sharing would not exceed 20 percent of the total model-based payment amount for the Part B drug, even if the drug was considered a low-value drug. CMS clarifies that cost sharing changes would be applied at the HCPCS level to all drug NDCs in a HCPCS code. CMS is not proposing manufacturer-specific or NDC-specific cost sharing amounts, nor is it proposing that providers or suppliers have flexibility to change or waive cost sharing amounts. What CMS is proposing is that Medicare's payment percentage would increase while the total allowed charges for the drug would remain unchanged.

e. Public feedback and notification. CMS would provide for an opportunity for public input for 30 days on the specific application of a proposed VBP tool. CMS would notify the public by posting on the CMS website of application of any VBP tools 45 days before its implementation.

3. Development of a Clinical Decision Support (CDS) Tool

CMS proposes a two-component Clinical Decision Support (CDS) tool for physicians in the VBP arms of the model. The tool would use high quality evidence to educate physicians on best practices. It also would provide clinicians with feedback on prescribing patterns relying for this on regularly updated claims data reports.

The CDS may include: general clinical information (e.g., updated guidelines for the clinical use of drugs and updated safety information); processed patient data, or a mixture of both. Also identified are: 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. CMS notes evidence indicating that CDS tools such as these and feedback to clinicians about their prescribing practices can be effective in changing practice patterns to better align with evidence-based developments and best practices.

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. CMS emphasizes that the 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…."

Physician feedback. CMS would also provide feedback to physicians in the VBP arms of the model using 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. Using this online tool under the Part B Drug Payment Model, providers and suppliers would be able to access reports on their Medicare Part B drug claims, their claims patterns in their geographic area and national patterns.

C. Interactions with Other Payment Provisions (pages 13248-13250)

1. Overview

In this section, CMS lays out its approach 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 CMMI initiatives. CMS anticipates undertaking efforts similar to what it has done with other initiatives to prevent duplication and to monitor arrangements that minimize duplication of effort.

2. Most Shared Savings Programs and Models

CMS observes that the proposed Part B drug payment model is not like the Medicare Shared Savings Program (MSSP) and shared savings models such as the Next Generation Accountable Care Organization (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 model also does not define episodes of care. Instead, it would make payments for specific drug claims that are submitted by a provider or supplier to the Medicare Administrative Contractors (MACs) that typically process their drug claims. Because the adjustments made to the ASP add-on and other Part B payment amounts would typically represent a small proportion of the beneficiary's total payments for care, CMS proposes not to exclude from inclusion in the Part B Drug Payment Model those beneficiaries assigned to ACOs in the MSSP or otherwise accounted for in shared savings models. It also does not propose a separate reconciliation process or modification to the reconciliation process for these beneficiaries. Thus, with the exception of the Oncology Care Model (OCM), discussed below, CMS does not plan to exclude or apply reconciliation processes to other shared savings programs or models.

3. Oncology Care Model (OCM)

The OCM, scheduled for implementation later in 2016, incorporates a two-part payment system for participating practices, intended to create 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 the episode's duration 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 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.

CMS says that overlap would occur between the Part B Drug Payment Model and OCM in that both models affect providers' and suppliers' incentives for the use of oncology drugs, but in different ways. CMS plans to proceed with both models, and proposes to include OCM practices in all arms of the Part B Drug Payment Model.

CMS says that including OCM practices in the Part B Drug Payment Model will not compromise its ability to evaluate effectively the effects of either model and CMS explains how its sampling methodology and model design more generally will allow it to do

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). It encompasses only the items and services that are needed for the in-home administration of IVIG; payments for IVIG are not changed. CMS therefore proposes not to exclude patients in the IVIG demonstration from inclusion in the Part B Drug Payment Model.

IV. Provider, Supplier, and Beneficiary Protections (page 13250)

CMS advises that providers, suppliers, and beneficiaries who are included in the proposed model would have access to the existing claims appeals process and a proposed Pre-Appeals Payment Exceptions Review process to resolve disputes arising from the policies implemented by the Part B Drug Payment Model.

A. Pre-Appeals Payment Exceptions Review Process (§511.315)

Under this proposed new section, a Pre-Appeals Payment Exceptions Review Process would be added to the current appeals process. It would be available to any providers, suppliers, or beneficiaries receiving services in PCSAs assigned to one of the VBP arms. The process would be applicable to phase II payments and would not include modifications to the ASP add-on. It 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 was warranted in the beneficiary's situation, and explain why the price provided under the phase II pricing policy did not provide accurate compensation for the prescribed drug. Pre-Appeals Payment Exception decisions would have to be issued, in writing, within 5 business days of receipt of the request for a payment exception.

CMS notes that although a Pre-Appeals Payment Exceptions Review decision would not confer appeal rights, a provider, supplier, or beneficiary dissatisfied with such decision or a pricing decision could still utilize the current appeals process in 42 CFR part 405 subpart I following submission of a claim.

B. Current Appeals Procedure

CMS emphasizes that this exceptions review process is intended as an option that would precede, not replace, the Medicare claims appeals process currently in place. Moreover, it would be voluntary and intended to resolve payment disputes before the appeals process. Utilizing or bypassing the Pre-Appeals Payment Exception Review would not affect the right of a provider, supplier, or beneficiary to access the current appeals process, following a claim submission. In either the situation where the provider, supplier, or beneficiary submits a request for a Payment Exception Review, and that request is denied, or where the provider, supplier, or beneficiary does not choose to go through that process, the amount paid on a submitted claim would be the amount established through phase II pricing policy.

Again, the provider, supplier, or beneficiary could choose to appeal the payment amount, under 42 CFR part 405 subpart I, after the phase II price was paid for a drug. Under that provision of existing rules, MACs make an initial determination in response to a claim for benefits submitted by a provider, supplier, or beneficiary. CMS proposes that the phase II pricing policy established by Medicare (proposed §511.305) and any pricing determination rendered through the Pre-Appeals Payment Exceptions Review process be given substantial deference. However, it would not be binding on any appeals adjudicator, regardless of whether the party requesting an appeal first utilized the Payment Exceptions process. If the provider, supplier, or beneficiary was dissatisfied with the MAC's initial determination, they could request that the MAC perform a redetermination under 42 CFR 405.940. If the provider, supplier, or beneficiary was dissatisfied with the redetermination, they could then request a reconsideration by the Qualified Independent Contractor (QIC) under 42 CFR 405.960. A provider, supplier, or beneficiary could then request a hearing before an Administrative Law Judge (ALJ) under 42 CFR 405.1000, if the claim(s) at issue met the amount in controversy requirement ($150 for CY2016). Finally, a provider, supplier or beneficiary could 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 was satisfied ($1,500 for CY 2016).

V. Regulatory Impact Analysis (pages 13252-13258)

A. Overall Impacts of the Proposed Part B Drug Payment Model

CMS reiterates that phase I of the payment model has been designed to be budget neutral to Part B spending using CY 2014 claims data. It proposes to update the flat fee amount each year based on the CPI MC. CMS believes 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 but it does 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 (see 81 *FR* 13253).

CMS has not provided an estimate of the impact for phase II but says that it intends to achieve savings through the use of the value pricing tools.

B. Detailed Economic Analyses

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

a. 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 (81 *FR* 13255 and reproduced at the end of this summary) shows the estimated impact of this proposed rule on physicians, practitioners, and other suppliers. Excluded are specialties with less than $10 million in total drug spending; outpatient hospital spending is included as a specialty to demonstrate budget neutrality. A description of the content in each of the columns is presented on 81 *FR* 13256.

ii. Changes to ASP Add-on Amount on Hospitals

Table 3 (81 *FR* 13256 and reproduced at the end of the summary) shows the estimated impact of the 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).

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

For phase I, CMS estimates that the aggregate beneficiary share within the context of the model would remain unchanged since the alternative ASP add-on amounts would 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. 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. Individual beneficiaries could see increases or decreases in their cost-sharing consistent with any redistribution in payment.

CMS notes that to the extent that phase II savings are realized, both the beneficiary and Medicare program would benefit. In addition, CMS has proposed that that beneficiary cost sharing would not exceed 20 percent of the total model-based payment amount for the Part B drug.

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

Rows	Specialty	Physician Specialty Descriptor	Total Medicare Payment				Tot	
			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)	Phys Spe % C
1	**All**	**Hospital OPPS and MPFS**	$127,417	0.0%	0.0%	0.3%	$20,391	
2	**Hospital**	**Hospital**	$50,043	-0.3%	-0.3%	-0.3%	$7,209	
3	**Total ****	**All Specialties**	$77,374	0.2%	0.2%	0.6%	$13,181	
4	83	Hematology/Oncology	$5,150	-0.4%	-0.5%	-0.2%	$4,059	
5	18	Ophthalmology	$6,234	-0.6%	-0.7%	-0.4%	$2,387	
6	A5	Pharmacy	$3,316	1.8%	1.5%	2.6%	$1,432	
7	66	Rheumatology	$1,699	-1.1%	-1.1%	-1.0%	$1,205	
8	90	Medical Oncology	$1,499	-0.5%	-0.5%	-0.4%	$1,193	
9	87	Other	$486	-2.9%	-2.9%	-2.4%	$429	
10	11	Internal Medicine	$6,266	0.6%	0.5%	1.0%	$412	
11	34	Urology	$1,619	0.1%	0.1%	0.2%	$349	
12	13	Neurology	$1,162	-0.3%	-0.3%	-0.1%	$231	
13	20	Orthopedic Surgery	$1,792	1.9%	1.9%	2.0%	$223	
14	82	Hematology	$206	-0.5%	-0.5%	-0.3%	$164	
15	50	Nurse Practitioner	$1,444	0.8%	0.5%	2.1%	$136	
16	08	Family Practice	$4,825	1.1%	0.9%	1.6%	$119	
17	06	Cardiovascular Disease (Cardiology)	$3,850	0.3%	0.3%	0.2%	$113	
18	97	Physician Assistant	$879	1.1%	1.0%	1.4%	$79	
19	10	Gastroenterology	$658	-0.2%	-0.2%	0.0%	$76	
20	44	Infectious Disease	$177	3.2%	3.4%	-0.2%	$71	
21	03	Allergy/Immunology	$270	-0.3%	-0.3%	-0.3%	$66	
22	25	Physical Medicine And Rehabilitation	$589	1.0%	1.0%	1.1%	$57	
23	98	Gynecological/Oncology	$85	0.6%	0.6%	0.6%	$51	
24	39	Nephrology	$1,357	0.2%	0.2%	0.1%	$50	
25	07	Dermatology	$3,036	0.0%	0.0%	0.1%	$30	
26	29	Pulmonary Disease	$665	0.3%	0.2%	0.3%	$28	
27	46	Endocrinology	$410	0.1%	0.1%	0.1%	$25	

Rows	Specialty	Physician Specialty Descriptor	Total Medicare Payment				Tot	
			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)	Phys Spe % C
28	37	Pediatric Medicine	$58	-0.4%	-0.6%	1.5%	$21	
29	92	Radiation Oncology	$1,489	0.0%	0.0%	0.0%	$18	
30	16	Obstetrics/Gynecology	$419	0.3%	0.3%	0.3%	$17	
31	09	Interventional Pain Management	$390	2.0%	2.0%	1.8%	$16	
32	72	Pain Management	$253	1.7%	1.7%	1.5%	$13	
33	05	Anesthesiology	$343	1.7%	1.7%	1.6%	$12	
34	01	General Practice	$404	1.2%	1.0%	1.9%	$11	

* 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. CMS notes 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

TABLE 3—OUTPATIENT IMPACT ANALYSIS OF THE PART B DRUG PAYMENT MODEL

Row		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)	(2)	(3)	(4)	(5)	(6)
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
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
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

TABLE 3—OUTPATIENT IMPACT ANALYSIS OF THE PART B DRUG PAYMENT MODEL—Continued

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

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