KING & SPALDING

# Client Alert

FDA & Life Sciences Practice Group

March 16, 2016

## CMS Unveils Proposed Part B Drug Payment Demo

***Comments Due to CMS by May 9, 2016***

On Tuesday, March 8, 2016, the Centers for Medicare & Medicaid Services ("CMS" or "the Agency") published a proposed rule ("Proposed Rule") to test new models ostensibly to improve how Medicare Part B pays for prescription drugs and supports physicians and other clinicians in delivering higher quality care. CMS published its single-spaced, three-column version of the Proposed Rule in the Federal Register on Friday, March 11, 2016 (available here).

Comments on the Proposed Rule are due to CMS ***on or before Monday, May 9, 2016.***

The Proposed Rule sets out the implementation of a new Medicare payment model under the authority of section 1115A of the Social Security Act ("the Act"). Section 1115A authorizes the Center for Medicare & Medicaid Innovation 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. CMS proposes to exercise this authority to test whether the alternative payment designs outlined in the Proposed Rule will lead to a reduction in Medicare Part B drug expenditures. According to a CMS press release, the proposal is "designed to test different physician and patient incentives to do two things: drive the prescribing of the most effective drugs, and test new payment approaches to reward positive patient outcomes."

Specifically, CMS proposes to test a two-phase Medicare Part B Drug payment model. The first phase would involve reducing the statutorily-mandated 6 percent add-on to a Medicare Part B drug's Average Sales Price ("ASP") that CMS uses to calculate Medicare Part B drug payments (*see* Social Security Act § 1847A(b)) to **2.5 percent plus a flat fee payment of $16.80 per drug per day**. The second phase would implement so-called "**value-based" purchasing tools** similar to those employed by other entities that manage health benefits and drug utilization (*e.g.*, commercial health plans, pharmacy benefit managers ("PBMs"), hospitals, and Medicare Part D plans).

For more information, contact:

**David J. Farber**
+ 1 202 626 2941
dfarber@kslaw.com

**John D. Shakow**
+ 1 202 626 5523
jshakow@kslaw.com

**Seth H. Lundy**
+ 1 202 626 2924
slundy@kslaw.com

**Preeya Noronha Pinto**
+ 1 202 626 5547
ppinto@kslaw.com

**Elizabeth F. Lindquist**
+ 1 202 626 5585
elindquist@kslaw.com

**King & Spalding**
***Washington, D.C.***
1700 Pennsylvania Avenue, NW
Washington, D.C. 20006-4707
Tel: +1 202 737 0500
Fax: +1 202 626 3737

**www.kslaw.com**

The demonstration project proposed on Monday is not a permanent change to the way Part B drugs are reimbursed. Rather, it is a five-year experiment, in which Part B dispensing entities in different geographic regions of the country will be subjected to either a payment scheme different from the traditional ASP plus 6 percent, new "value-based purchasing tools," or both. Presumably, the results of this five-year test will inform the establishment of permanent modifications to the Part B drug reimbursement program.

The Proposed Rule does nothing to modify the underlying statutory and regulatory price reporting rules, including those pertaining to calculation of the Medicaid Drug Rebate Program Average Manufacturer Price ("AMP"), Best Price, and Unit Rebate Amount ("URA"), the Medicare Part B ASP, and the Public Health Service 340B Drug Pricing Program ceiling price. Nor does it alleviate potential fraud and abuse concerns that have discouraged manufacturers from successfully pursuing alternative payment arrangements to date.

**Background**

An Agency transmittal to Medicare contractors dated February 5, 2016 that CMS accidentally posted on its public website indicated that CMS planned to test changes in the way Medicare Part B pays providers to administer drug treatments. At that time, a CMS spokesperson noted that if the Agency followed through with the demonstration, it would first propose it publicly and finalize the model through notice and comment rulemaking. The memorandum to Medicare contractors stated that CMS merely wanted to give providers interim guidance so they have time to prepare.

According to the February 5 transmittal, CMS was considering two types of demonstrations. One focused on the 6 percent add-on to ASP that providers are paid to administer Part B drugs. CMS also indicated it was developing methods to test the impact of targeted pricing changes to payments for individual Part B drugs beyond changes to the ASP-based payment. The Office of Management and Budget received the planned Part B drug reimbursement demonstration on February 25, 2016. The Proposed Rule published on March 8, 2016 is consistent with the demonstration described in the Agency's February 5 transmittal.

**Phase I – Change in ASP-Based Payable Amount**

In Phase I, CMS proposes to implement a variation to what they call the "add-on" component of Part B drug payment methodology. Specifically, CMS proposes to change the add-on amount from 6 percent of ASP (ignoring sequestration) to 2.5 percent plus a flat fee payment of $16.80 per drug per day.[1] The Agency's theory is that this alternative approach would strengthen the financial incentive for physicians to choose higher *value* (as opposed to higher cost) drugs, because the flat $16.80 fee would apply to both low and high cost drugs. Six percent of a $1,000 drug is greater than 6 percent of a $100 drug, the Agency notes, and physicians should not be incentivized to prescribe the $1,000 drug solely because its "add-on" is greater than that of the $100 drug.

CMS presumes that physicians view the 6 percent "add-on" as *profit*, impliedly suggesting that the choice of one drug or another is driven (at least in part) by an unseemly desire to increase profit. One could just as easily conclude, however, that the 6 percent payment in excess of ASP was not designed by Congress in 2003 to be a profit payment to

[1] The flat fee payment would be $16.80 per drug per day for Year One of the demonstration project. The flat fee in subsequent years would be raised with reference to increases in the CPI-U. The $16.80 figure was calculated by CMS to make the total Part B payment budget neutral in Year One.

a physician, but was rather an attempt to make physicians whole, including the half of them who, by definition, pay more than the calculated *Average* Sales Price. Manipulating this statutory formula, therefore, may well put more physicians under water on their Part B reimbursement. We think it is misguided to consider the 6 percent premium to the average price as nothing more than straight profit, as CMS seems to do in the Proposed Rule.

Although it proposes to use this particular formula to set the alternative add-on amount,[2] the Agency also solicits comments regarding whether any additional approaches, such as ASP plus a tiered percentage add-on amount, should be tested. CMS is also seeking comments regarding whether these two approaches are sufficiently different to warrant separate payment arms under the proposed model.

Notably, the Proposed Rule does not articulate any changes to drug manufacturers' calculation of ASP, which is a more significant driver of Medicare Part B drug expenditures than the add-on payment amount (for a given HCPCS code, approximately 94 percent of an ASP-based Part B drug payment is calculated from manufacturers' reported ASP data). CMS emphasizes that it is not proposing a reduction in total spending for Part B drugs, but, rather, is proposing to test redistribution of the add-on payment on Part B drugs expenditure and outcomes.

**Phase II – Value-Based Tools**

In Phase II, CMS proposes to implement what it calls value-based purchasing ("VBP") in conjunction with the Phase I variation of the ASP add-on payment amount for drugs paid under Part B. According to the Agency, Phase II would use tools currently employed by entities that manage health benefits and drug utilization (*e.g.*, commercial health plans, PBMs, hospitals, and Medicare Part D plans). CMS indicates that it will review several tools, including reference pricing, discounting or rebates, pricing based on safety and cost-effectiveness for different indications, outcomes-based risk-sharing agreements (which is likely the only truly "value-based" concept in the proposal), and elimination of patient co-insurance amounts. The Agency also addresses adoption of clinical decision support tools,[3] and will discuss the potential applicability of such tools to the Part B drug and hospital outpatient benefits. CMS is also soliciting comments on creating value-based purchasing arrangements directly with manufacturers, taking an episode-based or bundled pricing approach, and the applicability of the Part B Drug Competitive Acquisition Program.

Specifically, the Proposed Rule seeks comments on testing the following alternative approaches for Part B drugs:

- ***Reference pricing***. The Proposed Rule would test the practice of setting a standard payment rate for a group of therapeutically similar drug products. In other words, CMS would only reimburse a provider at the lowest cost of any product in the "group" or "therapeutic class" designated by the Agency. This concept was previously utilized by CMS and called "Least Costly Alternative" or LCA pricing, until the courts struck it down as in violation of the Medicare statute. The concept, however, is highly problematic, particularly for drugs that are not interchangeable which are consolidated into the same "class" for purposes of provider reimbursement.
- ***Discounting or eliminating patient cost-sharing***. Patients are often required to pay for a portion of their care through cost-sharing. The Proposed Rule would decrease or eliminate cost-sharing to improve

[2] The Agency proposes to keep the 2.5 percent add-on constant over the duration of the model, but 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.

[3] According to CMS, this tool would provide education and data on the use of certain Part B drugs to prescribers, but such information would not be meant to interfere with or substitute for medical decision-making.

beneficiaries' access and appropriate use of effective drugs. While not addressed in the Proposed Rule, it is inevitable that adjustments to co-pay amounts would also result in certain co-pay increases, a common formulary management tool used by PBMs and others that might shift the cost onto beneficiaries to access medications. CMS also proposes drug discounts and rebates, which are payment methodologies not currently used in the Part B program, and for which no implementation mechanisms currently exist.

- ***Indications-based pricing***. The Proposed Rule would vary the payment for a drug based on its clinical effectiveness for different indications. This proposal would raise significant "off-label" concerns if the different indications were not strictly approved on the product's label, an issue CMS does not address in the Proposed Rule.
- ***Feedback on prescribing patterns and online decision support tools***. The Proposed Rule would create evidence-based clinical decision support tools as a resource for providers and suppliers focused on safe and appropriate use for selected drugs and indications.
- ***Risk-sharing agreements based on outcomes***. The Proposed Rule would allow CMS to enter into voluntary agreements with drug manufacturers to link patient outcomes with price adjustments. This is perhaps the only true "value-based" concept in the Proposed Rule. Unfortunately, however, CMS does not address the well-recognized impediment to these arrangements today. More specifically, value-based prices could negatively impact a manufacturer's Medicaid "Best Price," 340B price, and Federal Supply Schedule price. While CMS may presume that by implementing VBP arrangements it will also bring down prices in those other arenas, manufacturers, if given the chance, likely will not be willing to undertake these arrangements without relief from ancillary impacts in other programs.

CMS is also soliciting comments on the following issues for consideration in future rulemakings:

- How to create value-based purchasing arrangements within the Part B program with manufacturers under Medicare fee-for-service payment for drugs;
- Whether the Agency should consider implementing an updated version of the Competitive Acquisition Program; and
- Whether the Agency should pursue a more bundled or episode-based approach that moves beyond a fee-for-service payment structure.

Notably, CMS's proposal does nothing to address the Medicaid Best Price issues that currently present a very significant barrier to manufacturer implementation of innovative pricing models. A significant reduction in the price of a covered drug can be associated with significant increases in rebate payments to the federal government due to the Medicaid Best Price rule. Absent introduction of a legislative, regulatory, or policy exemption, the current Medicaid Drug Rebate Program pricing rules hamper the ability of pharmaceutical manufacturers to implement innovative pricing models that could drive increased competition in both the commercial and public sectors.

**Phase I Project Setup and Scope**

To eliminate selection bias, CMS is proposing to require participation of all providers and suppliers furnishing *any* Part B drugs[4] included in the proposed model who are located in the geographic areas selected for inclusion in the

[4] In the Proposed Rule, the term "drugs" refers to drugs and biologicals currently paid under Part B, including biosimilars. Drugs paid under Part B generally fall into three categories: drugs furnished incident to a physician's service in the physician office

model. Such providers include, for example, 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. CMS proposes to include the majority of Part B drugs in the proposed model. Based on payment data for Part B drugs, CMS anticipates that physicians and outpatient hospitals will see the greatest impact from the proposed model.

CMS further proposes to exclude drugs infused with a covered item of DME in Phase I (but not the entire model). Payment for this subset of DME drugs is made based on the AWP in effect on October 1, 2003. CMS proposes 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.

CMS proposes to use Primary Care Service Areas ("PCSAs") as the geographic area in which the Phase I model will be tested. The Agency proposes random assignment of all PCSAs to one of four groups: the three test arms (paying a modified ASP add-on amount, implementation of VBP tools, and both modified ASP add-on and VBP tools at the same time), or a fourth control group. CMS proposes to include the majority of drugs paid under Part B in the model (*i.e.*, in general, drugs that appear on the quarterly ASP Price Files), but exclude some categories of drugs from the proposed Part B Drug payment model (*e.g.*, drugs separately billed by End-Stage Renal Disease facilities).

The Proposed Rule states 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 of 6 percent or payments with the modified add-on amount. *See* Table 1.

**Phase II Project Setup and Scope**

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

Phase II would begin no sooner than January 1, 2017. Upon initiation of Phase II, 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. Under the Proposed Rule, providers and suppliers in geographic areas selected for one arm of the model (*i.e.*, everyone but the control group) will experience both Phase I pricing and Phase II VBP pricing. CMS expects that Phase II could take several years to fully implement. The Agency notes in the Proposed Rule 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.

---

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).

**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 percent (control) | ASP + 6 percent (control) |
| | ASP + 6 percent with VBP tools |
| ASP + 2.5 percent and flat fee drug payment | ASP + 2.5 percent and flat fee drug payment |
| | ASP + 2.5 percent and flat fee drug payment with VBP tools |

CMS indicates that in Phase II it may incorporate changes to the furnishing, supplying, and dispensing fees that are associated with 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 (note that this subset of drugs that are furnished by DME suppliers does not include drugs that are infused with covered DME). CMS also proposes that the waiver 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. CMS is proposing to waive this section to include infusion drugs that are furnished through covered DME items in Phase II of the model.

* * *

The K&S Reimbursement and Government Pricing Teams are ready to assist you in the preparation of comments to this Proposed Rule at every stage — evaluation, consideration, and articulation. Please keep us in mind if there is any way we can help. We have extensive experience interpreting Proposed Rules and in drafting agency comments. We would be very happy to help you create effective, thoughtful, coherent, and persuasive comments on any and all reimbursement and government pricing issues, including those presented in this Proposed Rule. For more information, please see www.kslaw.com/practice_areas/pags/PharmaGovPricingCompliance.pdf.