Issue Brief

FEDERAL ISSUE BRIEF • March 10, 2016

CMS Issues Proposed Part B Drug Payment Model Rule

The Centers for Medicare and Medicaid Services has issued a proposed rule to test new models regarding Medicare Part B payments for prescription drugs. The proposed 119-page rule is scheduled for publication March 11. The version should be available at: http://federalregister.gov/a/2016-05459. A 60-day comment period ending May 9 is provided.

CMS says 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.

CMS says the new payment model is authorized under the authority of the Center for Medicare and Medicaid Innovation (Innovation Center).

Many Part B drugs, including drugs furnished in the hospital outpatient setting, are paid using the methodology in section 1847A of the Social Security Act. In most cases, this means payment is based on the average sales price plus a statutorily mandated 6.0 percent add-on.

The proposed rule seeks comments on testing six different alternative approaches for Part B, which include the following.

Improving incentives for best clinical care

Medicare Part B generally pays physicians and hospital outpatient departments the average sales price of a drug, plus a 6.0 percent add-on. The proposed model would test whether changing the add-on payment to 2.5 percent plus a flat fee payment of $16.80 per drug per day changes prescribing incentives and leads to improved quality and value. This proposed change aspect is budget neutral.

Discounting or eliminating patient cost-sharing

Patients are often required to pay for a portion of their care through cost sharing. This proposed test would decrease or eliminate cost sharing to improve beneficiaries' access and appropriate use of effective drugs.

Feedback on prescribing patterns and online decision support tools

This proposed test 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.

Examples could include best practices in prescribing or information on a clinician's prescribing patterns relative to geographic and national trends.

continued

4712 Country Club Drive
Jefferson City, MO 65109

P.O. Box 60
Jefferson City, MO 65102

573/893-3700
www.mhanet.com

MHA
MISSOURI HOSPITAL ASSOCIATION

Indications-based pricing

This proposed test would vary the payment for a drug based on its clinical effectiveness for different indications. For example, a medication might be used to treat one condition with high levels of success but an unrelated condition with less effectiveness, or for a longer duration of time. The goal is to pay for what works for patients.

Reference pricing

This proposed model would test the practice of setting a standard payment rate — a benchmark — for a group of therapeutically similar drug products.

Risk-sharing agreements based on outcomes

This proposed test would allow CMS to enter into voluntary agreements with drug manufacturers to link patient outcomes with price adjustments.

PAYMENT MODEL

CMS proposes a two-phased model.

In phase I of the model, providers and suppliers would be placed in a control or study groups based on primary care service areas, which are clusters of zip codes based on patterns of Medicare Part B primary care services (excluding the state of Maryland where hospital outpatient departments operate under an all-payer model) as follows.

No earlier than 60 days after the final rule is released

CMS would begin to test the changes to Medicare Part B average sales price payments for drugs by creating a control group and a study group. One group would remain under the 6.0 percent add-on arrangement and the second would receive a 2.5 percent add-on of the average sales prices of a drug plus a flat $16.80 per drug per day payment.

No earlier than January 2017

CMS would begin to test value-based purchasing arrangements by further dividing the average sales price test and control groups. The same set of value-based purchasing tools will be used in each of the two new study groups.

In phase II, CMS proposes to implement value-based purchasing. Phase II would use tools currently employed by commercial health plans, pharmacy benefit managers, hospitals and other entities that manage health benefits and drug utilization.

Summary of the Proposed Model	
No earlier than 60 days after the final rule	**No earlier than January 2017**
106% Average Sales Price (control)	106% ASP
	106% ASP with value-based purchasing tools
102.5% ASP + $16.80 flat per day per drug payment	102.5% ASP + $16.80
	102.5% ASP + $16.80 with value-based purchasing tools

continued

COMMENT

The proposal is already meeting stiff resistance from many organizations and from some key Congressional members. Like the recent adoption of the Comprehensive Joint Replacement initiative, this proposal would be mandated for all providers in a geographic area. At this stage, the proposal does not identify which providers would be in which specific groups. But unlike the CJR, the model is applicable in all geographical areas except Maryland (see more below).

MODEL SCOPE

CMS proposes 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. CMS proposes to exclude some categories of drugs, including drugs separately billed by end-stage renal disease facilities.

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 would receive payments with either the existing statutory add-on amount or payments with the modified add-on amount.

Providers and suppliers in geographic areas selected for one arm of the model will experience both phase I pricing and phase II VBP pricing. CMS says it expects that phase II could take several years to fully implement. The 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.

PRIMARY CARE SERVICE AREAS

CMS proposes to use Primary Care Service Areas as the geographic basis area. CMS 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.

According to CMS, PCSAs were defined and updated under contract to the Health Resources and Services Administration by The Dartmouth Institute. There are 7,144 PCSAs in the U.S., covering all 50 states. Because the waiver for Medicare hospital payment rules in the Maryland All-Payer Model may create unobservable bias in the prescribing patterns or payments for the Part B drugs in this model test, CMS proposes 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.

COMMENT

A footnote suggests the website that identifies the PCSAs is located at: http://bhpr.hrsa.gov/healthworkforce/data/primarycareserviceareas/index.html

ECONOMIC EFFECTS

Under phase I, CMS proposes to modify the ASP add-on amount to be 2.5 percent plus a flat fee of $16.80. CMS proposes 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.

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

continued

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.

In phase II, CMS proposes applying VBP tools including value-pricing and clinical decision support tools. The pricing under this phase would not be budget neutral, and CMS intends to achieve savings.

METHODOLOGY FOR CREATING MODELING DATA SET

CMS proposes 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 6.0 percent add-on.

CMS proposes a number of exclusions that would apply specifically to supplier 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 for a HCPCS code included on the ASC approved list of procedures), '26' (Military Treatment Facility), '31' (Skilled Nursing Facility 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. CMS proposes 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.

FINAL COMMENT

It will be early May before the comment period closes. This provides an extremely short timeframe for CMS to galvanized its final framework if it truly intends to implement this program in the fall.

At the same time, much is still unknown about who is in which of the payment groups and how the so-called random selection process is to be made.

Perhaps what is most disturbing is the program is to extract savings from providers. It appears to do nothing to help resolve the tremendously high and increasing costs set by the pharmaceutical industry itself. Of course, CMS and HHS's hands are tied by law to intercede. So, the real question to ask is where is the Congress?

Analysis provided for MHA by Larry Goldberg, Goldberg Consulting