STATEMENT OF

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ON

"EXAMINING THE PROPOSED MEDICARE PART B DRUG DEMONSTRATION"

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"Examining the Proposed Medicare Part B Drug Demonstration"
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Chairman Hatch, Ranking Member Wyden and members of the Committee, thank you for the invitation to discuss the Centers for Medicare & Medicaid Services' (CMS) initiative to improve how Medicare pays for Part B drugs and to support physicians and other clinicians in delivering higher quality care in the Medicare program.

Part B drug spending has risen significantly over time. Total Part B payments for separately paid drugs in 2015 were estimated at $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. 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]

CMS has heard from many stakeholders about concerns about the cost, value, and access to prescription drugs. As part of an initiative to address rising drug costs, the Department of Health and Human Services (HHS), convened a forum that brought together consumers, physicians, clinicians, employers, manufacturers, health insurance companies, representatives from state and federal government, and other stakeholders to discuss ideas on how the health care system can meet the dual imperatives of encouraging drug development and innovation, while ensuring access and affordability for patients. To help further this mission, CMS issued a proposed rule to test a new model to help improve patient care and the value of Medicare drug spending.

This proposal is part of the Administration's broader strategy to encourage better care, smarter spending, and healthier people by paying for what works, unlocking health care data, and finding new ways to coordinate and integrate care to improve quality. CMS values public input and comments as part of the rulemaking process, and looks forward to continuing to work with stakeholders through the rulemaking process to maximize the value and learning from the proposed tests. We have received feedback from a wide range of stakeholders on several issues,

[1] CMS Proposed Rule, "Medicare Program; Part B Drug Payment Model", https://www.federalregister.gov/articles/2016/03/11/2016-05459/medicare-program-part-b-drug-payment-model

including the size of the model, patient access in small practices and rural areas, and the importance of patient input. We are reviewing all comments closely to determine whether adjustments are needed. Our goal is to be responsive to the public comments and input from Congress while preserving the integrity and effectiveness of the model.

Proposed New Medicare Part B Drug Payment Model

Medicare Part B includes a limited drug benefit that encompasses certain drugs and biologicals. 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. These types of drugs include intravenous infusions (IVs) like cancer treatment drugs, injectables like antibiotics or eye care treatments, and other drugs that require a medical professional to administer.

Many Part B drugs, including drugs furnished in the hospital outpatient setting, are paid based on the Average Sales Price (ASP) plus a statutorily mandated 6 percent add-on. The ASP is calculated quarterly using the manufacturer-submitted data on sales to all purchasers (with limited exceptions specified in statute, 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 ASP payment amount does not take into account the effectiveness of a particular drug nor the cost of clinically comparable drugs. The Medicare Payment Advisory Commission (MedPAC) has noted that ASP methodology may encourage the use of more expensive drugs because the 6 percent add-on generates more revenue for more expensive drugs.

The proposed rule that CMS issued describes a new Part B Drug Payment Model that would test whether alternative drug payment designs may improve how Medicare Part B pays for prescription drugs and supports physicians and other clinicians in delivering higher quality care. More specifically, this proposed rule is designed to test different provider and patient incentives to do two things: drive the prescribing of the most effective drugs and test new payment approaches that reward positive patient outcomes. Physicians often can choose among several drugs to treat a patient, and the current Medicare Part B drug payment methodology can penalize doctors for selecting lower-cost drugs, even when these drugs are as good or better for patients based on the evidence. Among the approaches to be tested are the elimination of certain incentives that work against the selection of high performing drugs, as well as the creation of

positive incentives for the selection of high performing drugs, including reducing or eliminating patient cost sharing to improve patients' access and appropriate use of effective drugs.

Phase 1: Adjustments to the ASP+6 percent add-on methodology

The proposed model would test whether changing the current 6 percent 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. CMS would update the flat fee at the beginning of each year by the percentage increase in the consumer price index for medical care for the most recent 12-month period.

CMS expects that the add-on payment of 2.5 percent plus a flat $16.80 fee will cover the cost (the ASP) of any drug paid under Medicare Part B. The flat fee is calculated such that it is budget neutral in aggregate. CMS intends for the test to result in savings through changes in prescribers' behavior, 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.

Phase 2: Value-Based Purchasing (VBP) Tools

Commercial health plans, pharmacy benefit managers, hospitals, and other entities that manage health benefits and drug utilization successfully employ an array of tools including value-based pricing and feedback on prescribing patterns to improve the value of drug payments. To produce a menu of value-based purchasing options, CMS reviewed the numerous tools used by entities that manage drug and health benefits and identified those that may be applicable to payment for Part B drugs with the same positive results.

The proposed rule sought comments on testing different alternative approaches for Part B drugs to improve outcomes and align incentives to improve quality of care and spend dollars wisely; these include:

- 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.
- 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 test would analyze 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.

Scope of the Model

The proposed model would run for five years with the goal of having the incentive and value-based purchasing tests fully operational during the last three years to evaluate changes and collect sufficient data. All providers and suppliers furnishing and billing for Part B drugs would be required to participate in the model. This would help ensure that observed outcomes do not suffer from selection bias inherent in a voluntary participation model and would help test whether the model can ultimately be generalized to providers and suppliers billing for Part B drugs with various characteristics, such as different geographies, patient populations, and specialty mix. With limited exception, CMS proposed to include all Part B drugs and biologicals in this model.

Under the proposal, 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 upon patterns of Medicare Part B primary care services (excluding the state of Maryland where hospital outpatient departments operate under an all-payer model). The exact geographic locations the model would be operational in would be posted once the model is finalized, as we have done with other models.

Maintaining Beneficiary Access to Quality Care

Ensuring beneficiary access to high quality care and treatment is always at the forefront of CMS' work. In Medicare Part B, most beneficiaries pay a monthly premium for coverage of certain services including prescription drugs administered by infusion or injection in physician offices and hospital outpatient departments, doctors' services, outpatient care, and durable medical equipment (DME). Beneficiaries must also meet a deductible of $166 in 2016; once that is met, the beneficiary typically pays 20 percent of the Medicare-approved amount for the services they receive. Under this structure, beneficiaries utilizing Part B drugs, especially those using higher cost drugs, may face significant out-of-pocket expenses. To the extent that prescribing patterns do shift toward lower cost drugs, in aggregate, beneficiaries would benefit along with the Medicare program.

Under the proposed model, beneficiaries would still have access to the same drugs and would retain the complete freedom of choice of doctors, hospitals, and other providers or suppliers. The proposed model would not affect drug coverage or any other Medicare benefits. The proposed model also includes a number of beneficiary protections. All standard Medicare appeals processes would stay the same. The proposed model would include a new pre-appeals exceptions review process under Phase II, in addition to the standard Medicare appeals processes, that would allow the beneficiary, provider, or supplier to explain why Medicare's value pricing policy is not appropriate for the beneficiary and to seek an exception from the model's pricing approach. Exceptions decisions would be issued within five business days. In addition, CMS would be closely monitoring beneficiary access and health outcomes during the model. There would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model.

The public comment period for the Proposed Rule concluded on May 9, 2016, and CMS is carefully considering all the public comments on this proposal that were received by the close of the comment period. HHS and CMS value public input, and we look forward to continuing to work with stakeholders to maximize the value and learning from this model.

Conclusion

Millions of Americans rely on medications to manage chronic illnesses and treat acute conditions. CMS is dedicated to ensuring that its beneficiaries have and maintain access to the high quality treatments they need while pursuing better drug value. Moving forward, HHS and CMS are committed to continuing to listen and work together with stakeholders to advance ideas that improve access, affordability, and innovation so all Americans have access to the breakthroughs ahead. There are no easy answers to these multifaceted challenges, but there is a significant benefit – to all of us – of working together to find a solution. I appreciate the Committee's interest and look forward to answering your questions.