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ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

MEMORANDUM

May 16, 2016

To: Subcommittee on Health Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on "The Obama Administration's Medicare Drug Experiment: The Patient and Doctor Perspective"

On **Tuesday, May 17th, at 10:00 a.m., in Room 2123 of the Rayburn House Office Building**, the Subcommittee on Health will hold a hearing titled "The Obama Administration's Medicare Drug Experiment: The Patient and Doctor Perspective."

I. BACKGROUND

Medicare is a federal health insurance program that provides care for individuals aged 65 and older as well as specified conditions such as end-stage renal disease or amyotrophic lateral sclerosis (Lou Gehrig's disease).[1] The program is divided into four parts: A, B, C, and D.

Medicare Part B insurance covers physicians' services, hospital outpatient services, in-patient mental health care, durable medical equipment in addition to some other services and medical tests. While enrollment in Part B is voluntary, over 90 percent of those eligible choose to enroll.[2] In 2014, 49.3 million Americans enrolled in Part B, resulting in $265.9 billion in

[1] Patricia A. Davis, et al, *Medicare Primer*, Congressional Research Service, (Mar. 31, 2016) (online at http://www.crs.gov/reports/pdf/R40425).

[2] Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, *2015 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds,* (July 22, 2015) (online at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2015.pdf).

overall expenditures. Beneficiaries enrolled in Part B are generally required to pay a monthly premium, which was $104.90 in 2015. Part B benefits are also subject to an annual deductible, which was $147 in 2015, and most of the services are subject to a 20 percent coinsurance, including the cost of drugs used for treatment.

Medicare Part B reimburses health care providers for drugs administered in their offices. Providers are responsible for purchase and storage of these drugs, and Medicare reimburses the provider after they are delivered to the patient. Examples of these medications include vaccinations, treatment for anemia in patients with end-stage renal disease, certain immunosuppressive drugs for organ transplant patients, and a variety of other medications.[3] Overall, CMS estimates that it spent a total of $22 billion on Part B drugs in 2015.[4]

Physician reimbursement for drugs administered to patients through the Part B program was set in the Medicare Prescription Drug Improvement and Modernization Act of 2003.[5] This legislation included a formula to directly tie physician reimbursement to a drug's average sales price (ASP). Specifically, physicians are reimbursed at ASP + 6 percent. The additional 6 percent was likely designed to cover acquisition, storage, and other overhead costs associated with the pharmaceuticals.[6] ASP is calculated by the Centers for Medicare and Medicaid Services (CMS) based on a weighted average of all sales of a particular drug nationwide using quarterly data submitted by the manufacturers.[7] Part B drug reimbursement is currently subject to a two percent sequester cut like the rest of the Medicare program.

II. THE CENTER FOR MEDICARE AND MEDICAID INNOVATION

The Center for Medicare and Medicaid Innovation (CMMI) was established by section 3021 of the Affordable Care Act to test and evaluate new payment models for current Medicare,

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[3] Patricia A. Davis, et al, *Medicare Primer*, Congressional Research Service (Mar. 31, 2016) (online at http://www.crs.gov/reports/pdf/R40425).

[4] Centers for Medicare and Medicaid Services (CMS), *Medicare Program; Part B Drug Payment Model; Proposed Rule*, Federal Register, (Mar. 11, 2016) (online at https://www.gpo.gov/fdsys/pkg/FR-2016-03-11/pdf/2016-05459.pdf).

[5] Sherry Glied and Kevin Haninger, *Medicare Part B Reimbursement of Prescription Drugs*, Assistant Secretary for Planning and Evaluation, (June 1, 2014) (online at https://aspe.hhs.gov/report/medicare-part-b-reimbursement-prescription-drugs).

[6] *See* MedPAC, *June 2015 Report to the Congress: Medicare and the Health Care Delivery System*, Chapter 3, p68 (online at http://www.medpac.gov/documents/reports/chapter-3-part-b-drug-payment-policy-issues-(june-2015-report).pdf?sfvrsn=0).

[7] CMS, *How does CMS calculate the average sales price (ASP)-based payment limit?* (online at https://questions.cms.gov/faq.php?id=5005&faqId=1937).

Medicaid, or Children's Health Insurance Program (CHIP) beneficiaries.[8] The Center exists for the specific purpose of testing "innovative payment and service delivery models to reduce program expenditures…while preserving or enhancing quality of care" for beneficiaries.

The statute gave the Secretary of the Department of Health and Human Services broad authority to develop and implement new payment and service delivery models.[9] This includes the ability to expand the scope or duration of any model being tested through the rulemaking process. Of note, models can range in size from small disease-specific tests to community-wide projects to national models. CMMI uses a variety of factors to select demonstration projects including the alignment with the department's goals for delivery system reform, strength of evidence base, potential for quality improvement, potential for cost savings, and others.[10]

Every Innovation Center demonstration requires an evaluation of effectiveness. The evaluation must include both any effects on quality of care as well as any changes in spending.[11] Overall, the system is designed to promote rapid dissemination and implementation of evidence-based practices.

In total, CMMI is allocated $10 billion over 10 years to operate all demonstrations, including model development, implementation, and evaluation.

III. MEDICARE PROGRAM PART B DRUG PAYMENT MODEL

Recently, CMS announced a proposed rule to test a new Medicare Part B prescription drug demonstration project.[12]This model aims to evaluate whether alterations to the Part B drug reimbursement and purchasing structures will affect prescriber medication choice, while improving quality and/or reducing costs. The model includes two phases: the first phase will assess the effectiveness of the ASP +6 percent reimbursement standard, and the second phase will evaluate a variety of value-based pricing approaches. The proposed model is designed to be nationwide and will be randomized by Primary Care Service Areas (clusters of zip codes).

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[8] CMS, *About the CMS Innovation Center*, (May 6, 2016) (online at https://innovation.cms.gov/about/index.html).

[9] 42 U.S.C. 1315a (online at https://www.ssa.gov/OP_Home/ssact/title11/1115A.htm).

[10] CMS, *Model Design Factors* (online at https://innovation.cms.gov/Files/x/rfi-websitepreamble.pdf).

[11] CMS, *About the CMS Innovation Center*, (May 6, 2016) (online at https://innovation.cms.gov/about/index.html).

[12] CMS, *CMS proposes to test new Medicare Part B prescription drug models to improve quality of care and deliver better value for Medicare beneficiaries*, (Mar. 8, 2016) (online at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-03-08.html).

A. 1st Phase – Testing Physician Behavior Effects in Response to Adjusting ASP Reimbursement

In the first phase, the model tests the difference between reimbursing ASP +6 percent and ASP +2.5 percent plus a flat fee of $16.80. According to CMS, the goal of this phase is to evaluate whether the payment change will reduce disincentives for a physician to prescribe an equally effective, but less costly drug.[13] For example, under the current system, if one drug's ASP is $100 and another is $1000, the provider would be reimbursed $106 or $1060, respectively. Under the proposed formula, the physician would instead be reimbursed $119.30 or $1041.80. CMMI theorizes that by narrowing the difference in the "add on" payment, there will be decreased financial incentive to provide one drug over another. Of note, the ASP +2.5 percent + $16.80 was developed in order to make the first phase of the model revenue neutral compared to ASP +6 percent.

B. 2nd Phase - Testing Tools for Assisting Prescriber CareDelivery of Care

The second phase of the model proposes to examine the impact of certain value-based purchasing efforts.[14] To this end, CMS intends to test a variety of approaches that reward providers for treatment regimens that improve quality while either decreasing or holding costs steady, rather than strict volume based payments.

CMS's proposed rule outlines four potential pricing strategies: reference pricing, indication-based pricing, outcomes-based risk-sharing agreements, and discounting or eliminating patient coinsurance amount.

Reference pricing refers to setting a standard payment rate for a group of therapeutically similar drug products.

Indication-based pricing refers to situations where one drug can be used in multiple different clinical conditions. In this strategy, a drug would receive varying levels of reimbursement depending on its effectiveness for specific conditions.

Outcomes-based risk-sharing agreements would allow CMS to enter into voluntary agreements with manufacturers that would link healthcare outcomes with payment. Under these agreements, upward or downward price adjustments could be made depending on the results of specific patient outcomes.

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[13] *Id.*

[14] CMS, *Medicare Program; Part B drug Payment Model*, Federal Register (Mar. 11, 2016) (online at https://www.federalregister.gov/articles/2016/03/11/2016-05459/medicare-program-part-b-drug-payment-model).

Finally, CMS would consider the reduction or elimination of coinsurance on drugs that have been shown to produce disproportionately high-quality, low-cost outcomes when used appropriately.

In addition to the pricing strategies, the second phase of the demonstration aims to test new tools to assist prescriber's delivery of care. This includes online decision support tools to relay best practices, safety information, and individual prescribing patterns in comparison to others in their community or nationwide.

The second phase of the model is designed to be more limited in scope than the first phase. CMS has specified that not all Part B drugs will be included. As proposed, this phase will apply only to a specified group of drugs or patient conditions. Furthermore, the proposed rule outlines an additional 45 day comment period prior to implementation of any value-based pricing strategies.

C. Demonstration Project Timeline

The demonstration project was announced on March 8, 2016 with an open public comment period through May 9, 2016. The first phase is proposed to begin in late 2016, at least 60 days following finalization of the proposed rule. The second phase of the proposal will begin no sooner than January 1, 2017. Overall, the model will run for five years, with the goal of having all aspects of the model fully operational during the last three years to ensure sufficient data for evaluation.

IV. H.R. 5122 - TO PROHIBIT FURTHER ACTION ON THE PROPOSED RULE REGARDING TESTING OF MEDICARE PART B PRESCRIPTION DRUG MODELS

H.R. 5122, introduced by Representative Larry Bucshon (R-IN), states that "the Secretary of Health and Human Services may not take any action to finalize, implement, or enforce the proposed rule entitled "Medicare Program; Part B Drug Payment Model."

V. WITNESSES

Debra Patt, MD, MPH, MBA
Vice President, Texas Oncology
Medical Director, The US Oncology Network
Chair, Clinical Practice Committee American Society of Clinical Oncology

Marcia Boyle
President and Founder
Immune Deficiency Foundation

Michael Schweitz, MD, FACP, MACR
National Advocacy Chair
Coalition of State Rheumatology Organizations

Heather Block
Patient Advocate

Joe Baker
President
Medicare Rights Center