U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

May 15, 2016

TO: Members, Subcommittee on Health

FROM: Committee Majority Staff

RE: Hearing entitled "The Obama Administration's Medicare Drug Experiment: The Patient and Doctor Perspective"

I. INTRODUCTION

On May 17, 2016, at 10:00 a.m. in 2123 Rayburn House Office Building, the Subcommittee on Health will hold a hearing entitled "The Obama Administration's Medicare Drug Experiment: The Patient and Doctor Perspective."

II. WITNESSES

The Subcommittee will hear from the following 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, Editor and Chief Journal of Clinical Oncology- Clinical Cancer Informatics, and Board Member, Community Oncology Alliance.
- Marcia Boyle, President and Founder, Immune Deficiency Foundation
- Michael Schweitz, MD, FACP, MACR National Advocacy Chair, Coalition of State Rheumatology Organizations (CSRO)
- Heather Block, Patient Advocate
- Joe Baker, President, Medicare Rights Center

III. BACKGROUND

The Medicare program provides healthcare coverage to over 54 million beneficiaries and is projected to cover 80 million beneficiaries by 2030. The Medicare program provides access to prescription drugs under fee-for-service through both Medicare Parts B and Part D.

Medicare Part B is the medical insurance arm of the Medicare program, generally covering medical services provided in an outpatient setting; for example diagnostic tests, ambulance transport, and outpatient treatments for complex medical conditions administered by a physician, typically in a physician office. Under Medicare Part B, beneficiaries are able to obtain infusion and injectable drugs and biologics administered within physician offices and hospital outpatient departments as well as certain drugs furnished by suppliers.

For most Part B drugs Medicare reimburses under the general payment methodology set in statute at the Average Sales Price + 6 percent. This formula has been used since 2003.

However, in 2013 this payment was altered by the sequestration which lowered reimbursement to ASP+4.3%.

According to one survey of oncologists, sequestration reductions alone led to 50% of those surveyed reporting that patients were sent elsewhere for their chemotherapy treatments[1]. The add on to the ASP does not represent the physicians profit. Instead, it is designed to cover the costs associated acquiring the drug, including losses on the acquisition of those drugs priced above the ASP. This add on payment is also designed to cover the cost of storage, preparation and admiration of the drugs, any leftover drug that is not administered to the patient, any drugs not provided to patients, the costs associated with administrating the drug to the patient, and billing the Medicare program.

Generally, cost sharing under Medicare Part B is 20% but can be impacted by supplemental coverage. Part B physician-administered drugs must be purchased by the physician and are then reimbursed when the treatment is provided to the patient.

As reported by MedPAC, Medicare 2013 spending "(program payments and beneficiary cost sharing) on Part B–covered drugs paid ASP + 6 percent amounted to over $19 billion dollars (more than $15 billion of Medicare program payments and nearly $4 billion of beneficiary cost sharing). Of that spending, physician offices accounted for over $11 billion, hospital outpatient departments accounted for nearly $7 billion, and suppliers accounted for over $1 billion.[2]" In comparison, in 2013 the Medicare program accounted for $582.9 billion in spending with total Part B expenditures of $247.1 billion[3].

IV. CMS PROPOSAL

On March 8, 2016 the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that if finalized, dramatically changes how almost all Part B administered drugs are reimbursed through a mandatory nationwide two stage program slated to go into effect in the Fall[4]. This program would not only make changes to the statutorily set reimbursement rate but would also impose untested purchasing arrangements.

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[1] American Society of Clinical Oncology. ASCO Sequestration Impact Survey: One Month Out, Sequestration Affecting Care of Medicare Cancer Patients. http://www.asco.org/advocacy/asco-sequestration-impact-survey-one-month-out-sequestration-affecting-care-medicare-cancer May 10, 2013.

[2] MedPAC June 2015 Report to Congress Chapter 3: Part B drug payment policy issues. Available online: http://www.medpac.gov/documents/reports/chapter-3-part-b-drug-payment-policy-issues-%28june-2015-report%29.pdf?sfvrsn=0

[3] Congressional Research Service: Medicare Financing October 22, 2014 (R41436) Patricia A. Davis, available online: http://www.crs.gov/Reports/R41436?source=search&guid=d070a704b7244f99b9aef9a8e3c21072&index=7

[4] Excluded drugs as proposed by CMS will include contractor priced drugs, Influenza, pneumococcal pneumonia and hepatitis B vaccines, Drugs infused with a covered item of DME in phase I, ESRD drugs, Blood and blood products, Drugs that are identified by FDA to be in shortage. https://www.federalregister.gov/articles/2016/03/11/2016-05459/medicare-program-part-b-drug-payment-model

Specifically, under Phase 1, the reimbursement for Part B drugs would be lowered from ASP + 6% to 102.5% of the ASP plus a $16.80 flat fee. It is important to note this calculation does not include the effects of sequestration, thus lowering reimbursement to ASP+0.86%+ the $16.80 flat fee. Many have expressed concerns this low level of reimbursement would make the acquisition of drugs by physician office unsustainable. Phase 2 would go into effect shortly after Phase 1 and would apply a variety of proposed value based purchasing arrangements on 50% of providers. Some have expressed concern that this change will lead to the federal government, rather than doctors and patients, determining the value of a medication based on cost and not on the health of a beneficiary. Providers nationwide would find themselves assigned to one of four test groups by 7,048 of the 7,144 primary care service areas (PCSAs). The first test group would be subject to the proposed reimbursement change to the ASP, the second to the value based purchasing arrangements, the third would be subjected to both and the fourth would be a control group and would see their reimbursement calculated as it is today. It is important to note all groups would have the impacts of sequestration applied to them.

Medicare beneficiaries who receive physician administered drugs tend to be among the programs sickest and most vulnerable. In response, hundreds of beneficiary, patient, disease and provider organizations have expressed their series objections and concerns with the proposal and the ramifications it could have on patient access to the medications they need and patient care. In addition, many of these same groups have expressed dismay at the development of the proposal up to this point – citing the lack of transparency and the lack of stakeholder input. It is also important to note that the proposed rule does not take into account the changes being proposed due to the implementation of The Medicare Access and CHIP Reauthorization Act (MACRA). The proposal would disrupt the work physicians are undertaking to prepare for delivery system reform including the implantation of the Merit Based Incentive Program (MIPS), and the development of alternative payment models, including those negotiated with CMS in some of the very same areas, such as oncology, most impacted by this proposal.

While these concerns are numerous, the mere scope and design of this proposal, including waiving several parts of statute, its nationwide application, the untested application of value based purchasing mechanisms, and the dramatic reduction in reimbursement have led many to call for a withdrawal of the proposed rule.

V. H.R. 5122

The Committee will also review legislation introduced by Dr. Bucshon would prohibit further action on the proposed rule, effectively blocking any effort by CMS' to finalize this rule.

VI. STAFF CONTACTS

If you have any questions regarding this hearing, please contact J.P. Paluskiewicz with the Committee staff at (202) 225-2927.