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Cancer Action Network  
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September 11, 2017

Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1678-P  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, D.C. 20201

**Re: CMS-1678-P – Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs Program Proposed Rule**  
82 Fed. Reg. 33558 (July 20, 2017)

Dear Administrator Verma:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the proposed rule implementing changes to the calendar year (CY) 2018 Medicare Hospital Outpatient Prospective Payment Program. ACS CAN is the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society and supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. As the nation's leading advocate for public policies that are helping to defeat cancer, ACS CAN ensures that cancer patients, survivors, and their families have a voice in public policy matters at all levels of government.

ACS CAN offers the following comments on the proposed rule:

**V. PROPOSED OPPTS PAYMENT CHANGES FOR DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS**

**B. Proposed OPPTS Payment for Drugs, Biologics, and Radiopharmaceuticals Without Pass-Through Payment Status**

*7. Alternative Payment Methodology for Drugs Purchased Under the 340B Drug Discount Program*

CMS is proposing to change its Part B drug reimbursement policies for 340B hospitals by adjusting the payment rate for separately payable drugs and biologics (other than drugs on pass-through and vaccines) acquired under the 340B program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. CMS also proposes to add a modifier to identify whether a drug purchased under the Hospital Outpatient Prospective Payment system was purchased under the 340B discount program.

ACS CAN supports attempts to better align the operation of the 340B program with Congressional intent. ACS CAN is supportive of the 340B program, which is designed to allow participating hospitals and other entities that primarily provide services to low-income individuals to obtain discounted prices on outpatient prescription drugs.

We note that the 340B program has grown substantially over the years. According to the Medicare Payment Advisory Commission (MedPAC), between 2005 and 2010 the number of hospital entities participating in the 340B program increased 134 percent.<sup>1</sup> Between 2004 and 2013, Medicare spending for Part B drugs included in the 340B program increased 543 percent (from \$0.5 billion in 2004 to \$3.5 billion in 2013).<sup>2</sup> The MedPAC report also demonstrated that spending on outpatient chemotherapy drugs was higher at 340B entities compared to their 340B counterparts.

We therefore support efforts to strengthen the program and we look forward to working with CMS and Congress to ensure that the 340B program operates in a sustainable manner that is best for the low-income patients it supports.

## **X. PROPOSED NONRECURRING POLICY CHANGES**

### **F. Potential Revisions to the Laboratory Date of Service Policy**

CMS proposes to revise its date of service requirements for clinical lab tests and the technical component of pathology services. Under current regulations, lab tests that are conducted within 14 days of a hospital discharge are reimbursed as part of the bundled payment the hospital receives from Medicare. Labs are prevented from billing Medicare directly and must seek reimbursement directly from the hospitals.

The current policy has the unintended consequence of encouraging hospitals to delay sending specimens to independent laboratories until after the 14-day discharge period when the lab tests are no longer part of the hospital's bundled services. For some cancer patients, a delay of up to 14 days can interfere with their ability to get timely information about their specific cancer which is critical for determining the type and frequency of treatment. Citing stakeholder concerns, CMS is considering potential modifications to the date of service policy that would allow laboratories to bill Medicare directly for certain laboratory tests. Specifically, CMS is proposing to create a new exception to the date of service policy for molecular pathology tests and advanced diagnostic laboratory tests (ADLTs) which would allow the laboratories to bill Medicare directly for these tests.

ACS CAN supports CMS' proposal, which we believe will result in cancer patients receiving more timely access to laboratory services. We do not believe this is the intent of the rule and appreciate CMS' proposed policy.

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<sup>1</sup> Medicare Payment Advisory Commission, Report to Congress: Overview of the 340B Drug Program, May 2015.

<sup>2</sup> Id.

**Conclusion**

On behalf of the American Cancer Society Cancer Action Network we thank you for the opportunity to comment on the proposed rule. If you have any questions, please feel free to contact me or have your staff contact Anna Schwamlein Howard, Policy Principal, Access and Quality of Care at [Anna.Howard@cancer.org](mailto:Anna.Howard@cancer.org) or 202-585-3261.

Sincerely,

A handwritten signature in black ink, appearing to read "Christopher W. Hansen". The signature is fluid and cursive, with a large initial "C" and a long horizontal stroke at the end.

Christopher W. Hansen  
President  
American Cancer Society Cancer Action Network