

# CANCER LEADERSHIP COUNCIL

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS  
ADDRESSING PUBLIC POLICY ISSUES IN CANCER

October 5, 2020

The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue SW  
Washington, DC 20201

RE: CMS-1736-P, Medicare Program: Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule; Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-Owned Hospitals

Dear Administrator Verma:

The undersigned organizations represent cancer patients, health care professionals, and researchers. We are pleased to have the opportunity to comment on the proposed rule related to the hospital outpatient prospective payment system, laboratory date of service policy, and other matters.

We note that our comments and advice are offered in the midst of a pandemic that has caused serious disruptions in the delivery of cancer care and has adversely affect access to cancer screening and routine care that might lead to cancer diagnosis. The effects on patients are serious, as they may suffer worsening of disease while treatment is delayed, or their cancer may be diagnosed at a later date and at a later stage. Both providers and patients have worked hard to address the challenges to delivering and receiving cancer care in the time of a pandemic, embracing telehealth services and ensuring proper use of personal protective equipment and other mitigation strategies to permit safe delivery of cancer care face-to-face. All the actions taken to address the pandemic bear costs, both in health terms and financially. We note this extraordinary time to suggest that reductions in reimbursement be approached with care. Additional challenges to the health care system may only serve to adversely affect patient access to quality care.

## ***CY 2021 OPPS Payment Methodology for 340B Purchased Drugs***

The Centers for Medicare & Medicaid Services (CMS) proposes to revise payment policy for outpatient drugs that are purchased under the 340B program. For calendar year (CY) 2018, CMS made a substantial change in payment for drugs purchased through the 340B Program. In place of the payment rate of ASP plus 6%, the agency set the Medicare payment rate at ASP minus

22.5%. For calendar year 2019, this payment standard was extended to 340B drugs furnished by non-excepted off-campus provider-based departments.

The United States Court of Appeals for the District of Columbia, in a ruling on July 31, 2020, affirmed that CMS has the authority to reduce Medicare payment rates for 340B drugs reimbursed through the outpatient prospective payment system (OPPS).

CMS proposes for calendar year 2021 to further reduce Medicare payment for 340B drugs. For 2021 and years beyond, the agency proposes to adopt a rate of ASP minus 34.7 percent, with a 6 percent add-on amount for overhead and handling costs, for a proposed net rate of ASP minus 28.7 percent. The agency indicates that the proposed payment rate is based on data on drug acquisition costs in calendar year 2018 and 2019 that was collected through the Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Drugs.

We have serious reservations about relying on a survey that was undertaken in the middle of the pandemic as the basis for substantial reductions in payment for 340B drugs. According to CMS, only 7% of respondents answered the detail survey, 55% responded to the quick survey option, and 38% did not respond. We are not surprised that the response to this survey was not stronger, because hospitals were asked to respond at a time when their resources were dedicated to coronavirus pandemic response.

Our fundamental concern is that the reduced reimbursement rate that is based on a less-than-robust survey will adversely impact the vulnerable and low-income patients that the 340B program is intended to help and the institutions that serve those patients. The 340B program is of importance to institutions that serve a significant volume of cancer patients who depend significantly on drug therapies as part of their comprehensive cancer treatment.

We understand that there is interest in ensuring that the 340B program meets its original intent. Rather than apply additional reimbursement reductions to the program, we recommend that CMS, working with the Health Resources and Services Administration, undertake an evaluation of the 340B program to consider its alignment with the original goals and aims of the program. We also recommend that the evaluation focus on the appropriate size of the program and the kind of program safeguards that should be implemented. Reforms of the program should be considered after an evaluation of the program that engages all stakeholders. Another payment reduction will not serve the purpose of guaranteeing that the program operates to serve vulnerable patients in receipt of quality and affordable health care.

### ***Laboratory Date of Service Rule***

All of our organizations share the goal of ensuring that cancer patients receive care that is best for them and meets their needs and wishes. No matter the decision that cancer patients make about their care, appropriate and accurate diagnosis is critical to their decision-making. This includes access in timely and affordable fashion to clinical diagnostic laboratory tests.

We commend CMS for its proposal to exclude certain cancer-related, protein-based Multianalyte Assays with Algorithmic Analyses (MAAAs) from the OPPS packaging policy. By excepting these cancer tests from the date-of-service policy and allowing them to be billed directly to Medicare by laboratories, delays in testing can be addressed and patient diagnosis,

treatment decision-making, and initiation of care can proceed without interruption or unreasonable delay.

Although cancer care providers and their patients have worked hard to address pandemic-related disruptions in care, we are concerned that delays and disruptions early in the pandemic and the impact of those delays on outcomes. There have been other disruptions related to cancer, including delays in screening that may result in diagnosis at a later stage of disease.

We are pleased that, at a time when the cancer community is working hard to address pandemic-related care disruptions, the agency has addressed the date of service rule at least for cancer-related, protein-based MAAAs. We encourage CMS to consider the same exceptions to MAAAs for other diseases in future rulemaking efforts.

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We appreciate the opportunity to comment on these issues that affect cancer patients' access to quality care.

Sincerely,

**Cancer Leadership Council**

*CancerCare*  
Fight Colorectal Cancer  
Hematology/Oncology Pharmacy Association  
LUNgevity Foundation  
Lymphoma Research Foundation  
National Coalition for Cancer Survivorship  
Prevent Cancer Foundation  
Susan G. Komen