



September 11, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1678-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Sent electronically

Re: CMS-1678-P — Hospital Outpatient Prospective Payment System, Notice of Proposed Rulemaking — Potential Revisions to the Laboratory Date of Service Policy

Dear Administrator Verma:

The Personalized Medicine Coalition (PMC) appreciates the opportunity to submit comments regarding the Centers for Medicare & Medicaid Services (CMS) Hospital Outpatient Prospective Payment System (OPPS) — Notice of Proposed Rulemaking (NPRM): *Medicare Program Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs*.

PMC, which represents innovators, scientists, patients, providers, and payers, promotes the understanding and adoption of personalized medicine concepts, services, and products for the benefit of patients and the health care system. Our interest in the proposed rule pertains to how the concepts therein can support this emerging field. Our comments focus specifically on laboratory date of service (DOS) policy revisions contained in the CMS Hospital OPPS Proposed Rule for Calendar Year (CY) 2018.

Personalized medicine is an emerging field that uses diagnostic tools to identify specific biological markers, often genetic, to help determine which medical treatments and procedures will be best for each patient. By combining this information with an individual's medical history, circumstances, and values, personalized medicine allows doctors and patients to develop targeted prevention and treatment plans in order to provide the right treatment in the right dose to the right patient at the right time.

Personalized medicine is helping to shift the patient and provider experience away from trial-and-error and toward a more streamlined process for making clinical decisions, which will lead to improved patient outcomes, a reduction in unnecessary treatments costs, and better patient and provider satisfaction, particularly for chronic conditions that disproportionately affect Medicare beneficiaries. PMC members are leading the way in personalized medicine and recommend that patients who may benefit from the approach undergo appropriate testing as soon as possible during their clinical experiences.

BOARD OF DIRECTORS

President
Edward Abrahams, Ph.D.

Chair
Stephen L. Eck, M.D., Ph.D.
Aravive Biologics

Vice Chair
Jay G. Wohlgenuth, M.D.
Quest Diagnostics

Treasurer
Peter Maag, Ph.D.
CareDx

Secretary
Amy P. Abernethy, M.D., Ph.D.
Flatiron Health

Bonnie J. Addario
Bonnie J. Addario Lung Cancer
Foundation

Steven D. Averbuch, M.D.
Bristol-Myers Squibb Company

Paul R. Billings, M.D., Ph.D.
Biological Dynamics, Inc.

William W. Chin, M.D.
PhRMA

Donna Cryer, J.D.
Global Liver Institute

William S. Dalton, Ph.D., M.D.
M2Gen

Tim Garnett, FRCOG, MFFP, FFPM
Eli Lilly and Company

Brad Gray
NanoString Technologies

Kris Joshi, Ph.D.
Change Healthcare

Susan McClure
Genome magazine

Howard McLeod, Pharm.D.
Moffitt Cancer Center

J. Brian Munroe
Endo Pharmaceuticals

Michael Pellini, M.D.
Foundation Medicine

Kimberly J. Popovits
Genomic Health

Hakan Sakul, Ph.D.
Pfizer, Inc.

Michael S. Sherman, M.D., M.B.A.
Harvard Pilgrim Health Care

Michael Vasconcelles, M.D.
Unum Therapeutics

Statement of Neutrality

Many of PMC's members will present their own responses to CMS and will actively advocate for those positions. PMC's comments are designed to provide feedback so that the general concept of personalized medicine can advance, and are not intended to impact adversely the ability of individual PMC members, alone or in combination, to pursue separate comments with respect to the proposed rule or related issues. PMC's response is focused exclusively on personalized medicine issues related to the DOS policy revisions outlined in the NPRM.

Acknowledgement of Need for DOS Policy Revision

Personalized medicine depends in part on information from molecular pathology tests, advanced diagnostic laboratory tests (ADLTs), and some multianalyte assays with algorithmic analysis (MAAAs) to inform disease risk, diagnosis, prognosis, and treatment of patients with certain complex conditions.

Under current rules, hospitals are required to bill CMS for molecular pathology tests, ADLTs, and MAAAs that are performed within 14 days after a patient's discharge from the hospital if the tests do not fall under CMS' existing OPSS packaging exceptions, regardless of where the diagnostic tests were conducted. Laboratories outside the hospital must then seek payment directly from the hospital for services performed. In some cases, the administrative burdens caused by this policy led to delayed diagnostic testing that could guide the most appropriate treatment decisions for individual patients. The policy has thereby inadvertently led to a delay in implementing personalized medicine, hindering its adoption in the U.S. health care system.

After publication of the Medicare Physician Fee Schedule final rule in 2006, when it became clear that the laboratory date of service for hospital outpatients is the date a specimen was collected, CMS received public comments highlighting billing complexities, inconsistent coverage, and potential test ordering disincentives that could result from this policy. While the CMS rule did not intend to complicate disease diagnosis, delay treatment, or stifle personalized medicine, PMC applauds CMS' acknowledgement of the problem and its effort to address these concerns in the CY 2018 proposed rule.

Recommendations to Ensure Revised DOS Policy Incentivizes Appropriate Deployment of Personalized Medicine Tests

PMC supports CMS' approach, detailed in the CY 2018 proposed rule, which would allow laboratories to bill Medicare directly for tests that are excluded from the OPSS packaging exemptions. The agency's focus on reducing operational issues caused by the existing policy is laudable. The Coalition urges you, however, to consider the broadest possible application of the proposed changes. To ensure the most rapid and appropriate deployment of personalized medicine, PMC believes specifically that the modifications adopted by CMS in the final rule should not be limited to certain ADLTs but should encompass all ADLTs, molecular pathology tests, and MAAAs, which, as indicated, are integral to personalized medicine. These tests are typically performed outside the hospital using specimens taken from hospital outpatients and have a pattern of clinical use that makes them less connected to the primary services a patient receives in the outpatient setting. We recognize that some specialized hospital laboratories may perform their own molecular pathology tests. In these cases, the hospital would remain the billing entity under a DOS policy revision.

Recommendations to Ensure Revised DOS Policy Can Accommodate Liquid-Based Tests

PMC also encourages CMS to recognize that blood, urine, and other liquid-based tests provide important clinical results and should be considered in revisions to the DOS policy. As written, the CY 2018 proposed rule only allows a performing laboratory to bill for a test if a physician orders the test following the date of a hospital outpatient's discharge, a policy that may be suitable for tissue-based tests where the test is typically ordered after a sample is collected but could result in the exclusion of liquid-based tests, which are generally ordered on or before the date a sample is collected. If a hospital outpatient has not been discharged at the time a test was ordered by the physician and a liquid-based specimen is collected, the hospital is still required to bill Medicare even when a laboratory

performs the service. Removal of the order date requirement from the final rule would level the playing field for liquid-based tests and allow CMS' DOS policy to keep pace with innovation.

Conclusion

In summary, PMC recognizes and appreciates CMS' efforts to address concerns regarding the DOS billing practices set forth in the 2006 Medicare Physician Fee Schedule final rule. The Coalition supports changes to the laboratory DOS policy, and recommends that:

1. Modifications adopted by CMS in the final rule should not only apply to certain ADLTs, but should encompass all ADLTs, molecular pathology tests, and MAAAs.
2. Requirements for test ordering dates after a patient's discharge should be removed to accommodate for differences in specimen collection patterns for liquid-based tests.

Thank you for considering our comments on the laboratory DOS policy changes contained in the CY 2018 proposed rule. PMC and CMS are united by a shared goal of providing access to the safest and most effective medical technologies. If you have any questions about the content of this letter, please contact me at 202-589-1769 or cbens@personalizedmedicinecoalition.org.

Sincerely yours,



Cynthia A. Bens
Vice President, Public Policy