PERSONALIZED MEDICINE COALITION

October 5, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G 200
Independence Avenue, SW
Washington, DC 20201

Re: CMS-1736-P-Medicare Program: Hospital Outpatient Prospective Payment 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 Personalized Medicine Coalition (PMC) appreciates the opportunity to submit comments regarding the Centers for Medicare & Medicaid Services (CMS)' Calendar Year (CY) 2021 Proposed Rule for *Hospital Outpatient Prospective Payment (OPPS) 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.*

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 CY 2021 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 proposed rule and how we believe they can best support the future of personalized medicine.

Personalized medicine is a rapidly evolving 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.

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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 diseases and 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.

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 adversely impact the ability of individual PMC members, alone or in combination, to pursue separate comments with respect to the proposed rule or related issues.

Acknowledgement of Need for Additional Laboratory 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, stratification, and treatment of patients with certain complex conditions.

Prior to initial changes made by CMS in CY 2018 at the request of PMC and other stakeholders, laboratories outside of hospitals were required to seek payment from a hospital rather than Medicare for services they performed within 14 days after a patient's discharge. In some cases, the administrative burdens caused by this policy led to delays in the diagnostic testing necessary to guide the most appropriate treatment decisions for individual patients. Thus, while CMS did not intend to complicate disease diagnoses or delay treatments, this policy was hindering the implementation of personalized medicine.

Through the CY 2018 OPPS rule, which provided for direct billing of some molecular pathology tests, CMS began to correct billing complexities, inconsistent coverage and test ordering disincentives. PMC applauded these steps, though we commented that the policy changes should encompass all ADLTs, molecular pathology tests, and MAAAs in order to ensure appropriate deployment of personalized medicine. PMC therefore appreciates that CMS is revisiting the issue in the current OPPS proposed rule.

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

When the date of service is the date a specimen is collected rather than the date a test is performed, a test may not be ordered when it could be the most critical for a patient. As referenced in the CY 2021 proposed rule, there have been continued concerns that hospitals may delay ordering tests for 14 days or

more after the hospital outpatient encounter to bypass the laboratory DOS policy where CY 2018 changes did not apply.

Delays in testing and subsequent initiation of treatment are problematic for patients and providers. Allowing reasonable and necessary tests to be billed to Medicare directly by the laboratories who perform the testing can reduce unnecessary delays and may improve patient outcomes. The changes in the CY 2021 proposed rule will change the prognoses and improve care for some cancer patients. We therefore believe CMS should apply this rationale to other disease areas in current and future rulemaking so that the environment supports the appropriate deployment of personalized medicine in the U.S. health care system.

PMC is encouraged that CMS is considering the exclusion of certain cancer-related protein-based MAAAs from the OPPS packaging policy in the CY 2021 proposed rule, which would allow them to be paid for separately under the Clinical Lab Fee Schedule (CLFS) and be billed to Medicare by laboratories through the DOS policy exception. In previous comment letters PMC has supported extending the laboratory DOS exception to all MAAAs, asking that CMS contemplate all advanced diagnostics, including liquid-based tests, that enable personalized medicine when considering policy revisions. We appreciate the recognition by CMS in the proposed rule that treatments based on the result of cancer-related protein-based MAAAs are typically furnished after a patient has left the hospital, in which case they are not tied to the same hospital outpatient encounter during which the specimen is collected. This clinical pattern of use is not unique to cancer and we urge CMS to consider additional modifications to apply the laboratory DOS exemption to all MAAAs, including those for other diseases, in the final CY 2021 OPPS rule, ensuring beneficiary access to appropriate personalized medicine technologies.

Conclusion

Thank you for considering our comments on the laboratory DOS policy changes contained in the CY 2021 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 202-499-0986 or cbens@personalizedmedicinecoalition.org.

Sincerely,

Cynthia A. Bens
Senior Vice President, Public Policy