



September 27, 2019

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: CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1717-P) — 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) Proposed Rule containing policy changes and payment rates for the Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center Payment System for Calendar Year (CY) 2020.

PMC, which represents more than 200 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 detailed in the CMS Hospital OPPS Proposed Rule for CY 2020. Revisions to limit direct billing by performing laboratories to only Advanced Diagnostic Laboratory Tests (ADLTs) or to add a requirement for physician certification of future use of a test's results would roll back positive changes already made by CMS in 2018 and, we believe, jeopardize beneficiary access to necessary diagnostic testing.

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.

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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 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.

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 proposed laboratory DOS policy revisions.

Restatement of Need for Original Laboratory DOS Policy Revision

Personalized medicine depends in part on information from molecular pathology tests, advanced ADLTs, and some multianalyte assays with algorithmic analysis (MAAAs) to inform disease risk, diagnosis, prognosis, and treatment of patients with certain complex conditions. After publication of the Medicare Physician Fee Schedule Final Rule in 2006, it became clear that the laboratory DOS for hospital outpatients would be the date a specimen is collected. Under that rule, hospitals would be required to bill CMS for molecular pathology tests, ADLTs, and MAAAs that were performed within 14 days after a patient's discharge from the hospital if the tests did not fall under CMS' OPSS packaging exceptions, regardless of where the diagnostic tests were performed. Laboratories outside the hospital had to seek payment from the hospital for services they 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.

Revisions to the laboratory DOS policy offered by CMS in 2017 as part of the CY 2018 Hospital Outpatient PPS Proposed Rule sought to reverse delays in testing by allowing laboratories to bill Medicare directly for tests that were excluded from OPSS packaging exemptions. PMC commented on the proposed rule. In our comments, we applauded CMS' acknowledgement of the problem and supported CMS' approach to reducing operational issues caused by the earlier policy. We requested that CMS not limit final modifications to DOS policy to certain ADLTs, but expand the revisions to encompass a broader range of tests (molecular pathology tests, all ADLTs, MAAAs, and liquid-based tests) to incentivize appropriate deployment of personalized medicine tests.

Changes established by the CY 2018 Hospital Outpatient PPS Final Rule DOS policy at 42 CFR 414.510(b)(5) have improved beneficiary access to clinically important diagnostic testing services and

timely treatment for complex conditions. We are aware that some stakeholders have informed CMS that CY 2018 DOS policy changes created difficulties because of a lack of existing systems to provide performing laboratories with a beneficiary's hospital outpatient status, beneficiary demographic information, and insurance information. We acknowledge these difficulties, but we do not believe the revisions to the DOS policy under consideration by CMS for CY 2020 are the most appropriate solutions.

Two of the potential revisions to the laboratory DOS policy proposed by CMS for CY 2020 would reverse progress that has been made in ensuring patient access to timely testing that guides treatment. They would also create additional administrative complexities for providers that will impact patient care.

Limiting DOS Exception to ADLTs will Impact Timely Deployment of Personalized Medicine Tests

In CY 2020, CMS proposes to limit the DOS policy exemption at 42 CFR 414.510(b)(5) to ADLTs. Not all molecular pathology tests that a beneficiary may need are eligible for ADLT designation. CMS should provide data or the information source it used to conclude that molecular pathology tests should be removed from the DOS exception. If this change is finalized, only four tests that have been designated as ADLTs would be covered by the exception. CMS established the revised laboratory DOS policy at 42 CFR 414.510(b)(5) in 2018 and included molecular pathology tests under the exception because of concerns that the then-existing policy was resulting in delayed orders for personalized medicine tests and delayed access to test results. We are concerned that CMS no longer believes these beneficiary access concerns apply to molecular pathology tests.

The rationale provided in the CY 2020 Proposed Rule for limiting the exception to ADLTs is that because molecular pathology tests are not required by statute to be furnished by a single laboratory, "hospital laboratories and independent laboratories are not prevented from performing molecular pathology testing." However, a large number of molecular pathology tests are sole-source assays performed by small laboratories and are unlikely to ever be sold as a kit or performed by a hospital laboratory.

Molecular pathology tests, such as sole-sourced assays, continue to present the same beneficiary access concerns as ADLTs. We believe that applying the DOS exception to only ADLTs will not prevent performing laboratories from reverting back to pre-2018 patterns of holding molecular pathology tests for 14 days in order to bill Medicare directly and avoid seeking payment from the hospital.

Requiring Physicians to Determine Future Use of Test Results Creates Burdens and Impacts Care

The CY 2020 Proposed Rule includes a potential revision to the current laboratory DOS policy that would require an ordering physician to determine whether the results of the ADLT or molecular pathology test are intended to guide treatment during a hospital outpatient encounter. If the proposed revision is finalized, an ordering physician would have to determine that the results of a test are not intended to guide treatment during a subsequent hospital outpatient encounter in order for a performing laboratory to bill Medicare directly. This proposed revision is subject to physician judgement, making it difficult to implement in a consistent and predictable manner. It also removes the ability of performing

laboratories to bill Medicare directly for many tests they perform, which is the root cause of beneficiary access issues CMS began solving in 2018.

Under the proposed policy change, ordering physicians would be required to document their decision on the use of test results and inform both the laboratory and the hospital so the correct party bills. Physicians would also need to respond to any queries about their decisions and provide patient information to the billing hospital or performing laboratory. We are concerned about the burden this new requirement would place on physicians. It may reduce the time they have to perform actions directly related to treatment planning with their patients.

Conclusion

In summary, PMC recognizes and appreciates CMS' efforts to address stakeholder concerns regarding the laboratory DOS policy established by the CY 2018 Hospital Outpatient PPS Final Rule at 42 CFR 414.510(b)(5). The Coalition opposes changes to the laboratory DOS policy that limit direct billing by performing laboratories to only ADLTs as well as those that would add a requirement for physician certification of future use of a test's results. PMC respectfully requests that CMS not finalize changes to the test results requirement 42 CFR 414.510(b)(5) or limit the laboratory DOS exception at 42 CFR 414.510(b)(5) to ADLTs. Instead, CMS should work together with a broader range of stakeholders to pursue additional options that may reduce operational issues caused by the existing policy.

Thank you for considering our comments on the laboratory DOS policy changes contained in the CY 2020 proposed rule. PMC welcomes the opportunity to serve as a resource for you in continuing to shape this policy so that it achieves the goal we share with CMS of delivering appropriate, efficient, and accessible health care to patients. If you have any questions about the content of this letter, please contact me at 202-589-1769 or cbens@personalizedmedicinecoalition.org.

Sincerely,



Cynthia A. Bens
Senior Vice President, Public Policy