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Association for the Advancement of Blood & Biotherapies

September 14, 2026

Dr. Mehmet Oz, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1848-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

**Re: Medicare and Medicaid Programs; CY 2027 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies (CMS-1848-P)**

Dear Dr. Oz:

The Association for the Advancement of Blood & Biotherapies (AABB) appreciates the opportunity to comment on the proposed rule updating the Medicare physician fee schedule (PFS), the clinical laboratory fee schedule (CLFS), and other Part B payment policies for calendar year (CY) 2027.

AABB is an international, not-for-profit association representing institutions and individuals involved in transfusion medicine and biotherapies. The association is committed to improving lives by making transfusion medicine and biotherapies safe, available and effective worldwide. AABB advances this mission by developing and delivering standards, accreditation, and educational programs that optimize patient and donor care and safety. AABB individual membership includes physicians, nurses, scientists, researchers, administrators, medical technologists, and other health care professionals.

AABB offers comments on two areas of the proposed rule: (1) Software as a Medical Service (SaMS) laboratory analyses; and (2) the request for information (RFI) on duplicate laboratory testing, imaging, and result sharing and interoperability.

## 1. SOFTWARE AS A MEDICAL SERVICE (SaMS) LABORATORY ANALYSES

AABB understands CMS' interest in developing policies that accommodate emerging technologies, including software-based algorithmic analyses of laboratory data. AABB recommends that CMS not finalize the proposal to reclassify SaMS analyses performed on laboratory tests from the CLFS to the PFS and the OPPS. SaMS laboratory analyses should remain on the CLFS while CMS develops a durable framework with the laboratory community for the following reasons:

### *A. CMS should ensure that its policies for SaMS laboratory analyses are coordinated across CLIA, the PFS, the OPPS, and the CLFS.*

In July 2026, CMS published three separate actions that include questions or proposals related to laboratories' use of software algorithms and artificial intelligence (AI): (1) this PFS proposed rule (CMS-1848-P); (2) the CY 2027 Hospital Outpatient Prospective Payment System proposed rule (CMS-1850-P); and (3) a request for information on the Clinical Laboratory Improvement Amendments (CLIA) (CMS-3485-NC).

These technologies cut across CLIA, the PFS, the OPPS, and the CLFS. Revising payment policies related to SaMS analyses performed on laboratory tests before the agency has completed the inquiry it opened through the CLIA RFI risks establishing a payment framework that is not aligned with stakeholder feedback or with the agency's own regulations.

### *B. These services do not fit the resource-based methodology of the PFS.*

SaMS laboratory analyses are misaligned with the PFS resource-based payment methodology, which considers physician work, practice expense, and malpractice liability. The resources consumed by SaMS laboratory analyses, such as software development, validation, computational infrastructure, and laboratory operations, do not currently map well to the relative value unit (RVU) framework. The CLFS, by contrast, was designed to accommodate the unique characteristics of laboratory testing, such as the CLIA regulatory environment and the operational models of laboratory providers.

Any eventual payment methodology for these services should account for the full set of recurring resources required to deploy SaMS laboratory analyses safely. Those resources include not only software development and computational infrastructure, but also clinical validation, ongoing performance monitoring/quality assurance, governance, cybersecurity, and professional oversight by qualified laboratory personnel. These costs do not disappear because the analytic component of the service is software-based, and a valuation methodology that omits them will understate the cost of furnishing the service.

### *C. The proposal would subject SaMS laboratory analyses to budget neutrality and cost-sharing requirements.*

AABB is concerned about the consequences of moving SaMS laboratory analyses from the CLFS to the OPPS and the PFS, which would subject these services to beneficiary cost-sharing and budget neutrality adjustments. Thus, these policy proposals have the potential to shift the cost of these services to Medicare beneficiaries and providers.

AABB encourages CMS to work with the laboratory community to assess and better understand the clinical, operational and regulatory issues associated with implementing SaMS analyses for laboratory tests before making changes to the payment policies. It is critical that CMS work with stakeholders to identify long-term payment solutions that reflect the complexities of algorithmic technologies in laboratory medicine.

## II. REQUEST FOR INFORMATION ON DUPLICATE LABORATORY TESTING, IMAGING, AND RESULT SHARING AND INTEROPERABILITY

AABB offers the following responses to the questions included in the RFI as they relate to laboratory testing:

**Should CMS consider possible changes to payment policies when diagnostic tests are billed duplicatively; that is, additional imaging or diagnostic laboratory tests for the same condition? For example, is there a time period which an image or laboratory test should automatically be considered ‘‘duplicate’’ and therefore subject to payment consequences? To which kinds of tests or subsets of tests should such policies apply?**

AABB requests that CMS avoid adopting duplicate-testing policies that create barriers to time-sensitive and emergency testing for patients requiring blood transfusions, apheresis, cellular therapies, or other biotherapies.

It is important that CMS differentiate between repeat testing and duplicate testing. In transfusion medicine, cellular therapy, and other biotherapies, repeat testing within short intervals is frequently required due to clinical circumstance, by professional standards, and in some cases by federal regulation. Repeat testing in these fields is not an unnecessary duplication to be eliminated; rather, it is often the standard of care. Such testing serves a critical patient safety function and is a well-established safeguard.

Examples of common repeat tests for patients requiring blood transfusions, cellular therapies or other biotherapies may include:

- pretransfusion compatibility testing, including ABO/Rh typing, antibody screening, antibody identification and crossmatching;
- second ABO determinations performed on independently collected specimens as a patient-safety measure
- testing performed as part of a transfusion reaction investigation, including direct antiglobulin testing, or as part of another clinically indicated evaluation of hemolysis;
- laboratory testing performed during active hemorrhage, massive transfusion protocol activation, or surgical or trauma resuscitation;
- laboratory testing performed before, during, or after therapeutic apheresis procedures to determine eligibility, guide the procedure prescription, monitor patient safety, or assess treatment response;
- CD34+ enumeration and other testing performed to time, guide, or assess hematopoietic progenitor cell mobilization and collection;
- donor eligibility and product testing required by FDA regulation or by AABB standards;
- chimerism, engraftment, and toxicity monitoring following transplantation or administration of cellular or gene therapies; and
- extended red cell antigen phenotyping or genotyping performed when prior results cannot be obtained or verified.

A test should not be classified as duplicative solely because the same test was performed within a specified time interval. Clinical necessity, rather than the interval between tests, should determine whether testing is duplicative. In transfusion medicine, cellular therapy, and other biotherapies, medically necessary repeat testing frequently occurs within hours, and in some circumstances within minutes. Medicare already recognizes this distinction. Modifier 91 identifies medically necessary repeat clinical laboratory testing.

Laboratory tests for patients requiring blood transfusions, cellular therapies or other biotherapies are often time-sensitive and may be needed to respond to an emergency. In these cases, testing decisions need to be made in minutes and cannot wait for payment adjudication or documentation review. We encourage CMS to avoid policies that will make providers hesitate or defer providing medically necessary laboratory tests.

**For laboratory interoperability specifically, what barriers continue to impede exchange despite the availability of established standards, and what policy levers could help address those barriers? Should we consider incentives to support laboratory adoption and implementation of health data standards?**

Interoperability for laboratories cannot be addressed in isolation. Laboratories, such as blood banks, operate as part of larger healthcare organizations and the healthcare ecosystem. Policies that advance interoperability must recognize these interdependencies and be designed in coordination with policies affecting hospitals, health systems, electronic health record (EHR) vendors, laboratory and blood bank information systems, and other stakeholders. HHS can emphasize conformance testing, implementation standards, and resources for adoption across the healthcare ecosystem. A requirement directed at laboratories alone will not produce usable exchange if the systems on either side of the interface are not built to receive and act on the data.

Nor is a mandate by itself sufficient to achieve interoperability. Many healthcare IT systems remain proprietary, and standardizing clinical data formats, terminology, and data elements requires investment and coordination across vendors and systems. Additionally, building and integrating health information exchange capabilities, ensuring HIPAA compliance and data security, and establishing data governance protocols are costly. Merely mandating interoperability without providing resources for implementation and integration will create compliance burdens on providers without achieving the intended clinical benefits.

Despite those challenges, we recognize that the ability to access and share test results and clinical information has direct consequences for patient care, and improving it is a goal AABB shares. For example, when a patient with sickle cell disease presents at a hospital emergency department and requires a blood transfusion, transfusion medicine physicians, blood bank professionals, and treating clinicians can make more informed decisions about blood product selection if they can access the patient's complete transfusion history, including previously identified alloantibodies and adverse reactions. That history is frequently unavailable. Alloantibodies can diminish or disappear over time and escape detection on pre-transfusion screening, and patients with sickle cell disease commonly receive transfusions at multiple institutions.

The safety problem in this setting is not limited to the exchange of an individual laboratory result. Transfusion medicine depends on the preservation of longitudinal clinical history. A previously identified alloantibody remains clinically significant even after it has evanesced and is no longer detectable on the current antibody screen. Transfusion reaction history and other durable transfusion-related information may likewise remain clinically actionable long after the encounter in which they were recorded. Interoperability needs to support persistent, longitudinal, and semantically reliable data that a receiving system can correctly interpret and act upon, rather than the transmission of discrete, contemporaneous results alone.

The Department of Health and Human Services analyzed this issue in a 2023 interim report on the development of a national red blood cell antibody patient data exchange. The report identified interoperability as an overarching barrier to developing a national red blood cell antibody exchange and explained that mandated interoperability measures have proven difficult to achieve and have produced divergent standards.[1] We encourage CMS to engage

[1] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Health, Toward the Development of a National Red Blood Cell Antibody Patient Data Exchange (RBCAX): 2023 Interim Report,

with the laboratory community to understand the resources and cross-sector coordination needed to achieve the goal of improving interoperability.

Thank you for the opportunity to provide feedback on the proposed rule updating the PFS, CLFS, and other Part B payment policies for CY 2027. If you have any questions or need additional information, please contact me at lmstone@aabb.org.

Sincerely,

Leah Stone
Vice President, Public Policy and Advocacy
Association for the Advancement of Blood & Biotherapies

*available at* https://www.hhs.gov/sites/default/files/toward-development-national-red-blood-cell-antibody-patient-data-exchange.pdf (last visited August 31, 2026).