4550 Montgomery Avenue | Suite 700, North Tower | Bethesda, MD 20814 | 301.907.6977 | aabb.org

Association for the Advancement of Blood & Biotherapies

August 31, 2026

The Honorable Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1850-P
P.O. Box 8010
Baltimore, MD 21244-8010

RE: Medicare Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Proposed Rule for CY 2027 (CMS-1850-P)

Dear Administrator Oz:

The Association for the Advancement of Blood and Biotherapies (AABB) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed revisions to the Hospital Outpatient Prospective Payment System (OPPS) and Medicare Ambulatory Surgical Center (ASC) Payment System for Calendar Year (CY) 2027, published in the Federal Register on July 7, 2026. Our comments address the agency's proposals concerning Software as a Medical Service (SaMS) analyses performed on laboratory tests.

AABB is an international, not-for-profit association representing institutions and individuals involved in transfusion medicine and cellular therapies. 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 understands CMS' interest in developing policies that accommodate emerging technologies, including SaMS analyses for laboratory tests. As algorithmic and software-driven laboratory testing services continue to evolve and expand, it is critical that Medicare's payment policies keep pace with innovation and recognize the professional expertise that must accompany technology. However, AABB urges CMS to avoid finalizing its proposed changes for SaMS analyses performed on laboratory tests.

In July 2026, CMS published in the Federal Register three separate actions related to laboratory practice and laboratories' use of software algorithms and artificial intelligence tools: (1) the CY 2027 Hospital Outpatient Prospective Payment System proposed rule (CMS-1850-P) (OPPS); (2) the CY 2027 Physician Fee Schedule proposed rule (CMS-1848-P) (PFS); and (3) a request for information on the Clinical Laboratory Improvement Amendments (CLIA) (CMS-3485-NC). Each includes questions or proposals that touch on how laboratories use software algorithms and artificial intelligence.

Because these technologies cut across CLIA, the PFS, the OPPS, and the Clinical Laboratory Fee Schedule (CLFS), AABB encourages CMS to coordinate policy development across these programs rather than advancing along separate tracks. Revising the payment classification of SaMS analyses performed on laboratory tests before the agency has completed the inquiry it opened through the CLIA request for information risks establishing a payment framework that is not aligned with stakeholder feedback or the agency's own regulations. Additionally, we are concerned that moving SaMS analyses from the CLFS to the OPPS could shift costs to 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.

We appreciate the agency's attention to these emerging technologies and share its interest in exploring a payment approach that supports access to high quality, innovative care.

Sincerely,

Leah Stone

Leah Stone
Vice President, Public Policy and Advocacy
AABB