



October 13, 2026

The Honorable Mehmet Oz, M.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-3487-NC, Medicare Program; Regulatory Alignment for Predictable and Immediate Device (RAPID) Coverage Pathway

Dear Administrator Oz:

The Association for Advancing Tissue and Biologics (AATB) appreciates the Centers for Medicare and Medicaid Services' (CMS) work with the Food and Drug Administration (FDA) to provide accelerated Medicare beneficiary access to certain Class II and Class III FDA Breakthrough-designated devices through the proposed Regulatory Alignment for Predictable and Immediate Device (RAPID) coverage pathway. **We urge you, however, to (1) expand the RAPID coverage pathway to include other products that receive similar designations from the FDA, including the Regenerative Medicine Advanced Therapy (RMAT) designation; and (2) address other barriers between the FDA and CMS that unnecessarily delay beneficiary access to innovative products.**

AATB is a non-profit organization dedicated to advancing the safety, quality, availability, and benefits of donated human tissue for transplantation worldwide. AATB achieves this through standards development, accreditation, education, and collaboration with regulatory partners to ensure donated tissue has the greatest impact on patient care.

The RMAT designation was enacted as part of the 21st Century Cures Act, and products qualify if they are "a regenerative medicine therapy, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, except for those regulated solely under Section 361 of the Public Health Service Act and part 1271 of Title 21, Code of Federal Regulations."¹ RMAT-designated products must also be "intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition;" and demonstrate in

¹ <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/regenerative-medicine-advanced-therapy-designation>

preliminary clinical evidence that “the drug has the potential to address unmet medical needs for such disease or condition.” These requirements are similar to the Breakthrough Devices program criteria, especially the Breakthrough Device requirement that “no approved or cleared alternatives exist; it offers significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients’ ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies.”

Given the similarities between these two categories of products – primarily, that both categories either address unmet medical needs or represent a significant improvement over existing products – we encourage CMS to expand the RAPID coverage pathway to RMAT-designated products. Doing so would ensure that sponsors of RMAT-designated products are appropriately considering and gathering evidence to demonstrate that the product will provide positive clinical health outcomes for the Medicare population. We understand that once the product receives FDA authorization, the RAPID coverage pathway would ensure a proposed National Coverage Determination (NCD) is released, with a final NCD coming 60 days later for Class II devices and 90 days later for Class III devices. We believe release of a final NCD within 60 days after FDA authorization would be appropriate for RMAT-designated products, consistent with Class II devices.

There are other steps CMS can take, in coordination with the FDA, to ensure Medicare beneficiaries have prompt access to life-saving or life-transformative human tissue-based products. One concern is that CMS and its Medicare Administrative Contractors (MAC) have increasingly required tissue processors to obtain and furnish letters from the FDA’s Tissue Reference Group (TRG) to confirm a product’s regulatory status prior to establishing coding or Medicare payment. The FDA offers TRG letters on a voluntary basis to manufacturers who wish to seek certainty regarding the appropriate regulatory paradigm for their products. Requests for TRG letters from CMS and the MACs have overwhelmed the FDA’s TRG, as AATB recently described in a letter to the FDA.² AATB has now surveyed our members three times (in 2022, 2024, and 2026) regarding their experience with the TRG, and our findings are increasingly concerning.

Since our first survey in 2022, the average TRG response time reported by our members has nearly doubled, from 140.7 days to 276.2 days. None of the inquiries with a final response in our survey this year received a response within 180 days (three times FDA’s stated goal of responding within 60 days). AATB believes these increases are due to requests for “proof” that products are eligible for regulation solely under section 361 of the Public Health Service Act (PHSA) and the regulations in 21 CFR part 1271 (361 status), even though such documentation is not necessary to legally market human cells, tissues, and cellular and tissue-based products (HCT/Ps) with 361 status under FDA regulations. Given the delays in obtaining Medicare coverage and payment that TRG letter requirements impose, AATB urges CMS to

²<https://www.aatb.org/sites/default/files/Government%20Advocacy%20Correspondence/AATB%20Tissue%20Reference%20Group%20Experience%20Final%20August%202026.pdf>

eliminate any requirement for human tissue manufacturers to provide a TRG letter and coordinate with the FDA to ensure products are appropriately marketed based on their regulatory status.

We also note that CMS's payment rate for skin substitutes in 2026 (which the agency is retaining for 2027) continues to be a challenge for many AATB members. We recognize that reform was needed, but we believe CMS went too far in setting a payment rate of 127.14/cm² for skin substitutes furnished in office and outpatient settings.³ AATB members are concerned that they will be forced to go out of business or are investing in other lines of business, which we believe will curtail innovation in the wound care space and, in the long run, threaten patient access to important medical products. We urge you to address this issue in the calendar year 2027 Outpatient Prospective Payment System and Physician Fee Schedule (PFS) final rules.

Combined, CMS' actions in recent years have created a very difficult environment for human tissue manufacturers. Expanding the RAPID coverage pathway to include RMAT-designated products would help spur innovation in the industry; eliminating TRG letter requirements and increasing the payment rate for skin substitutes would help as well.

Thank you for considering these comments. AATB stands ready and willing to assist in any way that you deem appropriate.

Respectfully,

A handwritten signature in black ink that reads "Marc Pearce". The signature is written in a cursive, flowing style.

Marc Pearce
President & CEO
Association for Advancing Tissue and Biologics

CC: Acting FDA Commissioner Kyle Diamantas

³<https://www.aatb.org/sites/default/files/Government%20Advocacy%20Correspondence/AATB%20CY27%20MPFS%20Proposed%20Rule%20Comment%20Letter%20FINAL.pdf>