Alliance for Regenerative Medicine

June 9, 2026

Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1849-P
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted electronically via http://www.regulations.gov

Re: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2027 Rates; Requirements for Quality Programs; and Other Policy Changes (CMS-1849-P)

Dear Administrator Oz,

The Alliance for Regenerative Medicine ("ARM") appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") proposed payment updates to the fiscal year ("FY") 2027 Hospital Inpatient Prospective Payment System (the "Proposed Rule").[1]

The Alliance for Regenerative Medicine (ARM) is the leading international advocacy organization championing the benefits of engineered cell therapies and genetic medicines for patients, healthcare systems, and society. As a community, ARM builds the future of medicine by convening the sector, facilitating influential exchanges on policies and practices, and advancing the narrative with data and analysis. We actively engage key stakeholders to enable the development of advanced therapies and to modernize healthcare systems so that patients benefit from durable, potentially curative treatments. As the global voice of the sector, we represent more than 400 members across 25 countries, including emerging and established biotechnology companies, academic and medical research institutions, and patient organizations.

There has been a rapid pace of advancement in the field of cell and gene therapies (CGTs), leading to the development of novel treatments for a growing list of therapeutic applications.

As of Q4 2025, there were 1,856 engineered cell therapy and genetic medicine developers worldwide sponsoring 2,130 clinical trials across dozens of indications, including rare monogenetic diseases, oncology, cardiovascular, central nervous

[1] 91 Fed. Reg. 19312, April 14, 20206, available at: https://www.federalregister.gov/d/2026-07203.

system, musculoskeletal, metabolic disorders, ophthalmological disorders, and more.[2]

The U.S. Food and Drug Administration (FDA) has approved 50 CGTs to date, including treatments for aggressive forms of blood cancer, solid tumors, and rare genetic diseases, such as hemophilia B, dystrophic epidermolysis bullosa, and spinal muscular atrophy. The U.S. could see up to seven new CGTs approved in 2026,[3] and an estimated 85 conditions will be treated with CGTs by 2033.[4]

The modality of CGT treatments is also evolving. While chimeric antigen receptor T-cell (CAR-T) therapies are the most prevalently used to treat Medicare beneficiaries, the CGT pipeline for conditions impacting the Medicare population is expanding beyond oncology care.

ARM appreciates that the proposed rule contains technical refinements that ARM supports—most notably, CMS's continued effort to refine the calculation of the relative weight for MS-DRG 018. At the same time, ARM is concerned that several of the proposals, if finalized as drafted, would meaningfully impair patient access to innovative cell and gene therapies and undermine the Medicare program's ability to recognize FDA-vetted innovations in a timely manner. Our comments are summarized as follows:

- **CMS should continue refining the MS-DRG 018 relative-weight methodology, including the exclusion of clinical-trial, expanded-access, and no-cost cases from the average-cost calculation.** The proposed methodology preserves the integrity of the MS-DRG 018 relative weight, ensures that non-commercial cases do not distort payment rates across the IPPS, and properly implements the statutory mandate to set MS-DRG weights based on actual resource use.

- **CMS should reaffirm that substantial clinical improvement (SCI) is to be evaluated against the most clinically relevant comparator(s) reflecting the standard of care, rather than against every available therapy in a disease area.** The cross-modality comparator approach reflected in the proposed Orca-T disapproval has no basis in 42 C.F.R. § 412.87(b), departs from prior NTAP practice, and would systematically disadvantage CGTs, which are typically developed against a defined standard-of-care comparator.

- **CMS should withdraw the proposed repeal of the NTAP alternative pathway and, instead, expand the pathway to additional FDA**

[2] Alliance for Regenerative Medicine, Q4 2025 Sector Snapshot, available at: https://alliancerm.org/wp-content/uploads/2026/05/Sector-Snapshot-Q4-2025_01.pdf

[3] Alliance for Regenerative Medicine, Q1 2026 Sector Snapshot, April 2026, available at: https://alliancerm.org/wp-content/uploads/2026/04/Q1-2026-ARM-CGT-Sector-Snapshot_April-2026.pdf

[4] Tufts NEWDIGS, Cell and Gene therapy (CGT) pipeline deep dive, available at: https://newdigs.tuftsmedicalcenter.org/payingforcures/defining-disruption/cell-and-gene-therapy-products-and-%20pipeline/cgt-pipeline-deep-dive/#gsc.tab=0

expedited-program designations. The pathway was deliberately designed to align Medicare payment with FDA's expert recognition of clinical urgency and unmet need; the projected NTAP expenditures cited in the proposed rule are built on applicant-supplied estimates that historical data demonstrate systematically do not come to fruition in the real-world due to various offsetting factors; and ARM has long urged CMS to extend alternative-pathway treatment to products with RMAT and Breakthrough Therapy designations by the FDA, not to withdraw the pathway altogether.

- **CMS should not constrict its recognition of "commercial availability" delays in calculating the newness period.** CGT launches routinely lag FDA marketing authorization for legitimate operational reasons—including manufacturing scale-up, treatment-center certification, payer contracting, and distribution-network establishment—and CMS's existing case-by-case framework already protects against abuse without the proposed cap.

- **CMS should develop and publish, through notice-and-comment rulemaking, transparent and prospective criteria for MS-DRG 018 assignment, supported by a Request for Information on the future structure of the MS-DRG System for CGTs.** As the CGT landscape continues to expand, the absence of clear, predictable assignment criteria creates payment volatility, complicates economic modeling, and ultimately threatens patient access; an RFI would equip CMS with the empirical and stakeholder record needed to evaluate any future restructuring of MS-DRG 018, as well as payment solutions for CGTs mapped to other DRGs.

- **CMS should confine the proposed reasonable-cost language at 42 C.F.R. § 413.24(d)(8) to its inpatient cost-allocation function and disclaim any broader determination that hospital costs for apheresis or other CGT preparatory services are reimbursed through the manufacturer's purchase price.** CMS's "fully loaded price" rationale rests on assumptions about manufacturer pricing structure that do not hold across the CGT landscape—particularly where the infuser and the collector are separate entities; CMS should also authorize adequate separate payment for outpatient apheresis and other preparatory services for CGTs in the next OPPS rulemaking cycle.

- **CMS should use the IPPS rulemaking to inform stakeholders on the implementation of the MAO-negotiated-rate policy CMS finalized in the CY 2026 OPPS final rule.** That policy operates on MS-DRG relative weights—an IPPS payment instrument—but the FY 2027 IPPS proposed rule is silent on the policy's implementation timeline, methodological details, and projected effects, leaving stakeholders without an opportunity to engage CMS on choices that will determine whether the policy preserves payment adequacy for high-cost, FFS-concentrated therapies.

ARM reiterates its commitment to collaborating with CMS to develop payment policies that support innovation, protect patient access, and maintain U.S.

leadership in regenerative medicine. ARM's detailed comments and recommendations follow.

I. ARM Supports CMS's Continued Refinement of the MS-DRG 018 Relative-Weight Methodology.

CMS proposes to continue applying its MS-DRG 018 relative-weight methodology, finalized in prior rulemaking, that excludes from the average-cost calculation those cases identified as clinical-trial cases, expanded-access cases, and other cases in which the immunotherapy product is not purchased in the usual manner (such as cases obtained at no cost), and to apply a proposed adjustor of 0.17 to those excluded cases when computing the national average cost per case for purposes of the relative weights, budget neutrality, and outlier modeling.[5]

ARM supports this proposal as a sound and necessary technical refinement that preserves the integrity of the MS-DRG 018 relative weight, ensures that clinical-trial and no-cost cases do not distort payment rates across the IPPS, and properly implements the statutory mandate to set MS-DRG weights based on the relative resources used in furnishing the typical case. The data reinforce the necessity of the adjustor: based on the December 2025 update of the FY 2025 MedPAR file, the average cost of clinical-trial cases assigned to MS-DRG 018 ($71,039) was only 17 percent of the average cost of non-clinical-trial cases assigned to that DRG ($412,218). Without the proposed adjustor, the inclusion of those clinical-trial and no-cost cases at full weight would materially understate the true resource intensity of MS-DRG 018 and depress the relative weight—and, by extension, payment—for the high-cost commercial cases the DRG is designed to capture.

ARM encourages CMS to continue methodological refinement and stakeholder engagement as additional claims data become available reflecting condition code 90 reporting. In addition, we recommend CMS conduct outreach and education for hospitals on the use of the condition code for no cost product cases that in FY2028 will replace the drug charge threshold as a proxy for identifying and excluding them from rate-setting. It is our understanding that the code is not appearing in claims yet, which may indicate the need for hospitals to be educated on the code and the requirement to add it to claims for no cost product cases starting FY2028. Continued transparency and education about the underlying data and the technical adjustments CMS makes to that data is essential as the CGT product landscape continues to expand.

II. CMS Should Reaffirm Prior NTAP Practice That Substantial Clinical Improvement (SCI) is to be Evaluated Against the Most Clinically Relevant Comparator(s) Reflecting the Standard of Care, Rather Than Against Every Available Therapy in a Disease Area.

Note: ARM does not take a position on the merits of any individual NTAP application. Rather, ARM is concerned that the CMS commentary for the NTAP application discussed below reflects an emerging methodological approach to SCI

[5] 91 Fed. Reg. at 19394.

adjudication that is very difficult for CGTs with small target populations to achieve, if at all.

CMS proposes to disapprove the new technology add-on payment ("NTAP") application for Orca-T on the grounds that the application does not satisfy the substantial-clinical-improvement ("SCI") criterion. CMS cites two primary concerns: (i) insufficient evidence identifying a patient population that is ineligible for or unresponsive to existing treatments; and (ii) the applicant's failure to compare Orca-T outcomes against CAR T-cell therapies and chemotherapy, in addition to the alloHSCT comparator used in the application.[6]

ARM is concerned, however, that CMS's treatment of the Orca-T application reflects an emerging methodological approach to SCI adjudication—one that effectively requires applicants to produce cross-modality comparative evidence against every available treatment in a disease area—that has no basis in the governing regulation, departs from prior NTAP practice, and would systematically disadvantage CGTs if applied broadly. ARM urges CMS to reaffirm that the SCI inquiry is to be conducted against the most clinically relevant comparator(s) reflecting the standard of care for the indicated population, consistent with CMS's prior NTAP determinations. ARM's rationale is set forth below.

A. <u>The SCI regulation does not require comparison against every available therapy in a disease area.</u>

The governing regulation requires CMS to assess whether a technology represents a "substantial clinical improvement over existing technologies," not whether it is superior to every alternative in a disease space.[7] The enumerated SCI factors—reduction in mortality, reduction in adverse events, decreased rate of subsequent diagnostic or therapeutic interventions, decreased number of future hospitalizations or physician visits, more rapid beneficial resolution of the disease process, and other measures of clinical improvement—are framed in the alternative and do not require head-to-head evidence against every modality used in the indication.[8]

CMS's stated concern–that the applicant did not compare its product to CAR T-cell therapies and chemotherapy in addition to alloHSCT–effectively imposes a cross-modality comparator requirement that the regulation does not contain. The text of § 412.87(b)(1) does not require comparison to every clinically distinct therapeutic modality used anywhere in the indicated patient population; it requires a substantial improvement "over existing technologies." An applicant satisfies that standard by demonstrating substantial improvement over the most clinically relevant comparator(s) for the eligible population—not by exhaustively comparing the new technology to every product across every modality used in the disease area.

[6] 91 Fed. Reg. at 19419.
[7] 42 C.F.R. § 412.87(b)(1).
[8] 42 C.F.R. § 412.87(b)(1)(i)–(viii).

B. The cross-modality comparator approach, if generalized, would systematically disadvantage CGTs.

In prior NTAP cycles, CMS has accepted SCI evidence comparing a new technology to a defined standard-of-care comparator, without requiring exhaustive comparison to every therapeutic modality used in the disease area. The shift reflected in this proposed disapproval would represent a meaningful departure from that practice, and CMS should provide a reasoned explanation for any such departure. Absent such an explanation, applicants and the public have no notice of the new evidentiary expectations.

CGTs are especially vulnerable to CMS's apparent approach as they typically are developed against a defined transplant or chemotherapy comparator that reflects the actual treatment decision in the eligible patient population, not against every available product in the therapeutic space. Pivotal trial designs are constrained by ethical, statistical, and feasibility considerations, and applicants reasonably select comparators that reflect the clinical decision the new therapy is designed to inform. Requiring head-to-head evidence against modalities that the applicant's eligible population would not actually receive imposes infeasible study designs—beyond the standards that the FDA determines adequate to justify approval—and effectively forecloses NTAP eligibility for an entire class of innovative therapies.

ARM accordingly urges CMS to reaffirm, in the final rule and in subsequent NTAP determinations, that SCI is to be evaluated against the most clinically relevant comparator(s) reflecting the standard of care for the indicated population. CMS should not, sub silentio, raise the evidentiary bar in a way that disadvantages CGTs.

III. CMS SHOULD WITHDRAW ITS PROPOSAL TO REPEAL THE NTAP ALTERNATIVE PATHWAY.

CMS proposes to repeal the alternative NTAP pathways for FDA-designated Breakthrough Devices and for QIDP/LPAD-designated antimicrobials, beginning with applications received for FY 2028 and subsequent fiscal years, requiring all future applicants—regardless of FDA designation—to meet the full SCI criterion and all other traditional pathway requirements.[9] CMS cites generalized concerns about the "limited evaluation process" associated with the alternative pathways as the basis for repeal, but does not identify any specific alternative-pathway approval that produced inappropriate spending, inferior outcomes, or systematic misuse.

ARM strongly opposes the repeal. The alternative pathway was deliberately created across two administrations to align Medicare payment with FDA's expert recognition of clinical urgency and unmet need, and it has functioned as designed—reducing the lag between FDA marketing authorization and Medicare payment recognition for a defined, FDA-vetted set of technologies treating serious conditions. To the extent CMS's repeal proposal is influenced by recent growth in alternative-pathway approvals or by projected NTAP expenditures, those projections rest on

[9] 91 Fed. Reg. at 19457.

applicant-supplied utilization estimates that historical data demonstrate systematically do not come to fruition in the real-world due to various offsetting factors. ARM urges CMS to withdraw the repeal proposal and, before taking further action, to publish actual NTAP utilization data so that any policy change rests on observed program experience rather than projection. ARM's rationale is set forth below.

A. The alternative pathway exists to preserve patient access to FDA-recognized breakthrough technologies, and that purpose remains compelling.

The alternative pathway was deliberately created to align Medicare payment with FDA's expert determination that certain technologies address life-threatening or irreversibly debilitating conditions, lack adequate alternatives, or offer significant advantages over existing treatments. CMS established the alternative pathway for Breakthrough Devices in the FY 2020 IPPS final rule[10] and extended it to QIDP/LPAD-designated products in the FY 2021 IPPS rule.[11] The pathway was designed to reduce the redundancy and lag between FDA's expert clinical-significance determinations and Medicare payment recognition, and it has done so. FDA's Breakthrough Device designation, in turn, requires a finding that the device provides for more effective treatment of a life-threatening or irreversibly debilitating condition and either represents breakthrough technology, has no approved alternative, offers significant advantages, or is in the best interest of patients.[12] The alternative pathway respected that finding by treating Breakthrough Device designation as evidence that the technology is not substantially similar to existing technologies.

Notably, in establishing the alternative pathway, CMS expressly weighed cost concerns against access benefits and concluded that the access rationale prevailed. CMS explained that, "while we appreciate the commenter's concern regarding additional Medicare program expenditures, for the previously stated reasons, we believe it is appropriate to facilitate beneficiary access to transformative new medical devices by establishing an alternative pathway for a device that receives FDA marketing authorization and is subject to the FDA's Breakthrough Devices Program that does not require substantial clinical improvement be demonstrated as a condition of approval because the evidence base to demonstrate substantial clinical improvement may not be fully developed at the time of FDA marketing authorization for such devices."[13] That balance was struck deliberately, and CMS has not articulated a reasoned basis for revisiting it.

The proposed repeal is hard to reconcile with CMS and HHS's repeated framing of antimicrobial innovation as a key public health priority given the threat of anti-microbial resistance. In prior IPPS rulemaking establishing the alternative pathway for QIDPs/LPADs, CMS emphasized that these FDA designations warrant

[10] 84 Fed. Reg. 42044, (Aug. 16, 2019).
[11] 85 Fed. Reg. 58432 (Sept. 18, 2020).
[12] 21 U.S.C. § 360e-3(b)(2).
[13] 84 Fed. Reg. at 42295

streamlined NTAP access because they reflect important clinical and public health needs. Repealing the pathway would withdraw a reimbursement signal that manufacturers, hospitals, and capital providers reasonably built into commercialization plans for technologies addressing the most difficult-to-develop areas of medicine. The pathway was extended to QIDP and LPAD products precisely because inpatient antimicrobials face especially acute market-access barriers under DRG-based payment, and because congressional and FDA policy has long sought to encourage—not constrain—antimicrobial development.

Compounding this concern is that CMS does not acknowledge the structural problems that hospitals and innovators already face under the existing NTAP framework, even as it proposes to make qualification more difficult. Among other issues, NTAP eligibility is determined post-claim through, meaning that hospitals furnishing a new technology cannot know at the point of admission whether the case will ultimately receive add-on payment. Similar to other technologies, receiving NTAP helps facilitate timely hospital access to innovative antimicrobials when MS-DRG base rates lag new-technology costs. Tightening the eligibility standard without addressing these underlying predictability problems compounds, rather than mitigates, the access barriers facing these FDA-vetted innovations. It is concerning that CMS does not address this important factor that applies to all NTAP application pathways in the proposed repeal of the alternative pathway.

B. <u>To the extent the repeal is influenced by recent growth in alternative-pathway approvals or projected NTAP expenditures, those projections do not reflect real-world offsetting factors that routinely cause actual NTAP utilization to fall below applicant-supplied projections.</u>

For FY 2027, CMS projects that NTAP expenditures will increase by approximately $464 million, with aggregate NTAP impact across all 41 continuing technologies exceeding $836 million.[14] These projections, however, are built primarily from applicant-supplied estimates of expected case volumes and per-case maximum payment amounts—not from observed Medicare claims experience.[15] Applicant-supplied volume estimates predictably skew high. Although applicants provide their best good-faith estimates, real-world experience shows those figures may not come to fruition for several reasons, including but not limited to evolving hospital adoption lag, site-readiness constraints, clinical guidelines, coding practices including instances where a hospital does not include an ICD-10 PCS code identifying the technology, manufacturing delays, charging practices that may result in cases not receiving the maximum NTAP amount, and competing therapies or other market entry dynamics, any of which can result in slower-than-expected commercial uptake. CMS, in turn, does not independently model the offsetting factors that, in the real world, routinely cause actual NTAP utilization to fall below applicant projections.

[14] 91 Fed. Reg. at 19849.
[15] *Id*. at 19850

Moreover, NTAP payments are inherently self-limiting. Payment is capped at 65 percent (or 75 percent for QIDPs and certain gene therapies) of the lesser of the technology's cost or the amount by which the case cost exceeds the standard MS-DRG payment, and the newness window is limited to two-to-three years.[16] The structure ensures that any single technology's contribution to NTAP spending is bounded and time-limited, with cost folded into the relative-weight calculation thereafter. The volume of alternative-pathway approvals, accordingly, reflects the volume of FDA Breakthrough Device designations being granted—not any deficiency in the pathway itself. CMS has not demonstrated that any approved alternative-pathway technology generated NTAP spending disproportionate to its clinical use, nor has CMS published utilization data comparing alternative-pathway and traditional-pathway technologies. Without that data, the implicit assumption that alternative-pathway approvals are driving inappropriate program growth is not supported by the record.

C. CMS should withdraw the repeal proposal and conduct a retrospective claims analysis of actual NTAP utilization.

ARM recommends that, before finalizing any policy change premised on projected NTAP expenditures, CMS conduct a retrospective claims analysis comparing actual utilization of NTAP-approved technologies to the manufacturer-supplied utilization projections submitted with each application. Such an analysis would allow CMS to determine the extent to which its projected program outlays actually reflect real-world experience versus applicant-supplied estimates. Specifically, ARM recommends CMS publish, through an RFI: (i) actual NTAP expenditures under the alternative pathway for FYs 2021–2025, broken out per technology; (ii) the variance between proposed-rule and final-rule projections for those years; and (iii) the ratio of actual to projected utilization for each alternative-pathway technology that has completed its newness window. That transparency would allow stakeholders and CMS alike to evaluate whether the pathway is in fact driving any disproportionate cost growth, or whether—as historical projection patterns strongly suggest—real-world NTAP utilization falls materially below applicant-supplied estimates.

To the extent CMS has identified specific concerns about evidence quality under the alternative pathway, the appropriate response is targeted refinement, not wholesale repeal of a policy that delivers FDA-vetted innovations to Medicare beneficiaries. Wholesale repeal is not narrowly tailored to any specific identified deficiency in the existing pathway and would foreclose patient access to technologies that the FDA has already singled out for special clinical urgency.

D. Narrowing opportunities to apply for NTAP could result in more limited patient access to innovative therapies. ARM reiterates its longstanding recommendation that CMS streamline NTAP designation for cell and gene therapies by expanding—not contracting—the alternative NTAP pathway to encompass additional FDA expedited-program designations.

[16] 42 C.F.R. § 412.88.

ARM is concerned that, by narrowing opportunities to apply for NTAP, CMS's proposal to repeal the alternative NTAP pathway could result in more limited patient access to innovative therapies. Even for manufacturers without current LPAD/QIDP products, eliminating this alternative pathway signals a move away from predictable, timely NTAP access for innovative therapies more broadly. This raises launch reimbursement and patient access uncertainty and potentially dampens investment in future high-need medical technologies.

Furthermore, ARM uses this rulemaking to reiterate that, even as CMS reconsiders the scope of the alternative pathway, the appropriate policy direction is expansion to additional FDA-vetted designations rather than wholesale withdrawal.

The NTAP program plays a crucial role in facilitating access to new and innovative technologies by providing additional reimbursement to hospitals for the costs associated with adopting these therapies. This is especially true for novel cell and gene therapies. CGTs hold immense promise for patients suffering from a range of conditions, including certain cancers, and rare diseases. However, hospitals can face a significant financial barrier to furnishing CGTs, which often require complex manufacturing processes, specialized infrastructure, and intensive monitoring. CGTs frequently provide therapies for patients and conditions with no other treatment options and can be highly individualized. When these and other new products are first available to Medicare patients, their costs are not adequately accounted for in IPPS rate-setting for at least two years after a product is introduced, due to the lag time associated with the rate-setting methodology. Thus, earning NTAP status can make it easier for hospitals to adopt a new technology and improve patient access to cutting-edge care.

In response to prior IPPS rulemakings and requests for information on how to reduce administrative burdens of the Medicare program on CMS and manufacturers, ARM has consistently urged CMS to streamline NTAP eligibility for FDA-designated Regenerative Medicine Advanced Therapies (RMATs) and Breakthrough Therapies by automatically deeming therapies with these designations as satisfying the NTAP program's "newness" and "substantial clinical improvement" criteria.[17] Each of these designations reflects an FDA determination that the technology addresses a serious or life-threatening condition and warrants expedited regulatory review. By way of their definition, the RMAT and BT designations are specifically geared to whether the therapy offers more innovative options for treatment than those currently

[17] Alliance for Regenerative Medicine, Comment Letter on Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2026 Rates; Requirements for Quality Programs; and Other Policy Changes (CMS-1833- P), June 10, 20205, available at: https://alliancerm.org/wp-content/uploads/2025/06/ARM-FY-2026-IPPS-CommentLetter-FINAL-1.pdf; Alliance for Regenerative Medicine, Comment Letter on Unleashing Prosperity Through Deregulation of the Medicare Program (Executive Order 14192) – Request for Information (RFI), June 10, 2025, available at: https://alliancerm.org/wp-content/uploads/2025/06/ARM-response-CMS-Medicare-DeRegulation-RFI-FINALformatted.pdf; Alliance for Regenerative Medicine, Comment Letter on Request for Information (RFI): Ensuring Lawful Regulation and Unleashing Innovation To Make American Healthy Again (AHRQ-2025- 0001), July 14, 2025, available at: https://alliancerm.org/wp-content/uploads/2025/09/ARM-Comments-on-HHS-RFI-on-Deregulation-AHRQ-2025-0001-FINAL.pdf.

available. The RMAT designation focuses on whether the applicant can demonstrate that a CGT "has the potential to address unmet medical needs for" the condition it is intended to treat. The BT designation likewise is reserved for therapies "for which preliminary clinical evidence indicates that the product may demonstrate substantial improvement over available therapies on one or more clinically significant endpoints."[18] Extending alternative-pathway treatment to these designations would advance the same access-promoting and clinical-urgency rationales that motivated CMS's establishment of the Breakthrough Device and QIDP/LPAD pathways in the first instance, reflect the rigorous evidentiary standards required for such designations, and reduce unnecessary administrative burdens for both applicants and CMS in evaluating the NTAP program's "newness" and "substantial clinical improvement" criteria. We refer CMS to ARM's prior comments on the IPPS for additional recommendations on how to streamline the NTAP program.

If CMS proceeds with the proposed withdrawal, the resulting disruption to investment decisions in innovative medicines including but not limited to CGTs could be substantial. Biotechnology firms have made multi-year commercialization commitments in reliance on the alternative pathway, and abrupt withdrawal of that pathway will reorient capital away from the high-risk, long-duration development programs that produce transformative therapies. That outcome would directly undermine the United States' ability to compete with the People's Republic of China, which has made CGT a national strategic priority and is rapidly closing the gap with U.S. innovators on critical lifesaving therapies.[19] CMS should not finalize a policy that disadvantages U.S.-developed innovation at the precise moment when sustained investment incentives are most needed to maintain American leadership in advanced medicines.

IV. CMS SHOULD NOT CONSTRICT THE RECOGNITION OF "COMMERCIAL AVAILABILITY" DELAYS IN CALCULATING THE NEWNESS PERIOD.

CMS proposes to limit recognition of post-FDA commercial-availability delays to the period before a technology's NTAP becomes effective, such that for a technology not yet commercially available when its NTAP takes effect, the newness period would be deemed to begin on September 30 preceding the NTAP start date.[20] CMS explains that, although it has historically recognized a date later than FDA marketing authorization as the start of the 2- to 3-year newness period where an applicant documents an actual post-approval delay in availability, the increasing volume and complexity of asserted delays—combined with CMS's recent policy extending NTAP for an additional fiscal year when the 3-year anniversary falls on or after October 1—could allow technologies to remain NTAP-eligible for four or more years and could permit applicants to indefinitely postpone commercial availability

[18] See FDA, Expedited Programs for Regenerative Medicine Therapies for Serious Conditions – Guidance for Industry, February 2019, available at: https://www.fda.gov/media/120267/download.

[19] CTGT/ATMP Clinical Trials Surge in China, as First Stem Cell Therapy Product is Conditionally Authorized, Hogan Lovells (Sept. 30, 2025), https://www.hoganlovells.com/en/publications/ctgtatmp-clinical-trials-surge-in-china-as-first-stem-cell-therapy-product.

[20] 91 Fed. Reg. at 19402

for business reasons while the technology (and others sharing the same codes) continues to receive add-on payments.

ARM appreciates CMS's concerns, but does not believe that a blanket policy constricting the availability of a later newness start date based on "commercial availability" across all NTAP candidate products is the appropriate solution—particularly because CMS has not provided any evidence that this standard is in fact being exploited by NTAP applicants. ARM accordingly recommends that CMS withdraw this proposal and continue to rely on a case-by-case assessment of whether a particular newness start date warrants application of the "commercial availability" standard. ARM's rationale is set forth below.

A. Cell and gene therapies routinely face legitimate commercial-launch lags that are not addressed by the proposed cap.

Cell and gene therapy commercial launches frequently lag FDA marketing authorization due to manufacturing scale-up, treatment-center certification (e.g., REMS authorization), payer contracting, distribution-network establishment, and corporate transactions affecting the launch timeline. These lags are not pretextual; they reflect the operational realities of administering personalized CGT products that require specialized infrastructure at the site of care. A CGT launched immediately upon FDA marketing authorization, without the necessary site-certification and distribution infrastructure in place, would be no more accessible to Medicare beneficiaries than one not yet approved.

CMS's blanket application of a restrictive policy for implementing its "commercial availability" standard ignores these class-specific characteristics and effectively penalizes manufacturers for conducting the operational due diligence necessary to commercialize a CGT responsibly. The proposal disproportionately penalizes the most innovative—and most operationally complex—technologies, because those technologies have the longest legitimate post-approval launch timelines.

B. CMS's existing framework already protects against abuse without the proposed cap.

ARM also questions why the current framework is inadequate. Existing NTAP guidance requires applicants to document and explain any delay between FDA marketing authorization and commercial availability, and CMS retains discretion to scrutinize claimed delays on a case-by-case basis. Capping the recognized delay at the NTAP-effective date for the applied-for fiscal year would reach legitimate launch timelines indistinguishably from any abusive ones.

Although CMS cites an "increasing volume and complexity" of applicant-asserted commercial-availability delays, the agency does not point to a single instance in which a recognized delay turned out to be inappropriate. The proposal effectively treats the rising number of requests as evidence that the standard is being manipulated, without any record support for that inference. And to the extent CMS's underlying concern is that recognizing a documented delay could push NTAP eligibility beyond three years, the appropriate response is case-by-case denial

where that risk is present—not a blanket rule that penalizes every applicant with a legitimate post-approval launch delay.

Rather than introducing barriers to CGT innovation and commercialization, we encourage CMS to focus on reforms that unlock the intended impact of the NTAP program while doing so in a fiscally and administratively responsible way.

V. CMS Should Adopt Transparent, Prospective Criteria for MS-DRG 018 Assignment and Solicit Stakeholder Input on the Assignment of CGTs into the MS-DRG System More Broadly as the Cell-and-Gene Therapy Landscape Continues To Evolve.

CMS proposes to maintain the designation of ICD-10-PCS code XW033DA (administration of donislecel-jujn (LANTIDRA™)) as a non-O.R. procedure that does not map to MS-DRG 018, on the basis that islet cell transplantation is, in CMS's view, clinically distinct from CAR T-cell and other immunotherapies.[21] CMS reiterates that the category of cell and gene therapies "continues to evolve" and that it is "carefully considering" stakeholder feedback on the appropriate methodology, but proposes no change to the underlying MS-DRG 018 assignment framework.[22]

ARM does not take a position on the specific clinical determination as to LANTIDRA, but uses this proposal as an opportunity to raise an ongoing, structural concern: CMS lacks a transparent, predictable, and clinically coherent framework for determining which cell and gene therapies map to MS-DRG 018 versus other MS-DRGs. That opacity makes it difficult for manufacturers to anticipate MS-DRG mapping during development, complicates economic modeling, and creates payment volatility that ultimately affects patient access. ARM accordingly urges CMS to develop and publish, through notice-and-comment rulemaking, prospective criteria for MS-DRG 018 assignment as the cell-and-gene therapy product landscape continues to expand. In addition, ARM recommends that the RFI solicit input on the broader assignment of CGTs into the MS-DRG system and additional opportunities to improve Medicare inpatient reimbursement for other existing and future CGTs as the field evolves. ARM's rationale is set forth below.

A. ARM urges CMS to issue a request for information on the future structure of MS-DRG system, including but not limited to MS-DRG 018

ARM believes it is urgent for CMS to begin laying the groundwork for a potential restructuring of the MS-DRG system. To ensure MS-DRG assignments support stability in hospital reimbursement and patient access, CMS should seek consistency and predictability regarding MS-DRG assignment for CGTs. This is particularly important for MS-DRG 018. As more therapies enter the market with significantly different clinical profiles, care pathways, or cost characteristics, the internal coherence of MS-DRG 018 is being challenged. Substantial variation in the average cost or complexity of these therapies could result in payment misalignment

[21] 91 Fed. Reg. at 19367.

[22] *Id.*

and weaken the MS-DRG's ability to function as a clinically and financially rational payment mechanism.

To that end, ARM urges CMS to issue a Request for Information (RFI) seeking public input on the criteria and policy considerations that should guide any future decision to split MS-DRG 018 into more tailored groupings. Specifically, we encourage CMS to solicit feedback on potential thresholds for clinical similarity, treatment complexity, or cost and resource use heterogeneity that would justify a split; how medical versus surgical modes of administration might be considered; whether minimum case volumes should be required; and how such a split could be implemented without disrupting predictability or access for providers and patients. An RFI would provide an important opportunity for CMS to gather data and stakeholder perspectives on how best to preserve the integrity of inpatient payment policy as the mix of therapies assigned to MS-DRG 018 continues to evolve. If therapies with disparate costs or different care profiles are assigned to MS-DRG 018, then the DRG-based payment rate may decline over time, which would pose a barrier to Medicare beneficiaries receiving needed care, including treatment with CAR T for which the MS-DRG 018 was originally intended. CMS should also gather stakeholder input on longer-term payment solutions for CGTs as the field continues to evolve and impact the clinical coherence of other MS-DRGs that include CGTs, such as MS-DRG 016.

ARM believes that a transparent and forward-looking process, grounded in public input, will best equip CMS to balance flexibility for innovation with the need for MS-DRG groupings that remain coherent in terms of resource utilization and clinical characteristics.

B. ARM urges CMS to solicit feedback in the RFI on specific transparency and procedural issues associated with a MS-DRG 018 assignment process.

As submitted in prior rulemakings, ARM urges CMS to take several steps to improve transparency and stakeholder engagement. CMS can solicit feedback on these specific provisions as part of an RFI.

First, ARM recommends a substantive reform: CMS should formalize and publish the criteria it uses to evaluate whether a given therapy is appropriately mapped to MS-DRG 018 or to another DRG. These criteria should address not only the procedural characteristics and care setting associated with the therapy, but also expected resource intensity, patient acuity, and therapeutic class. While ARM recognizes that CMS must often make initial MS-DRG assignment decisions in the absence of mature claims data, greater clarity on the qualitative or proxy factors that inform these determinations would substantially enhance confidence in the process.

Second, ARM urges CMS to adopt a procedural reform by establishing a formal mechanism through which stakeholders may provide timely input on proposed DRG assignments for new cell and gene therapies—ideally *before* final mapping decisions are published in the IPPS final rule. The current lack of visibility into mapping proposals associated with new ICD-10-PCS codes discussed at the Fall and Spring

Coordination and Maintenance (C&M) Committee meeting significantly limits meaningful stakeholder engagement. As highlighted by commenters, the absence of a forum to comment on MS-DRG assignment decisions for new codes until after the proposed rule is released, by which time the assignments may already be effectively finalized, undermines stakeholders' ability to be informed about issues that directly affect their reimbursement and beneficiary access to this class of innovative technologies.

As an example, CMS could dedicate space in each IPPS proposed rule to identify relevant ICD-10-PCS codes that might be assigned to MS-DRG 018, along with preliminary rationales for these potential assignments. This approach is especially warranted for MS-DRG 018, which uniquely derives its assignment logic primarily from the therapeutic intervention rather than diagnosis, making its composition almost exclusively dependent on the nature of the underlying technology. The tentative nature of ICD-10-PCS procedure code requests should not prevent such preliminary discussions, as the IPPS proposed rule is inherently designed to provide public notice on items under consideration by the agency. To clarify the tentative nature of this notice, CMS could include appropriate disclaimers that its discussion of assignment logic for specific codes is informational and subject to revision if additional information warrants different assignment decisions. Such disclaimers would advance the current Administration's goals of improving government transparency, as reflected in recent Executive Orders regarding accountability and information sharing.

C. ARM proposes specific topics on which CMS should solicit feedback through the RFI.

ARM recommends that the RFI solicit input on the following structural/procedural questions, as well as broader opportunities to improve Medicare reimbursement for existing and future CGTs as the field evolves. The goal of these questions is to generate an empirical record needed to evaluate not only the potential restructuring of MS-DRG 018, but the broader assignment of CGTs into the MS-DRG system – including but not limited to MS-DRG 018, 016, and any new MS-DRG.

ARM has organized the topics around the two foundational principles that govern DRG creation and assignment— resource use and clinical coherence —with additional categories addressing the operational variables that distinguish current and emerging CGTs used in the inpatient setting.

i. Resource Utilization

- Given the range and unique nature of current CGTs and CGTs in the pipeline, how do you expect the resource utilization for therapies grouped within the MS-DRG system, including MS-DRG 016 and MS-DRG 018, to diversify over time?
- What measures of resource use should CMS consider in determining whether existing or new cell and gene therapies are appropriately grouped together— for example, average cost per case, average length of stay (overall and ICU),

staffing intensity, pharmacy resource use, or use of intensive monitoring services?
- At what threshold of cost or resource heterogeneity within a MS-DRG should CMS consider that the relative weight no longer reflects the average resources required to care for cases in the DRG, such that a split or re-mapping is warranted?
- Should the geometric mean length of stay continue to be used as the principal length-of-stay metric for a MS-DRG that includes CGTs, or would a different metric better reflect the length-of-stay distributions emerging in this category?
- How should CMS treat the substantial cost of the biological product itself in resource-utilization analysis, given that product acquisition cost may dominate the per-case cost calculation and obscure differences in clinical resource use across therapies?
- How should CMS account for resource use associated with conditioning regimens, donor apheresis (in the allogeneic context), HLA matching, infusion versus surgical administration, post-infusion monitoring, complication management, and other ancillary services, each of which may not scale uniformly with the underlying cell or gene therapy?

ii. Clinical Coherence

- Given the range and unique nature of current CGTs and CGTs in the pipeline, such as emerging CGTs for neurodegenerative diseases and the broader autoimmune space, how do you expect CGTs to diversify over time and impact clinical coherence of MS-DRGs 018, 016, and any other MS-DRGs that include CGTs?
- What clinical features should CMS consider in determining whether two cell or gene therapies are sufficiently similar in terms of treatment complexity and clinical similarity to be grouped within a single MS-DRG—for example, mechanism of action, target cell population, indicated patient population, line of therapy, or curative versus chronic intent?
- Should mechanism of action (e.g., chimeric antigen receptor T-cell engineering, T-cell receptor engineering, gene editing, gene replacement, gene addition, ex vivo cell expansion, or in vivo gene transfer) serve as a primary or secondary axis of clinical coherence within a CGT MS-DRG like MS-DRG 018, and if so, how should CMS distinguish among these mechanisms in mapping ICD-10-PCS codes?
- How should CMS treat allogeneic versus autologous cell therapies for purposes of clinical coherence, given the substantially different patient-selection criteria, donor-sourcing requirements, immunologic risk profiles (e.g., graft-versus-host disease in allogeneic settings), and post-infusion monitoring obligations associated with each?
- How should CMS treat ex vivo gene therapies (in which cells are modified outside the body and reinfused) versus in vivo gene therapies (in which a vector is administered directly to the patient) for purposes of clinical coherence, given that the inpatient course associated with each can differ materially?

- How should CMS treat CGT regimens administered via infusion versus surgery within the clinical-coherence framework?
- How should CMS treat single-infusion versus multi-dose or staged-administration regimens within the clinical-coherence framework?

iii. Volume, mode of administration, and additional questions.

- What minimum case-volume threshold should be required before CMS creates a new MS-DRG (or splits an existing MS-DRG) for a cell or gene therapy, and how should CMS balance the statistical reliability that comes with higher volumes against the access concerns that arise when low-volume but high-resource therapies are grouped with dissimilar therapies? How should CMS account for low case-volume associated with many CGTs (both in MS-DRG creation and DRG rate-setting)? Are there alternative sources for substantiating case-volume requirements?
- Should MS-DRG 018 continue to derive its assignment logic primarily from the therapeutic intervention (i.e., the ICD-10-PCS procedure code), or should CMS consider hybrid logic that also incorporates principal diagnosis, particularly as cell and gene therapies expand into non-oncology indications?
- How should CMS treat the O.R. versus non-O.R. designation of administration codes for cell and gene therapies, given that most CAR T-cell and similar products are administered as infusions that do not require an O.R. but nonetheless involve substantial peri-infusion clinical resources?
- What stakeholder-engagement process should CMS adopt for any future split, re-mapping, or restructuring of MS-DRG 018, including whether such changes should be preceded by a dedicated RFI cycle, by a separate proposed rule, or by both?
- How should CMS coordinate any future restructuring of MS-DRG 018 with related payment policies, including the MS-DRG 018 clinical-trial relative-weight methodology, NTAP applications and approvals for cell and gene therapies, and the OPPS treatment of cell and gene therapy products administered in the outpatient setting?

iv. Other Medicare reimbursement policy issues

- For providers and hospitals groups, what challenges have you faced in seeking reimbursement for new CGTs? How could CMS mitigate charge compression and reduce the reliance on outlier dollars as CMS considers future payment reforms for MS-DRG 018? Are there costs that you incur, such as for apheresis or other ancillary services, that CMS's current reimbursement policy does not adequately address? What steps can CMS take to improve the adequacy and predictability of reimbursement as any future changes to MS-DRG 018, and CGT-related MS-DRGs more broadly, are implemented?
- For manufacturers, what has been your experience in navigating Medicare reimbursement in bringing CGTs to market? And are there other challenges CMS should consider addressing within the MS-DRG system, such as CMS's historical approach to bundling the costs of ancillary services into reimbursement for the drug?

- What other Medicare reimbursement and access challenges do you anticipate based on the pipeline of CGTs coming to market?
- What improvements could CMS consider to the NTAP program to better account for the investments in staff, training, and infrastructure that an inpatient hospital may need to make to administer novel CGTs (e.g., increasing the add-on payment beyond 65%, or 75% in some instances)? Are there other improvements CMS should consider to improve the NTAP program?

The questions identified above are not intended to be exclusive; they are intended to anchor the RFI in the statutory and regulatory criteria that govern MS-DRG creation and assignment, and to ensure that any future restructuring of MS-DRG 018 is grounded in the empirical and clinical realities of the CGT landscape rather than in claims-data inertia.

VI. CMS Should Confine the Proposed Reasonable-Cost Language to Inpatient Cost Allocation and Should Not Treat It as a Determination That Hospital Preparatory Service Costs for CGTs Like Apheresis Are Already Reimbursed.

CMS proposes to codify at 42 C.F.R. § 413.24(d)(8) that the CAR T-cell biologic purchase price "includes costs for the complete process of extracting and preparing the biological for infusion," and on that basis to exclude the purchase price from the accumulated-cost statistic on Worksheet B-1 of the Medicare Cost Report.

ARM does not object to the technical accounting outcome the proposal seeks to achieve. ARM is concerned, however, that the rationale CMS has offered to support the proposal—namely, that the manufacturer's purchase price is "fully loaded" and already encompasses "the complete process of extracting and preparing" the biological for infusion—rests on factual assumptions that do not withstand scrutiny across the full range of CGT products now reaching the Medicare population. ARM urges CMS to confine the proposed § 413.24(d)(8) language to its inpatient cost-allocation function and to expressly disclaim any broader determination that hospital apheresis costs or other CGT-related preparatory services are reimbursed through the manufacturer's purchase price. ARM's concerns with the "fully loaded price" rationale, and the ways in which that rationale fails to reflect current cell-therapy economics, are set forth below.

A. CMS's "fully loaded price" rationale rests on assumptions about manufacturer pricing structure that do not hold across the cell and gene therapy landscape.

CMS's proposed regulatory text, and the preamble discussion that accompanies it, treat the CAR T-cell biologic purchase price as if it were a single, vertically integrated price that necessarily encompasses every input upstream of inpatient infusion—including, expressly, "the complete process of extracting and preparing the biological for infusion." That premise does not align with the underlying transactional reality.

In current commercial practice, the entity that infuses the cell therapy product (the treating hospital) and the entity that collects the patient's starting material (the apheresis provider) may not be the same organization, and the manufacturer's price to the infuser does not, as a uniform matter, fold in the collector's full cost stack. Some manufacturers have developed a range of contractual structures—including bona fide service fee arrangements with third-party apheresis organizations, standalone apheresis-center qualification agreements, and direct payments for collection logistics and shipping—each of which may sit outside of, and be priced separately from, the biologic purchase price the hospital sees on its invoice. CMS's recent OPPS rulemaking activity, including the proposed (and ultimately withdrawn) treatment of manufacturer payments to third-party apheresis organizations as ASP price concessions in the CY 2025 OPPS rulemaking cycle, reflects CMS's own awareness that apheresis economics ride on a separate transactional rail from the biologic price.

Because the infuser and the collector can be—and increasingly are—separate entities, treating the manufacturer's purchase price as conclusively "fully loaded" with respect to extraction and preparation costs systematically overstates what that price actually pays for. The hospital that performs apheresis on a Medicare beneficiary incurs nursing labor, procedure-room time, supplies, scheduling and EHR infrastructure, billing infrastructure, and quality-and-compliance overhead in furnishing that service to the beneficiary. Whether and to what extent the manufacturer's price to the infuser reimburses those costs depends entirely on the collector-manufacturer contract structure for the specific product—a transactional layer that the proposed regulatory text and preamble discussion do not engage with at all.

B. CMS should adopt the proposed § 413.24(d)(8) language only as an inpatient cost-allocation rule and disclaim any broader determination about reimbursement for CGT preparatory services such as apheresis.

ARM accordingly urges CMS to take two steps. First, in this rulemaking, CMS should adopt the proposed § 413.24(d)(8) language only as an inpatient cost-allocation rule, and clarify on the record that the language does not constitute a determination that the manufacturer's purchase price reimburses hospitals for the cost of apheresis or other CGT preparatory services they furnish to Medicare beneficiaries. Specifically, ARM urges CMS to state expressly in the preamble to the final rule that (i) the phrase "the complete process of extracting and preparing the biological for infusion" describes the manufacturer-side activities embedded in the biologic purchase price; (ii) it does not adjudicate whether, or to what extent, hospital-side apheresis costs or the costs of other CGT preparatory services and procedures are reimbursed through that price; and (iii) the cost-allocation rule at § 413.24(d)(8) does not displace, modify, or resolve the longstanding reimbursement questions that ARM and others have raised in successive IPPS and OPPS rulemaking cycles regarding preparatory services for all cell and gene therapies such as apheresis, biopsy, and surgical removal**.** That clarification would prevent the proposed language from being read more broadly than its cost-allocation function requires and would preserve CMS’s flexibility to revisit reimbursement apheresis

and other CGT preparatory services on its own merits rather than allowing that question to be foreclosed by an inpatient cost-allocation rulemaking that did not squarely confront it.

Second, as discussed above, the patient journey from cell collection to infusion can vary, with steps occurring in both inpatient and outpatient settings, and across unrelated providers. Assuming that the cost of the product is itself a "fully loaded" cost, underestimates the provider work and patient journey across these regimens. Therefore, in the next OPPS rulemaking cycle, we urge CMS to authorize adequate separate payment for outpatient apheresis associated with CAR T-cell therapy as well as other preparatory services associated with CGTs. Outpatient separate payment is the appropriate vehicle because outpatient is where apheresis is actually furnished and where it is already tracked through CPT-based coding. ARM recognizes that the design of any such payment must coordinate with the existing manufacturer BFSF channel to avoid duplicative compensation for the manufacturer-procurement layer of apheresis economics, and ARM stands ready to work with CMS on a payment design that compensates hospitals for the costs they actually incur in furnishing outpatient apheresis or other CGT preparatory services to Medicare beneficiaries while preserving the integrity of CMS's product-payment and ASP frameworks.

VII. CMS SHOULD USE THE IPPS RULEMAKING TO ADDRESS INCORPORATION OF MEDICARE ADVANTAGE NEGOTIATED RATES INTO THE MS-DRG RELATIVE WEIGHTS

In the CY 2026 OPPS final rule, CMS finalized a market-based methodology for calculating IPPS MS-DRG relative weights that will incorporate median payer-specific negotiated charges between hospitals and Medicare Advantage Organizations (MAOs).[23] Under the finalized policy, hospitals paid under the IPPS will be required to report median MAO-negotiated charges by MS-DRG on the Medicare Cost Report beginning with FY 2026 cost reports, and CMS will incorporate that data into MS-DRG relative weight calculations beginning in FY 2029.[24] The finalized policy marks a significant shift in inpatient rate-setting policy.

ARM opposed the proposal in its comments on the CY 2026 OPPS proposed rule, on the grounds that (i) MAO-negotiated rates and Medicare fee-for-service ("FFS") rates are not comparable as a methodological matter; (ii) MAO rates reflect private-sector cost-management mechanisms (including selective contracting, prior authorization, step therapy, and other utilization controls) that are not available under FFS Medicare; (iii) the populations enrolled in Medicare Advantage and FFS differ in ways that materially affect cost structure and utilization; and (iv) once MAO rates are incorporated into MS-DRG weights, the resulting effects on payment adequacy will be difficult to disentangle or reverse. ARM urged CMS to, before finalizing any policy that could affect MS-DRG weights for these treatments, conduct additional impact analyses specific to high-cost therapies like CGTs, and to take a more cautious approach that preserves current rate-setting methodologies

[23] 90 Fed. Reg. 53448, 54013 (Nov. 25, 2025).
[24] *Id.*

while exploring more targeted improvements. ARM remains concerned, in particular, that the policy risks systematically understating the resource intensity of inpatient cases involving CGTs—cases that are concentrated in MS-DRG 018 and a small number of related DRGs, and that disproportionately involve high-acuity FFS beneficiaries whose care needs may not be reflected in MAO utilization patterns.

Notwithstanding the substantive concerns ARM and others raised in the OPPS comment cycle, CMS finalized the policy as proposed. ARM raises the policy here, in the FY 2027 IPPS rulemaking cycle, because the policy operates on a payment instrument established under the IPPS and because the FY 2027 IPPS proposed rule, which is the next IPPS rulemaking vehicle following CMS's finalization of the policy, is silent on the policy's status, implementation timeline, methodological details, and projected effects on MS-DRG relative weights. That silence is difficult to reconcile with the basic notice-and-comment expectations, and it leaves stakeholders without a meaningful opportunity to engage CMS on the implementation choices that will determine whether the policy can be operationalized in a manner that preserves payment adequacy for high-cost, FFS-concentrated therapies.

Going forward, ARM urges CMS to address all aspects of MS-DRG relative weight methodology—including the implementation of the MAO-negotiated-rate policy, any future modifications to that policy, and any related methodological choices—through the IPPS rulemaking cycle. The annual IPPS proposed and final rules are the established and statutorily contemplated vehicles for changes to MS-DRG classifications and relative weights, and they are the rulemaking cycles that stakeholders expect to monitor for changes affecting inpatient payment.

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ARM appreciates the opportunity to comment on the FY 2027 IPPS Proposed Rule and reiterates its commitment to working with CMS to develop payment policies that support patient access, reward innovation, and sustain U.S. leadership in the development and delivery of cell and gene therapies. The recommendations set forth above are intended to ensure that the FY 2027 IPPS final rule advances consistent, clear, and dependable reimbursement systems that enable innovators to commercialize transformative treatments, healthcare providers to administer them confidently, and ensure timely access for patients— especially Medicare beneficiaries. As the CGT pipeline continues to expand into conditions affecting broader Medicare populations, CMS has an opportunity to establish payment policies that promote access while maintaining fiscal responsibility, and ARM stands ready to engage further with CMS on each of the topics addressed in these comments.

We thank CMS for its consideration of our comments. Please contact me at ddavenport@alliancerm.org with any questions.

Sincerely,

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