ASTCT
American Society for
Transplantation and Cellular Therapy

This document contains submitted ASTCT comments and selections from CMS' responses in the FY 2026 Medicare Hospital OPPS Final Rule, dated November 25, 2025. As such, the Executive Summary has been removed from this version.

Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

September 15, 2025

SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

RE: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Overall Hospital Quality Star Ratings; and Hospital Price Transparency [CMS-1834-P]

Dear Administrator Oz:

The American Society for Transplantation and Cellular Therapy (ASTCT) is pleased to submit the following comment letter regarding the CY 2026 OPPS Proposed Rule.

ASTCT is a professional membership association of more than 3,900 physicians, scientists, and other health care professionals promoting hematopoietic stem cell transplantation (SCT) and cellular therapy through research, education, scholarly publication, and clinical standards. Our Society's clinical teams have been instrumental in developing and implementing clinical care standards and advancing cellular therapy science, including participation in trials that led to current Food and Drug Administration (FDA) approvals for chimeric antigen receptor T-cell (CAR-T) therapy and hematopoietic stem cell (HSC) gene therapies for genetic immune system and blood disorders. For more than 25 years, ASTCT members have focused on innovation in the treatment of hematologic malignancies, hematologic disorders, and other immune system diseases.

ASTCT would welcome the opportunity to meet with CMS and discuss ways to improve payment for CAR-T, SCT, and gene therapies.

If CMS has any questions regarding these comments, please contact Molly Ford, ASTCT's Director of Government and Payer Relations, at mford@astct.org.

David Porter, MD
President, ASTCT
2025-2026

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

ASTCT
American Society for
Transplantation and Cellular Therapy

Table of Contents

Autologous Cell-based Immunotherapy and Gene Therapy (autoCGT) Proposal 3

Exclusion of Cell and Gene Therapies From the C–APC Policy 4

Method to Control Unnecessary Increases in the Volume of Outpatient Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs) 5

Request for Information (RFI): Expanding the Method to Control for Unnecessary Increases in the Volume of Covered HOPD Services to On-campus Clinic Visits 9

Changes to the Inpatient Only List 10

Proposed Updates to Requirements for Hospitals to Make Public a List of Their Standard Charges 11

Proposed Market-Based MS–DRG Relative Weight Data Collection and Change in Methodology for Calculating MS–DRG Relative Weights Under the Inpatient Prospective Payment System 13

Request for APC Reconfiguration and Status Indicator Changes 20

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

This document contains submitted ASTCT comments and selections from CMS' responses in the FY 2026 Medicare Hospital OPPS Final Rule, dated November 25, 2025. As such, the Executive Summary has been removed from this version. Selected comments are excerpts; members are encouraged to read CMS' full commentary in the Final Rule.

Autologous Cell-based Immunotherapy and Gene Therapy (autoCGT) Proposal

CMS requested comments about a series of proposals related to payment for cell collection and the calculation of Average Sales Price (ASP) in the Medicare Physician Fee Schedule (MPFS) PR. ASTCT submitted our comments to CMS as part of that rulemaking process and is including a summary here due to its implications for payment within OPPS, as well.

ASTCT has repeatedly advocated for separate payment for the clinical services associated with cell collection. **ASTCT once again requests that CMS recognize the Category I CPT codes released by the American Medical Association for cell collection and cell processing services (38225-38227) and provide separate payment for them by changing their assigned status indicator of "B" to status indicator "S".**

In keeping with this view, ASTCT does not support CMS' proposals to include cell collection costs in a product's payment or to treat fees associated with cell collection as price concessions.

Providers are not typically engaged in the complexities of ASP calculations and have no knowledge of the types and scope of arrangements CMS is proposing to define as price concessions. The arrangements between a manufacturer and its distributor(s), data partner(s), and other fee-based contractors are proprietary and outside the sphere of influence for any clinical service provider. Additionally, given the personalized nature of autoCGTs, there are very few discounts available to purchasing providers, creating a situation where ASP and acquisition costs have been essentially equal.

If CMS' proposed price concession assumptions drive the absolute value of ASP+6% down significantly, providers will face a net negative impact on payment when these products are used to treat Medicare beneficiaries. Without a mechanism to understand the net impact to ASP, providers of autoCGTs are left with no choice but to protest the set of proposals in its entirety.

In its proposal to treat payment for cell collection as a price concession, CMS states that these clinical services are *"part of the COGS"* (Cost of Goods Sold) for these products. This does not make sense, since a required manufacturing step cannot also be a discretionary post-production concession to its purchase price. ASTCT suspects that CMS is making the assumption that manufacturers are paying infusing providers for cell collection and, therefore, an equivalent amount should be reduced from the ASP-based payment to the provider.

From an operationalization perspective, finalization of these proposals as written would create an astounding level of provider questions related to compliance, billing, and cost reporting. There is no feasible way to seek and receive guidance on these issues in time for a January 1, 2026 effective date.

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

Access to autoCGTs for Medicare beneficiaries will decrease dramatically if provider payment is forced below the costs of acquiring these unique therapies, as would likely be the case with the current proposals. ASTCT understands CMS' focus on drug pricing, but there are other ways to seek partnership with manufacturers and providers beyond implementing negative pressure on ASP methodology.

ASTCT asks CMS to refrain from finalizing any proposals associated with ASP calculation in this year's final rule and carefully consider stakeholder feedback before proposing further adjustments in forthcoming policy cycles.

CMS Response: *In the CY 2026 PFS proposed rule (90 FR 32546 through 32547), CMS proposed that (1) preparatory procedures for tissue procurement required for manufacturing an autologous cell-based immunotherapy or gene therapy be included in the payment of the product itself and (2) that, beginning January 1, 2026, any preparatory procedures for tissue procurement required for manufacturing an autologous cell-based immunotherapy or gene therapy that were paid for by the manufacturer be included in the calculation of the manufacturer's ASP. As stated in the CY 2026 OPPS/ASC proposed rule (90 FR 33649 and 33650), we made readers aware of this proposal as it may impact therapies paid under the OPPS and ASC payment system. We directed readers to submit their comments on this topic to the CY 2026 PFS proposed rule. We stated that comments submitted to the PFS rule will be responded to in the CY 2026 PFS final rule with comment period along with the finalized policy. We refer readers to the CY 2026 PFS final rule with comment period for a summary of comments, our responses, and the finalized policy for CY 2026.* [FR 5378]

[A note to ASTCT readers: CMS did not finalize its MPFS proposal to treat manufacturer payments to providers for patient-specific preparatory procedures as price concessions within the ASP calculation. The 2026 MPFS ASTCT comment letter that includes CMS' responses and final policies on this issue is available at https://www.astct.org/Advocacy/Policy-Letters-and-Statements]

Exclusion of Cell and Gene Therapies From the C–APC Policy

In the CY 2025 Final Rule, CMS finalized a policy to not package payment for cell and gene therapies into C–APCs when those cell and gene therapies are not functioning as integral, ancillary, supportive, dependent, or adjunctive to the primary C–APC service. ASTCT continues to appreciate and support this policy. In this year's PR, CMS stated the following: "*For new cell and gene therapy products that are not integral, ancillary, supportive, dependent, or adjunctive to any C–APC primary service, we will continue to add their product specific HCPCS codes, when created, to the C–APC exclusion list*."

ASTCT supports this process improvement, as it no longer requires individual stakeholders to advocate for addition to the list when the pass-through status time period concludes.

Similarly, we ask that CMS provide more information about how stakeholders with HCPCS codes established before this practice should request their code be added to the exclusion list off-cycle from the rulemaking period so they do not have to wait a full year and risk being caught up in the standard methodology. For example, HCPCS code Q2056 for ciltacabtagene autoleucel (a CAR-T therapy) is listed in the July 2025 Addendum B file with a *, indicating a change from pass-through status (SI of "G") to a status indicator of "K." Because CMS did not include Q2056 in the proposed exclusions table published

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

with the rule, the assignment of status indicator "K" for CY 2026 would mean the code would be subject to the standard C-APC methodology, despite it being a CGT that meets the finalized parameters for exclusion.

Therefore, ASTCT requests that HCPCS code Q2056 be added to the exclusions table and that CMS share a preferred process for how CGT stakeholders with codes about to lose pass-through status are to request being added to the exclusions list off-cycle from the rulemaking process.

CMS Response: ***Comment:*** *A few commenters asked for CMS to add HCPCS code Q2056 (Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose) to this list of Cell and Gene Therapies excluded from C–APC packaging for CY 2026. Commenters noted that this product's pass-through status expired June 30, 2025, and that it was previously indicated as a cell and gene therapy that would be excluded from C–APC packaging. Several commenters asked CMS to be vigilant with adding new products as they are approved and to introduce a formal process for the public to alert CMS that there is a new cell and gene therapy HCPCS code that should be excluded from payment.*

Response: *We thank commenters for recommending the addition of HCPCS code Q2056 to the cell and gene therapy C–APC exclusion list. This HCPCS code has been added to the table of cell and gene therapies excluded from C–APC packaging for CY 2026. We want to clarify for commenters, that although HCPCS code Q2056 was omitted from the CY 2026 OPPS/ASC proposed rule table, the code was excluded from C– APC packaging effective July 1, 2025, after its drug pass-through status expired. Per our finalized policy in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93932 through 93938), for new cell and gene therapy products that are not integral, ancillary, supportive, dependent, or adjunctive to any C–APC primary service, we will continue to add their product specific HCPCS codes, when created, to the C–APC exclusion list. We review products that are updated through the quarterly process to determine if there are qualifying cell and gene therapies that should be excluded from C–APC packaging. We welcome readers to contact us if they have a suggestion of a new qualifying cell and gene therapy that should be excluded from C–APC packaging. We note that we did not make a proposal to alter the substance of the overall policy excluding cell and gene therapies from the C–APC packaging; consistent with public comments received, we are continuing this policy for CY 2026. In response to comments, the finalized list of qualifying products can be found in Table 3 consistent with our finalized policy in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93932 through 93938).* [FR 53471]

Method to Control Unnecessary Increases in the Volume of Outpatient Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs)

ASTCT understands and supports CMS' mission to ensure that care for Medicare beneficiaries is delivered in the most cost-efficient way possible. We also appreciate the agency's goals of ensuring Medicare beneficiaries, especially those who are chronically ill and receiving high levels of care, are not subject to needlessly high co-pays. **ASTCT disagrees, however, with the agency's proposal to use its authority to reduce the payment of 61 HCPCS codes that are assigned to drug administration APCs provided in excepted off-campus PBDs.**

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

Congress grandfathered certain off-campus provider-based departments (PBDs) under the Bipartisan Budget Act of 2015 such as those that billed Medicare for outpatient services before November 2, 2015, and created additional exemptions subsequently under the 21st Century Cures Act, such as on-campus PBDs, dedicated emergency departments, cancer hospitals, and those under construction when the law was enacted. These exemptions were in part due to Congress recognizing that the patients treated in these locations were different from those seen in free-standing physician offices and/or newly built or acquired locations. This proposal, if finalized, would effectively reduce the payment hospitals receive for these services to 40% of the APC rate. Therefore, CMS should not finalize applying the PFS equivalent payment rate to these locations.

ASTCT also disagrees with CMS' premise that there has been an "unnecessary increase in volume" – meaning that CMS believes that beneficiaries who can safely receive drug administration in a lower-cost setting are instead receiving services in a higher-paid setting due to payment incentives created by higher OPPS rates. This ignores multiple facts about care provision in the United States – primarily, that hospitals do not scout for patients; rather, patients are referred by physicians to hospitals and physicians order the services patients receive at certain locations based on their care needs. This typically means that hospitals treat patients who are sicker than those who are seen in physician's offices, *per physician directive*. This is especially true for drug administration services, which can be complex when administered to very ill patients with multiple comorbidities and concomitant therapies.

CMS appears to be saying that a higher OPPS rate compared to a lower MPFS rate for the same CPT code creates perverse incentives about where patients are treated. But this statement overlooks the fact that OPPS and MPFS are two different and unique payment systems. Simplistic comparisons between the two cannot be made, for several reasons. First, CMS sets OPPS rates annually, using auditable hospital cost report and claims data; MPFS rates are not updated on the same scheduled and do not use the same data sources.

Second, CMS uses packaging to develop OPPS rates, but packaging is not used for MPFS rates. This is a significant difference and cannot be overlooked. Packaging results in many items and services, including low-cost drugs and biologicals, ancillary services, lab tests, minor procedures, and more, not being paid in the hospital setting, whether on-campus, off-campus, or off-campus excepted. These services are paid separately in the free-standing physician offices, resulting in higher cumulative total payment for claims with the same services.

Third, just because the same CPT code appears on claims submitted from different settings does not mean that the services provided are identical. For example, CPT code 96413 indicates that an hour of chemotherapy infusion was provided, but it reflects different services and resources across depending on the care setting, due to the packaging methodology in OPPS. While the same OPPS payment is made to both non-excepted and excepted off-campus PBDs for CPT code 96413, CMS cannot assume that the patients being treated are clinically identical or are receiving the same type of additional services during the encounter. Just as CMS erroneously compared CPT code 96413 provided in a free-standing physician's office to hospital locations, it is once again erroneously assuming that the reduced payment being made to non-excepted off-campus PBDs should automatically be applied to excepted off-campus PBDs and that they will be able to continue to treat complex patients safely and effectively.

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

ASTCT asks that CMS abandon this proposal as further supporting data is required, it is not making accurate cross-system comparisons, and it has a lack of authority based the prior Congressional directive.

CMS Response: ***Comment:*** *Commenters explained that the BBA of 2015 created two categories of provider-based departments (PBDs): (1) those established before November 2015 and (2) those established after November 2015. For those PBDs in existence prior to November 2015, commenters stated that the Congress required CMS to continue paying off-campus PBDs (referred to in the statute as ''excepted'' off-campus PBDs) at the same rate as hospitals; for post-November 2015 PBDs, the Congress required CMS to pay PBDs at the same rate as independent physicians' offices. Commenters believed that the Congress reinforced this policy choice by providing that ''mid-build'' PBDs should be paid at the same rates as existing, pre-November 2015 off-campus PBDs, that is, the same rate as hospitals. Some commenters asserted that section 603 of the BBA, represents the Congress' thoughtful consideration of MedPAC's recommendation to eliminate the difference in payment between hospital outpatient departments and physician's offices in certain circumstances, and CMS' proposal undermines the balance struck by the Congress.*

Response: *We disagree with commenters that by passing legislation a decade ago that does not reference section 1833(t)(2)(F) of the Act, Congress impliedly meant to circumscribe our authority under that provision. As the D.C. Circuit explained when rejecting a similar argument, ''[n]othing in the text of section 603 of the BBA indicates that preexisting off- campus PBDs are forever exempt from adjustments to their reimbursement'' and instead ''leav[es] the exempted providers subject to all the provisions of the OPPS statute, including subparagraph (2)(F).'' AHA, 946 F.3d at 1246.*

Additionally, as the D.C. Circuit explained, even assuming that section 603 of the BBA could be read to judge increases in volume at preexisting off-campus PBDs are not ''unnecessary'' under section 1833(t)(2)(F) of the Act, that judgment would extend only to 2015 and ''would not mean that Congress considered acceptable the continued volume increases later taking place'' in other years. When the Congress passed the BBA of 2015, Medicare OPPS expenditures were $56 billion and growing at an annual rate of about 7.3 percent. In addition, the percentage increase in volume and intensity of outpatient services was increasing at 3.4 percent. In 2019 without the volume control method, OPPS expenditures would have been approximately $74.5 billion, growing at a rate of 9.1 percent, with the volume and intensity of outpatient services increasing at 5.4 percent. For 2026, we estimate that, without an expansion of this policy to drug administration services, OPPS expenditures would be $101.0 billion, growing at a rate of 8.6 percent, with the volume and intensity of outpatient services increasing at 6.8 percent. A review of claims processed in CY 2022 showed that only 2.3 percent of payments for outpatient services are made at the PFS equivalent rate for off-campus PBDs. We would not be able to adequately address the unnecessary increases in the volume of clinic visits in OPDs after 2015 if we did not apply this policy to all off-campus OPDs. [FR 53811]

Comment: *Other commenters took issue with the overall comparison between OPPS and PFS payment rates as commenters believe they reflect fundamentally different approaches to valuing services. Commenters believe that there is no basis for substituting payment rates from one system to the other. Some commenters were concerned that the Medicare PFS payment rates are not sustainable for physicians. One commenter, a large medical association, stated that while it generally supported site*

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

neutral payments, it did not ''believe that it is possible to sustain a high-quality health care system if site neutrality is defined as shrinking all payments to the lowest amount paid in any setting''. The commenter went on to state that ''CMS should not implement site neutrality in a way that reduces payment to the lowest common denominator and should reinvest savings from lowering facility payments to other Part B services, including payments under the physician fee schedule''.

Response: *As we stated in the CY 2019 OPPS/ ASC final rule with comment period (83FR 59005), to the extent that similar services can be safely provided in more than one setting, we do not believe it is prudent for the Medicare program to pay more for these services in one setting than another. We believe the increase in the volume of clinic visits, in particular, was due to the payment incentive that exists to provide this service in the higher cost setting. Because these services could likely be safely provided in a lower cost setting, we believed that the growth in clinic visits paid under the OPPS was unnecessary. Further, we believed that setting the OPPS payment at the PFS-equivalent rate would be an effective method to control the volume of these unnecessary services because the payment differential that is driving the site-of-service decision would be removed.*

We note that the overall amount of Medicare payments to physicians and other entities made under the PFS is determined by the PFS statute, and the rates for individual services are determined based on the resources involved in furnishing these services relative to other services paid under the PFS. To the extent the commenter believes that the PFS rate for a particular service is misvalued relative to other PFS services, we encourage the commenter to nominate the service for review as a potentially misvalued service under the PFS. [FR 53816]

Comment: *Commenters state that CMS fails to provide any deference to physician's judgment as to the clinical necessity of the OPD setting. Commenters explained that our discussion of the proposed payment reduction for chemotherapy and other drug administration services furnished in excepted, off-campus PBDs too heavily equates outpatient services furnished in physicians' offices and those furnished in hospital outpatient departments. Commenters stated that aligning payment would treat an OPD and a physician's office as virtually interchangeable. This approach, commenters stated, fails to acknowledge the difference in the resources and level of care offered by hospital outpatient departments and the variability in the acuity and needs of patients undergoing chemotherapy or other drug administrations represented by these codes. Commenters contend that there are certain services that cannot be furnished in a physician's office, as demonstrated by the fact that there is no non-facility payment rate under the PFS for those services, and there are instances where a physician, in his or her judgment, would determine that a hospital outpatient department, not a physician's office, is the appropriate setting for a particular patient. This decision may be based on the patient's needs, the presence of comorbidities, or a desire for the resources available in an outpatient department. Commenters stated that with respect to drug administration services more specifically, a physician may refer a patient to the hospital for a particular infusion or other drug administration because of the acquisition cost of the drugs, the equipment needed to safely store and mix the drugs, and the inherent danger and complexity that the handling and mixing of chemotherapy drugs poses to the patient and staff.*

Response: *We thank the commenters for their input; however we believe that payment should have no influence on what setting of care a physician decides is most appropriate for their patient. That decision should be based on the medical needs of the patient. Our proposed policy does not prevent beneficiaries*

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

from receiving these services in an OPD if it is medically necessary. Studies examining the role of vertical integration on physicians' choice of care setting show that physicians are much more likely to admit a given patient to their acquiring hospital and that these same hospitals tend to be higher cost, less convenient, and lower quality than nearby options— suggesting negative patient welfare effects.197 We are simply removing an incentive that unnecessarily increases outpatient volume for drug administration services. Across the OPPS we are finalizing policies, like the elimination of the Inpatient Only List and changes to the Ambulatory Surgical Center Covered Procedures List, to empower physicians to have the ultimate say in what site of service is best for their patients. [FR 53820]

After consideration of the public comments we received, we are finalizing our proposal to use our authority under section 1833(t)(2)(F) of the Act to apply an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate) for HCPCs codes assigned to the drug administration services APCs, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier ''PO'' on claim lines) without modification. In addition, we are finalizing our proposal to implement this policy in a nonbudget neutral manner without modification. We will monitor the impacts of this policy to ensure that beneficiaries continue to have access to quality care. [FR 53821]

Request for Information (RFI): Expanding the Method to Control for Unnecessary Increases in the Volume of Covered HOPD Services to On-campus Clinic Visits

ASTCT disagrees with CMS expanding its proposed volume control method to other services – specifically to on-campus clinic visits in the future – because the OPPS and the MPFS are vastly different payment systems. CMS' concept of packaging under OPPS as described above means a wide array of items and services are packaged when paid to hospitals but are paid separately to free-standing physician offices under MPFS.

Under OPPS, that hospitals use HCPCS code G0463 to report and describe a wide array of visit types (e.g., simple, complex, long, short, etc.). The single payment associated with G0463 under the OPPS is intended to cover this array of visits and the items and services provided by the hospital. There are many examples of packaged services that would never be paid separately in addition to the visit (e.g., an array of services with Status Indicators "N", "Q1", "Q4" procedures) where the "primary" service (e.g., SI "S" or "T") is provided, along with lots of other services which are not paid for separately. This is very different from payment to free-standing physician offices under MPFS, where items and services are paid for separately.

In contrast, physicians have an assortment of Evaluation and Management (E/M) codes and other visit codes to report services provided under MPFS, all of which have varying payment amounts to reflect the services and resources utilized. Because there is no packaging under MPFS, the visit during the patient encounter is paid for separately in addition to all the other items and services rendered to the patient.

Hospitals are already challenged by being paid a single packaged rate for all their various types of patient visits. CMS' proposal to pay only 40% of the APC rate in order to align OPPS and MPFS payment rates is completely untenable. The agency's proposal will exponentially increase the burden hospitals already face in providing comprehensive care to their patients.

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

ASTCT urges CMS to forgo further attempts to reduce hospital payments through site neutrality measures.

CMS Response: *We thank commenters for their detailed comments regarding expanding the method to control for unnecessary increases in the volume of covered OPD services. We received a range of comments on expanding the method to the on-campus setting for clinic visits, imagining without contrast in off- campus PBDs, and other services that may have experienced unnecessary growth. We intend to take these comments into consideration as we develop our proposals for future rulemaking*. [FR 53821]

Changes to the Inpatient Only List

ASTCT understands that CMS proposes to phase out the Inpatient Only List (IPO) list over three years, beginning in CY 2026 with the removal of 285 mostly musculoskeletal services. We are in support of this change *only* if CMS is explicit that the clinician's judgement is the sole determining factor for whether a patient receives a procedure or service, as an inpatient vs. an outpatient. This is especially crucial for cell and gene therapies (CGT), given how rapidly treatments are evolving, the type and mix of patients being treated, and the limited number of specialized treatment centers that are able to provide these therapies. CGT clinicians must retain the authority to determine whether a patient receives a service as an inpatient or an outpatient. These determinations, of course, depend on the patient's needs, but also factor in the facilities' resources and capabilities. Any policy change must respect this clinical discretion.

CMS must also make clear to Medicare Advantage (MA) Plans and other payers that its elimination of the IPO list has nothing to do with the patient's status going forward. ASTCT has significant concerns that MA Plans, which already resist compliance with CMS' two-midnight rule for covered Part A stays, will use the phase-out of the IPO to deny legitimate inpatient claims. Without the IPO list as a compliance anchor, MA plans could more aggressively downgrade patients to outpatient or observation status. Doing so will create additional prior authorization burdens, upfront denials, concurrent review friction, and costly utilization review disputes. The outcome will be administratively burdensome and is likely to impact timely access to patient care. Therefore, ASTCT asks CMS to require MA plans to follow fee-for-service coverage and payment standards with respect to clinician orders for inpatient care, and to prohibit site-of-service denials for procedures that are removed from the IPO list.

In addition, if CMS finalizes phasing out the IPO list and simultaneously adds procedures to the Ambulatory Surgical Center (ASC) Covered Procedure List (CPL), careful monitoring of quality and patient outcomes will be essential. ASTCT is particularly concerned that ASCs may transfer high-intensity or high-risk patients that they cannot fully manage to hospitals, which could raise potential safety concerns. To ensure beneficiary safety protections, CMS should update ASC Conditions of Participation to require: 1) ASC clinicians to hold admitting privileges at the hospital to which patients would be transferred and, 2) A formal transfer agreement between ASCs and hospitals. We strongly believe that CMS must remain proactive in protecting beneficiary safety and quality during and after the IPO-phase-out.

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

If CMS finalizes phasing out the IPO as proposed, ASTCT requests that the agency explicitly state that the clinician's judgement is the sole determining factor for whether a patient receives a procedure or service as an inpatient vs. an outpatient.

ASTCT also asks CMS to require MA plans to follow fee-for-service coverage and payment standards with respect to clinician orders for inpatient care, and to prohibit site-of-service denials for procedures that are removed from the IPO list.

CMS Response: ***Comment:*** *Many commenters supported our proposal to eliminate the IPO list and defer to physicians' judgment on site of service determinations. These commenters stated that CMS' proposal would provide patients with greater flexibility to receive affordable care and allows for more patient-centered care. The commenters also believed the proposed change could potentially decrease overall healthcare costs and improve clinical outcomes for patients. Some commenters stated that there is no clinical difference between a surgery performed in an inpatient setting and an outpatient setting, and that eliminating the IPO list would create more flexibility for physicians and beneficiaries. These commenters also stated that there were already safeguards in place to ensure patient safety, such as State and local regulations, hospital conditions of participation (CoPs), and quality and monitoring initiatives. We also received comments in support of the removal of several specific codes from the IPO list for CY 2026, stating that these procedures can be or are already being performed safely in the outpatient setting.*

Response: *In summary, and after consideration of the comments received, given recent developments in surgical technique and technological advances in the practice of medicine, innovations in infection control and site of service shifts to the outpatient setting spurred by the COVID–19 PHE, as well as the various safeguards discussed previously in this section, we finalize eliminating the IPO list over the course of the next 3 years, starting with the removal of 285 mostly musculoskeletal-related services, as provided in Table 119, for CY 2026. We finalize our proposal eliminating the criteria for removing procedures from the IPO list currently codified at §419.23, as a conforming change. We are also finalizing amending §419.22(n) to state that, effective on January 1, 2026, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition period, with the list eliminated in its entirety by January 1, 2028. We believe that there are a number of safety mechanisms that will continue to ensure the safety of our beneficiaries and the quality of care, including physician judgment, State and local regulations, accreditation requirements, medical malpractice laws, hospital conditions of participation, and other CMS initiatives. The services removed from the IPO list for CY 2026 and their final status indicators and APC assignments (if applicable) are included in Addendum B of this final rule with comment period, which is available on the CMS website. The complete list of codes that describe services that are finalized to be paid by Medicare in CY 2026 as inpatient only services is included as Addendum E to this CY 2026 OPPS/ ASC final rule with comment period, which is available on the CMS website.* [FR 53788]

Proposed Updates to Requirements for Hospitals to Make Public a List of Their Standard Charges

ASTCT supports price transparency policies that provide patients with clear, accurate information. We believe, however, that the proposed additional changes to Hospital Price Transparency (HPT)

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

requirements for CY 2026 will not advance the goal of providing meaningful information so consumers can plan for the costs associated with their care.

Among the potential HPT changes, CMS proposes revisions to §180.20 to add definitions for "*tenth (10th) percentile allowed amount," "median allowed amount," and "ninetieth (90th) percentile allowed amount.*" These values would be derived from 835 electronic remittance advice (ERA) transaction data and included in machine-readable files (MRFs).

ASTCT is concerned that CMS proposes to enforce additional requirements on hospital providers, but there is no similar scrutiny, enforcement, or penalty whatsoever on health plans (i.e., the Transparency in Coverage requirements). This is further obviated by the fact that the payers (not providers) are in the best position to provide their members with accurate information about costs and responsibility at any given hospital.

ASTCT is concerned that 835 ERA files contain data that are inconsistent with the payer-specific rates negotiated in hospital contracts. Providers commonly dispute payments because payers routinely do not pay according to their contracted rates. Payers use a myriad of payment-reduction and payment-avoidance tactics to deny and/or delay claims that are both accurate and correctly submitted. CMS' proposed use of ERA files could lead the agency to publish erroneous and false information.

Furthermore, payers are notorious for utilizing codes such as Claim Adjustment Reason Code (CARC) and Remittance Advice Remark Codes (RARC) inconsistently, both among distinct payers as well as for transactions within the same contract. Until CMS enforces HIPAA standard transaction requirements (not only for remittances, but for claims as well), the agency should not force the use of 835 ERA data.

Providers have already expended an inordinate number of resources to comply with HPT requirements. The proposed additional changes run counter to the Administration's stated desire to eliminate wasteful and administratively burdensome regulations. Finally, CMS also has not shown any evidence that consumers are using HPT data in any meaningful way.

ASTCT does not support additional changes to current HPT requirements and instead requests that CMS more closely scrutinize, enforce, and penalize health plans that fail to do their part as required by law.

Notwithstanding our objections, if CMS finalizes the proposed changes, we estimate that providers would need, at minimum, one additional year to implement any additional HPT requirements. Requiring providers to comply by the beginning of 2026 is completely impossible. **ASTCT requests that any implementation of these policies be delayed until at least CY 2027.**

CMS Response: *We believe that hospitals should adopt the new and updated data elements as soon as possible to improve public use of hospital standard charge information. However, in light of the comments, we understand that hospitals may require additional time to develop and encode the additional required information, particularly the new data requirements associated with the median, 10th percentile, and 90th percentile allowed amounts, and the count of allowed amounts. Therefore,*

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

while we are finalizing revisions to §180.50 effective beginning January 1, 2026, we will delay enforcement of those specific new requirements at §180.50 until April 1, 2026. [FR 54009]

Proposed Market-Based MS–DRG Relative Weight Data Collection and Change in Methodology for Calculating MS–DRG Relative Weights Under the Inpatient Prospective Payment System

ASTCT strongly opposes CMS' proposal to introduce a market-based methodology that relies on median Medicare Advantage Organization (MAO) negotiated charges. ASTCT also notes that proposing a methodology for one payment system (IPPS) within the PR of a *different* payment system (OPPS) does not reflect the intent of the annual rulemaking cycles and will not result in the amount or kind of stakeholder feedback necessary to properly evaluate a proposal.

CMS is Mischaracterizing Providers' Appropriate Practice of Following CMS' Own Charging Guidance

ASTCT is concerned with CMS' characterization and rationale for the current proposal. CMS suggests that the goal is to reduce reliance on "*highly inflated*" and "*inherently unreasonable*" hospital chargemasters that CMS claims are *"…used to secure higher payments from Medicare and private payers*." This assertion ignores decades of Medicare Cost Reporting history as well as CMS' own guidance given to providers through preamble text in various final rules as well as long-standing guidance from the *Provider Reimbursement Manual*.

For example, almost two decades ago, in the CY 2006 Outpatient Final Rule, CMS responded to commenters questions about reporting device charges by stating, *"…hospitals have the ability to set charges for items properly so that charges converted to costs can appropriately account fully for their acquisition and overhead costs…."*[1] CMS' perspective is repeated within the *Provider Reimbursement Manual* (Part 1, Chapter 22, Section 2203), which states, *"[E]ach facility should have an established charge structure which is applied uniformly to each patient as services are furnished to the patient and which is reasonably and consistently related to the cost of providing the services."*[2]

CMS' current proposal also overlooks the reality of IPPS payment formulas. CMS' methodology for paying providers for inpatient hospitalizations includes a process by which CMS reduces billed charges by Cost-to-Charge Ratios (CCRs) to estimate a "calculated cost." This methodology therefore requires providers to increase charges so that the payment formulas yield a reasonable estimate of actual cost. For purchased items like drugs and devices, providers essentially need to take their invoice cost and mark-up that amount by the same CCR factor that CMS will later apply, so that the payment calculation yields a final cost approximation in keeping with the provider's actual cost. In other words, if hospitals added smaller mark-ups to their true costs, CMS' estimates of their calculated costs would result in massive underpayment.

---

[1] Centers for Medicare & Medicaid Services (CMS), *Medicare CY 2006 Outpatient Final Rule*, Baltimore (MD): CMS, November 10, 2005. Online: https://www.federalregister.gov/documents/2005/11/10/05-22136/medicare-program-changes-to-the-hospital-outpatient-prospective-payment-system-and-calendar-year

[2] Centers for Medicare & Medicaid Services (CMS), *Provider Reimbursement Manual, Publication 15-1 (Part 1, Chapter 22; Section 2203)*, Baltimore (MD): CMS, October 17, 2019. Online: https://www.cms.gov/regulations-and-guidance/guidance/manuals/paper-based-manuals-items/cms021929.

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

In recent years, provider concerns about the optics of setting charges in accordance with CMS' guidance have led ASTCT and others to request explicit guidance from CMS that charging practices which may appear *"inappropriate"* are, in fact, both acceptable and necessary under the agency's own methodology. This is particularly true for CGTs, due to their very high starting acquisition costs. ASTCT appreciates that CMS has responded to these comments in recent rulemaking, confirming that providers may set their charges in a manner that reflects their costs and aligns with their Cost-to-Charge Ratios (CCRs).

ASTCT has specifically sought clarification in the context of New Technology Add-On Payment (NTAP) and outlier formulas, regarding whether it is appropriate for providers to set charges based on their own CCRs. For example, if a provider has a CCR of .25 and purchases a cell therapy product for $500,000, the provider would, at a minimum (as this does not reflect overhead or handling), need to report a $2,000,000 charge so that CMS' calculation reflects the $500,000 cost. In response, CMS affirmed in both the FY 2021 and FY 2022 IPPS final rules that: *"there is nothing that precludes hospitals from setting their drug charges consistent with their CCRs."* [3,4] Additionally, the most recent guidance comes in the recently released FY 2026 IPPS Final Rule, where CMS responded to commenters questions about how to set charges by pointing them back to the long-standing guidance in the *Provider Reimbursement Manual*.

Taken together, this guidance makes clear that CMS has long expected providers to set charges in a way that aligns with the formulas. The only way for providers to remain compliant with CMS' charging requirements, while ensuring CMS' calculated cost adequately represents actual cost, is to apply a markup as described above. In other words, it is CMS' *own* charging policies that produce the appearance of "*highly inflated"* charges in hospital chargemasters.

Therefore, it is alarming to ASTCT that CMS would now criticize providers for following the aforementioned framework. This is unfair and inconsistent with the Agency's own rules. Furthermore, this framing is also dangerous, as it suggests providers are manipulating Medicare when in fact they are complying with CMS' system. To now blame hospitals or to lead the public to perceive hospital charges as "*inherently unreasonable*" is misleading and disheartening.

If CMS wishes to fundamentally alter hospital charging practices via this proposal, it must first redesign the IPPS payment formulas that rely on CCRs and revise decades of Agency policy. ASTCT has consistently urged CMS through the IPPS rule-making cycle to do exactly that: create a methodology that better accounts for novel therapies and avoids mischaracterizing compliance as abuse.

[3] Centers for Medicare & Medicaid Services (CMS), *Medicare FY 2021 Inpatient Final Rule*, Baltimore (MD): CMS, September 2, 2020. Online: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2021-ipps-final-rule-home-page

[4] Centers for Medicare & Medicaid Services (CMS), *Medicare FY 2022 Inpatient Final Rule*, Baltimore (MD): CMS, August 13, 2021. Online: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2022-ipps-final-rule-home-page.

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

Limitations of Using MAO-Negotiated Rates & Median Allowed Amounts for MS-DRG Relative Weights

CMS' stated goal of better aligning MS-DRG relative weights with hospital resources is important, and one we share. However, relying on median payer-specific charges that hospitals have negotiated with MAOs will not advance CMS' objectives to better understand IPPS resource use for MA beneficiaries.

CMS itself acknowledges that MA rates are generally correlated with, and often directly derived from, Medicare Fee-for-Service (FFS) rates – i.e. MS-DRG-based payments. Substituting these charges is therefore essentially circular logic, replacing one Medicare-linked amount with another. This approach is unlikely to improve resource alignment overall, and any changes to weights based on this methodology could still be inappropriate and unrelated to resource use. This is primarily because MAO-negotiated rates are often shaped by market dynamics that could have little to do with actual cost. For example, hospitals may accept lower MA rates in exchange for higher commercial rates from the same payer across multiple lines of business, or they may agree to lower rates for certain MS–DRGs as part of a broader contracting strategy driven by leverage or network considerations rather than resource needs.

If CMS substitutes a "median allowed amount" when negotiated charges are unavailable, the problem worsens. Allowed amounts reflect what payers paid, not necessarily resource utilization, and are often reduced by underpayments and denials. For example, MAOs frequently fail to recognize certain billed charges for outlier or stop-loss payments even when billed through HIPAA standard transactions. Despite the fact that CMS emphasized in the 2024 MA plan year final rule that MAOs must comply with CMS coding and claims submission guidelines under HIPAA (88 FR 22198), the experience of our members is that some MAOs remain non-compliant. As a result, actual payments are commonly and significantly lower than expected, sometimes for reasons that may not comply with federal requirements. Using these figures would inject even greater inaccuracies into the weighting formula, further damaging and penalizing hospitals. Until CMS enforces adherence to HIPAA standard transactions, median payer-negotiated payment rates, cannot serve as a reliable or representative basis for MS-DRG relative weight setting.

ASTCT requests that CMS withdraw its market-based weighting methodology and instead 1) evaluate incorporating Medicare Advantage shadow claims into rate-setting, and 2) work collaboratively with stakeholders to develop an inpatient payment system that more accurately reflects the resources required to care for Medicare beneficiaries.

CMS Response: ***Comment:*** *The vast majority of commenters were opposed to the proposals that hospitals report median payer specific negotiated charges for MAOs on the Medicare cost report and that CMS use that data to recalibrate the IPPS MS–DRG relative weights. Commenters asserted that the proposals are not authorized by and conflict with CMS's statutory authority, are arbitrary and capricious, and require new unsupported expansive interpretations of the statute. Commenters indicated that the statute requires the MS–DRG weights reflect ''the relative hospital resources used''—that is a resource-based system—not market rates negotiated with MA plans. Commenters stated that the cost reporting provisions CMS invoked authorize collection only of information necessary to determine appropriate payment amounts due to a provider—not the collection of information that they asserted cannot lawfully be used to set payments.*

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

In contrast to the proposed approach, many commenters indicated that the current MS–DRG cost-based methodology established in the FY 2007 IPPS rulemaking is a longstanding and better framework for improving the MS–DRG relative weights consistent with the statute. Commenters indicated that although CMS is focused on the charges in the hospital chargemaster as being inflated and not reflecting resource use, the current methodology is not based on charges, but rather on charges converted to cost.

Some commenters who opposed finalizing our proposal agreed with CMS that conceptually a methodology that relies more on market-based concepts would be preferable to the current system of administered pricing, but disagreed that our current proposal was an appropriate approach because they asserted that it risked circular and destabilizing effects across both FFS and MA and could create uncertainty within the MA program, FFS program, and value-based payment models that depend on a stable FFS baseline. They indicated CMS should engage with interested parties through multiple avenues to identify effective, stable alternatives. Examples of suggested alternatives included more sophisticated cost accounting systems, improved cost reporting, and CMS demonstrations.

***Response:** We agree with commenters that CMS is required to assign and update MS–DRG weighting factors to reflect relative resource use. Section 1886(d)(4)(A) of the Act states that the Secretary shall establish a classification of inpatient hospital discharges by diagnosis-related groups and a methodology for classifying specific hospital discharges within these groups. Section 1886(d)(4)(B) of the Act states that for each such diagnosis-related group the Secretary shall assign an appropriate weighting factor which reflects the relative hospital resources used with respect to discharges classified within that group compared to discharges classified within other groups. Section 1886(d)(4)(C)(i) of the Act states that the Secretary shall adjust the weighting factors at least annually to reflect changes in treatment patterns, technology, and other factors which may change the relative use of hospital resources. As indicated by commenters with respect to the current methodology, relative resources are accounted for when hospitals establish the costs of services. We continue to believe that the costs of services are considered when hospitals and payers negotiate rates. Commenters noted that the negotiated rates are influenced by many factors, including bargaining leverage, patient populations, network needs, utilization management practices, local market concentration, out-of-network Medicare payment requirements, quality and value initiatives, episodes of care, and other contract and pricing dynamics. While the negotiated rates may reflect a variety of factors, it does not follow that the resources necessary to perform the services based on these negotiated rates would not be considered in the negotiations. As an extreme example for purposes of illustration, in contract negotiations hospitals would not generally negotiate payments of $1,500 for heart transplant cases and MA organizations would not generally negotiate payments of $150,000 for simple pneumonia cases because those rates would not reflect the relative resources required to provide those services. Furthermore, as network needs (e.g. network adequacy) are considerations in the negotiations between hospitals and payers and network needs involve anticipated patient utilization, we do not believe that hospitals and payers would consider anticipated patient utilization when negotiating contracts without considering the resources necessary (that is, costs) to provide those items and services for that level of patient utilization anticipated. We continue to believe that payer-specific negotiated charges that hospitals negotiate with MA organizations capture the relative resources used to provide services to patients in order to maximize profits (or, in the case of not-for-profit hospitals, net income), subject to market constraints and conditions (supply and demand, community benefit requirements, etc.).*

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

Because we believe the payer-specific negotiated charges reflect relative resources used (i.e. costs) for the reasons described earlier, our proposal is entirely consistent with and based on longstanding interpretations of the statute with respect to the relationship between resources and costs. We disagree with commenters that our proposed policy is in any way arbitrary or capricious or relies on new expansive unsupported interpretations of the statute. For the same reasons, we also disagree with commenters who stated we lack authority and did not articulate a sufficient policy basis for our data collection policy. As discussed in the CY 2026 OPPS/ASC proposed rule, sections 1815(a) and 1833(e) of the Act provide us with the authority to collect data for purposes of determining the amount of payments due to the provider under the Medicare program. We proposed to collect this negotiated charge data so that it may be used in determining relative weights for purposes of payment under the IPPS. We also note that we referenced the requirement that providers follow reasonable cost principles under section 1861(v)(1)(A) of the Act when completing Medicare cost reports and reiterate that section 1861(v)(1)(A) of the Act requires reporting of data elements beyond just cost, including non-cost items and items used to determine the cost of services.

In response to comments that the current approach for establishing the MS–DRG relative weights involves estimating cost from charges, we note that it still relies on data derived from hospital chargemasters as input and it still relies on an estimation methodology to convert those charges to cost. As we indicated in the FY 2007 IPPS rulemaking (71 FR 47894–95) when initially adopting a charges-to-cost methodology, no payment methodology can be perfect because DRG-specific costs cannot be determined. We indicated that we believed that the cost-based methodology represented an improvement over the prior charge- based methodology. Similarly, we believe that while a market-based methodology, a different type of cost-based methodology, may also not be perfect, it would be an improvement over the current methodology. By using payer specific negotiated charges, we can reduce our reliance on the hospital chargemaster and utilize this data in Medicare payment methodologies so that payments more closely reflect the market cost and therefore the relative market value and resource utilization for inpatient items and services.

In response to comments that our proposed approach risks circular and destabilizing effects across both FFS and MA and could create uncertainty within the MA program, FFS program, and value-based payment models that depend on a stable FFS baseline, we disagree. We continue to believe that if market-based data (median payer-specific negotiated charges for MA organizations) are incorporated into the calculation of the MS–DRG relative weights, initially there will be limited impact on the relative weights given the current similarity between MA organization rates and Medicare FFS rates. As discussed in the CY 2026 OPPS/ASC proposed rule, we intend to provide an opportunity for the public to review the data we collect prior to use of these data in a market-based relative weight methodology. To the extent the data shows that there would be more than a limited impact on the relative weights initially, which we do not believe will be the case, CMS will be able to further consider the impact and appropriate approach to utilizing this market-based data in the MS–DRG relative weight methodology. We will continue to provide impact analyses of changes in the MS–DRG relative weights in the annual IPPS rulemaking. Also, as discussed in the CY 2026 OPPS/ASC proposed rule we expect for some period of time following implementation of this market-based MS–DRG relative weight methodology to continue to estimate and publicly provide the MS–DRG relative weights calculated using the current methodology for informational purposes. We also note that our adoption of a market-based methodology does not

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

preclude continued engagement with interested parties to identify further improvements to our payment systems. [FR 54020]

Comment: *Commenters stated that the proposals would create distortions in the MS–DRG relative weights and that CMS has not modelled the impacts of or otherwise accounted for these distortions in the proposed policy. Commenters asserted these distortions are evidence as to why the proposed approach would be unlawful if adopted (that is, not resource-based), as well as evidence as to why the proposed approach is inappropriate even if CMS had the authority to adopt it. Commenters discussed the statutory requirement at section 1886(d)(4)(C)(i) of the Act to update the relative weights at least annually to reflect ''changes in treatment patterns, technology . . . and other factors which may change the relative use of hospital resources'' and asserted that the proposal failed to do so. Commenters stated that because MA rates are often based on Medicare FFS rates the proposal would over time lock in outdated weights in a closed loop that adds no independent information on these factors. According to the commenters, this locked in ''circularity'' would contradict the statutory requirement to update weights to reflect changes in resource use. Some commenters stated that over time as the MS–DRG weights become outdated MA plans and hospitals would rely more on non-MS–DRG based approaches. Commenters further stated that even absent circularity, the MA negotiated rates cannot assist with determining when changes to the MS–DRG classification system itself are necessary (for example splitting MS–DRGs) because unlike the current case-level methodology the MA negotiated rates do not provide information on resource use variations within an MS–DRG. Commenters also stated that the MS–DRG relative weights could be distorted by a lag between when a hospital updates its price transparency data and when it submits its cost report.*

Commenters stated that in cases where MA plans pay hospitals for inpatient services based on charges, MS–DRG relative weights would be distorted by different cost-to-charge ratios across departments. Commenters stated the proposed process would yield higher relative weights for MS–DRGs that had higher mark-ups of charges relative to costs to the extent some MA plans still pay hospitals a rate based on discounts off charges.

Commenters stated that the combined data across hospitals would not be nationally representative for a variety of reasons. Commenters stated that in cases where MA plans pay hospitals for inpatient services as a percentage of FFS Medicare payments, MS–DRG relative weights would be distorted by existing FFS Medicare policy-based payments that do not correspond to the relative cost of providing the service. Commenters cited the example of FFS Medicare payments to hospitals including uncompensated care payments to help support hospitals' costs of treating the uninsured as well as wage index policies reflected in the current payment rates. Commenters stated the proposal would yield higher relative weights for MS–DRGs for procedures disproportionately performed at hospitals that receive these additional policy-based payments. Commenters indicated that the proposed methodology would use no data from subsection (d) providers that exclusively contract with MAOs on a capitated basis and/or have no MA network participation agreements. They also stated payment elements that are excluded from the payer-specific negotiated rates for MAOs may skew the data. For example, they stated that the payer-specific negotiated rate would exclude components of the total payment amount that are based on risk- sharing or value-based payment methodologies, and the use of those payment methodologies is not uniformly distributed across hospitals. Commenters stated that using Medicare data on fee-for-service case counts to develop a single weighted average standardized median MAO payer-specific

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

negotiated rate by MS–DRG across hospitals means that data from hospitals with less MA penetration, which have less at stake in MA negotiations, is weighted more heavily than data from hospitals with high MA penetration that have more at stake. Commenters also stated that the impact of stoploss provisions and prior authorizations are similarly not uniformly distributed and would skew the relative weights. Commenters also asserted that the proposed approach is not actually market-based due to a lack of competing hospitals and/or a lack of competing MAOs in many areas.

Commenters also stated that CMS has not and cannot analyze the impacts of its proposed policy because it has not yet collected the data and contrasted the impact analysis of this proposed policy with the impact analysis performed when CMS adopted the current cost-based MS–DRG methodology. Commenters stated that the policy could reduce access to care, particularly for high-cost new technologies such as innovative cell and gene therapies, and in rural communities.

Response: *With respect to the comments that our proposals would create distortions in the MS–DRG relative weights, we note that there is some similarity between these comments and the comments that we received during the FY 2021 rulemaking (85 FR 58883). We appreciate the additional feedback from commenters regarding differences in payment methodologies and other factors that influence the contracts between MA organizations and hospitals. We thank commenters for their concerns regarding the comparability of payer-specific negotiated charges by MS–DRG due to these and other factors and the potential impact on the MS–DRG relative weights. We believe, as discussed earlier, based on the literature review we conducted and feedback from commenters, that MA rates and Medicare FFS rates are often similar and/or are highly reliant on one another. However, as previously discussed, MA rates to MA contracted inpatient hospitals are not required to be the same as (or based on) Medicare FFS rates. We continue to believe that if market-based data (median payer-specific negotiated charges for MA organizations) are incorporated into the calculation of the MS–DRG relative weights, initially there will be limited impact on the relative weights given the current similarity between MA organization rates and Medicare FFS rates, but that over time the proposal would create an opportunity for negotiations to reflect market dynamics, as noted by a commenter who supported our proposed policy. As discussed earlier, to the extent the data shows that there would be more than a limited impact on the relative weights initially, which we do not believe will be the case, we intend to provide an opportunity for additional public input and will continue to provide impact analyses of changes in the MS–DRG relative weights in the annual IPPS rulemaking. We remain open to adjusting our finalized policy for the MS–DRG relative weights through future rulemaking prior to the effective date if appropriate.*

We note that we did not propose modifications to the process for making adjustments to the MS–DRG classification system itself, nor did we propose changes to the new technology or outlier payment policies at this time. We may revisit these issues in future rulemaking as part of our larger goal of reducing reliance on the hospital chargemaster. [FR 54022]

Comment: *Commenters stated that proposing a methodology for one payment system within the CY 2026 OPPS/ASC proposed rule of a different payment system does not reflect the intent of the annual rulemaking cycles as it will not result in the amount or kind of interested party feedback necessary to properly evaluate the proposal.*

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

Response: *We may, in certain circumstances, propose policies in a rule associated with a different payment system, including when those policies have cross-cutting implications or when statutory or operational considerations necessitate timely implementation. We believe that the established notice-and- comment rulemaking process for the OPPS provides interested parties with the opportunity to review the proposal and affords all interested parties the ability to submit feedback. We also note the substantial overlap between subsection (d) hospitals and hospitals subject to the OPPS. After consideration of the comments received, and for the reasons previously discussed, we are finalizing our proposed market-based data collection requirement as proposed.* [FR 54024]

Request for APC Reconfiguration and Status Indicator Changes

Request for APC Reassignment for CPT Code 38228

ASTCT requests that CMS reassign CPT code 38228 from the Level IV Drug Administration APC 5694 to the same APC used for autologous stem cell administration (5242). This change would ensure consistency in assignment and provide a payment rate that more accurately reflects the facility costs associated with outpatient administration of CAR-T cell therapy.

Like autologous stem cell transplant, outpatient CAR-T administration requires significant nurse monitoring. This is why the AMA placed CPT code 38228 in the same section of CPT as the stem cell transplant codes, rather than in the drug administration section. CMS has also recognized these similarities in the inpatient setting. Initially, ICD-10-PCS codes for the administration of several CAR-T products were assigned to the autologous stem cell transplant MS-DRGs 016 and 017, until CMS created a dedicated MS-DRG 018 for CAR-T and Other immunotherapies.

ASTCT requests that CMS reassign CPT code 38228 to APC 5242, as this would result in reimbursement to providers that more appropriately covers the resources required to administer CAR-T to hospital outpatients.

CMS Response: ***Comment:*** *Several commenters recommended the reassignment of CPT code 38228 to APC 5242 (Level 2 Blood Product Exchange and Related Services). A commenter suggested that rationale for the reassignment of CPT code 38228 to APC 5242 is that APC more accurately reflects the higher facility costs associated with the significant nurse monitoring for the outpatient administration of CAR T-cell therapy. The commenter supported this claim as the AMA placed CPT code 38228 in the same section as stem cell transplant codes, which were initially recognized in the inpatient setting under MS–*DRGs *016 and 017. Another commenter also stated CPT code 38228 is analogous to CPT code 38241 (Hematopoietic progenitor cell (hpc); autologous transplantation) and that CMS initially assigned CAR–T related codes to autologous stem cell transplant MS–DRGs 016 and 017, which they believe is the appropriate crosswalk for OPPS.*

Another commenter disagreed with the current APC 5694 assignment and stated that CPT code 38338 (and CPT codes 67028 and 67516) do not have the facility NA indicator in the Medicare Physician Fee Schedule and the RUC assigned both facility and non-facility RVUs. Thus, the commenter stated that physicians perform and document the services when they perform the services in facilities.

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

Response: *We continue to believe that the procedures described by CPT codes 38225, 38226, and 38227 describe the various steps required to collect and prepare the genetically modified T-cells, and Medicare does not generally pay separately for each step used to manufacture a drug or biological product. We believe CPT code 38228 is appropriately assigned to APC 5694, which shares similar clinical and the resource costs and clinical similarity of the service to existing procedures; input from CMS medical advisors; and information from interested specialty societies. We evaluated the resource use as other complex cancer drug administrations. We note that the IPPS established MS–DRG 018 for CAR–T and other immunotherapies and CAR– T therapies are no longer assigned to MS–DRGs 016 and 017. We also disagree that CPT code 38228 is similar clinically and in resource to CPT code 38241 because we view CPT code 38228 as the administration of the CAR–T drugs, while CPT code 38241 involves the transplantation of hematopoietic progenitor cells. Therefore, we are not convinced by the commenter's reason to reassign CPT code 38228 to APC 5242. Furthermore, we believe it is inappropriate to use the IPPS MS–DRGs as an analog to the APC assignments in the OPPS because there are significant differences in resource consumption between the HOPD and inpatient setting*.

We are also not compelled to reassign CPT code 38228 to APC 5242 because of the lack of the NA indicator in the Medicare Physician Fee Schedule and because the RUC assignment of both facility and non-facility RVUs do not support the reassignment of CPT codes 38338, 67028 and 67516 to APC 5242. We rely on input from a variety of sources for our APC assignments, including, but not limited to, review of recommendations, modeled the suggestions, analyzed the cost results of the suggested APC reassignments, and received additional input from our medical advisors. We note that the drug administration codes that the commenter mentioned were assigned to their respective APCs with similar clinical and resource similarity. Furthermore, the commenter only suggested an APC reassignment for CPT code 38228 but did not provide any APC suggestions for CPT codes 67028 and 67516.

After consideration of the public comments we received, we are finalizing our proposed APC assignment and status indicator for CPT code 38228 to APC 5694 without modification. Refer to Table 50 for the final OPPS APC and status indicator assignment for CPT code 38228 for CY 2026. We refer readers to Addendum B to this final rule with comment period for the payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website. [FR 53569]

Status Indicators for Remote Physiological Monitoring

ASTCT requests that CMS recognize the hospital resources required when clinicians order and hospital staff provide remote patient monitoring (RPM) services for patients with acute and chronic conditions. Many of our immunocompromised patients, stem cell transplant patients, and cell and gene therapy patients can benefit from RPM services, but delivering these services draws on substantial hospital resources. This includes, but is not limited to, setting up devices; educating patients on their use; and monitoring data to ensure they are transmitted, received, and compiled for clinicians to use as they provide patients with ongoing care.

While we are eager to expand RPM to monitor and manage patients and improve outcomes, ASTCT is concerned that CMS' assignment of status indicator "B" may discourage providers from furnishing these services. Status indicator "B" is problematic because it signals that CMS expects hospitals to report some other code in place of the one that accurately represents the service provided. In practice, hospitals

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733

often substitute the generic clinic visit code (G0463), which is assigned status indicator "V" and has an APC payment rate. However, reporting G0463 does not accurately convey the specific service actually being provided, either to the patient on their explanation of benefits or to CMS via the claim, even though payment is received.

ASTCT requests that CMS recognize the importance of digital health technologies and the significant role they play in advancing patient care by recognizing the actual CPT codes released by the AMA for remote patient monitoring (RPM) and changing the status indicator assigned to all RPM codes from "B" to separately payable status indicator "V" or "Q1," depending on the nature of the service.

CMS did not address this request within the text of the final rule. However, Addendum B of the CY 2026 OPPS final rule shows CMS kept the "B" status indicators for the RPM codes.

ASTCT appreciates CMS' review of our comments and would be pleased to engage on any technical questions the agency may have.

330 North Wabash Avenue, Suite 2000 • Chicago, Illinois 60611 • P: (312) 321-6820 • F: (312) 673-6733