ASTCT
American Society for
Transplantation and Cellular Therapy

This document contains submitted ASTCT comments and selections from CMS' responses in the FY 2026 MPFS Final Rule, dated November 5, 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 12, 2025

SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

RE: Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program [CMS-1832-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 MPFS 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 approvals for chimeric antigen receptor T-cell therapy and SCT 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 other cell 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

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Autologous Cell-based Immunotherapy and Gene Therapy Proposals: Average Sales Price, Price Concessions, and Bona Fide Service Fees

CMS should pay providers separately for cell collection

ASTCT has repeatedly requested that CMS recognize separate payment for the distinct, provider-furnished clinical services associated with CAR-T therapy, as it does for all other covered clinical services. We maintain this viewpoint after considering this proposal. For an individual beneficiary with blood cancer, a physician evaluates multiple treatment options and determines that provision of CAR-T will be the most efficacious for that individual. In such a situation, collecting a beneficiary's stem cells requires a series of complex and personalized clinical decision-making; the engagement of experienced staff working in specialized clinical settings; and the use of highly technical equipment. This process is significantly different from typical pharmaceutical manufacturing based on plant- or chemically-derived base materials. These distinct clinical services are ordered by treating specialists and furnished by hospitals. *Manufacturers have no purview on these services and the hospitals are fully responsible for the individualized clinical care of the beneficiary*.

ASTCT does not support CMS' proposal that preparatory procedures for tissue procurement and/or cell collection be included in the payment of the product itself for autologous cell-based immunotherapy and gene therapies (autoCGTs).

COGS cannot also be price concessions

CMS states that these clinical services are *"part of the COGS"* (Cost of Goods Sold) for these products, which is in direct opposition to its proposal that payment for these services should be treated as a price concession.

The OIG report cites Section 1847A(c) of the Social Security Act in defining price concessions as "volume discounts, prompt pay discounts, cash discounts, free goods contingent on purchase requirements, chargebacks and rebates other than those obtained through the Medicaid Drug Rebate Program." The examples listed are truly price concession – i.e., *concessions or discounts to the purchase price of a drug by a customer*. These discounts are fundamentally different than the processes and costs (the COGS) that go into the actual production of a drug or biologic.

CMS' focus on allogeneic products makes this even more clear, stating: "*In addition, if certain therapies could be scaled in a way that they could be allogenic in nature, we see that the tissue procurement step would even more clearly be considered a manufacturing step. (90 FR 32547)".* CMS is correct that allogeneic therapies would not be possible without the acquisition of cells, either in a one-to-many (off-the-shelf or "universal") or a one-to-one relationship. The cells would be from a donor; therefore, those costs would clearly be up to the manufacturer to bear as part of the manufacturing process, leaving no justification for treating those costs as a price concession.

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Given CMS' stated view of cell collection as part of COGS for autoCGTs, CMS should regard these services as a bona fide service fee, not a price concession; in CMS' own words, they are, instead, a ***"pivotal part of the manufacturing process"*** and should be treated as such.

ASTCT suspects that CMS' proposal to treat cell collection as a price concession partially stems from a belief that providers are being paid at two time points: first by manufacturers for cell collection, and later by CMS for the product administration. CMS' proposal implies that payment the infusing provider receives should be reduced by the amount they received as compensation for cell collection by manufacturers at an earlier time point. Working from this premise, ASTCT notes that CMS is making multiple assumptions about cell collection practices that ASTCT does not believe to be substantiated, including that most providers are paid by manufacturers currently (or will be in the future) and that the entity collecting cells is the same as the provider infusing them. Hospital capacity for apheresis is a concern and alternative models are being considered. If a manufacturer chooses or needs to contract with a third-party entity that has apheresis capabilities, then the infusing provider is not receiving any payment for those services and continues to pay full cost for acquisition of the product. CMS has not shared any data as to the volume and/or type of entities that are receiving payment for cell collection services, yet it is proposing to implement an unjustified payment discount across all treating providers based on this premise.

ASTCT does not support CMS' proposal that any payments entities have received for cell collection from manufacturers should be treated as price concessions.

CMS' proposal will cause significant operational challenges and questions

If CMS finalizes these policies, providers may view them as a mandate to seek reimbursement from manufacturers. But, there are multiple complications would result from a patient's hospital being, essentially, "under arrangement" to a manufacturer for a portion of the patient's care. Our members have accordingly raised a number of operational questions related to CMS' proposals.

Hospital concerns are particularly acute for centers that perform the initial cell collection and also infuse a product at a later point – these patients are being treated for their cancer and will likely receive active treatment for their condition on the same date of service as their collection. Per CMS' 2008 Final Rule, *"[i]t is extremely important that hospitals report all HCPCS codes consistent with their descriptors, CPT and/or CMS instructions and correct coding principles, as well as all charges for services they furnish, whether payment for the services is made separately or packaged." (72 FR 66634)* Hospitals seeking to comply with this requirement would need a mechanism by which they could still bill all services provided to a patient and indicate which specific services should be considered non-payable by CMS.

If it finalizes the proposal, CMS will need to issue guidance as to what specific codes or services are included in its scope, release new modifiers or data elements so providers can still report all services provided to patients, and modify cost-report instructions to account for potential changes to how cell collection, lab processing and product costs flow into the overall hospital cost-to-charge ratio calculations.

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ASTCT asks that CMS consider alternative options for autologous cell and gene therapies

CMS has made clear that drug pricing is a priority of the administration. ASTCT supports this premise, as our member clinicians are highly aware of the financial devastation that a diagnosis of cancer or other severe illness has on Medicare beneficiaries. ASTCT also acknowledges that the therapies used by our membership are many of the most expensive products approved for use by the U.S. Food and Drug Administration (FDA). However, CMS has multiple ways to support beneficiaries in accessing cutting edge therapies that do not involve a financial loss to the providers that are interested in administering them. These include expansion of its highly successful CMMI Cell and Gene Therapy Access Model to include Medicare beneficiaries and additional therapies, and/or partnering with expert cell and gene therapy programs to reimburse for in-house manufacture of certain cell and gene therapies.

The ASTCT remains ready and willing to meet with CMS for additional discussion of alternatives.

Providers need more time to evaluate and consider CMS' proposals

In this year's rule, CMS proposes multiple modifications to the ASP calculation – all of which will impact ASP-based payment. Yet, the agency has not given stakeholders sufficient time to decipher and comment on highly technical calculations, many of which are far beyond their usual areas of expertise.

ASP calculations and reporting are primarily understood by a limited number of experts within CMS or at drug manufacturing organizations and are very rarely discussed in the MPFS PR. The changes that CMS is now proposing will directly and substantially impact provider payment almost immediately (January 2026), with little time for non-expert stakeholders, such as ASTCT physicians, to understand and respond to the proposals. There is even less time for CMS to analyze and thoughtfully incorporate stakeholder comments into the final rule.

CMS' proposals could significantly and negatively impact the payment providers receive when administering lifesaving therapies like autoCGTs. **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. 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.

If CMS' proposed price concession assumptions drive the absolute value of ASP+6% down (or ASP+4%, accounting for sequestration), providers will face a net negative impact on acquiring these products for use with Medicare beneficiaries. 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. Finalizing the proposal as written creates a significant risk of decreasing Medicare beneficiary access to autoCGTs.

ASTCT's requests that CMS delay implementation of any ASP proposals and, instead, allow another rule-making policy cycle in which to consider stakeholder feedback.

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CMS Response: ***Comment***: *Many commenters did not agree with CMS' current payment policy for CAR T-cell therapies, under which services described by CPT codes 38225, 38226, and 38227 are bundled into the payment for the product, and the proposal to extend that approach to other autologous cell-based immunotherapy and gene therapy. They stated that preparatory procedures such as cell collection, apheresis, laboratory processing, and dose preparation are clinician-ordered, resource-intensive, and medically necessary, and therefore should be reimbursed separately rather than treated as manufacturer COGS. Commenters further stated that the current bundling policy for CAR T-cell therapies oversimplifies the nature of cell and gene therapies, undervalues physicians' work (for example, clinical oversight and coordination), and is inconsistent with CMS' approach for stem cell transplants and other therapies in which analogous services are paid separately. Several commenters were concerned that continued bundling could worsen ''underwater reimbursement,'' leading to practice closures, consolidation, and shifts to higher-cost inpatient settings or to integrated centers that can absorb unreimbursed costs, thereby increasing overall system costs.*

Response: *We appreciate commenters' feedback regarding the characterization of preparation services, such as cell collection by apheresis and local processing, for CAR T-cell therapies. Consistent with prior rulemaking under both the OPPS and the PFS—ranging from the CY 2019 OPPS/ASC final rule (83 FR 58904 through 58908) to the most recent CY 2025 OPPS/ASC final rule (89 FR 94080 through 94082) and the CY 2025 PFS final rule (89 FR 97778 through 97780)—we continue to view these services as integral preparatory steps in the manufacturing of the therapy and, therefore, included in the payment for the product. Medicare does not pay separately for each step used to manufacture a drug or biological product; these manufacturing-related services are accounted for in the drug payment code, while administration services are separately recognized. We do not agree with commenters' comparisons to payment for stem cell transplant services and other therapies where collection and processing may be separately payable, as we do not consider those frameworks directly analogous to CAR T-cell therapies and other autologous cell-based immunotherapy and gene therapy products. In the stem cell transplant context, payment policies established under section 1886(d)(5)(M) of the Act and related implementing regulation at § 412.113(e) address clinical services furnished to the beneficiary and, in some cases, provide a distinct reasonable-cost cell-acquisition payment to subsection (d) hospitals. By contrast, for CAR T-cell therapies and other autologous cell-based immunotherapy and gene therapy paid under section 1847A of the Act, patient-specific collection and local processing are steps used to manufacture the labeled biological product and are reflected in the product payment, while the administration service is separately payable. Maintaining this approach across payment systems promotes consistency in the treatment of these complex therapies. Accordingly, we are finalizing that 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, consistent with the existing payment policy for CAR T-cell therapies. For concerns about potential payment adequacy, practice viability, and site-of service shifts, we will continue to evaluate and monitor claims data, clinical practice patterns, and site of-service trends to determine whether additional refinements may be warranted in future rulemaking.* [FR 49544]

Comment: *Several commenters requested a clearer definition of ''tissue procurement'' and suggested that ''cell collection'' more accurately describes the procedures involved in autologous cell based immunotherapy and gene therapy. They noted that ''tissue procurement'' is a broad term that could cause confusion, as it may encompass clinical activities (for example, diagnostic tissue biopsies) beyond*

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those intended for payment and ASP reporting. Commenters also noted that, in some cases, a finalized CAR T-cell product is never administered to the beneficiary due to factors such as manufacturing failure or disease progression that may render the patient ineligible or result in death during the production period. They recommended complementary payment tools for preparatory procedure payment and requested clarification on how payment policy applies in these circumstances.

Response: *We agree with commenters that ''cell collection'' is a more precise term than ''tissue procurement'' to describe the preparatory procedures such as apheresis or other collection of patient cells used as starting material for autologous cell-based immunotherapy and gene therapy, and we will adopt this terminology where appropriate for clarity. We further clarify that when the required procurement procedure does not involve apheresis (for example, when starting material is obtained via procedures including, but not limited to, surgical biopsy, tumor harvest, or tumor resection), the term ''tissue procurement'' remains appropriate in the context of manufacturing autologous cell-based immunotherapy and gene therapy. This clarification promotes consistent terminology and reporting and does not expand nor narrow existing payment scope. This finalized policy applies to patient-specific procurement and associated processing required by the product's manufacturing and release specifications. We thank commenters for providing their unique perspectives and experiences in situations where the manufacturing process does not result in a final product being administered to a beneficiary and recommendation on complementary payment tools; these issues are out of scope for this final rule.* [FR 49545]

Comment: *Several commenters requested clarification on how the policy would apply to allogeneic cell and gene therapies that require donor search, evaluation, and cell procurement. They explained that these steps—such as identifying and matching donors through national registries, performing compatibility testing, coordinating donor cell collection and transport, and monitoring donor health—are critical for patient and donor safety, can vary widely by case, and may occur even when the therapy is not ultimately administered. Commenters requested CMS to separately reimburse for these steps to reflect their complexity and variability. Alternatively, commenters requested for clarification whether these steps paid by manufacturers qualify as BFSFs.*

Response: *This rule addresses autologous cell-based immunotherapy and gene therapy manufacturing steps only. Policies specific to allogeneic donor procurement or transplant services are outside the scope of this rule. That said, as discussed earlier in this preamble, procurement of starting material—whether patient-derived (autologous) or donor-derived (allogeneic)—is integral to the manufacturing process and a component of a manufacturer's COGS. If, in the future, allogeneic therapies are scaled and a manufacturer makes payments to non-purchasing third parties for donor search, evaluation and cell procurement services, such payments may qualify as BFSFs and be excluded from ASP when they satisfy the four-part test at § 414.802. This final rule does not establish new payment policy specific to allogeneic donor search, evaluation, or cell procurement, nor does it alter existing transplant-related procurement policies. We may consider whether additional clarification is warranted in future rulemaking as allogeneic cell-based therapy evolves. Therefore, after consideration of public comments, we are finalizing as proposed to continue the existing payment policy for CAR T-cell therapies and to extend it to autologous cell-based immunotherapy and gene therapy. Under this policy, the costs of patient- specific cell or tissue procurement and processing remain bundled into the payment for the product.* [FR 49545]

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Comment: *Many commenters did not agree with CMS' proposal to treat preparatory procedures—such as cell collection and local processing—as not BFSFs and to require their inclusion in the calculation of ASP. Commenters stated that payments for these procedures meet the regulatory BFSF criteria and that treating them as price concessions would artificially lower ASP and reimbursement, create operational burdens, and limit patient access. Some commenters requested CMS to address potential interactions between ASP and other pricing metrics. Commenters also stated that, for many beneficiaries, cell collection occurs at a different facility and by a different provider than the entity that ultimately administers and bills for the product. Commenters further stated that CMS lacks explicit statutory authority to redefine ASP inputs in this manner because section 1847A of the Act ties ASP to sales to purchasers, not payments to non-purchasing service providers, and the Congress has not directed manufacturers to add specific manufacturing costs into ASP. Some commenters recommended that CMS delay implementation by 12 to 24 months, requested clarification that payments to non- purchasing third parties (for example, the American Red Cross) should not affect ASP calculations, and suggested for clearer guardrails for manufacturer-provider arrangements if manufacturers pay for cell collection or processing.*

Response: *We are persuaded by the commenters that when a manufacturer pays for a preparatory procedure, it could be classified as a bona fide service. Therefore, after consideration of public comments, we are not finalizing our proposal that such payments cannot be classified as BFSFs. Likewise, we are not finalizing the proposal to require inclusion in ASP, beginning January 1, 2026, of manufacturer-paid preparatory procedures for tissue procurement (including ''cell collection'') required for manufacturing an autologous cell-based immunotherapy or gene therapy product. Instead, we agree that manufacturer payments for preparatory procedures—such as cell collection and local processing—may meet the four-part regulatory criteria for BFSFs under § 414.802 when they are itemized, represent FMV, are performed on behalf of the manufacturer, and are not passed through to a purchaser. These payments compensate for services integral to the manufacturing process and are not discounts or rebates that reduce the cost to the purchaser. When these criteria are satisfied, such payments are excluded from price concessions under § 414.804(a)(2)(ii); because ASP is calculated net of price concessions under section 1847A(c)(3) of the Act, these amounts are not deducted from ASP. These clarifications apply regardless of whether collection and infusion occur at the same or different facilities.*

We believe this interpretation is most consistent with the statutory framework for ASP and the regulatory definition at § 414.802, and it avoids unintended downward pressure on ASP-based reimbursement that could impede beneficiary access. Because manufacturers already maintain documentation relevant to BFSF analyses, this clarification aligns ASP reporting with existing requirements and does not impose new burden. We reiterate that payments properly classified as BFSFs are not price concessions in ASP calculations, and manufacturers must continue to maintain documentation supporting their BFSF determinations and reasonable assumptions.

For payments made to non-purchasing third parties, payments that meet the BFSF criteria are excluded from ASP. More broadly, ASP represents the manufacturer's sales to all purchasers; therefore, payments to entities that do not purchase the product are not price concessions to a purchaser and, when properly classified as BFSFs, do not affect ASP.

This policy addresses only how manufacturer-paid amounts are reflected in ASP; it does not require hospitals or physicians to enter financial arrangements with manufacturers or dictate commercial terms. By not mandating such arrangements, we provide interested parties flexibility to

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structure relationships consistent with operational needs and applicable law, supporting site-specific decisions and reducing administrative burden. Except for the ASP reporting clarification described in this section, this final rule does not change any statutory or regulatory price-reporting definitions or methodologies, including AMP and best price. [FR 49546]

Proposed Efficency Adjustment to Work RVUS

CMS is proposing a negative two and a half percent (2.5%) adjustment to more than 7,000 non-time-based codes starting in 2026 and is also proposing that this efficiency adjustment be applied every three years. CMS is proposing to apply the efficiency adjustment to the work relative value units (RVUs), as well as corresponding updates to the intraservice portion of physician time inputs for non-time-based services. CMS stated in the proposed rule that the agency believes that non-time-based procedures become more efficient as they become more common, professionals gain more experience, technology is improved, and other operational improvements are implemented. CMS also stated that there is typically a two-to-three year time lag between when survey data were collected and when CMS uses the data in rate-setting. CMS is proposing a five-year look-back period for the initial application of the efficiency adjustment, thus the 2.5% figure was derived by tallying the last five years' private, non-farm, productivity adjustments in the Medicare Economic Index (MEI).

ASTCT does not support CMS' proposed implementation of an efficiency adjustment for work RVUs of non-time based services in CY 2026.

ASTCT has concerns with CMS' broad assertion that all services become more efficient to perform as they become more common. While this may be true for some services, painting all physician non-time based services with a broad brush fails to take into account the increasing complexity of medicine as well as the development of novel therapies. Ensuring that Medicare beneficiaries have access to the most current treatments depends in large part on proper evaluation of the cost of these services and the work that physicians do to provide them.

Cell and gene therapies are a prime example of services that can become increasingly complex as they become more common. While ASTCT's clinicians have been providing these since 2017, the class is still evolving. CMS cannot assume an experiential efficiency simply because clinicians have treated more patients. In fact, ASTCT clinicians reported that the more patients they see in the stem cell transplant and cell and gene space, the more diverse and complex these patients are. Treating cancer patients and others who might be candidates for cell and gene therapies is truly new; clinicians are still learning about the cell and gene therapies and how to treat these diseases.

Even if CMS' assertion that services become more efficient with frequency were true, a uniform -2.5% reduction in the work RVUs is not appropriate. Any change to the RVUs should, instead, be based on a more detailed review of the resources involved in rendering services at the CPT code level. As CMS notes in the discussion, codes that were flagged for re-revew are only recommended for a decrease in RVUs by the Resource Utilization Committee (RUC) less than 40% time. This outcome indicates that resource use and effort are largely consistent across time. Additionally, repeating these cuts every three years in perpetuity will quickly result in values that are non-sustainable and, over time, will eventually reach zero. **ASTCT strongly urges CMS not to finalize this proposal. However, if CMS does move forward with**

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implementation of an efficiency adjustment, ASTCT recommends that the agency identify specific codes and propose them through rule-making for potential future application. Newly released codes (those within the last five years, at least) such as CPT code 38228 for CAR-T administration, should be exempted.

CMS Response: ***Comment***: *We received many comments regarding the efficiency adjustment proposal. Concerns expressed by the commenters include:*

- *That the proposed efficiency adjustment proposal does not account for the complexities of individual procedures or the varying efficiencies across different specialties. The commenters stated that applying a uniform reduction could undermine the financial stability of practices, especially in rural and underserved areas where access to care is already limited. They state the proposed reduction could lead to reduced patient access to essential services, particularly in specialties facing workforce shortages. The commenters state the proposed efficiency adjustment prioritizes speed over quality of care and puts patients' safety at risk.*
- *That the proposal lacks transparency as to the data and methodology used to justify the efficiency adjustment. The commenters stated the proposal is arbitrary and capricious under section 5 USC 706(2)(A) of the Administrative Procedure Act (APA).*
- *That CMS should adopt a more targeted approach to incorporate efficiency gains within specific services or code families.*
- *That CMS should finalize a policy that will benefit all specialties and not just those that frequently bill time-based codes.*
- *That certain specialties have limited use of physician extenders. While some specialties gain efficiencies through the use of physician extenders, such as nurse practitioners and physician assistants, others are unable to leverage these physician extenders, thus limiting their potential for efficiency gains.*
- *Why certain specialties and code families (for example, E/M, behavioral health, care management, maternity, telehealth) are exempt, and that clear justification for the exemptions were not provided.*
- *A letter published by the Journal of the American College of Surgeons[53] indicated that for inpatient only procedures, surgical times are not declining, rather procedures had longer or similar operative times. Therefore, surgical and procedural services are not becoming more efficient over time, and in some cases, are becoming less efficient. Another study showed that in Q2 2025, "productivity is up 12% for physicians and 11% for advanced practice providers compared to two years ago."*
- *Technology can, at times, increase the amount of physician time and cognitive skill required to perform a service. For example, a few commenters specifically mentioned that reading CT scans and MRIs today requires reviewing more images than it did in past years. Commenters stated CMS' assumption does not consider factors such as increases in care complexity, patient acuity, staff salaries, AI-generated insights, and the electronic health record ("EHR") systems that require the same or more resources than in the past.*
- *Adjusting physician work RVUs and intraservice time for all non-time-based codes, while exempting commonly performed services that are often used as key reference services, will cause*

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disruption in the processes to update the Resource-Based Relative Value Scale (RBRVS) and ensure appropriate relativity of new and revised codes, and there would be rank-order anomalies within and across code families.

Response: *We appreciate the commenters for their responses and appreciate the additional information. We understand the concerns raised by the commenters about the broad application of the proposed efficiency adjustment and the potential impact on specific specialties, patient access and care quality, particularly in rural and underserved areas. However, existing processes to account for efficiencies have been insufficient, as we described in the proposed rule (90 FR 32399 through 32403). Even when codes are revalued, it is based on survey data, with the corresponding shortcomings that we have articulated. In the CY 2026 PFS proposed rule (90 FR 32402), we recognized that while efficiencies may accrue more in some services compared to others, the fact that PFS intraservice time is higher than empirical intraservice time on average for studied non-time-based services,55,56 means that applying the efficiency adjustment will more accurately reflect empiric data compared to not doing so.*

In response to commenters concerned about technological advances in imaging and their impact on physician intraservice time, we note that imaging and other test interpretations have some of the highest mean empirical time to PFS intraservice time ratios of the services studied. We appreciate that changes in technology may have varying impacts on different services, and welcome empiric data from commenters for future rulemaking.

In response to commenters' references to the published letter from the Journal of American College of Surgeons, we reviewed the letter and note that while operative times increased for approximately 51 percent of CPT codes evaluated, they remained the same for approximately 38 percent of CPT codes and declined for approximately 11 percent. Furthermore, the stated increase in operative time given in the letter is 3.1 percent. We note that this information was published in a research letter, and therefore, we are not privy to the detailed methods used by the authors. However, we point commenters to a recent review of PFS intraservice times and times observed in the American College of Surgeons National Surgical Quality Improvement Program (NSQIP), and estimates derived from Medicare anesthesia claims which indicates that NSQIP median operative and anesthesia times are on average, 16 to 17 percent lower than PFS intraservice times.

Additionally, we have seen that even after a change in valuation (such as a decrease in PFS time), the PFS intraservice time still is above empirically-observed time. This is why, as we articulated in the proposed rule, we had discussed that CMS would preferentially consider empiric information submitted by interested parties, if they believe the efficiency adjustment led to incorrect valuation of the service. We believe that robust empiric data is important to avoid some of the shortcomings of survey data in accounting for efficiencies over time. We believe the efficiency adjustment will promote interested parties to submit more precise empiric data, which means that there will still be changes on a service-by-service basis, even if the efficiency adjustment itself affects all non-time-based services. As we proposed, interested parties can submit their requests as part of the Potentially Misvalued Codes initiative, as described in section II.C. of this final rule. We look forward to continued engagement with the public on

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this topic and are interested in information that could assist us in potentially refining this policy through future rulemaking. [FR 49339]

Comment: *Several commenters state that the RUC process already accounts for efficiency and applying an efficiency adjustment to codes recently reviewed would be redundant. The commenters stated that CMS should exempt newly established codes, codes established in recent years, or codes that have been recently reevaluated by the RUC.*

Response: *We understand and appreciate the RUC for providing recommendations to CMS over the years. For many years, we did not have other sources of data to inform valuation of service paid under the PFS, and the RUC recommendations derived from surveys have been particularly important in the revaluation of services. However, studies have demonstrated that CMS continues to overvalue non-time-based services, with PFS time greater than mean procedure time by more than 20 percent,61 which is in part due to the lack of both regular revaluing of all codes, and the nature of the survey data that has been the foundation of many of the RUC recommendations. The survey data used in RUC recommendations often have low response rates (as low as the single digits, even when publications for research usually require a response rate of at least 60, and appropriate characterization of non-responders to ensure that nonresponse bias does not threaten the validity of the findings), the survey data is based on clinical vignettes that have raised concerns for bias.63 This leads to the RUC Relativity Assessment Workgroup's Potentially Misvalued Services Project recommending the valuation of approximately 40 percent of identified services be decreased. And even after a revaluation in the PFS, recent data demonstrates that PFS time still is higher than actual intraservice time. This is why, to better recognize efficiencies gained, we proposed an efficiency adjustment. We welcome interested parties to submit empiric data that is robust in nature related to certain services, if they believe it is not correct to assume that efficiencies are gained over time, and we will consider whether or not reevaluation is needed as part of the Potentially Misvalued Codes initiative.*

Additionally, we are persuaded by the commenters' feedback that it would not be appropriate to apply the efficiency adjustment to new services, given that practitioners would not be able to accrue efficiencies for services that are new in the first year. Therefore, we are exempting codes new for CY 2026 from the efficiency adjustment for CY 2026. [FR 49340]

Comment: *We received several comments regarding the cadence of the efficiency adjustment proposal. Several commenters also requested that CMS clarify its decision to continually apply the efficiency adjustment every 3 years. A few commenters stated that anything more than a one-time adjustment is unwarranted. Other commenters described that efficiencies cannot continue to be gained year-over-year and that at some point, there is a maximum efficiency that can be realized, and going beyond that point will compromise patient care. A commenter stated that the efficiency adjustment is different from the GPCI and MP updates, in contrast to those updates, which have occurred every 3 years for decades with finite and consistent impact on*

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affected services, the efficiency adjustment has the potential to be substantially disruptive to the fee schedule every year it is implemented. The commenter recommended CMS to defer subsequent efficiency adjustments until the impact on Medicare patient care can be appropriately evaluated to ensure that it is not harmful. A commenter stated that technological adoption is rarely linear and believes 3 years is insufficient to determine that innovation and efficiency have been embedded across an entire procedure or service. The commenter recommended CMS extend the adjustment period beyond 3 years to provide adequate time to assess the impacts of innovative technologies on their workflows and care delivery. Another commenter stated implementing a consistent 2.5 percent reduction every 3 years indefinitely risks causing ongoing cuts to payments for certain services, without clear evidence that further efficiencies are actually achievable. Another commenter stated that CMS did not specify an endpoint for the efficiency reduction. The commenter continued to state that as proposed, CMS would, theoretically, continue to apply the efficiency adjustment until such time that the intraservice time is zero.

***Response**: We appreciate the commenters for their thoughtful input. We acknowledge the concern that efficiencies may not accrue indefinitely and that overly repeated application of the efficiency adjustment could have cumulative effects over time. As such, we will continue to monitor the impact of the efficiency adjustment. While we proposed a 3-year cadence, we may revisit the frequency and consider establishing a sunset provision or other refinements in future rulemaking.*

After consideration of public comments, for CY 2026 we are finalizing to establish an efficiency adjustment to the work RVUs, as well as corresponding updates to the intraservice portion of physician time inputs for non-time-based services, with refinements. We will apply the efficiency adjustment to the intraservice portion of physician time and work RVUs every 3 years. To calculate the efficiency adjustment, we are finalizing the use of the MEI productivity adjustment over a 5-year look back period from CY 2022 to CY 2026. [FR 49344]

Updates to Practice Expense (PE) Methodology – Site of Service Payment Differential

For 2026, CMS proposes a significant change to the practice expense methodology. The proposal would reduce the work RVU input (a key input for the indirect component of the facility PE RVU formula) to 50 percent of the amount used for non-facility PE RVU computation. This is a substantial change, as the work RVU in the PE formula serves as a proxy for how much time indirect resources use when providing a service.

ASTCT does not support CMS' proposal given we fundamentally disagree with CMS' premise that payment for indirect costs for facility-based physicians is being duplicated.

We appreciate and support CMS' mission to ensure that Medicare dollars are being spent appropriately. However, we disagree with CMS' basic premise that payment for indirect costs for facility-based physicians is being duplicated. Physicians who provide services in a facility-setting incur indirect practice expenses. This is true regardless of whether they are employed by the facility or are private practice

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physicians with privileges at a facility. Further, CMS's own guidance to hospitals (detailed in Part 1 of the Provider Reimbursement Manual) makes clear that physician administrative costs are *excluded* from what hospitals can report as allowable hospital costs in the cost report.

Section 2110.4 of the cost resport instructions preclude hospitals from including professional billing costs as allowable costs. Professional billing costs necessarily include coding, medical records, scheduling, billing, peer-to-peer medical conversations, and prior authorization requirements, among others. They can *only* be recouped through MPFS due to the aforementioned prohibiltion on hospitals claiming these costs. For CPT codes that are primarily performed in facilities, the PE RVUs should already reflect the necessary indirect costs based on CMS' current allocation methodology, and should not be reduced. We appreciate that CMS has requested input on whether its proposal is appropriate, but CMS' request also bolsters our concern that it is inappropriate to propose a reduction without better understanding the data.

ASTCT recommends that CMS postpone implementing any reduction to the indirect PE RVUs for facility-based physicians. In the meantime, the agency should work to collect data, by specialty, that shed better light on the varying levels of indirect practice expense for facility- vs. non-facility-based physicians.

CMS Response: ***Comment:*** *Several commenters stated that CMS' fundamental assumptions regarding employed physician costs are disconnected from the reality of modern healthcare practice arrangements. These commenters stated that despite the documented trend toward declining private practice ownership and increasing physician employment by larger health systems, the assumption that employed physicians do not incur significant administrative and overhead costs is incorrect. The commenters stated that physicians providing care in facility settings continue to face substantial indirect costs including coding, billing, scheduling, and administrative overhead, regardless of their employment status. The commenters stated that the AMA's PPI survey data provides a concrete quantification of these costs, with estimates of indirect costs of $57 per hour for hospital-based medicine and $62 per hour for hospital-based surgery. The commenters stated that many hospital-employed physicians operate under arrangements where practice expense costs are charged back to their departments, including rent or leasing space based on square footage used, staffing costs, billing infrastructure, and administrative support. Another commenter noted that some independent medical groups have professional service contracts with hospitals, rather than employment arrangements. The commenters stated that the proposed flat 50 percent reduction to the work RVU allocator fails to account for these varied arrangements and represents an oversimplified approach to a complex issue. The commenters requested that CMS focus on collecting up-to-date information on the true cost of practicing in facility vs. non-facility settings before assuming differences warrant a 50 percent reduction.*

Response: *We appreciate these comments, and we acknowledge that practice arrangements vary significantly in current practice. Again, we remain open to more specific data that addresses the variability, as well as feedback on how to update the valuation and payment methodologies to better reflect the relative resources involved in furnishing the services. In the meantime, we continue to believe the underlying assumptions within the methodology should be reasonably grounded in the best information available. We agree with commenters that physicians generally incur indirect costs in the facility setting, and that is why we retained allocating significant amounts of indirect PE RVUs per work*

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RVUs in the facility setting. As some commenters pointed out, in many cases the proposed allocation may still overestimate indirect costs. Under the current methodology, there are only two sites of service where PE RVUs vary (nonfacility and facility). We believe that the proposed policy more accurately reflects indirect PE in the facility setting compared with the previous assumption that the indirect costs are relatively equal. With respect to comments about the PPI survey data, as detailed in section II.B of this final rule, we are concerned that given the low response rate of the PPI survey data, the indirect cost estimates are not an accurate reflection of the typical indirect PE costs faced by physicians who furnish most of their services in the facility setting. [FR 49294]

G2211 Utilization Assumptions

In 2024, CMS implemented a new add-on code G2211: *Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition.*

Medicare claims data analysis indicates that the utilization of this code was greatly overestimated at the time of implementation. This overestimation dramatically impacted the Medicare conversion factor via a budget neutrality adjustment and, thus, negatively impacted physician paymemt. This overestimation is still impacting the MPFS today.

Beginning with this rulemaking cycle, CMS has access to actual utilization data for this code from 2024. The data show that the initial utilization of this code was greatly overestimated. CMS should ensure utilization assumptions for CY 2026 are adjusted for this initial overestimation. Accurate utilization assumptions for G2211 are especially important given the agency's proposal to expand the use of this code to home and resident E/M visits.

ASTCT recommends that CMS use available data to ensure accurate utilization assumptions for CPT code G2211 are being made for CY 2026 and update the budget neutrality adjuster accordingly.

CMS Response: ***Comment****: Many comments supported our proposed refinement to HCPCS code G2211 to make this add-on code payable when reported with home residence E/M visits. Many commenters recommended that we make the add-on code applicable to other or all types of E/M visits and to home visits reported by community health centers and rural health clinics. A commenter also suggested making the transitional care management (TCM) services codes new base codes for HCPCS code G2211. Another handful of commenters opposed our proposal.*

Many commenters, including those who supported our proposal, expressed concerns over the CY 2024 PFS final rule estimate of the utilization of HCPCS code G2211 resulting in a negative impact to the conversion factor for that year. Some commenters expressed concern that our proposal to make the home residence E/M visit codes base codes for the HCPCS code G2211 add-on code would trigger larger budget neutrality adjustments going forward. Many commenters recommended a prospective budget neutrality adjustment to the 2026 Conversion Factor (CF) to account for the estimated utilization that was not realized in CY 2024.

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Response: *We appreciate the commenters for their feedback that this policy will support ongoing, longitudinal care relationships with primary care providers for populations with complex co-morbidities. We also acknowledge receipt of recommendations beyond the scope of this proposal, requesting additional service codes be designated base codes to which the HCPCS code G2211 add-on code would apply, requesting that we revisit the modifier 25 payment policy restriction on certain services or procedures reported on the same day by the same practitioner, and recommendations to provide patient education about applicability of patient co-pays.*

Regarding the concerns about utilization estimates, we acknowledge that the CY 2024 utilization estimate exceeded actual reporting of HCPCS code G2211 in CY 2024. We remind commenters that we do not make retrospective budget neutrality adjustments and would not compare actual claims reported for new coding against the utilization estimates made in the PFS final rule for the year in which such reporting began. As noted in the CY 2024 PFS final rule (88 FR 78975), CMS makes budget neutrality calculations on a prospective annual basis and uses claims data for the services as they become available in subsequent years, to inform budget neutrality adjustments. Utilization is variable and for new coding, estimates sometimes do not anticipate the volume of reporting that is actually realized. We continue to anticipate that utilization of the inherent complexity add-on code will continue to increase over time, consistent with utilization patterns for other new services, and we remain interested and appreciative of feedback regarding how to encourage its appropriate use. [FR 49463]

Status Indicator PC/TC change for 38228: CAR-T Administration

CPT Code 38228: Status Indicator Update

In May 2023, the CPT Editorial Panel approved the addition of four new codes to report CAR-T services, which replaced existing Category III codes. A new subsection in the CPT book with guidelines was also released. The various codes describe steps of a complex process that involves physicians either performing or supervising the service.

ASTCT is specifically concerned about CMS' treatment in the MPFS of CPT code 38228 - *Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous*. Patients and healthcare providers invest significant time, spanning weeks or even months, in preparation for the administration of this product, which is patient-specific. CAR-T administration encapsulates the stressors inherent in treating patients in an advanced state of illness, for whom CAR-T therapy represents a personalized and often last-chance intervention.

The RUC forwarded recommendations for CMS' consideration for CY 2025 when the codes were finalized and CMS shared these in the CY 2025 OPPS Proposed Rule. CMS indicated active pricing for code 38228 (administration of autologous CAR-T) by assigning a work RVU of 3.00 and RUC direct practice expense inputs. ASTCT was pleased to see this, as it reflected expectations based on the multi-society work effort in securing these codes through the CPT and RUC processes. Moreover, it aligned with the separate payment policy for the predecessor Category III CPT code 0540T irrespective of whether CAR-T was administered in a facility or non-facility setting and signaled separate payment would continue for the new Category I CPT code.

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In reviewing the files released with CY 2026 MPFS final rule, ASTCT noticed that CMS assigned a PC/TC indicator in the MPFS RVU file of "5" ("incident to") to CPT code 38228. We belive this is an error as CPT code 38228 should not be categorized as an "incident to" service. The predecessor code was not designated as an "incident to" service and CMS had assigned a PC/TC indicator of "9," which appropriately allowed facility-based physicians to be paid under carrier pricing.

The AMA/CPT subsection guidelines for CPT code 38228 also make clear that this is a physician service. The guidelines state, *"The procedure to administer CAR-T cells includes physician or other qualified health care professional monitoring of multiple physiologic parameters, verification of cell processing, evaluation of the patient during, as well as immediately before and after the administration of the CAR-T cells, direct supervision of clinical staff, and management of any adverse events during the administration..."*

When CPT code 38228 is billed by the facility-based physician on a 1500 professional claim with a facility POS (21 or 22), it signifies that the physician (or other qualified non-physician practitioner) personally supervised the initiation of the product infusion; was present for the first 15 to 30 minutes of the service; and remained immediately available to manage toxicities and complications that may occur during the infusion. The physician evaluates the patient at the end of the infusion and documents all of the activities in the patient's medical record.

ASTCT has concerns about CMS' PC/TC indicator assignment of "5" to CPT code 38228 for two reasons. First, CMS did not discuss this intended change in the CY 2025 MPFS proposed rule, otherwise we and other stakeholder groups would have submitted detailed comments at that time.

Second, clinicians have contacted ASTCT and shared they have received denials from their MACs for billing CPT code 38228 on their 1500 professional claims with a hospital POS (21 or 22) given the PC/TC indicator assignment of "5" signifies non-payment in the facility setting. As the majority of CAR-T is still provided to hospital inpatients and outpatients (rather than in the office setting), and the predecessor Category III CPT code 0540T resulted in separate payment through carrier pricing for facility-based physicians, we believe CMS inadvertently assigned the wrong PC/TC indicator to CPT code 38228.

During the process of petitioning for this CPT code alongside other stakeholders, 38228 was positioned as similar to CPT codes 38240-38243 (stem cell transplant codes), as these codes also signify physician involvement in the delivery of the service. To that end, the best analog code for the PC/TC indicator for CPT code 38228 is CPT code 38241, for an autoSCT, that has a PC/TC indicator of "0." This identifies codes that describe physician services where the PC/TC concept does not apply since professional services cannot be split into professional and technical components, which is true for stem cell transplant services as well as CAR-T administration.

Therefore, ASTCT requests that CMS correct the PC/TC indicator of CPT code 38228 from "5" to "0" to appropriately capture the nature of the service being provided and to align it with other similar services (e.g., 38240, 38241, 38242). This will enable physicians providing CAR-T therapy to hospital inpatients (POS = 21) and hospital outpatients (POS = 22) to receive payment.

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Additionally, given that CMS has allowed payment for the predecessor code in the past, ASTCT requests CMS make this change retroactive so that clinicians that received denials during CY 2025 may resubmit claims for payment processing.

CMS Response: ***Comment:*** *Several commenters stated that CMS assigned a PC/TC indicator of ''5'' (incident to) for CPT Code 38228 (Chimeric antigen receptor T-cell (CAR–T) therapy; CAR–T cell administration, autologous) when it was finalized in the CY 2025 PFS final rule. The commenters stated that CPT Code 38228 is not an incident to service, as the physician personally supervises the initiation of the product infusion and is present for the first 15 to 30 minutes. The commenters identified this as a potential technical error and recommended that CMS update the PC/TC indicator for CPT code 38228 from a ''5'' to a ''0'' to appropriately capture the nature of the service and to align it with other similar services such as CPT codes 38240 and 38242.*

Response: *We appreciate the feedback from the commenters and, after reviewing the subject, we agree that this appears to be an unintended technical error. We are therefore finalizing a change in the PC/TC indicator for CPT code 38228 from ''5'' to ''0'' for CY 2026.* [FR 49285]

Comment: *Many commenters did not agree with the assignment of PC/TC indicator ''5'' to CPT code 38228, which describes the administration of autologous CAR T-cell therapy. They stated that CAR T-cell administration should not be categorized as an ''incident to'' service and recommended revising the indicator from ''5'' to ''0 (physician service),'' consistent with similar services such as autologous stem cell transplant infusion (CPT code 38241). Several commenters also requested that this correction be applied retroactively to January 1, 2025, and that CMS direct MACs to reprocess affected claims.*

In addition, commenters objected to CMS' bundling of preparatory services described by CPT codes 38225 (cell collection), 38226 (cell processing/cryopreservation), and 38227 (receipt and dose preparation), which CMS has assigned status indicator ''B'' under both the OPPS and PFS, making them non-payable. They noted that this approach is inconsistent with CMS' payment policies for stem cell transplants, where collection and processing are separately reimbursed. Commenters recommended assigning status indicator ''S'' and place these codes in appropriate APCs to reflect the clinical complexity and resource intensity of these services.

Response: *We made no specific proposal related to the CAR–T cell administration codes. Therefore, these comments are out of scope. Similarly, we did not propose changes to status indicators for CPT codes 38225 (cell collection), 38226 (cell processing/cryopreservation), and 38227 (receipt and dose preparation). As discussed above in this section, we are finalizing that 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, consistent with the existing payment policy for CAR T-cell therapies.* [FR 49545]

Proposal to Modify the Medicare Telehealth Services List and Review Process

ASTCT supports CMS' proposals to consolidate the process for adding services to the list of approved Medicare Telehealth Services. We agree that the most applicable and important criterion is whether a service can be furnished using interactive, two-way audio-visual technology.

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ASTCT also agrees with CMS' proposal to remove frequency limitations for subsequent visits on a permanent basis and to adopt a definition of direct supervision that allows the supervising physician or qualified health professional to furnish such supervision through real-time audio-visual interactive telecommunications.

ASTCT requests that CMS extend the waiver of provider enrollment requirements for CY 2026 and beyond. The waiver permits practitioners to bill from their currently enrolled location when providing telehealth visits from their homes, rather than enrolling their home address in order to bill for the service.

Allowing the waiver to expire at the end of 2025 would create a significant amount of additional and unnecessary administrative burden for providers and accordingly reduce beneficiaries' access to telehealth. In addition to privacy concerns, the home address requirement will create cross-MAC complexity when provider home addresses are in a different region from their place of employment.

CMS Response: ***Comment***: *Many commenters generally supported our proposal to simplify our review process to add services to the Medicare Telehealth Services List, including removing steps 4 and 5 and eliminating the provisional and permanent categories. The commenters appreciated that this simplified process would reduce the administrative burden, enhance provider flexibility, and provide greater clarity, stability, and predictability for providers. The commenters also supported our emphasis on clinical judgment and supporting practitioners in practicing, to the extent possible, on the most clinically sophisticated tasks and making the most of their professional training. The commenters also supported that this policy change could improve access for beneficiaries while preserving patient-centered care, without compromising patient safety. Some commenters requested that we monitor the impact of this policy change to ensure beneficiary safety, quality, and access. A few commenters did not support our proposal because they believe that the elimination of steps 4 and 5 of the review process does not support a consistent, evidence-based safeguard to ensure that the outcomes of telehealth services are comparable to those of in-person services.*

Response: *We appreciate the commenters for their feedback. We continue to believe that the professional judgment of the physician or practitioner is sufficient to ensure a service can be safely furnished via telehealth and that the service will be clinically beneficial to the beneficiary. We believe that the determination to utilize the professional judgment of the physician or practitioner will better allow practitioners to determine if telehealth is appropriate for that specific Medicare beneficiary and that specific clinical scenario. We will continue to consider the feedback from interested parties for future rulemaking. After consideration of public comments, we are finalizing as proposed.* [FR 49319]

Comment: *Several commenters generally supported the permanent removal of frequency limitations for Subsequent Inpatient Visits, Subsequent Nursing Facility Visits, and Critical Care Consultation Services. The commenters stated that removal of these frequency limitations could enhance continuity of care, provide greater flexibility for clinicians, and allow clinicians to use their judgment in determining the appropriate cadence of telehealth interactions based on patient needs. Some commenters did not support our proposal, citing quality of care and safety concerns. One of these concerns was specifically for nursing residents,who may have complex health conditions that require careful monitoring and assessment, or conditions that make telehealth visits difficult. A few commenters supported our proposal*

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but encouraged us to pair the removal of frequency limitations with safeguards such as enhanced claims monitoring or evidence-based utilization management.

Response: *We appreciate the information from commenters regarding both patient safety concerns and concerns regarding supporting healthcare access. We believe that the complex professional judgment of the physician or practitioner will better allow practitioners to determine if the frequency of telehealth services are appropriate for that specific Medicare beneficiary and that specific clinical scenario. We may consider additional safeguards for future rulemaking. After consideration of public comments, we are finalizing as proposed.* [FR 49325]

Comment: *Several commenters generally supported the permanent adoption of this policy and its revised definition, citing that virtual direct supervision does not inherently give rise to patient safety issues and that this policy could assist in a time of provider shortages. . .*

Response: *We appreciate the commenters for their support and suggestions on how we may refine our policy and will take them under consideration for future rulemaking. . . After consideration of public comments, we are finalizing as proposed.* [FR 49327]

Comment: *A few commenters expressed concerns regarding the perception of an expiring flexibility for telehealth practitioners to use their currently enrolled location instead of their home address when providing services from their home due to a lack of a proposal to extend this flexibility in the proposed rule. In these comments, interested parties voiced concerns about the safety and privacy of health professionals who work from home and furnish telehealth services. The commenters requested that CMS take steps to protect telehealth practitioners by adjusting enrollment requirements so that individual practitioners did not have to list their home addresses on enrollment forms. In the CY 2024 and CY 2025 PFS final rules we stated that, through CY 2025, we would permit a distant site practitioner to use their currently enrolled practice location instead of their home address when providing telehealth services from their home.*

Response: *Given that CMS issued an FAQ (located at https://www.cms.gov/medicare/quality/physician-compare-initiative/frequently-asked-questions) providing additional information on how to suppress street address details as providers continue to use their currently enrolled practice location instead of their home address when providing telehealth services from their home, we do not believe that additional ''extensions'' are required via rulemaking. We remind interested parties that we defer to State law regarding licensure requirements for distant site Medicare telehealth practitioners. In addition, we note that a separate Medicare enrollment is required for each State in which the practitioner furnishes and intends to bill for covered Medicare services. We would also like to clarify that in the future any updates to this policy will be issued via subregulatory guidance.* [FR 49330]

Remote Physiological Monitoring

ASTCT appreciates that CMS's proposals support the AMA's expansion of CPT codes for Remote Patient Monitoring (RPM) services. As our members continue to expand the use of remote monitoring to support care for their patients after stem cell transplant or cell therapy treatments, it is critical that these services be recognized by CMS. To better serve their patients, our members are setting up post-

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treatment RPM protocols that include the use of 24/7 tracking of vital signs through biometric sensors[1] and assessing neurocognitive function through electronic surveys and tests.[2]

The current status indicator of "B" assigned to these codes will will undermine CMS' interest in collecting more data on the usage of these codes.

ASTCT asks that CMS assign OPPS-payable status indicators for RPM codes ("V" for RPM codes focused on intial set-up; "Q1" for subsequent/add-on codes) now so that hospital reporting of these services can be tracked and analyzed for future ratesetting proposals.

CMS Response: CMS did not respond to this request as the requests pertain to OPPS status indicators. ASTCT anticipates potential discussion of this issue in the CY 2026 OPPS Final Rule.

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

[1] Moore SL, Peterson GJ, Montoya SR, et al., "Using technology for patient-centered care at home after CAR T-cell therapy or stem cell transplant: a prospective feasibility study," *Front Immunol*. 2025 Jun 18;16:1403249. doi: 10.3389/fimmu.2025.1403249. PMID: 40607376; PMCID: PMC12213405.

[2] Wilemon T, "VICC launches new telehealth program for CAR-T patients," *VUMC News*, February 28, 2019. Online: https://news.vumc.org/2019/02/28/vicc-launches-new-telehealth-program-for-car-t-patients/

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