ASTCT
American Society for
Transplantation and Cellular Therapy

Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244
SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

August 27, 2026

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-1850-P]

Dear Administrator Oz:

The American Society for Transplantation and Cellular Therapy (ASTCT) is a professional membership association of more than 3,900 physicians, investigators, and other health care professionals. Our mission is to advance hematopoietic cell transplantation and cellular therapies through groundbreaking research, high-quality education, impactful advocacy, and clinical excellence. ASTCT's comments in relation to the CY 2027 OPPS proposed rule continue to reflect our focus on making innovative therapies available to all Medicare beneficiaries who need them.

ASTCT thanks CMS for the opportunity to provide comments on the proposed rule. We are ready to discuss any aspect of our comments further with your staff.

Regards,

Margaret L. MacMillan, MD, MSc, FRCPC
ASTCT President
2026-2027

Please send any correspondence to ASTCT Director of Government Relations, Molly Ford, at MFord@astct.org.

Executive Summary

ASTCT appreciates the opportunity to provide comments on the CY 2027 OPPS proposed rule. The following is a summary of our requests from this letter.

- **APC reassignment for CPT 38228:** ASTCT requests that CMS reassign CPT code 38228 from APC 5694 to APC 5242 to mitigate the unintended consequences stemming from its inclusion APC 5694 and improve clinical alignment.
- **Cell and Gene Therapy (CGT) C-APC Exclusion List:** ASTCT asks CMS to consider both the addition of a check-box in the MEARIS HCPCS Level II code application to flag therapies that should be reviewed for addition to the exception list and to develop a mechanism to identify this status in Addendum B, such as the use of a new status indicator.
- **340B Conversion Factor Remedy:** ASTCT requests that CMS maintain the *status quo* 0.5 percent reduction that is in place today, instead of finalizing the proposal to increase the reduction to 3.0 percent.
- **Payment Reduction for 340B Drugs:** ASTCT reiterates its request that CMS not finalize its proposed ASP-33.4 percent payment cut for 340B-acquired drugs for CY 2027. CMS should, instead, conduct further analyses to understand whether the concerns driving these proposals are widespread or are limited to a group of bad actors that should be held accountable, rather than all 340B purchasing providers. ASTCT also asks that CMS review its data for CGTs, using either its own C-APC exclusion list or the Food and Drug Administration (FDA) list of approved CGTs, to understand the acquisition costs for this subset of therapies. If CMS moves forward with reducing payment to 340B purchasing providers, the agency must retain the plus-six percent add-on payment currently being utilized.
- **Software as a Medical Service:** ASTCT supports CMS' proposal to rename "Software" as "Software as a Medical Service (SaMS)" and assign designated SaMS codes to new technology APCs. ASTCT also supports CMS' proposal to assign 10 HCPCS codes that describe various SaMS analyses performed on laboratory tests to new technology APCs. ASTCT agrees with the creation and assignment of new status indicator "O1" to SaMS and recommends that CMS assign this to all existing SaMS "S" or "Q1" CPT codes.
- **Price Transparency:** ASTCT urges CMS to forgo any additional price transparency requirements unless and until CMS (1) demonstrates comparable enforcement of transparency obligations on health plans; (2) validates that consumers are using existing MRF and consumer-friendly display data in a meaningful way; and (3) provides hospitals at least one year of lead time to implement any new requirements.

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CPT 38228 (CAR-T Administration): APC Reassignment Request

Last year, ASTCT requested that CMS reassign CPT code 38228 (CAR-T cell administration) from APC 5694 (Level IV Drug Administration) to APC 5242 on the basis that outpatient CAR-T administration is more similar clinically to autologous stem cell transplant than to complex drug administration.

CMS declined the change, stating:

> *We believe CPT code 38228 is appropriately assigned to APC 5694, which shares similar clinical and resource use as other complex cancer drug administrations… 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. [FR VOL 90, No. 225; 53570]*

ASTCT continues to disagree with CMS that CAR-T is similar to standard complex drug administration. We reiterate our request that CMS change the APC assignment to better support clinical alignment and appropriate reimbursement for outpatient CAR-T administration.

ASTCT, along with many other stakeholders, opposed CMS' drug administration volume control proposal in the calendar year (CY) 2026 OPPS rule-making cycle. Despite objections, CMS adopted its proposed policy based on the rationale that the volume for drug administration services had grown due to payment incentives to furnish these services in a higher-paid setting, rather than for other clinical reasons. With the CY 2026 finalization of the policy for excepted off-campus provider-based departments (PBDs), CPT 38228's placement in APC 5694 means that the CAR-T administration code was included in that volume-control policy across both excepted and non-excepted settings.

CMS' utilization rationale for drug administration is not applicable to CAR-T administration, since there is no evidence that outpatient CAR-T administration volume has increased due to hospitals shifting this service away from free-standing office settings to the hospital outpatient setting to capitalize on a payment differential. Growth in CPT 38228 claims volume in OPPS reflects a combination of several care aspects: improved clinical protocols and infrastructure to support outpatient treatment; growth in the number of providers offering CAR-T therapy to Medicare beneficiaries; and an increasing number of CAR-T products with toxicity profiles that allow a subset of patients to be safely treated as hospital outpatients rather than inpatients. CAR-T is just now beginning to be used in the free-standing setting, and there are very few providers currently capable of providing this level of care to patients in their offices, thus the number of administrations there remain inherently very small. Therefore, having CPT code 38228 subject to a payment reduction policy with the goal of driving more volume to the physician office setting is illogical.

Enabling a larger number of patients to receive CAR-T therapy safely as outpatients, when clinically appropriate, is a positive development for patients and the Medicare program alike. Providers should not be financially penalized for providing CAR-T to hospital outpatients simply because this service has been assigned to a drug administration APC.

ASTCT acknowledges that non-excepted off-campus PBDs already receive a rate equivalent to the Physician Fee Schedule amount for all HCPCS codes assigned to the drug administration APCs as a matter of existing policy. For this reason, CPT 38228 has been paid at this reduced rate in non-excepted locations for some time. This has not been a significant issue to-date, as CAR-T administration volume in the outpatient setting has been slow to increase until recent years due to the product toxicity profiles and the clinical needs of Medicare beneficiaries. However, ASTCT has been closely following the trends in hospital-based outpatient CAR-T volume by reviewing both single and total claims reported in CMS' cost statistics data file. We note that the last few years have exhibited a significant growth trend, appropriate to the changes in technology and experience in controlling toxicities, that we expect to continue. Therefore, ASTCT urges CMS to treat CPT 38228's unintentional exposure to the drug administration volume-control policy as another reason to remove the code from APC 5694. We ask CMS to take this action before access to CAR-T is negatively impacted by a policy change whose rationale is not justified for this service.

ASTCT also thinks that an analysis of the 38228 claims helps support our request to move the code to a different APC. ASTCT's review of the cost statistics data CMS released with this proposed rule shows that only about 14 percent of claims that contained CPT 38228 were used for rate-setting. This is not altogether surprising, given our assumption that most CAR-T claims will contain one or more other procedures and/or visit codes, as well as other packaged items and services, and would therefore be set aside as multiple-procedure claims. Given this, CMS is likely using the simplest claims – and potentially incomplete claims - for rate-setting rather than claims that would be more representative clinically. Like autologous stem cell transplant claims, ASTCT expects that CAR-T administration claims will frequently include additional services provided on the same day. These services may include evaluation and management (HCPCS G0463); observation services to monitor for post-infusion complications; hydration or therapeutic infusion services to manage side effects; and additional drugs or biologicals that may be required.

Outpatient CAR-T is still in its adolescence, and CPT code 38228 is relatively new. Total volume is expected to increase over time. We anticipate that there will be a correlated increase in the charges providers report as they learn to more accurately reflect the facility resources required to care for these patients. However, ASTCT does not expect to see a large proportion of single procedure claims developing, given the inherent complexity of the administration procedure and CMS' rate-setting logic around identifying single and pseudo-single procedure claims.

In conjunction with our review of CAR-T claims, ASTCT also examined CMS' cost statistics file and the two-times rule calculation PDF file that was published with the proposed rule. We sought to understand whether a two-times rule violation would support reassignment of CPT

code 38228 to APC 5242. At a gross level, our review found a large degree of variation across all 19 codes in APC 5694, as well as geometric mean costs that ranged from $72.71 to $1,336.11. ASTCT recognizes, however, that CMS does not test every code in an APC for a two-times rule violation. Instead, CMS applies the two-times rule only to "significant" codes, which CMS defines as those with more than 1,000 single claims, or more than 99 single claims that also make up at least 2 percent of the claims used to set the APC's cost. Applying that standard to APC 5694, 8 codes qualify as significant. Their costs cluster more tightly together, ranging from $313.91 to $572.98, a ratio of 1.83, which is within the statutory threshold. CPT 38228, with only 94 single claims, falls short of either significance threshold and, therefore, was not examined by CMS for a two-times rule violation. ASTCT notes that CPT 38228's geometric mean cost of $714.61 is 2.28 times the low end of the range set by the codes that drive APC 5694's payment rate.

ASTCT also examined whether reassignment to APC 5242—which includes CPT 38241 (autologous stem cell administration) and other services that are clinically comparable to CAR-T administration—would result in a closer clustering of costs. Our review reflects that it does not—at least not yet. Applying the same two-times rule logic to APC 5242, only 2 codes qualify as significant, and they, too, cluster closely in a range from $1,583.38 to $2,621.30. Adding CPT 38228 to this APC would simply flip the current problem seen in APC 5694 rather than solving it; that is, at $714.61, CPT 38228 would sit 2.22 times below the floor set by APC 5242's significant codes.

ASTCT shares this analysis with CMS to be transparent that a reassignment would not eliminate a two-times rule type violation; it would, instead, simply relocate it to another APC. Nonetheless, we believe that CMS should proceed with reassignment to ensure that CPT 38228 is assigned to a more clinically homogeneous APC and to alleviate the impact of the unnecessary volume control payment decrease that affects CPT 38228 simply because it is assigned to a drug administration APC (discussed above).

Fundamentally, ASTCT continues to view the clinical care for CPT 38228 as being analogous to the services described by CPT 38241 for autologous stem cell transplant. Since outpatient CAR-T administration is a comparatively new service, we believe that the current cost data used by CMS are likely to understate the true resource-intensity involved in treating these patients. We note that hospitals are still evaluating how to set an appropriate charge for this service that accurately reflects nursing and other facility resources involved in caring for these patients. ASTCT expects that reported costs will rise as claims volume grows and charge capture matures.

Given that some cost mismatch exists regardless of which APC houses CPT 38228, ASTCT believes it is more appropriate to place the code in a clinically comparable, slightly higher-paying APC: APC 5242. It should not remain grouped with codes it does not resemble either in terms of clinical services or in cost, as it currently is in APC 5694. In making this change, CMS would also remove CPT 38228 from exposure to the volume control policy that CMS implemented as of CY 2026. **Therefore, ASTCT requests that CMS reassign CPT code 38228 from APC 5694 to APC 5242 for CY 2027.**

Cell and Gene Therapy C-APC Exclusion

ASTCT continues to appreciate and support CMS' policy of excluding cell and gene therapies (CGTs) from C-APC packaging when those therapies are not integral, ancillary, supportive, dependent, or adjunctive to a primary C-APC service. We also continue to support CMS' practice of adding new product-specific HCPCS codes to the exclusion list as they are created, which reduces the burden on individual stakeholders to petition for inclusion each rulemaking cycle. Given the volume of HCPCS code applications CMS receives and the limited number of CGTs that would fall under this exception, ASTCT suggests that CMS consider a check-box on the HCPCS request forms on MEARIS for applicants to flag when they believe their therapy would qualify for this exception.

ASTCT also renews its request from last year's comment letter that CMS establish and describe a formal, off-cycle process by which stakeholders can request that a HCPCS code be added to the C-APC exclusion list when a product's pass-through status is expiring outside the standard rulemaking timeline. CMS has not addressed this request, and the recurrence of the same problem in this year's proposed rule illustrates why a durable process is needed. For example, HCPCS codes J1413, J3401, and J9029 all correspond to cell or gene therapies that have pass-through payment status ending December 31, 2026, immediately prior to the start of CY 2027, but none of them appear in the proposed CY 2027 exclusions table. Absent a mechanism for stakeholders to flag these products in advance of, or independent from, the annual rulemaking cycle, CGTs will likely continue to fall through this gap, regardless of CMS' diligence in updating the list during its rulemaking process.

Beyond the timing problem, there is not currently a place on the CMS website (other than the OPPS final rule) for stakeholders to review the current exclusion list and confirm the exception for a specific product. This is problematic for these specialized and high-cost therapies, given that providers will want confirmation of the exception when planning patient treatment pathways. ASTCT recommends that CMS meet this need through a mechanism it already uses: a dedicated status indicator that is shown with the code in Addendum B, which has been used in other situations where claims need to be processed or price in a certain way (e.g. K1 and H1).

We recommend that CMS establish a new status indicator for the CGTs it has placed on the exclusions list; for convenience we refer to this as status indicator "K2." When assigned, the same separate, ASP-based payment treatment that occurs with status indicator "G" would occur signaling that the product is excluded from C-APC packaging but no longer has pass-through status (or CMS could call it G1 instead of K2).

ASTCT requests that CMS use this rulemaking cycle to establish and publish a formal off-cycle process for exclusion-list additions. We ask CMS to consider both the addition of a check-box

in the MEARIS HCPCS Level II code application to flag therapies that should be reviewed for addition to the exception list at the time of code creation and a mechanism to identify this status in Addendum B, such as a new status indicator.

340B Conversion Factor Remedy: Proposed Acceleration to a 3.0 Percent Annual Reduction

ASTCT disagrees with CMS' proposal to increase the annual reduction to the OPPS conversion factor for non-drug items and services from 0.5 percent to 3.0 percent, effective January 1, 2027, as part of the prospective offset for the 340B remedy payments made in CY 2024. ASTCT notes that CMS itself proposed a 2.0 percent annual reduction for CY 2026 and did not finalize it in response to stakeholder concerns, including ASTCT's own. Therefore, a 3.0 percent proposal (6 times the current rate) is inherently problematic for the same reasons.

ASTCT requests that CMS maintain the *status quo* 0.5 percent reduction that is in place today instead of finalizing the proposal to increase the reduction to 3.0 percent.

340B Drug Payment Proposals Rate: Proposed ASP Minus 33.4 Percent

ASTCT disagrees with CMS' proposal to pay for drugs acquired under the 340B Program at ASP minus 33.4 (ASP-33.4) percent beginning CY 2027. We appreciate that CMS is striving for payment accuracy and that the agency has conducted a drug acquisition cost survey to better determine hospitals' costs. However, we do not believe that an aggregate, across-the-board payment reduction is consistent with the purpose of the 340B Program.

Congress created the 340B Program with bipartisan support in 1992 to help covered entities stretch scarce resources to serve low-income and other vulnerable patient populations. The savings generated by the differential between 340B acquisition costs and payer reimbursement are not a windfall for 340B hospitals. Rather, they are the mechanism by which the Health Resources and Services Administration's (HRSA's) program design allows covered entities to expand access to clinical services for the low-income, uninsured, and underinsured populations they serve. If CMS has concerns that some providers are not redirecting 340B savings toward this purpose, the appropriate response is for CMS to work with HRSA to evaluate how those savings are actually being used. The agency should not impose a blanket, aggregate payment reduction on every 340B hospital.

If CMS nonetheless finalizes a 340B payment reduction, it *must* pair that reduction with the ASP plus-six (ASP+6) percent add-on that CMS provides today in recognition of pharmacy overhead and handling costs that providers face. This is particularly important for ASTCT members, whose hospitals dispense high-cost cellular and gene therapy products—including CAR-T therapies—that require specialized apheresis and cell-processing capacity; chain-of-custody and chain-of-identity protocols; and compliance with many additional requirements. ASTCT continues to disagree with CMS' long-standing characterization that cell collection and cell processing are manufacturing steps that CMS' payment for the product covers, rather than separately payable clinical services.

In the CY 2026 Medicare Physician Fee Schedule (MPFS) final rule, CMS finalized a bundled payment policy for these therapies, which states that payment for the associated clinical services is included in payment for the product. Specifically, CMS stated:

> *We are finalizing continuation of the existing bundled payment policy for CAR T-cell therapies and extending it to autologous cell-based immunotherapy and gene therapy, such that preparatory procedures for patient-specific cell or tissue procurement required for manufacturing are included in the product payment." [FR Vol 90 No 212; 49545]*

Our members' long-standing position has been that payment, even at ASP+6 percent, does not appropriately account for the true costs of these clinical services. Payment at this plus-six percent level, however, allows for at least some dollars to be internally allocated back to the specialized apheresis and cell processing labs required to provide these life-saving treatments to Medicare beneficiaries. We reiterate that this *must* be preserved if CMS finalizes a 340B reduction.

A payment rate of ASP-33.4 percent—especially without any add-on payment—creates a net-negative impact for the product purchase itself. It also completely undercuts any pretense that CMS is providing a bundled payment for these clinical services as part of the product payment. CMS cannot simply ignore its own decision to bundle services into payments and then expect hospitals in the 340B Program to negotiate with manufacturers at extreme discounts to cover otherwise uncompensated costs.

If CMS moves forward with reducing payment to 340B purchasing providers, the agency must retain the plus-six percent add-on payment currently utilized. This is essential to sustain CGT programs as a critical resource for patients who have rare and complex illnesses.

CMS appears to assume that 340B hospitals will respond to this payment cut by seeking price discounts more than 33.4 percent, so as not to be financially underwater on the purchase and provision of these drug/biologicals to Medicare beneficiaries. ASTCT thinks that this is an unlikely scenario, since CGTs are an emerging class of therapies that are inherently low volume, require highly specialized manufacturing, and are often produced by small-scale biotechnology companies. These companies are unlikely to offer discounts of this magnitude to providers. Hence, providers will have to decide either to take a substantial loss at the 340B purchase price; purchase outside of the 340B Program and be unable to utilize their 340B savings as intended; or reconsider whether they should offer these products at all.

Additionally, CMS' discussion of the survey methodology and results indicates that CMS did not provide results specific to CGT; the closest approximating category is antineoplastics at minus 28.9 percent. This category, however, is still general enough to include products that have been available for decades and are used at high volumes, making them more appropriate candidates for price discounts and negotiations. As a result of the lack of specialized analysis of CGTs as a class, along with the low response rate from the academic centers that provide a substantial

percentage of this specialized care, it is critically important for CMS to look more closely at the impact this proposal would have on this area of medicine.

ASTCT asks that CMS review its data for CGTs, using either its own C-APC exclusion list or the Food and Drug Administration (FDA) list of approved CGTs. This will provide the agency with a better understanding of the actual discounts being applied to this small but critically important field and avoid applying a blanket or average payment discount to CGTs.

Finally, CMS' stated concern about beneficiary coinsurance does not, in ASTCT's view, justify this proposal. CMS cites reduced beneficiary copayments—estimated at $1.15 billion for CY 2027—as a rationale for this proposal. CGTs are largely utilized as a one-time intervention, and their co-pays are capped at the inpatient deductible; this amount would be stable whether the products were paid at ASP+6 percent or ASP-33.4 percent. Additionally, most Medicare beneficiaries carry secondary insurance that covers their cost-sharing obligations. Thus, any modest coinsurance savings will not offset the risk that an aggregate 33.4 percent cut poses to the financial sustainability of 340B hospitals that provide high-cost CGTs.

ASTCT reiterates its request that CMS not finalize its proposed ASP-33.4 percent payment cut for 340B-acquired drugs for CY 2027. CMS should, instead, conduct further analyses to understand whether the concerns driving these proposals are widespread or are limited to a group of bad actors that should be held accountable, rather than all 340B purchasing providers.

Volume Control Policy: Imaging Services without Contrast

CMS proposes to limit payment for imaging without contrast as part of its efforts to "control unnecessary increases in the volume of outpatient services furnished in off-campus provider-based departments." ASTCT is not concerned by the proposal's premise (e.g., that unnecessary utilization should be discouraged) but we are concerned that CMS attributes the growth of these imaging services to be payment-driven site-of-service selection instead of being based on clinical need. We continue to find this view alarming; it assumes that physicians are directing patients to receive care at hospital-based clinics as a profit maximization tactic.

Clinicians are not driven by payment rates. Clinicians order services based on the patient's need, complexity, continuity of care, patient safety, and timely availability of the necessary imaging services—not based on the settings with higher vs. lower payment rates. They utilize clinical judgment to assess medically complex patients' needs and the imperative to maintain continuity of care with the treating transplant or cellular therapy program. For example, stem cell transplant and cell therapy providers frequently evaluate a patient; order clinically indicated time-sensitive imaging during the same episode of care; and, subsequently, develop and implement a treatment plan within a matter of days.

If imaging providers who do not otherwise participate in the patient's care are required to become involved, it will introduce unnecessary care fragmentation, disrupt continuity of care,

and likely result in avoidable delays in diagnosis and treatment. This will be the case especially when the external providers are unfamiliar with the patient's disease and the specific imaging information needed to inform the care plan. In that case, patients may need to have repeat imaging performed, causing further delays and cost. CMS' proposal, if finalized, could specifically harm patient access to needed care, in the medically important timeframe, at the health care setting where they receive the rest of their care.

ASTCT is especially concerned about beneficiaries who are undergoing treatment for blood cancers or blood disorders, particularly immunocompromised patients who may be recovering from hematopoietic stem cell transplantation, CAR-T therapy, and other CGTs. These medically fragile patients require frequent monitoring and may live in communities that lack free-standing imaging facilities and for whom the only available facility may be an off-campus site. CMS' premise that patients are receiving care at more costly sites due to provider payment incentives continues to be illogical.

The specific services that CMS identifies as driving volume growth in the non-contrast imaging service APCs are, for ASTCT's patient population, standard components of clinically necessary surveillance and monitoring. They are not discretionary services that could be performed at later times by non-associated care teams. For example, long-term corticosteroid exposure for the treatment of graft-versus-host disease, and treatment-related bone loss more broadly, make bone density surveillance (HCPCS 77080) a recognized component of long-term transplant survivorship care. Cardiotoxic conditioning regimens and prior anthracycline-based chemotherapy require baseline and serial cardiac function assessments (HCPCS 93306), including monitoring associated with post-transplant sepsis or sepsis-like cytokine release syndrome following immune effector cell therapy. Chest radiography (HCPCS 71046) and non-contrast CT of the chest (HCPCS 71250) are standard tools for the surveillance and diagnosis of pulmonary complications (including graft-versus-host disease of the lung and opportunistic infection) in an immunocompromised patient population at persistently elevated risk. These are the same four codes CMS identifies as driving most of the excepted-PBD imaging without contrast volume growth.

ASTCT does not dispute that CMS may be seeing volume increases that should be reviewed. We believe, however, that there is a need for a more rigorous analysis that assesses the types of patients being treated, the conditions for which they are being treated, the number and types of services provided, and more. Additionally, CMS does not provide any verification that these services are actually available (and available in a timely manner) in non-hospital locations. Finalizing a policy that could force beneficiaries to access services that are not available will be detrimental to care and create frustration among both providers and patients. Looking solely at volume instead of case-mix could mask real reasons for the noted increases, and any payment reductions CMS may finalize could truly compromise patient's ability to access needed care.

ASTCT requests that CMS abandon its proposal to reduce the payment for non-contrast imaging services provided in excepted off-campus PBDs. CMS should continue to recognize these grandfathered locations for what they are: an extension of on-campus imaging services

provided in hospital-based clinic settings that may be more feasible to access. This is especially important for Medicare beneficiaries who are being treated for blood cancers or disorders.

Software as a Medical Service (SaMS)

ASTCT appreciates that CMS is thinking carefully about how to appropriately pay for FDA-approved technologies that represent clinical technologies that are used to support medical decision-making. We support these technological advancements and appreciate the ways they can be used to provide high-quality health care. But, CMS should proceed with caution and ensure that these services are *never* viewed as substitutes for the physician's clinical oversight and medical judgement, which are paramount in treatment decision-making. Clinical oversight and medical judgement should not be viewed as unnecessary simply because software is being utilized.

The table below shows examples of the types of services that would be affected by CMS' proposal. The following codes are for software analysis of CT scans that measure bone strength and mineral density. Our clinicians order these tests to help determine current fractures and fracture risk caused by bone loss from various cancer therapies. For the patients ASTCT's members treat, these analyses inform decisions with real clinical consequences—detecting fractures and quantifying fracture risk that shape whether and how cancer therapy proceeds. CMS should ensure its payment treatment of these services recognizes their role as adjuncts to physician judgment and preserves clinician access to them.

0555T	Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; retrieval and transmission of the scan data
0556T	Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; assessment of bone strength and fracture risk and bone-mineral density

ASTCT supports CMS' proposal to rename "Software" as "Software as a Medical Service (SaMS)" and to assign designated SaMS codes to new technology APCs while CMS studies the data and develops a longer-term payment methodology. We also support CMS' proposal to assign 10 HCPCS codes that describe various SaMS analyses performed on laboratory tests to new technology APCs, using the latest available Clinical Lab Fee Schedule (CLFS) data to crosswalk these codes to new technology APC payment rates. Finally, ASTCT agrees with the creation and assignment of new status indicator "O1" to SaMS and recommends that CMS assign this new status indicator to all existing SaMS CPT codes with status indicator "S" or "Q1."

Strengthening the Standardization and Comparability of Hospital Price Transparency Data

ASTCT supports price transparency policies that provide patients with clear and accurate information. Our concern is that CMS' continued focus on standardizing and expanding the Machine-Readable File (MRF) does not directly serve that goal. Instead, the existing MRF requirements (and others for which CMS is now requesting additional information) impose even more burden on providers without a directly corresponding benefit to the patients.

ASTCT agrees that free text fields in the MRF are difficult for users to parse and compare across hospitals. But these "users" are (according to CMS) innovators, researchers, employers and consumers, some of which, like commercial data vendors, profit directly from aggregating and reselling this data. The users are *not* patients navigating treatment.

ASTCT agrees with concerns raised by other stakeholders, including the American Hospital Association, that CMS should focus future price transparency efforts on information that would be the most effective at helping patients understand and compare their expected costs prior to care. Individualized estimates based on a patient's *actual* cost-sharing and their progress towards meeting their deductible will be much more useful to beneficiaries than continuing to expand a MRF whose primary users are commercial data aggregators.

ASTCT urges CMS to forgo any additional price transparency requirements unless and until CMS (1) demonstrates comparable enforcement of transparency obligations on health plans; (2) validates that consumers are using existing MRF and consumer-friendly display data in a meaningful way; and (3) provides hospitals no less than one year of lead time to implement any new requirements.

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