July 8, 2020

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1735P 7500 Security Boulevard
Baltimore, MD 21244

SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

RE: CMS-1735-P Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals

Dear Administrator Verma:

The American Society for Transplantation and Cellular Therapy (ASTCT) is pleased to offer comments on the proposed rule governing the Fiscal Year (FY) 2021 Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals. ASTCT is a professional membership association of more than 2,200 physicians, scientists, and other health care professionals promoting blood and marrow transplantation and other cellular therapies through research, education, scholarly publication, and clinical standards.

The internationally recognized clinicians in our Society have been instrumental in developing and implementing clinical care standards and advancing cellular therapy science, including the design of and participation in trials that led to Food and Drug Administration (FDA) approvals for Chimeric Antigen Receptor T-cell (CAR-T) therapy.

Our members are also innovators at the cutting edge of clinical and pre-clinical research on novel cellular therapies and other types of treatment for a broad range of diseases, including blood cancers, solid tumors and nonmalignant diseases that can be treated with cellular and gene therapies. The involvement of our membership in the research, design, testing, and utilization of advances in the field of hematology means that we have a vested interest in ensuring appropriate coding and reimbursement for these therapies. It is because of our spectrum of involvement and knowledge that we wish to comment on a number of proposals and items not only in the proposed rule but also related to it.
I. Summary of Comments and ASTCT’s Recommendations

ASTCT members are committed to protecting patients’ access to CAR-T therapy and cellular therapy, including hematopoietic stem cell transplant (HSCT) and non-transplant cellular immunotherapies. The Society has engaged multiple times with the Centers for Medicare and Medicaid Services (CMS) over the past three years, partnering with the Agency to improve Medicare payment policies for CAR-T therapy. Overall, we are pleased with, and support, CMS’ FY 2021 proposal for a new MS-DRG for CAR-T therapy, as it reflects much of what we have discussed with the Agency. We thank the Agency for its continued engagement with our organization. While CMS is moving in the right direction, there are some important technical issues that must be addressed to ensure these therapies are appropriately reimbursed, and that the integrity of the payment system is maintained. In the comments that follow, we describe in detail, our recommendations for CAR-T payment policy for FY 2021 and beyond, including ICD-10-PCS coding requests, future MS-DRG assignments, and the need for additional technical guidance. Below, we summarize ASTCT’s recommendations.

CAR-T Payment Policies for FY 2021 and Beyond

- **Finalize the Creation of MS-DRG 018 for CAR-T Cases**: ASTCT strongly supports CMS’ proposal to create a new CAR-T MS-DRG for procedures involving CAR-T therapies. We urge CMS to finalize MS-DRG 018 for FY2021.

- **Revise Proposed Relative Weight Calculation for MS-DRG 018**: ASTCT recommends that CMS treat revenue code 0891 charges as drug charges for the purpose of rate-setting, and suggests a methodology on how to include these charges to develop the relative weight for MS-DRG 018, until changes to the MedPAR data set can be made.

- **Review MedPAR Data Dictionary Definition for Organ Acquisition Revenue Codes**: ASTCT urges CMS to review the data dictionary and revise how certain revenue codes in the 081x-089x range are handled in rate-setting for future fiscal years.

- **Update Methodology to Pay Reduced Amount for Clinical Trials in FY 2021**: ASTCT requests CMS to either require Value Code 90 to collect actual acquisition cost data on claims or utilize some other mechanism to avoid over- and under-payment of FDA-approved, commercially available CAR-T products. If the Agency requires the use of Value Code 90, CMS should release instructions through sub-regulatory guidance.

- **Revise the Severity Level Assignment for Cytokine Release Syndrome (CRS) ICD-10-CM codes and Provide Coding Guidance on the Complication T-code to Report**: ASTCT recommends that CMS assign complication and comorbidity (CC) and major complication and comorbidity (MCC) status to the new CRS codes. We recommend that grade 2 CRS be assigned to a CC MS-DRG and grades 3-5 be assigned to an MCC MS-DRG.
• **Create Dedicated New Cost Centers for Cell and Gene Therapies:** ASTCT requests that CMS create two new, distinct pharmacy standard cost centers on the hospital cost report: one for cell therapy products, and the second for gene therapy products. Although some hospitals have already set up their own subscripted lines, CMS issued guidance requiring separate lines. This requirement will ensure accurate reporting, provide options for addressing charge compression, and allow CMS to create new national cost centers for future rate-setting.

• **Provide Coding Guidance for Reporting Out of Specification CAR-T Products:** ASTCT recommends that CMS issue clear guidance on how providers should report cases that utilize an “out of specification” (also called “expanded access use”) CAR-T product on inpatient claims: whether as a clinical trial using the Z00.6 code, or using another method.

• **Continue Using the “XW0” ICD-10-PCS Table & Require Collection of the National Drug Code (NDC) for the Administration of Autologous CAR-T Products:** ASTCT recommends that CMS delay introduction of the “XW2” ICD-10-PCS coding table until a broader stakeholder discussion can occur. Instead, for FY 2021, we recommend that CMS require the reporting of existing “XW0” ICD-10-PCS codes for the administration of both existing and new autologous CAR-T products along with NDCs for these products on inpatient claims. If CMS is unable to implement this recommendation for FY 2021, then we recommend that the Agency create new ICD-10-PCS codes in the “XW0” table for the two new products discussed at the March 2020 ICD-10 meeting consistent with the manufacturers’ request presented (as “Option 2”) and simultaneously grant the two existing products (Kymriah and Yescarta) the same coding convention. This will result in all four products being named specifically as part of the code description which allows for transparency, specificity, and parity. Both options help support the calculation of NTAP (when granted), ensures that hospital reimbursement for novel therapies is not compromised, and safeguards patient access to these vital and life-saving treatments.

• **Instruct the ICD-10-PCS Group to Maintain Non-Product Specific Autologous CAR-T ICD-10-PCS Codes and Create Separate New Allogeneic Codes:** ASTCT recommends this action, which will allow future autologous and allogeneic CAR-T therapies to be coded appropriately until product-specific codes are requested, or NDCs if implemented as requested above once products are FDA approved.

• **Convene a Town Hall Meeting Specific to Cell and Gene Therapies:** We encourage CMS to demonstrate its commitment to innovation, reduce administrative burden and provider confusion, and provide beneficiaries with access to critical new cell and gene therapies by convening Agency leaders and stakeholders in a future-looking forum that aims to integrate these therapies into its payment and coding systems in a more coordinated manner.
Implementation of Section 108: Cost Reimbursement for Allogeneic Donor Search and Cell Acquisition

- **Do Not Require Transplant Centers to Submit a Standard Average Charge for Donor Search and Cell Acquisition Across All Patients:** The Agency should allow providers to continue reporting actual acquisition charges rather than finalizing the proposal to require submission of a standard average charge.

- **Create a Process to Provide Interim Payments to Transplant Centers in FY 2021:** Until CMS has complete data from cost center 77 and prior years’ actual charges by ancillary cost center, the Agency must use alternative methods for interim payments. We suggest two methodologies to address this situation.

- **Release Additional Guidance and Clarification on Record-keeping Requirements:** To address the fact that transplant centers have multiple itemized statements about various donor services to evaluate, collect, and obtain cells for each transplant recipient, we recommend that CMS finalize specific clarifying language to address this reality.

- **Clarify Cost-reporting Instructions:** CMS should issue additional instructions and modified forms to help transplant centers to reclassify related donor expenses into cost report line 77 from routine and ancillary departments, thereby facilitating cost reimbursement for allogeneic HSCT.

**Additional Recommendations**

- **Update MedPAR Limited Data Set (LDS) Files and Involve Stakeholders in the Revision Process:** To facilitate stakeholders’ ability to simulate proposed policies and submit data driven recommendations using the MedPAR LDS CMS should resolve existing issues and include stakeholders in the process.

- **Allow Quarterly Approvals of NTAP for all Applications:** For any application that receives FDA approval, regardless of pathway, CMS should recognize NTAP payment in the first quarter after FDA approval.

- **Foster Transparency into the Committee Process and Deliberations:** The ICD-10 Coordination and Maintenance Committee and its partners should publicize key information about coding requests, including: what entity is making them; meeting transcripts; rationale for the Committee’s final decisions on requests; a response to public comments; and an explanation why coding requests are denied, rescheduled, and/or require resubmission.
• **Improve Stakeholders’ Ability to Participate in the Process:** The Committee should issue meeting notices, agendas, and coding request approvals with sufficient lead time to enable stakeholders to participate (i.e., 30 days prior to the meeting date).

• **Postpone CMS’ Market-based Pricing Proposal:** The Agency should not implement its market-based pricing proposal. Instead, CMS should summarize and respond to each proposal or ideas received, including holding public meetings to discuss these proposals. These include the Health Care Financial Management Association’s (HFMA’s) proposal as well as ideas ASTCT provides in this comment letter.

II. **CAR-T Payment Policy Proposals for FY 2021 and Beyond**

Before we delve into our remarks on CMS’ proposed FY 2021 CAR-T payment policy, we would first like to state that we are supportive of, and grateful for, what CMS has proposed. It is clear that CMS listened carefully to concerns expressed by ASTCT and other organizations and cellular therapy providers, and we commend the Agency for thinking critically and innovatively about how to design payment policy for this next fiscal year. ASTCT is pleased that CMS exercised its broad authority under §1886(d)(5)(I)(i) of the Social Security Act to “provide by regulation for such other exceptions and adjustments to such payment amounts under this subsection as the Secretary deems appropriate.”

Overall, we support CMS’ policies. Our comments and recommendations are technical in nature and ensure that potential program integrity issues are addressed prior to implementation of MS-DRG 018. These requests are consistent with the policy recommendations we have previously provided and are in service of improving patient access, program integrity, accurate data collection, and minimizing of errors and inaccuracies.

**A. Proposal to Create MS-DRG 018**

The NTAP for the two currently approved CAR-T products expires at the end of FY 2020, making the creation of a new MS-DRG for CAR-T cases imperative. We agree with CMS that CAR-T cases should be assigned to a different MS-DRG, rather than the autologous HSCT MS-DRG, and recommend that CMS finalize its proposal for the creation of a new MS-DRG for CAR-T cell therapy.

However, we request that CMS revise the methodology for the development of the relative weight for the new MS-DRG (see below) for FY 2021 and modernize the treatment of 089x series revenue codes in the MedPAR database, such that these revenue codes can be utilized as appropriate in future rate-setting.
B. Methodology for Developing the Relative Weight for MS-DRG 018

We recognize how significant it was for CMS to depart from its usual rate-setting process and commend the Agency for its innovative proposal for setting the new CAR-T MS-DRG 018’s relative weight. ASTCT agrees with CMS that, due to the realities of the CAR-T product cost and the claims data, rate setting for CAR-T requires additional steps to arrive at an appropriate MS-DRG weight. As we have commented previously, CAR-T therapy does not fit into the usual structure of MS-DRGs, since product costs far outweigh patient care costs, and a substantial proportion of CAR-T claims are clinical trial claims (reported with Z00.6). Variations in the pharmacy charge data across CAR-T claims may also be due to expanded access cases that do not incur a product cost (and that may or may not be reported with the Z00.6 code based on manufacturer and center practices), in addition to providers that are billing the product acquisition cost without appropriate mark-up.

As a result, ASTCT agrees with CMS’ proposal to exclude the following claims from the rate-setting process:

1. Claims with the Z00.6 ICD-10-CM diagnosis code for clinical trials; and
2. Claims with standard drug charges less than $373,000.

However, we are concerned that CAR-T product charges reported in revenue code 0891 were not included in rate-setting, judging from the proposed relative weight and our review of claims data for the cases that we believe were included in rate-setting. CMS did not specify what it included in the definition of “drug (or pharmacy) charges,” when excluding claims from the rate-setting process. Because of these concerns, we used the FY 2019 MedPAR proposed rule claims data to simulate the inclusion of the 0891 charges as a type of pharmacy charge, and to understand the impact that the inclusion or exclusion of these charges has on the proposed relative weight for MS-DRG 018.

The MedPAR data puts individual revenue codes into various categories, including “Pharmacy” (comprised of revenue codes 025x, 026x, and 063x). The Pharmacy category does not include the 089x revenue code series, despite the NUBC designating revenue code 0891 as an extension of pharmacy – part of a series of changes that support the separate reporting of cell therapy products as of April 1, 2019. The FY 2019 MedPAR data, used for FY 2021 rate-setting, is the first set of claims data to have CAR-T product charges in 0891 (for a six-month period of April 1 through September 30, 2019). CMS excludes revenue code series 081x and 089x charges (defined and grouped in a field called “Organ Acquisition Charges” in the MedPAR data dictionary) from rate-setting. This is appropriate for solid organ transplant cases, where acquisition costs are reimbursed differently than cases for HSCT, for example. As a result, CMS created a workaround for revenue code 0815 (allogeneic donor search and cell acquisition charges, previously reported under revenue code 0819) to ensure these charges are used in rate-setting and were not removed. We can identify 0815 charges in MedPAR, as a field was created to identify them as the “Revenue Center Allogeneic Stem Cell Acquisition/Donor Services.”
ASTCT analyzed the MedPAR data to see if a similar workaround was created for revenue code 0891, but did not find one. Instead, we discovered a separate data field called “Organ Acquisition Indicator Code.” This field enables the specific identification of CAR-T claims with revenue code 0891. We did not see any specific discussion in the NPRM about this data field, or documentation in MedPAR (other than what is described above), so we assumed that 0891 would be excluded from rate-setting for the proposed MS-DRG 018. This would parallel the process for other codes in the organ acquisition charges category, except 0815. To validate our assumption, we replicated CMS’ rate-setting logic by counting only the “Pharmacy” category as defined in MedPAR (revenue codes 025x, 026x, 063x). We arrived at the same case number and geometric length of stay as CMS reported in the tables that accompanied the NPRM. Next, we modeled what the inclusion of 0891 charges would do to the relative weight and the number of cases available for rate-setting. To do so, we used the “Organ Acquisition Indicator Code” from MedPAR to identify CAR-T cases where 0891 appeared on the claim. According to ResDAC documentation on this field, a value of “B1” indicates the presence of 0891 on the claim. There are other values in this field that correspond to other revenue codes in the 081x and 089x series that are included in the “Organ Acquisition Charges” field.

Once we identified CAR-T claims with 0891 on the claim, we assumed that the charges reported in the “Organ Acquisition Charges” field would be 0891 charges. CAR-T patients are, typically, extraordinarily ill and would never receive an organ transplant in combination with the administration of CAR-T therapy. We validated this by reviewing all other ICD-10-PCS procedure codes that appeared on the claims with the two CAR-T ICD-10-PCS codes, and did not see any organ transplant procedure codes. Given this—and the fact that organ transplant acquisition charges are reported using the organ acquisition revenue codes on the transplant claim itself—we are confident that the charges in the “Organ Acquisition Charges” field in MedPAR that are associated with CAR-T claims are only for charges reported in revenue code 0891. Therefore, we used the charges reported in that field and summed them with the “Pharmacy” field, then applied CMS’ rate-setting logic of excluding clinical trial claims from rate-setting (claims with diagnosis code Z00.6 or pharmacy charges (in this instance, including 0891 charges in pharmacy), of less than $373,000.

We found that, when replicating CMS’ rate-setting logic, and now including cases with revenue code 0891, the cases available for rate-setting rose from 116 to 141, an increase of 25 cases. Our simulations show the relative weight also increased slightly. Including revenue code 0891 charges resulted in changes to the geometric length of stay. For this reason, we believed CMS did not include 0891 charges when creating MS-DRG 018’s relative weight.

Subsequent to our analytic work, CMS provided a technical clarification confirming that revenue code 0891 charges were excluded from rate-setting. Though the volume of cases reported with 0891 charge in the data is small (only 76 out of 601 CAR-T cases), this policy is material, since it means that a significant number of correctly reported claims are being excluded. Furthermore, when the MedPAR data is updated for the final rule, it will likely include additional correctly coded claims, with the CAR-T product charge reported using revenue code 0891. As hospitals become more familiar with correctly coding CAR-T claims following NUBC transaction set
requirements, the volume of revenue code 0891 will increase significantly. Therefore, it is important to address this data issue now.

We recognize that this may be a significant revision to the MedPAR data set structure, and that separating out the 089x revenue codes from the true organ acquisition revenue codes may not be feasible for FY 2021. **However, we recommend that CMS utilize MedPAR data as they exist today, to incorporate 0891 charges into its rate-setting process for FY 2021. CMS can do this by utilizing the Organ Acquisition Indicator Code, the Organ Acquisition Charges field, and the [additional procedure codes/Transplant Indicator Code] in MedPAR, to isolate the 0891 charges.** We propose a three-step process:

1. Determine the presence of 0891 charges on the claim: use the Organ Acquisition Indicator Code of “B1” to determine which CAR-T cases had 0891 charges present on the claim.

2. Review those cases to determine if:
   - Any of the additional procedure codes reported on the claims are operating room procedures that that would typically map to a solid organ transplant MS-DRG;
   - Look to see if there is presence of other acquisition indicator codes beyond B1 on the claim to see if a value other than “0” in the MedPAR Transplant Indicator Code;
   - Remove any cases that appear to have other transplant procedures from rate-setting.

3. The rest of the CAR-T cases can be deemed to have only 0891 charges in the Organ Acquisition Charges field. The charges in this field should be summarized with the Pharmacy Charges Amount field, as one combined “Drugs Charge.”

Once these steps are completed, CMS could apply its rate-setting process and eliminate claims with either the presence of the diagnosis code Z00.6, or drug charges less than $373,000. We believe that utilizing the Organ Acquisition Indicator Code, along with the additional check described in step 2, will allow CMS to have a very high degree of confidence that the only charges in the Organ Acquisition Charges field are 0891 charges, and that these charges can be used for the purposes of creating the relative weight for MS-DRG 018 for FY 2021.

If CMS does not utilize this (or another) method to incorporate charges reported under revenue code 0891, cases will be excluded (i.e., due to low 025x, 026x, 063x pharmacy charges) from rate-setting that should not be. We recognize that even after including revenue code 0891 charges as drug charges, there will be claims that are removed from rate-setting due to overall drug charges falling below the $373,000 threshold. To ensure that the rate-setting process utilizes all appropriately coded claims, we urge CMS to consider the methodology described above, or a variation of it, to incorporate 0891 charges as drug/pharmacy charges in its rate-setting process for FY 2021.

**C. Review MedPAR Definition for Organ Acquisition Revenue Codes**
For FY 2022, we request that CMS find a way to isolate the 0891 charges in the MedPAR data set so they can be easily utilized for rate-setting. We also recommend that CMS look beyond just 0891 to reconsider how the entire 089x series is represented in the MedPAR data, since a similar workaround will also be needed for 0892 (gene therapy charges), as this revenue code is also not associated with organ acquisition. The 089x series may continue to expand/change in the future, thus breaking out these revenue code charges from the Organ Acquisition Charges bucket is important.

For 0891 and 0892, we recommend that CMS incorporate these revenue code charges into “Pharmacy,” since NUBC has designated revenue code 089x an extension of revenue code 25x for Pharmacy; at least until such time that CMS creates another category or bucket of charges separate from pharmacy for cell and/or gene therapies. In general, when CMS is determining how to break out these codes, we would recommend erring on the side of allowing greater visibility and specificity when viewing the data. We believe being able to separate out cellular therapy product costs from gene therapy costs, for example, might be material in future years as more products are approved and used in the inpatient setting. Building greater granularity into the system now may prevent issues in the future.

Finally, when looking at the CAR-T cases with revenue code 0891 charges, we noticed there were a number of non-clinical trial cases where charges were less than $10,000 overall. Since the revenue code is specific to CAR-T product charges, we assessed the possible reasons for such low charges. In its Special Edition Article SE19009, CMS presented various billing scenarios for inpatient and outpatient CAR-T services. One scenario involved CAR-T administration in the inpatient setting; in this scenario, the hospital could hold the charges for the outpatient services rendered two or more weeks prior to the inpatient admission and report them using revenue code 0891 on the CAR-T inpatient administration claim. We believe this is the most likely explanation for seeing non-clinical trial cases (i.e., no Z00.6 diagnosis code) with low charges reported in revenue code 0891 when the actual CAR-T product charge is being reported in revenue code 25x, for example.

The practice of bringing outpatient charges over to the inpatient bill when occurring more than three days prior (or one day prior for PPS-exempt providers) is problematic. ASTCT recommends that CMS correct the billing rules that instruct hospitals to put cell collection and processing charges occurring prior to an inpatient stay on inpatient claims. Prior documents have taken the position that the three-day payment window cannot be expanded without legislation, such as the 2014 report by the Office of Inspector General.1 Continuing with this instruction contradicts this prior position and, furthermore, creates the risk that claims could include inappropriate outpatient Part B costs in Part A payments. Continuation also complicates stakeholders and CMS’ ability to understand low charges in 0891 without a Z-code on the claim. We recommend that CMS allow hospitals to report all charges following typical Part A and Part B rules and for outpatient claims, to bundle or package or set the status indicator to “N.” This will resolve the problematic billing instruction.

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1 https://oig.hhs.gov/oei/reports/oei‐05‐12‐00480.pdf
D. Paying Appropriately for CAR-T Clinical Trial Cases Grouped to MS-DRG 018

ASTCT believes that CMS should mitigate the possibility of over- and under-payment when using the presence of the Z00.6 diagnosis code to determine whether or not to make a reduced MS-DRG 018 payment. We support and agree with CMS’ proposal to make a reduced payment for clinical trial cases. As CMS’ analysis showed, there are marked differences in the average costs for clinical trials (defined as the presence of the Z00.6 code and standardized drug charges less than $373,000), and non-clinical trial cases, where a facility had to purchase the CAR-T biologic. There are certainly a number of CAR-T clinical trial cases that should not be reimbursed at the full MS-DRG 018 proposed rate.

That said, CMS should be aware that there are other cases coded as clinical trials in which the CAR-T product was purchased. In these trials, the Standard of Care (SOC) includes providing CAR-T, but the therapeutic under investigation is something other than CAR-T. For example, a Phase II trial that is currently recruiting will study how well the anti-IL-1 drug anakinra works in preventing severe CAR-T related Immune Effector Cell Associated Neurotoxicity Syndrome (ICANS).[1] Another example is a multi-center, open label Phase IIb study will evaluate the safety and efficacy of the administration of tisagenlecleucel in combination with pembrolizumab, an immune checkpoint inhibitor, to attempt to decrease relapse rates.[2]

CMS’ proposed payment policy for the payment of CAR-T clinical trial cases (those reported with Z00.6) could inappropriately reduce payment in cases where the investigated intervention is something other than the CAR-T product. In such cases, providers incur the costs of the commercial CAR-T product. Unless CMS modifies its proposed policy in the final rule and identifies these cases for proper reimbursement, providers will be underpaid. **CMS must find an appropriate mechanism to provide MS-DRG 018 payment to cover a trial’s SOC elements. This issue, along with the overpayment issue, must be addressed from the outset of the creation of MS-DRG in order to safeguard program integrity, avoid administrative burden involved with appealing claims, and ensure timely payment to providers.**

This last element is not abstract—it is particularly critical now, during the COVID-19 pandemic, where revenues remain low and every dollar matters. Uncompensated costs of high-cost therapies like CAR-T can have a large impact on a hospital’s cash flow and sustainability. For the select centers that furnish CAR-T, there is no opportunity for the average payment concept inherent in IPPS to mitigate the losses. Our discussions with members and their institutions suggests this potential loss represents a real barrier for centers capable of, but not yet providing, CAR-T therapies, and that this is an important access barrier.

**ASTCT believes the most straightforward way to address this issue is for CMS to require that providers report Value Code 90 (previously 86).** Like all Value Codes approved by the NUBC, its use is optional per payer discretion. Nevertheless, this Value Code is being reported by providers to a number of payers. **ASTCT again requests that CMS require it be reported on all claims where cell therapy product charges are reported using revenue code 0891.**
Value Code 90 will allow CMS to see actual acquisition cost for the current CAR-T products. There are instances in which the provider does not incur any costs for the CAR-T product, such as when the CAR-T biologic is under investigation or, as with expanded access cases, it was given by the manufacturer to the provider at no cost for various manufacturing reasons. In these cases, the reported cost would be $0.00. CMS will be able to easily identify these cases, prevent over-payment, and mitigate any under-payment concerns, since the amount would appear in Value Code 90 (i.e., $373,000 for the two approved products for the adult r/r DLBCL indication, and $475,000 for the pediatric ALL indication).

Over time, CMS will experience the added benefit of being able to see amounts that are lower than the list price. For example, if manufacturers provide discounts; when applicable 340B discounts are applied for outpatient administration within the three-day payment window; or when new products come to market with lower prices. All of these data would be available for future rate-setting by CMS.

ASTCT and many other organizations, including the American Society of Hematology (ASH) and the American Hospital Association (AHA), have previously requested that CMS require reporting of Value Code 90 in the spirit of transparency. CMS could also create an edit between Value Code 90 and the CAR-T ICD-10-PCS procedure codes, to ensure the Value Code is reported. If this edit recognizes an incomplete claim, centers would have an opportunity to resubmit the claim with the completed Value Code field.

We are confident that any administrative burden will be outweighed by the value of the data collected and the potential to improve future rate-setting. In particular, as stated above, using the data reported in Value Code 90 will facilitate program integrity by minimizing program over- and under-payments. Finally, if CMS requires Value Code 90 to be reported starting October 1, 2020, it will be able to use the resulting information to appropriately pay for commercial and clinical trial CAR-T cases, and have data for possible rate-setting changes in FY 2023.

Although we think that utilization of the Value Code is the most straightforward way of determining this, CMS could also apply, for payment purposes, a methodology similar to what it proposes to use for rate-setting. That is, CMS would look for the presence of the Z00.6 code or drug charges reported in revenue codes 025x, 026x, 063x, or 0891 that are less than $373,000 for the purpose of flagging claims for reduced payment in FY 2021, rather than just looking for the presence of the Z00.6 code.

Applying this process for identifying clinical trials to pay at a reduced rate will help prevent the under- and over-payment issues described above. It will not, however, give CMS direct insight into actual acquisition cost data of the product in the same way that the use of the Value Code would. Nevertheless, it would be an alternative way to mitigate this issue.

E. Proposed MS-DRG Assignment and Severity Level for Cytokine Release Syndrome Codes
ASTCT disagrees with the severity level assignment for Cytokine Release Syndrome (CRS) ICD-10-CM codes. CRS is the most common complication of Immune Effector Cell (IEC) therapy, including CAR-T. Symptoms include fever at the onset, can be progressive, and can include hypotension, capillary leak (often associated with hypoxia), and end organ dysfunction.[3] The ASTCT has led efforts to standardize grading and reporting standards (previously assessed in three competing and conflicting scales); the ASTCT Consensus Grading system for CRS and Immune Effector Cell-associated Neurotoxicity (ICANS) is now the preferred standard for current and future trials and for reporting toxicities occurring after administration of approved products.

Patients with CRS grade 3 and higher require treatment for hypotension and hypoxia.[4] Patients with CRS grade 4 are hemodynamically unstable and have capillary leak.[5] Capillary leak can lead to pulmonary edema and impairment of ventilation and may require mechanical ventilation.[6] CRS grade 5 is defined as death due to CRS.[7]

Patients experiencing CRS require intense monitoring, which requires the hospital to expend additional time and resources for which it should be fairly compensated. Therefore, ASTCT urges CMS to assign complication and comorbidity (CC) and major complication and comorbidity (MCC) status to the new CRS codes. These patients exhibit symptoms that are in line with seven of the nine guiding principles CMS discusses in this rule to determine CC/MCC assignment. Rather than assigning all of the new codes to a “non-CC/MCC” group, ASTCT recommends that CMS assign the new ICD-10-CM diagnosis codes for CRS codes to CC and MCC MS-DRGs within the MS-DRG 814-816 series. Specifically, we recommend that CMS assign the Grade 2 CRS diagnosis code to a CC MS-DRG and Grades 3-5 to an MCC MS-DRG.

Finally, the ASTCT requests CMS provide clear coding guidance on what the appropriate complications T-code is that must be reported with the new CRS codes in order to facilitate assignment of cases into MS-DRGs 814-816.

**F. Create Dedicated New Cost Centers for Cell and Gene Therapies**

ASTCT requests that CMS create two new, distinct standard cost centers on the hospital cost report: one for cell therapy products tied to revenue code 0891, and the second for gene therapy products tied to revenue code 0892. Although some hospitals have already set up their own subscripted lines, CMS issued guidance requiring separate lines. This requirement is intended to ensure accurate reporting, provide more options for addressing charge compression, and allow CMS to create new national cost centers for future rate-setting.

**G. New ICD-10-PCS Codes Released for the Administration of CAR-T Products Following the March 2020 Public Meeting**
ASTCT has significant concerns about the recently finalized ICD-10-PCS codes for two new CAR-T products presented at the March 2020 ICD-10 Coordination and Maintenance Committee meeting. These are for Brexucabtagene Autoleucel (KTE-X19; XW23346 and XW24346) and Lisocabtagene Maraleucel (Liso-cell; XW23376 and XW24376).

Unlike the two existing ICD-10-PCS codes for CAR-T (XW033C3 and XW043C3), which describe the administration of CAR-T by central or percutaneous routes, the two new codes are product-specific and were released as part of a new ICD-10-PCS table. The two existing CAR-T codes are located in the New Technology section’s XW0 table (Administration of therapeutics and other substances, except blood and blood-products). The two new codes have been released in a new table, XW2, where the digit “2” represents a root operation called “Transfusion: putting in blood or blood products.”

We disagree with this decision for multiple reasons. First, this option was not discussed at the public meeting for ICD-10-PCS. It was not requested by either manufacturer, nor by provider groups such as ASTCT, ASH, AHA, nor the American Health Information Management Association (AHIMA) based on our discussions with these stakeholders.

Second, CAR-T products are regulated as biologics by the FDA. Although they are derived from T cells, they are not blood products like platelets or whole red blood cells. The T cells are genetically modified with a chimeric antigen receptor (CAR) construct that is engineered (man-made), vs natural. The resulting cells, are therefore substantially different from blood or blood products. Since it is something that is new in medicine, it is not surprising that several different terms are employed to describe it, such as “living drug,” “cellular therapy,” and “immune effector cell therapy.” These terms all recognize that CAR-T is not the same as a blood product.

Third, we strongly oppose CMS’ decision because it is inconsistent with the two existing ICD-10-PCS codes for the administration of CAR-T. It is illogical that the two existing codes are included in the XW0 table (described as, “Introduction: Putting in or on a therapeutic, diagnostic, nutritional, physiological, or prophylactic substance except blood or blood products”) while the two new codes are included in a new XW2 table (described as, “Transfusion: Putting in blood or blood products”). How can similar CAR-T products that CMS describes as being the same mechanism of action for purposes of NTAP status evaluation, be placed in two mutually exclusive tables? The third digit of the ICD-10-PCS code for the root operation conveys important information to clinicians and coding professionals; CMS’ finalized decision will raise questions, and cause unnecessary confusion, not to mention undermine the validity of the code set.

Fourth, as stated above, CAR-T therapy is recognized as a biologic based on the FDA-approval process. The NUBC created revenue code 0891 as an extension of the pharmacy revenue codes 025x and 063x in order to allow the CAR-T therapy product charge (as well as other cell therapy charges) to be reported as a pharmacy charge, rather than a blood or blood product. Therefore, defining CAR-T as blood products is inconsistent with HIPAA transaction code sets.
Additionally, from a procedural coding perspective, the therapeutic procedure is the administration of chimeric receptor T-cell therapy biologics. Nowhere in the new XW2 table is the term “chimeric antigen receptor T-cell therapy” stated, only the generic name of the specific drug. Physicians will not refer to the therapy in this manner, rather they refer to it as CAR-T. There are at least ten different products likely to be approved in the near future. By adhering to the plan to have product-specific ICD-10-PCS codes, CMS is adding burden to providers and payers – all HIPAA covered entities due to the fact that all covered entities must adhere to the transaction sets. CMS has an opportunity to correct course and leave the current ICD-10-PCS codes for the administration of CAR-T in the XW0 section and change to requiring the NDC for cell and gene therapy products billed under revenue code 089x. This elegant solution naturally solves the current and future problems associated with product specific ICD-10-PCS codes.

Finally, we find it problematic that the two currently approved CAR-T products cannot be distinguished from one another on inpatient claims, while two new codes will be distinguishable from one another on inpatient claims, which does not allow for any parity across these four products. This is particularly problematic, since three of the four products are for the same indication – Diffuse Large B-cell Lymphoma (DLBCL).

We have discussed our concerns with CMS and learned that this coding issue will be addressed at the September 2020 ICD-10-Coordination and Maintenance Committee meeting, with the expectation that the two existing codes will be migrated into the new XW2 table. For the reasons stated above, we disagree with this approach. The root operation associated with the XW2 table is inappropriate for describing CAR-T cell therapy products. Even if CMS decides to migrate the two existing codes to the new table, there will be a one-year gap during which the new products will be visible in the data, through reporting product-specific ICD-10-PCS codes, while the current products will not.

We are not opposed to knowing which specific product is used. On the contrary, we believe it is critically important for inpatient claims to distinguish among products, for research purposes, outcomes analyses, and payment of NTAP when granted. What we object to is the inappropriate assignment of CAR-T products to a code category for blood products, the inconsistency in the codes among the four CAR-T products, and the lack of specificity for the two current products. ASTCT believes that the identification of specific CAR-T products should not be performed using the ICD-10-PCS New Technology Table. Instead, we request CMS require all autologous CAR-T products to be reported with the existing ICD-10-PCS codes (XW033C3 and XW043C3), which describe the procedure to administer CAR-T products; and require NDCs to be reported on inpatient claims to differentiate among the products. This will allow CMS and other stakeholders to have the much-needed visibility of each product administered without co-opting the procedure coding system.

We have previously requested that, for NTAP-approved products, CMS consider requiring the NDC to be reported on the inpatient claim, rather than creating more Section X codes for each
product. If CMS made this a requirement, it would enable researchers and other stakeholders to distinguish the products used on claims as soon as CMS finalizes this instruction.

At the March 2020 ICD-10-PCS meeting, discussion occurred about the increasing number of Section X administration codes, and CMS stated that the Agency was working on the issue. For that reason, we hoped the change to NDCs would have been made by now. CMS may still be working on a better long-term solution to this issue and may have created the XW2 table as a short-term measure; however, we still believe this decision should be discussed with stakeholders before being implemented.

With respect to our recommendation that CMS require NDCs to be reported, ASTCT notes that all hospitals have a pharmacy database that includes NDC information for every drug in their pharmacy. Since any drug in the pharmacy can be used for both inpatients and outpatients, these databases include NDCs for all drugs in the pharmacy. Further, the NDC is included in the patient accounting system data whenever a drug is charged to a patient account, whether in the inpatient or outpatient setting. The use of NDC data in hospitals is ubiquitous because state Medicaid programs require this information on outpatient claims for the Medicaid Drug Rebate Program. The pharmacy database is linked to the hospital chargemaster.

When a drug is administered to a patient and charged to the patient account, the account has each drug’s NDC in the history. Many commercial payers require NDC and/or HCPCS codes for drugs and biologicals to be reported on inpatient claims, and reporting the NDC and/or HCPCS code detail for drugs and biologicals is not inconsistent with HIPAA transaction sets including the NUBC (please see Appendix A for additional details).

We also believe the codes in the new “XW2” table may not position the ICD-10-PCS coding set well for the future. There is already a need for allogeneic CAR-T ICD-10 codes, as well as codes for other routes of administration, and for other innovations in cellular therapy that are not likely to fit well into the XW2 table. Finally, with products being named in the code itself, we request CMS to maintain non-product specific autologous (and in the future, allogeneic) ICD-10-PCS codes so that non-FDA approved CAR-T products under study can continue to be accurately reported.

**H. Additional Coding Recommendations and Guidance Required**

The data currently available to the agency on CAR-T cases, although improved, remain limited in both volume and accuracy. ASTCT has repeatedly raised our concerns about the need to collect consistent and accurate data. **We urge CMS to make the changes we recommend below, in order to improve the accuracy of the data used for future rate-setting:**

- Release coding and billing guidance that instructs hospitals how to report expanded access cases (in which no CAR-T product cost is incurred) to CMS, either with the Z00.6 clinical trials diagnosis code or a new code or value on the claim.
• Extend the requirement of NDC reporting on inpatient claims to all cell therapies reported with revenue code 0891 and gene therapies reported with revenue code 0892.

III. COST-BASED REIMBURSEMENT FOR ALLOGENEIC BONE MARROW AND STEM CELL TRANSPLANT

ASTCT is pleased that transplant centers will finally begin to receive cost-based reimbursement for their donor search and cell acquisition costs, starting with cost reporting periods beginning on or after FY 2021. We appreciate the time and resources that CMS devoted (and will continue to devote) to collaborating on this issue with our organization and the National Marrow Donor Program (NMDP)/Be the Match. We believe that by working together, we can successfully develop policies to facilitate the implementation of Section 108 of the Further Consolidation Act of 2019 (Section 108).

We have detailed comments on specific aspects of CMS’ proposal for cost-based reimbursement of allogeneic bone marrow and stem cell transplants, concerning payment for acquisition costs; the proposed definition of allogeneic hematopoietic stem cell transplant (HSCT); items that are included as allogeneic HSCT acquisition costs; budget neutrality for the reasonable cost-based payment for allogeneic HSCT acquisition costs; and clarification of hospital cost-reporting instructions.

The ASTCT agrees with CMS’ proposal to create a new paragraph (e) at 42 CFR 412.113 to codify, via regulation, the requirements of Section 108. This codification will address the timing of this reimbursement change (i.e., beginning with cost reporting periods on or after October 1, 2020); the providers impacted (i.e., subsection d hospitals); the definition of “allogeneic transplants;” and the items included as acquisition costs, as described in the NPRM.

We do, however, have significant concerns with CMS’ proposal on implementing Section 108, specifically with the proposed definitions of standard charges and interim or pass-through payments, as described in subsequent sections

A. Standard Average Charges for Donor Search and Cell Acquisition

Current CMS regulations allow transplant centers to bill their actual donor charges on transplant recipient accounts. This allows centers to bill for actual charges (i.e., donor evaluation, donor work-up, testing, unrelated donor search and acquisition), regardless of whether the payer is CMS or a commercial plan. Simultaneously, the Provider Reimbursement Manual (Part 1, Section 2202.4) requires hospitals to uniformly apply any service charge to all patients.

CMS now proposes to require the application of the same average charge for all patients, which would be disastrous for transplant centers. Centers would be forced to apply the same average charge for all claims, including those submitted to commercial payers. The proposal would force transplant centers to report an average acquisition charge on all recipient accounts, rather than their actual charges, to other payers (i.e., commercial payers).
This could render commercial transplant contract language unenforceable, with providers unable to bill claims under the terms of existing contracts, as many, if not the majority of these contracts, require the billing of actual acquisition costs for a specific recipient as justified by third-party invoices. This would necessitate all transplant centers to renegotiate their commercial contracts, an administratively burdensome process that is likely to result in reimbursement challenges.

In the discussion that ASTCT and NMDP held with CMS in early June, both organizations urged CMS to abandon its proposal. Instead, we urged CMS to codify existing manual instructions that would enable transplant centers to continue holding their actual donor search and cell acquisition charges applicable to each transplant recipient’s case and include them on the Medicare recipient’s claim under revenue code 0815. We stand by - and repeat - our request.

**B. Interim or Pass-Through Payment**

CMS proposes to bill and pay the standard acquisition charge on an interim payment basis as a “pass-through” item (this is in accordance with 42 CFR 413.60 and 413.64). The Agency proposes to use the actual charges, by ancillary cost center, from the provider’s records that are included on the Medicare cost report, and to convert the charges to reasonable costs using ancillary cost-to-charge ratios (CCRs). A settlement determination would be made at the end of the cost reporting period. However, we note that CMS will lack reasonable cost information pursuant to its upcoming cost reporting instructions to use for interim payment purposes for at least the first few years after this change has been implemented, due to the lag of cost reporting data by 2-3 years.

Unfortunately, despite educational campaigns by national associations, many (if not most) transplant centers are not using cost center 77 on their cost reports. We believe this situation will improve over time when reimbursement is impacted by the use of cost center 77. Lacking complete data derived from cost center 77, however, as well as prior years’ actual charges by ancillary cost center, CMS has to create a workaround in order to provide interim payments to transplant centers in FY 2021. These payments must also align with budget-neutrality adjustments, further complicating the process.

ASTCT has identified two methodologies for addressing this situation described below and have received feedback from transplant centers that either method is acceptable:

- **Payment Summary and Reimbursement (PS&R) Report Method**

In this method, CMS would:

- use each transplant centers’ prior year PS&R report total Medicare charges that are billed under revenue code 0815;
- multiply these charges by the hospital’s CCRs;
- divide the result amount by 26 (i.e., initial bi-weekly interim payment);
- update this amount during the year (this activity would be conducted by the Medicare Administrative Contractors);
- and provide additional funds (or acquire payables) at the time of cost settlement.

This method aligns with CMS’ process for pass-through payments for solid organs and ensures consistency in reimbursement for transplant centers.

• **Claims-Based Method**

In this method, CMS would:
- use actual billed charges reported under revenue code 0815 from each of the transplant recipient’s claims;
- multiply the actual charges by the hospital’s CCR;
- and pay this amount as a pass-through payment amount in addition to the MS-DRG 014 payment.

This method results in less frequent need for payment (or acquiring payables) at the time of settlement, and more accurately reflects donor/cell acquisition costs over the course of the year.

**C. Definition of Allogeneic Hematopoietic Stem Cell Transplant and Items Included as Allogeneic Hematopoietic Stem Cell Acquisition Costs**

ASTCT agrees with CMS’ proposal to codify the statutory definition of an “allogeneic hematopoietic stem cell transplant” by adding new paragraph (e)(1) to 42 CFR 412.113. We also agree with the proposed definition: “with respect to an individual, the intravenous infusion of hematopoietic cells derived from bone marrow, peripheral blood stem cells, or cord blood, but not including embryonic stem cells, of a donor to an individual that are or may be used to restore hematopoietic function in such individual having an inherited or acquired deficiency or defect.”

ASTCT recognizes that Section 108 gives the Secretary authority to determine, through rulemaking, the items included as allogeneic HSCT donor acquisition costs. We are pleased by, and agree with, CMS’ proposal to continue defining allogeneic HSCT costs as they have always been defined and outlined in publication 100-04, Chapter 3, Section 90.3.3.A and Ch. 4 Section 231.11 as its basis.

These costs include:
- Registry fees from a national donor registry described in 42 U.S.C. 274k, if applicable;
- Tissue typing of donor and recipient, for stem cells from an unrelated donor;
- Donor evaluation;
- Physician pre-admission/pre-procedure donor evaluation services;
• Costs associated with the collection procedure (such as general routine and special care services, procedure/operating room, and other ancillary services, and apheresis services);

• Post-operative/post-procedure evaluation of donor; and

• Preparation and processing of stem cells derived from bone marrow, peripheral blood stem cells, or cord blood (but not including embryonic stem cells).

D. Clarification on Record-keeping Requirements

On a related note with respect to the items maintained in records, CMS proposes that transplant centers must “maintain an itemized statement that identifies the services furnished in collecting hematopoietic stem cells, the charges, the person receiving the service (donor/recipient, if donor the provider must identify the prospective recipient), and the recipient’s health care insurance number.” (See new paragraph 42 CFR 412.113(e)(5).)

This requirement overlooks the fact that a transplant recipient almost always has many itemized statements for donor services. This occurs because it is rare to find a match with the first relative who is evaluated and ‘worked-up’ – i.e. given a physical to confirm medical eligibility for donation. Usually, more than one relative is evaluated and worked-up before a match is identified. And in cases where no related match is found (which occurs quite frequently), unrelated donors are then evaluated and worked-up. This results in multiple itemized statements about various donor services to evaluate, collect, and obtain cells for a transplant recipient.

To address this, we recommend CMS finalize the following language instead of the originally proposed language: “Providers must maintain records for all costs defined at 42 CFR 412.113 (e)(1) to include all invoices/statements for purchased services and each itemized patient accounting statement for all donors and their service charges. Records must be for the person receiving the service (donor/recipient, if anonymous donor, the provider must identify the prospective recipient), and the recipient’s Medicare beneficiary identification number.”

E. Budget Neutrality for the Reasonable Cost Based Payment for Allogeneic Hematopoietic Stem Cell Acquisition Costs

Section 108 requires that the implementation of cost-based reimbursement for allogeneic HSCT be budget-neutral. We understand and agree with CMS’ explanation of the method used to calculate the required budget-neutrality adjustment, which uses allogeneic HSCT charges billed separately under revenue code 0815 from each transplant recipient’s inpatient hospital bill, multiplied by the hospital’s operating CCR. Above, we discussed two options that were developed jointly by ASTCT and NMDP for interim pass-through payment. We believe that both align with CMS’ budget-neutrality method.

F. Clarification of Hospital Cost Reporting Instructions
As CMS recognizes, it has been challenging for transplant centers to reclassify related donor expenses into cost report line 77 from routine and ancillary departments. **ASTCT agrees with CMS that additional cost-reporting instructions and modified forms are required to facilitate cost reimbursement for allogeneic HSCT.** Transplant centers would benefit greatly from explicit instructions on how to use standard cost center line 77 “Allogeneic Stem Cell Acquisition” in Worksheet A and other applicable worksheets. It is critically important for CMS to clearly describe appropriate use of this cost center line to record all acquisition costs related to allogeneic HSCT (both related and unrelated donors) either in Section 231.11, Chapter 4, of the Medicare Claims Processing Manual (Pub. 100–04) or through other instructions. This is necessary to ensure that costs are captured accurately and consistently by all transplant centers that provide allogeneic HSCT.

We look forward to reviewing and commenting on the forthcoming cost reporting instructions regarding line 77. It is our hope that CMS will provide a methodology by which centers can determine how to identify and allocate routine and ancillary costs that are part of allogeneic HSCT acquisition costs to this cost report line. **We request CMS to confirm that both direct and indirect costs should be reported on line 77.** We understand that CMS is developing a worksheet similar to Worksheet D–4 for solid organs and expect that its use will aid in capturing costs and charges that will facilitate making cost reimbursement for allogeneic HSCT, per Section 108.

**IV. UPDATE MEDPAR AND INVOLVE STAKEHOLDERS IN REVISION PROCESS**

Earlier in this letter, we detailed to CMS the steps we took to evaluate CAR-T claims in the MedPAR data. We have used the MedPAR LDS for several years to evaluate patterns and study the implications of policy on stem cell transplant and CAR-T cases. As we gain familiarity with this data set, we learn about new quirks in this data set. For instance, we learned that the field names in the MedPAR Data Dictionary do not match the actual field names in the data set itself. We also saw, when looking at documentation on various variables that can appear in MedPAR fields, that the documentation refers to descriptions of revenue codes and other data elements using outdated or no longer effective descriptions. While these examples can be managed, we feel that issues like this can limit the utility of the MedPAR LDS. Given its importance to rate-setting and that numerous stakeholders who are trying to fully understand CMS’ proposals utilize it in order to make data-based requests and suggestions to the agency on matters for which CMS has asked for comment, improvement is warranted. The issues become particularly problematic when it is not clear from documentation which field is which, when compared to the field names in the data; or if there are multiple fields with similar descriptions.

**We ask that CMS update MedPAR so that there is alignment between documentation and current NUBC-designated naming for variables like revenue codes, and also update MedPAR documentation for alignment with the field names in the database itself.** Improving documentation and the dataset will help stakeholders both with understanding policy implications, and being in the position to respond appropriately to CMS’ proposals and requests.
for information. We recommend that if CMS does perform an update of this nature, that it hosts a stakeholder call or similar event to gather additional feedback. The issues described here are just two concise examples and we are aware of multiple analysts and other parties who would have additional suggestions and questions to raise during any update process.

V. PROPOSED CHANGES TO NEW TECHNOLOGY ADD-ON PAYMENT

Our members remain concerned that, if Medicare reimbursement policies do not reflect the fact that scientific advances are rapidly changing the practice of medicine, the policies may slow the rapid pace of innovation in cell therapy. One way that CMS can keep pace with innovation is by modifying the NTAP process to allow quarterly approvals of NTAP for all applications that receive FDA approval, regardless of the approval pathway. CMS has proposed this change already for antimicrobial, antibacterial, and antifungal products as proposed at 42 CFR 412.87(d), but ASTCT does not believe this quarterly process should be limited to these types of products and these types of pathways.

ASTCT urges CMS to review NTAP applications and issue a preliminary decision (approval or rejection) to the manufacturer in a timely manner. We believe that a quarterly review process strikes the right balance between prompt decision-making and allowing CMS to review the applications thoroughly. For preliminarily approved NTAP applications, CMS should recognize NTAP payment in the first quarter after FDA approval. This will greatly increase beneficiary access to care, as providers will not wait to utilize new treatment options due to high costs and low reimbursement—as they initially did with CAR-T. We disagree with tying the NTAP approval process to a July 1st FDA approval date and recommend the implementation of an expedited process and timely application review, so that appropriate payment is made available to hospitals for approved NTAP products at the earliest date possible.

With the current structure, products receiving approval after July face up to 14 months of not having NTAP status as they wait for the next annual application and IPPS decision cycle. For therapies utilized during the inpatient treatment of blood cancers, this delay can have severe repercussions for facilities and beneficiaries. The financial impact of COVID-19 will be felt acutely by hospitals for several years and there will be extremely limited financial resources that can be devoted to onboarding new therapies without appropriate reimbursement, even if that therapy is critically important to Medicare beneficiaries.
VI. IMPROVING THE PROCESS OF THE ICD-10 COORDINATION AND MAINTENANCE COMMITTEE MEETINGS

The ASTCT has participated in the ICD-10 Coordination and Maintenance Meetings for several years, both as a requestor and as an interested party. We consider it important for our membership to be able to contribute to advancing the ICD-10 coding set, and to ensure that changes made are appropriate and help, rather than hinder, coding and research in our specialized areas of care. To that end we believe some improvements can be made to the public discussion process.

First, we believe the ICD-10 Coordination and Maintenance could improve transparency by 1) indicating who/where the coding requests originated from; and 2) the rationale behind the Committee’s decision to not accept the item for discussion as well as the rationale for all final decisions. The current process obscures both issues; coding requests and discussions during the public meeting are not always published in the form of a transcript or detailed proceedings in addition to a recording. This hinders stakeholders’ ability to align, discuss, and understand the requests submitted and decisions made.

Second, we would welcome more commentary from the two Coordination and Maintenance Committee partners, CMS and the National Center for Health Statistics (NCHS). It is not always apparent why a certain course of action was taken; some explanation or response to public comments on a decision would be a material improvement. This information is especially crucial when code requests are declined for presentation outright, when requests are moved to the next meeting date, when a second or third submission is required, and when trying to evaluate what sort of changes are material to the request.

Third, we believe the ICD-10 Coordination and Maintenance can improve the way in which stakeholders participate in the public meetings. Participation is often hampered by the fact that agendas are sometimes published only days in advance of a meeting, which truly impedes our clinicians from being able to participate. The ASTCT recommends that a notice of acceptance of coding requests and meeting agendas be made public no less than 30 days prior to the meeting date as this will allow for increased participation on the part of interested stakeholders.

VII. MARKET-BASED PAYMENT RATES FOR FUTURE-RATE SETTING

The ASTCT appreciates CMS’ recognition that its current rate-setting system suffers from significant problems—including charge compression and a dependence on gross charges—and that a new approach is necessary. The current rate-setting process, which is based on reducing billed charges to costs using 19 national CCRs, is 13 years old. It frequently results in MS-DRG and NTAP payments that are out of step with hospitals’ true costs.

As CMS is aware, ASTCT has been encouraging the Agency to explore ways to update the payment system ever since the approval of breakthrough cell therapies in the fall of 2017. Our
view is that the MS-DRG system is unable to account for 21st century therapies highlighting charge compression problems and the resulting need for hospital mark-ups to achieve the maximum NTAP (a maximum that is, moreover, out-of-step with actual costs). While not new, these issues are starting to have a measurable and sizable impact on rate-setting, provider-payments, and beneficiary access to care—especially when it comes to high-priced cell and gene therapies.

The Agency itself appears to agree with ASTCT. Commenting on a recently proposed rule on value-based purchasing for innovative therapies, CMS noted: “While the impact of these therapies can be transformative, their costs are unprecedented. New approaches to payment are needed to allow the market room to adapt to these types of curative treatments while ensuring that public programs like Medicaid remain sustainable.”[8]

ASTCT completely agrees with this need, particularly given the current and future pipeline of cell and gene therapies. This new branch of medicine is upon us and exploding with innovative and breakthrough therapies the likes of which have remained scientific aspirations, and for which the existing payment system was not designed. ASTCT believes that this new branch of medicine requires new payment methodologies. Moreover, we believe that all of the ideas CMS has received to date should be summarized and discussed in the final rule and through one or more separate stakeholder calls before anything new is implemented.

We have provided suggestions and are aware that other, thoughtful approaches have also been submitted to the Agency. It is critical that these approaches be thoroughly discussed with stakeholders. We also note that the ongoing Public Health Emergency will likely preclude CMS from getting the level of input and depth of comments needed to revise the payment methodologies. For these reasons, ASTCT urges CMS to withdraw its proposal for FY 2024.

Instead, we urge CMS to initiate wide-reaching and detailed discussions about potential proposals and simultaneously implement important technical changes to improve the system and inform stakeholders’ discussion. For example, CMS could collect actual cost data for cell and gene therapies through use of the newly approved NUBC Value Codes and establish new cost centers in the cost report for cell and gene therapies (as described above) to mitigate the need for mark-ups (this resembles CMS’ decision to establish the implantable device cost center for high-cost devices).

Alternatively, CMS could make incremental changes to the NTAP and outlier formulas to end their dependence on gross charges (described in detail below). These are examples of areas that CMS could address prior to changing the MS-DRG relative weight methodology, and concurrent to the field’s discussion and concurrence on a new system. In the following sections, we provide specific comments on CMS’ proposal along with our recommendations.
A. CMS’ Proposal to Collect and Use Median Payer Rates by MS-DRG

ASTCT opposes CMS’ proposal to require hospitals to report the median Medicare Advantage (MA)-negotiated payment rates (by MS-DRG) for all MA contracts, and their median commercial-payer negotiated payment rates (by MS-DRG) for all commercial contracts. This proposal will not be useful and will not give CMS the information it needs to make methodological changes, reduce costs, and move away from reliance on the charge master or cost reports.

In the proposed rule, CMS describes research concerning MA-negotiated rates indicating that they typically pay 100%—105% of traditional Medicare rates and, in real economic terms, possibly less, due to utilization controls for short-stay cases paid as outpatient cases under the Outpatient Prospective Payment System. Therefore, creating a new rate-setting methodology based on median MA rates derived from MS-DRGs will simply perpetuate the existing problems of charge compression and reliance on gross charges that is heavily influenced by CMS’ reliance on CCRs.

Changes to the payment system must go much farther than simply changing the “data source” used, particularly if those data are, in large part, derived from Medicare rates. Creating new relativities between MS-DRGs within the Medicare program using data derived from Medicare rates is circular and does not address the underlying problems.

We appreciate that CMS expressed interest in collecting median rates from other payers; however, these rates and the contracts that underpin them are highly variable. Many commercial-payer-negotiated payments include various types of additional payments that are not embedded in the DRG rate, such as teaching, new technology payments, stop-loss, outliers, and carve-outs. We cannot imagine how CMS could expect to use the reported median data to create a new national set of payment rates when the data are not comparable to MS-DRGs.

CMS discussed using actual reimbursement as opposed to negotiated rates. This would improve the information, but would still will leave significant gaps in the data because, among other reasons, commercial payers are increasingly moving to specialty pharmacies for drugs. With specialty pharmacies, the hospital does not incur cost or reimbursement for these drugs, yet the MS-DRGs to which these payments would be compared are intended to include all drug payments. CMS has no means to understand the data’s context that would provide for validity and integrity of the decisions and analyses the Agency plans to conduct with those data.

Moreover, we do not believe that CMS’ proposal to rebase the MS-DRG weights based on the median payment rates for MA or even commercial payer rates will achieve CMS’ goal of reducing reliance on the chargemaster. This is because outlier, new technology, and other payments would still be calculated based on gross charges.
B. Process-Related Concerns with CMS’ Proposal

Making fundamental changes to the rate-setting system is a significant endeavor, and one that is likely to have secondary and even tertiary impacts. These impacts are likely to be hidden unless the implications are evaluated and discussed by multiple parties.

Therefore, we recommend that CMS convene a public meeting where stakeholders can discuss proposals for change and provide additional input and ideas beyond what has been proposed for public comment in this rule. This would be similar to the town hall that CMS conducted for the CC/MCC analysis last year. We believe that a formal process like this could help identify the scope of intended consequences as well as potential unintended consequences and allow other heretofore unarticulated options for change to be brought forward. We also urge CMS to ensure that the conversation includes ICD-10-CM diagnosis coding, ICD-10-PCS, CPT, HCPCS, and reporting NUBC-required and -optional data elements. We welcome the opportunity to continue working closely with the Agency to find the most equitable and sustainable solutions, and to discuss our ideas about how CMS can begin modifying the MS-DRG payment system to accommodate the pipeline of cell and gene therapy products.

We believe the acceptance and implementation of new proposals is more likely to be successful if stakeholders are fully engaged in the process. This is critically important, since the details matter and could meaningfully impact the outcome of this change. Despite our significant concerns, ASTCT does support the need for new and creative solutions to improve future rate-setting. Below, we discuss some previously raised proposals—including proposals from ASTCT—that we believe are better, more incremental movements towards what the Agency is trying to achieve.

C. Healthcare Financial Management Association’s (HFMA) Proposal

The HFMA submitted a thorough and detailed comment letter in September 2019, responding to CMS’ Request for Information on cost-reporting, maintenance of chargemasters, and related issues. In this letter, HFMA and Leavitt Partners indicated they had convened an alliance, Chargemaster Alternatives for Medicare Payment (ChAMP), that included multiple health systems as members. ChAMP outlined a thoughtful proposal: use data from hospitals’ internal activity-based cost accounting systems to calculate and submit the allowable cost per discharge for inpatient discharges, and per ambulatory payment classification for outpatient services, as part of the Medicare cost-reporting process. The process is called the Direct Cost Model (DCM), and would replace CMS’s imputed cost per discharge or outpatient service in the calculation of cost-based payments and annual weight rebasing.

ChAMP’s proposal to include outpatient services is very important. CMS’ proposal would not achieve its objective to move away from gross charges, because hospitals MUST maintain gross charges at the same amount for the same service, and apply the changes to all patients, both inpatient and outpatient (per the Provider Reimbursement Manual Part 1, Section 2202.4).
definition). Any method to distance or remove payment methodologies from a reliance on gross charges and chargemasters MUST address all services—inpatient and outpatient at the same time—not merely inpatient services.

The HFMA proposal also utilizes the cost report, is understandable, could avoid some of the pitfalls discussed above, and has the potential to achieve some of CMS’ major objectives. We believe this proposal could, in time, help hospitals rebase charges and would also limit CMS’ reliance on gross charges and chargemasters.

We believe that CMS’ calculation of the burden on hospitals for its median payments proposal underestimates the amount of work that could be involved. While ChAMP’s proposal is significant, we believe it will yield more accurate results and better retain integrity in the system. We were disappointed that CMS did not provide any information or consideration of the DCM in the proposed rule, nor discuss ideas previously submitted by ASTCT and others.

D. Implement NTAP Changes by Increasing the NTAP Cap to 80 Percent for All New Technologies

ASTCT applauds CMS for increasing the NTAP cap for all new technologies from 50 to 65 percent starting in FY 2020. However, we do not believe this proposal goes far enough to encourage hospitals to adopt new technologies, particularly very expensive new therapies like CAR-T. Given that additional therapies are imminent and that there will be no sustainable alternative payment models for several years, we believe that CMS should increase the cap to 80 percent. The “lesser of” language from the NTAP regulation remains a major concern. To comply with this regulation without foregoing NTAP payment, hospitals are forced to engage in a mark-up practice that is unwieldy, uncomfortable, unfair, and unstable.

ASTCT recognizes CMS’ fiduciary responsibility to be stewards of the Part A trust fund, but immediate steps are needed to update the NTAP formula, which depends on gross charges and mark-up practices. Any method to increase the NTAP payment towards the cap so it does not solely depend on gross charges reduced to cost by application of a CCR would be an improvement.

E. Changing How NTAP and Outlier Payment Is Computed in An Effort to Remove Charge Compression Over Time

Instead of embarking on large-scale changes in FY 2024, ASTCT recommends that CMS consider incremental changes. One suggestion for doing so is to utilize actual CAR-T product acquisition cost to calculate NTAP and outlier payments for cell and gene therapies. We have shared this suggestion with the Agency previously in great detail and provide a summary of the proposal here.
ASTCT first proposed that CMS implement this concept in our September 2017 letter on CAR-T payment policy.[9] Our objective was to mitigate differential provider charging and mark-up practices for purposes of appropriate NTAP and outlier payment. Using this concept would enable CMS to recognize the actual product cost for CAR-T and other new technologies rather than estimating the cost through the typical process of reducing billed charges to cost using the hospital’s overall CCR. In the proposed FY 2020 rule, CMS requested comment on this idea but did not fundamentally propose any changes to how NTAP or outlier formulas will work in the future other than increasing the maximum NTAP cap to 65 percent for most products and 75 percent for a handful of others. ASTCT strongly believes the NTAP payment formula is ripe for change in order to remove the influence of gross charges and rely, instead, upon actual cost.

As of April 1, 2019, the CAR-T product charge can be isolated on claims via revenue code 0891 (Special Processed Drugs – FDA Approved Cell Therapy) and Value Code 90 (Cell/Gene Therapy Invoice Cost). As discussed above, this can identify actual acquisition costs on the claims. ASTCT continues to recommend that CMS recognize the actual product acquisition cost in the following manner for its NTAP and outlier calculations for future cell and gene therapy NTAPs:

1. Compute the “Patient Care Cost” Only: Subtract the line item drug charge reported in new revenue code 0891 from the total inpatient charges on the CAR-T claim. Multiply the result by the hospital’s overall CCR to get the calculated patient care cost.

2. Derive the new “Total Case Cost”: Add the calculated patient care cost to the CAR-T drug cost that results in the newly calculated cost.

3. Apply the result: Use the newly calculated cost as the starting point in the NTAP and outlier calculations.

This process will enable CMS to separately isolate the exact drug/cell therapy or gene therapy charges from all other pharmacy charges. Using the actual product cost in CMS’ various calculations would enable centers to receive the full NTAP regardless of their charging practices. This will provide CMS with complete and transparent information about product acquisition cost and any discounts, thereby meeting the Agency’s goals and ensuring it has accurate data for future rate-setting. We believe this policy represents a step in the right direction for providing more accurate and equitable payment for innovative new therapies for both centers and CMS.

This policy will begin to eliminate mark-up practices that are currently required due to CMS’ NTAP calculation and its rate-setting methodology. It begins to move the Agency away from charge compression, at least for these new technologies. It enables CMS to collect actual cost data, which are far more accurate than the data generated by the Agency’s current methodology (i.e., reducing charges to estimate product costs), which is one of CMS’ goals for future payment models. It has the potential to expand access and, importantly, prevent CMS from making overpayments to hospitals with extraordinary markups.
It also protects hospitals that receive the full NTAP during the NTAP period but, once NTAP expires, are at the mercy of what their peers bill, which affects CMS’ computation of the relative weight under the usual MS-DRG payment system.

Using this concept will help eliminate the use of the outlier payment pool to compensate for any NTAP shortfalls. That methodology results in extraordinary mark-up practices that will be mitigated by this approach, since the calculation uses actual product cost. Furthermore, it will keep CMS’ reimbursement formulas intact, only necessitating one change that can be applied to both NTAP and outlier in its calculations.

This approach is also unique to cell and gene therapies, since these are the only categories of therapies with their own revenue code and Value Code to help isolate both product charges and actual acquisition costs. This is not available to other NTAPs today, although we may see more revenue codes and/or Value Codes that would enable this methodology to be applied to other products in the future.

Collection of acquisition cost through Value Code 90 will improve reimbursement for centers and increase patient access while CMS continues contemplating longer-term payment models for cell and gene therapies, like CAR-T, that are unique to each patient.

F. Creating Patient Care Instead of Product Groupings

ASTCT believes CMS should consider creating cell therapy groupings that represent the average patient care cost for different types of cases separate from other payment groups that average together different types of product costs. While more definition will be required, we believe this idea should be explored, since it would enable CMS to retain clinically similar and resource homogeneous patient care groupings and also create product groupings by cost bands (not unlike what it does in the outpatient setting, for example). This allows CMS to remain with the averaging process that is the foundation of its PPS systems for both types of payment groups.

We believe there are several benefits to this approach. First, our clinicians are only able to control the patient care costs for CAR-T therapy and other cellular therapies coming to market soon, not the product cost that overwhelms the patient care cost in an unprecedented fashion within the DRG system. We believe it would be appropriate for CMS to limit the base MS-DRG payment to the patient care portion only and to allow for a separate payment group or MS-DRG for the product. CMS would have some flexibility in how to create one or more separate payment groups for various products over-time that reflects some form of averaging of either manufacturer reported ASPs or data obtained through Value Code 90.

Ideally, CMS would be able to create product payment groups relying on the data reported in Value Code 90 that will provide visibility of actual product acquisition cost. CMS will not have this data until FY 2023 rule-making at the earliest which is why this data should be required to be reported starting October 1, 2020.
VIII. CONCLUSION

Thank you for the opportunity to provide comments on the FY 2021 IPPS proposed rule. ASTCT welcomes the opportunity to discuss these recommendations in more detail or to answer any questions you may have. Please contact Alycia Maloney, ASTCT Director of Government Relations, at amaloney@astct.org for any follow up issues.

Sincerely,

Pavan Reddy, MD
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References

[4] Ibid.
[5] Ibid.
[6] Ibid.
[7] Ibid.
Appendix A: Additional Information on NDC Reporting and Official NUBC Information
Provided with the Permission of the AHA

ASTCT provides the following references for CMS to consider when it is deciding to ask for NDC codes on inpatient claims to identify drugs and biologicals. We note that CMS can ask for NDCs for cell and gene therapy products reported with the NUBC revenue codes in the 089x series.


- Also included are the two sections from the 2020 NUBC manual for institutional claims. Form locator 43 is where NDCs are reported on Medicaid outpatient claims and where this data field is reported when other payers require details. Also note the NUBC notes for form locator 44 for HCPCS codes – while HCPCS codes are not typically reported for inpatient services, NUBC states “Required for inpatient claims when appropriate HCPCS (drugs and biologicals only).” This enables commercial payers to require HCPCS and/or NDC codes for drugs and biologicals on inpatient claims. Even when a payer requires HCPCS codes only, often the NDC code automatically prints to the inpatient claim because the patient accounting system is set up to provide the detail on both when one or the other data element is required by the payer.

- ASTCT queried several providers, which reported the following feedback:
  - We have to report NDCs for outpatient Medicaid due to the drug rebate program.
  - Many commercial payers require NDC on outpatient claims, and heavily edit and deny based on the NDC reported. Some commercial payers also require NDCs for un-coded (i.e. no-HCPCS) drugs with rev code 250.
  - If payers require it, we report NDCs on inpatient claims.
  - Adding NDCs to claims is not hard; it requires some programming, which is possible to do – it makes the most sense if both HCPCS and NDC could be reported on inpatient claims for CAR-T.
  - We report NDC for Medicaid inpatient for immune globulin and for high-cost drugs, like CAR-T.
  - NDCs are set to print if that is required based on payor build; it is not difficult to program this; for example, if you have EPIC, you would just direct what revenue codes you want NDCs for in Willow and that flows into EPIC. So, we could easily do that for rev code 0891 for Medicare inpatient and it would be good to do this so we can tell what high-cost drugs are actually being given.
Effective Date: March 1, 2007

Data Element: Revenue Description/IDE Number/Medicaid Drug Rebate/Line Level Rendering Provider NPI

Definition: The standard abbreviated description of the related revenue code categories included on this bill. (See FL 42 for description of each revenue code category.) FL 43 is also used to report Investigational Device Exemption (IDE) Numbers, information on Medicaid drug rebates and line level reporting of Rendering Provider NPI on UB-04 paper claims.

Reporting:
- UB-04: Required (for paper bills only).
- 005010:
  - Revenue Description - Not Used.
  - IDE Number - Situational (Loop ID 2300 REF)
  - Medicaid Drug Rebate (NDC) - Situational (Loop ID 2410 Drug Identification - LIN, CPT)
  - Line Level Rendering Provider NPI - Situational (Loop ID - 2420C Rendering Provider Name)

Field Attributes: 1 Field 22 Lines*
24 Positions
Alphanumeric
Left-justified

Notes: The standard abbreviated description should correspond with the Revenue Codes as defined by the NUBC.

* The 23rd line contains an incrementing page count and total number of pages for the claim on each page, creation date of the claim on each page, and a claim total for covered and non-covered charges on the final claim page only indicated with a Revenue Code of “0001”.
Effective Date: January 1, 2008*, October 1, 2012
Meeting Date: 10/10/07, 9/19/12

Notes

Medicaid Drug Rebate Reporting

- Report the N4 qualifier in the first two (2) positions, left-justified.
- Followed immediately by the 11-character National Drug Code number in the 5-4-2 format (no hyphens).
- Immediately following the last digit of the NDC (no delimiter) the Unit of Measurement Qualifier. The Unit of Measurement Qualifier codes are as follows:
  - F2 - International Unit
  - GR - Gram
  - ME - Milligram
  - ML - Milliliter
  - UN - Unit
- Immediately following the Unit of Measurement Qualifier, the unit quantity with a floating decimal for fractional units limited to 3 digits (to the right of the decimal).
- Any spaces unused for the quantity are left blank.

Note that the decision to make all data elements left-justified was made to accommodate the largest quantity possible.

* Effective Date: For bills created on or after January 1, 2008. Reporting NDC may be deferred in states not ready to implement this methodology as of January 1, 2008.

The Description Field on the UB-04 is 24 characters in length. An example of the methodology is illustrated below.

```
N 4 1 2 3 4 5 6 7 8 9 0 1 U N 1 2 3 4 . 5 6 7
```

Line Level Rendering Provider NPI

- Report on lines containing professional fees revenue codes (096x, 097x, and 098x) the rendering physician or other practitioner NPI, if it differs from the rendering physician/practitioner reported at the claim level (FL 78-79).

Required for providers that under federal regulatory requirements submit a “combined claim”, that is, a claim that includes both facility and professional components. The requirement therefore applies to Critical Access Hospitals billing under Method II, Federally Qualified Health Centers, and Rural Health Clinics that submit claims to Medicare contractors for services provided to Medicare beneficiaries.
Effective Date: March 1, 2007

Data Element: HCPCS/Accommodation Rates/HIPPS Rate Codes

Definition:
1. The Healthcare Common Procedure Coding System (HCPCS) applicable to ancillary service and outpatient bills.
2. The accommodation rate for inpatient bills.
3. Health Insurance Prospective Payment System (HIPPS) rate codes represent specific sets of patient characteristics (or case-mix groups) on which payment determinations are made under several prospective payment systems.

Reporting: HCPCS and HIPPS Rate Codes
- UB-04: Situational. Required for outpatient claims when an appropriate procedure or HIPPS code exists for this service line item.
- UB-04: Situational. Required for inpatient claims when an appropriate HCPCS (drugs and/or biologics only) or HIPPS code exists for this service line item.
- 005010X223A2: Situational. Required for outpatient claims when an appropriate procedure code exists for this service line item.
- UB-04: Situational. Required for inpatient claims when an appropriate HCPCS (drugs and/or biologics only) or HIPPS code exists for this service line item.

Accommodation Rates
- UB-04: Situational. Required when a room & board revenue code is reported.
- 005010: Not Used. (Rationale: The rate can be computed by dividing the total charge by the number of units.)

HCPCS Modifiers
- UB-04: Situational. Required when a modifier clarifies or improves the reporting accuracy of the associated procedure code.
- 005010: Situational. Required when a (first, second, third or fourth) modifier clarifies or improves the reporting accuracy of the associated procedure code.

Field Attributes
- 1 Field
- 22 Lines (a)
- 14 Positions (b)

- Numeric for Accommodation Rates; alphanumeric for HCPCS and HIPPS Rate Codes.
- Right-justified for Accommodation Rates; left-justified for HCPCS and HIPPS Rate Codes.
- Dollar values reported for Accommodation Rates must include whole dollars, the decimal, and the cents.
Notes

Field Attributes
(a) The 23rd line contains an incrementing page count and total number of pages for the claim on each page, creation date of the claim on each page, and a claim total for covered and non-covered charges on the final claim page only indicated using Revenue Code 0001.

(b) For HCPCS, the field consists of 5 positions for the base code plus 8 positions for up to four HCPCS modifiers; thus, the field contains one extra/unused position.

(c) HIPPS rate codes are alphanumeric codes of 5 positions. Each code contains intelligence, with certain positions of the code indicating the case mix group itself, and other positions providing additional information; the additional information varies among HIPPS codes.

HIPPS Rate Codes
The Centers for Medicare & Medicaid services develops and publishes the HIPPS codes to establish a coding system for claims submission and claims payment under prospective payment systems. These codes represent the case mix classification groups that are used to determine payment rates under prospective payment systems. Case mix classification groups include, but may not be limited to, resource utilization groups (RUGs) for skilled nursing facilities, home health resource groups (HHRGs) for home health agencies, and case mix groups (CMGs) for inpatient rehabilitation facilities.

HCPCS Modifiers (Level I and Level II)
The UB-04 accommodates up to four modifiers, two characters each.

See AMA publication CPT 200x (x = to current year) Current Procedural Terminology, Appendix A - HCPCS Modifiers Section: “Modifiers Approved for Ambulatory Surgery Center (ASC) Hospital Outpatient Use”.

Various CPT (Level I HCPCS) and Level II HCPCS codes may require the use of modifiers to improve the accuracy of coding. Consequently, reimbursement, coding consistency, editing and proper payment will benefit from the reporting of modifiers. Hospitals should not report a separate HCPCS (five-digit code) instead of the modifier. When appropriate, report a modifier based on the list indicated in the above section of the AMA publication.