July 2, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
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:

On behalf of National Marrow Donor Program® (NMDP)/Be The Match®, we thank you for the opportunity to provide our comments on the notice of proposed rulemaking (NPRM) for the FY2021 Inpatient Prospective Payment System (IPPS).

For the thousands of Americans diagnosed every year with life-threatening blood cancers like leukemia and lymphoma, a cure exists. NMDP manages the largest and most diverse marrow registry in the world through a competitively-bid contract with the Health Resources and Services Administration (HRSA). Each year, Congress appropriates funds to operate this federal program, which is designated by Congress as the C.W. Bill Young Cell Transplantation Program (Program). Since the mid-1980s, Congress has reauthorized the Program with virtually unanimous support. Today, there are 22 million U.S. volunteers listed on the registry who are willing to donate, and more than 300,000 cord blood units—making a transplant cure available for thousands of Americans each year.

In this letter, NMDP provides comments on several topics and proposals in the NPRM.

Section 108 Implementation

NMDP is very pleased that cost-based reimbursement of inpatient hematopoietic stem cell transplant (HSCT) donor search and cell acquisition cost is now imminent for our member transplant centers. We are also very appreciative of the Agency taking time to collaborate with us and to carefully implement Section 108 of the Further Consolidation Act of 2019 (hereafter, Section 108) over the past several months. Our comments below address a number of CMS' proposals in the order in which they are presented in the NPRM.

Payment for Allogeneic Hematopoietic Stem Cell Acquisition Costs on a Reasonable Cost Basis

NMDP concurs with CMS' proposal to establish a new paragraph (e) at 42 CFR 412.113 to outline, via regulation, the requirements of Section 108. We also appreciate that CMS is, in this language, affirming the timing of this reimbursement change for cost reporting periods beginning

on or after October 1, 2020 for IPPS hospitals (*i.e.,* subsection d hospitals) that perform allogeneic HSCT transplants for Medicare fee-for-service (FFS) patients.

We understand that CMS is modeling this payment as closely as possible to solid organ reimbursement under 42 CFR 412.113(d) to provide cost reimbursement as required by Section 108. HSCT and solid organ transplant differ in ways that affect how their costs should be addressed. One significant way solid organ transplants differ is HSCTs are not overseen by an Organ Procurement Organization (OPO) or OPO rules, which were first implemented in the 1980s. Of note. HSCTs were developed after establishment of those rules in the 1980s, and Medicare remains a relatively small payer for HSCTs compared to commercial payers and Medicaid. Thus, in light of important distinguishing factors, NMDP submitted a comment letter on this topic in early June, detailing our recommendations. Our goal in doing so was to give CMS sufficient time to consider changes to the proposal for transplant centers to develop a standard charge based on the average of each center's HSCT donor search and acquisition services for all its allogeneic HSCT recipients. Please see Appendix A for a copy of that comment letter.

Below, we summarize the issue and provide additional context for CMS' consideration.

Standard Average Charge for HSCT Donor Services

NMDP asks CMS to review the proposed regulation language at 42 CFR 412.113(e)(3) together with the existing Provider Reimbursement Manual Part 1, Section 2202.4 requirement that hospitals must uniformly apply a service charge to all patients—whether they are inpatient or outpatient, Medicare beneficiaries or non-Medicare patients. Transplant centers would have to follow both rules. Hence, if CMS finalizes its proposal for 42 CFR 412.113(e)(3), transplant centers would have to use the same average charge on *all* of their transplants claims— not solely on Medicare accounts—including claims for commercial payers and Medicaid, just as PRM1 2202.4 mandates.

Currently, CMS allows transplant centers to bill actual donor charges on all recipient accounts. This long-standing instruction allows transplant centers to bill all payers (*i.e.,* Medicaid, Medicare, and commercial payers) actual charges for various donor evaluation, testing, and other unrelated donor search and cell acquisition charges. If CMS finalizes its proposal, transplant centers would no longer be able to report their actual charges to other payers; instead, they would be forced to report an average acquisition charge on all recipient accounts. Actual donor charges would have to be written off for all payers even though they would post to the donor accounts; the actual charges would not be able to be billed to any payer. This would fundamentally and significantly impact how transplant centers bill commercial insurances for donor search and cell acquisition services. It is likely to necessitate a change in the payment terms of each transplant center's negotiated contracts and, ultimately, the payment the centers receive.

In our early comments we requested CMS not finalize this proposal. Instead, we asked CMS to codify existing manual instructions that require transplant centers to hold 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.

NMDP believes that continuing to allow transplant centers to report their actual charges under revenue code 0815 is the simplest approach and that this will accomplish appropriate

implementation of Section 108 (*i.e.,* paying reasonable cost for allogeneic donor search and cell acquisition) while allowing transplant centers to continue billing their other payers in the manner to which they are accustomed and have contracted based on actual charges. To make changes that would require transplant centers to renegotiate contracts would be administratively burdensome and could result in negative unintended financial consequences to transplant centers, leading to possibly less access to care for patients.

Interim Pass-through Payment

CMS proposes that the standard acquisition charge would be billed and paid on an interim payment basis as a ‘‘pass-through’’ item in accordance with 42 CFR 413.60 and 413.64. CMS states that it would use the actual charges by ancillary cost center from the provider’s records included on the Medicare cost report, and convert these charges to reasonable costs using the corresponding ancillary cost-to-charge ratios (CCRs). At the end of the cost reporting period, a settlement determination would be made of the actual cost incurred compared to the interim payments made during the 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.

In addition, most transplant centers do not appear to have filed cost reports using cost center 77, despite educational efforts by the NMDP and other professional associations. Although transplant centers should have been using cost center 77, without clear guidance and additional instructions, it has proven difficult for centers to comply. We believe this will change once cost reimbursement depends upon accurate cost reporting and CMS releases new and explicit instructions on how centers should file their cost reports. Without complete cost data from cost center 77, and without information for prior years of actual charges by ancillary cost center, CMS will need another approach to begin paying transplant centers their interim payment for FY 2021.

Furthermore, as discussed below, CMS is making a budget neutrality adjustment and we believe it is important that the interim pass-through payments align with this budget neutrality adjustment.

Given these considerations, we believe that CMS has two options:

Option 1: Payment Summary and Reimbursement (PS&R) Report Method

- CMS uses each transplant center’s prior year PS&R report’s total Medicare charges billed under revenue code 0815.
- CMS multiplies these charges by the individual hospital’s CCRs.
- CMS divides this amount by 26 to develop the initial bi-weekly interim payment.
- CMS instructs its Medicare Administrative Contractors (MACs) to update this amount throughout the fiscal year, as appropriate, to minimize the amount of receivable/payable at cost settlement.

Option 2: Claims-Based Method

- CMS uses the actual billed charges reported under revenue code 0815 from each submitted transplant recipient’s claim multiplied by the hospital’s CCR.

- CMS pays this amount on the remittance as a pass-through payment amount in addition to the MS-DRG 014 payment.

NMDP recently queried several transplant centers and was told that both options have pros and cons but that, ultimately, either option is acceptable. The primary benefit of option 1 is that it aligns more closely with the way in which CMS handles pass-through payments for solid organs. It may also be closer to CMS' intentions, although this was not described in detail in the NPRM. Option 1 also results in more consistent cash flow for transplant centers. We believe the primary benefit of option 2 is that there would likely be a lower incidence of large receivable/payables at cost report settlement as long as CMS allows actual donor charges to be billed (as is the case today). This will better reflect the volume and type of donor/cell acquisition costs involved in the HSCTs provided by the transplant center throughout the year.

Maintenance of Records

CMS proposes in new paragraph 42 CFR 412.113(e)(5) to require transplant centers *"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."*

We concur that record-keeping is paramount but note that many itemized statements for donor services may be maintained for a single recipient. Recipients may have several relatives who are evaluated and worked-up to determine if they are a match. If there is a match, the related donor cells will likely be used. But, in cases without a match, the transplant center will evaluate unrelated donors and then incur the acquisition of unrelated cells for the recipient. Therefore, each recipient may have numerous itemized statements of various donor services to evaluate, collect, and obtain cells for transplant.

For clarity purposes, we recommend CMS finalize the following 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."

Proportion of Medicare Transplants

CMS proposes to add new paragraph (e)(4) to 42 CFR 412.113 to specify that the hospital's Medicare share of the HSCT donor acquisition costs is based on the ratio of the number of allogeneic HSCT that are furnished to Medicare beneficiaries to the total number of allogeneic HSCT that are furnished to all patients, regardless of payer, applied to reasonable cost.

NMDP concurs with this definition. We also understand that more details about its application will be forthcoming with the Paperwork Reduction Act (PRA) package related to cost reporting instructions, and that there will be an opportunity to comment on these details.

Definition of Allogeneic Hematopoietic Stem Cell Transplant

NMDP affirms CMS' proposal to codify the statutory definition of an "allogeneic hematopoietic stem cell transplant" with new paragraph (e)(1) to 42 CFR 412.113. NMDP has no comments concerning this paragraph and codification.

Items Included as Allogeneic Hematopoietic Stem Cell Acquisition Costs

Section 108 grants the Secretary authority to specify, through rulemaking, the items included as allogeneic HSCT donor acquisition costs. CMS proposes to specify the items in new paragraph (e)(2), and uses the existing manual definitions found in publication 100-04, Chapter 3, Section 90.3.3.A and Ch. 4 Section 231.11 as its basis.

CMS delineates that allogeneic HSCT donor acquisition costs would 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).

NMDP concurs with this delineation of the items included in allogeneic HSCT donor acquisition costs.

Clarification of Hospital Cost Reporting Instructions

As CMS describes, hospital cost-reporting forms were modified with policies described in the FY 2019 IPPS/LTCH PPS Final Rule. These policies added a new standard cost center, line 77 ''Allogeneic Stem Cell Acquisition'' to Worksheet A (and applicable worksheets) with the standard cost center code of ''07700." The new cost center line was established in order to record any acquisition costs related to allogeneic HSCT as defined in Section 231.11, Chapter 4, of the Medicare Claims Processing Manual (Pub. 100–04), in order to help develop more accurate estimates of these costs for future rate-setting.

CMS also accurately reports that the establishment of this line generated challenges in reclassifying expenses into the new cost center from routine and ancillary departments for services rendered to donors. NMDP recognized the confusion observed in the provider community resulting from a lack of instructions from CMS and has requested that CMS release more detailed instructions to address the many questions we have received about this issue.

NMDP understands CMS' comments on data inconsistencies in reporting of costs and charges for allogeneic HSCT acquisition. One reason for these inconsistencies is that the current cost reporting for Line 77 does not provide a method for determining other routine and ancillary costs that are part of allogeneic HSCT acquisition costs.

NMDP is appreciative of CMS' acknowledgement that, in order to accurately reimburse allogeneic HSCT cell acquisition costs on a reasonable cost basis (as required by Section 108), cost reports *must* accommodate reporting of both direct and indirect costs on Line 77. In addition, cost reports must accommodate the reclassification of both routine and ancillary costs associated with acquisition of HSCT cells from donors. We are encouraged that CMS will be modifying cost reporting forms and instructions and will develop a worksheet similar to the Worksheet D– 4 for solid organs. This worksheet will allow transplant centers to capture costs from Line 77 from the cost report, to report charges by routine and ancillary cost centers for donor services, and to compute the costs of these services.

NMDP understands that changes to the forms and instructions will be described in more detail in a forthcoming Paperwork Reduction Act (PRA) package which will additionally provide a comment period. We appreciate that this package will address a standardized format for data collection and Worksheet S–10 modifications needed. We look forward to the opportunity to provide meaningful comment to the Agency on these necessary details.

Budget Neutrality for the Reasonable Cost-Based Payment for Allogeneic HSCT Acquisition Costs

Section 108 provides that this cost-based payment be implemented in a budget-neutral fashion; we understand the Agency's explanation of the method used to calculate the budget-neutrality adjustment. We note that both options discussed above for the interim pass-through payment align with CMS' budget-neutrality method to use charges for allogeneic HSCTs that are separately billed under revenue code 0815 on each recipient's inpatient hospital bill, multiplied by the hospital's operating CCR.

Impact on Medicare Advantage Plans

While not discussed in the NPRM, whenever there is a significant change in payment methodology for fee-for-service (FFS) Medicare, it raises questions and concerns about the impact to Medicare Advantage (MA) patients. NMDP understands that the answer depends on whether the transplant center has a negotiated contract with the MA plan or not. If there is a contract, payment for allogeneic HSCT acquisition costs will continue per the terms of the contract. But, for out-of-network MA cases, FFS Medicare pays for cost-reimbursed services; according to the MA out-of-network guide[1], the MACs include these cases in their cost settlement.

NMDP asks that in the final rule, CMS addresses how Section 108 will change MA payment for allogeneic HSCT acquisition costs for both in-network and out-of-network cases.

NMDP also requests that CMS update all of its various manuals and other guidance materials that reference HSCT, including those listed below from the MA Payment Guide for Out of Network Payments.

Non- PPS payments include:

1. Direct graduate medical education payment (DGME);

[1] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/OONPayments.pdf

2. Capital for the first 2 years of a new hospital (generally 85% of Medicare allowed capital costs);
3. Organ acquisition costs (excluding bone marrow transplants);
4. Certified Register Nurse Anesthetists (CRNAs) for small rural hospitals;
5. Nursing and allied health education costs; and
6. Bad debt.

This is important to ensure that providers and payers understand the changes that have been made per Section 108.

Grouping Logic and OR Designation of MS-DRGs 014, 016 and 017

CMS proposes to change the designation of MS-DRGs 014, 016, and 017 from surgical to medical, but retain the pre-Major Diagnostic Category (MDC) grouping logic for these MS-DRGs. We do not believe there is any impact to designating these MS-DRGs as non-OR, particularly as many of the ICD-10-PCS codes are already defined as non-OR procedures. We note that, while the transfusion procedure for an HSCT does not utilize the operating room (OR), many HSCTs involve bone marrow that was harvested from a donor in the OR setting. As such, OR resources are involved with many allogeneic donor-harvesting procedures.

Under Section 108, payment for OR services to harvest bone marrow will be made via cost reimbursement and will no longer be included in the MS-DRG. Hence, this issue will become moot once CMS no longer includes donor service cost in MS-DRG 014. We recommend that the DRG change to non-OR be postponed until MS-DRG 014 no longer includes any OR services related to donor marrow harvesting.

NMDP also reviewed the proposed rule's list of ICD-10-PCS codes regarding open approach for transfusion. We queried the FY 2019 MedPAR claims data file and found only minimal use of these codes (*i.e.,* fewer than 11). We consulted our clinical advisors whether an "open procedure" (per the ICD-10-PCS definition: *"cutting through the skin or mucous membrane and any other body layers necessary to expose the site of the procedure")* would ever occur. Our clinical advisors reported that it is illogical to report such codes for allogeneic or autologous transplant procedures. Therefore, NMDP believes the low volume reflects an error in the data and recommend that CMS remove these codes altogether from the code set.

Support Data Integrity

In the CY 2017 Hospital Outpatient Prospective Payment System (HOPPS) final rule, CMS established a new revenue code, 0815. The new code replaced revenue code 0819 and is intended to capture the costs of donor search and cell acquisition activities for allogeneic HSCT. CMS also established an Integrated Outpatient Code Editor (I/OCE) edit so that any claims with the allogeneic HSCT CPT procedure code would be rejected in the absence of 0815 charges.

NMDP is very supportive of this edit and has encouraged CMS to develop a similar edit in the Medicare Code Editor (MCE) for inpatient claims. Specifically, NMDP asks CMS to implement an edit requiring all cases that group to MS-DRG 014 have charges reported with revenue code 0815. Mandatory reporting of revenue code 0815 will aid CMS in its calculations for budget neutrality and help transplant centers correctly report claims to CMS.

We also encourage CMS to adopt and instruct transplant centers to use the new value codes the National Uniform Billing Committee (NUBC) approved for allogeneic HSCT claims effective July 1, 2020. These codes are:

- **Value code 88:** This value code indicates the number of related donors who were evaluated and is reported on the recipient's transplant claim. A zero is allowed for instances when no related donors were evaluated.
- **Value code 89:** This value code is used to report the total charge amount for both related and unrelated donor services, including charges that were submitted on separate claims. This code would be reported on the recipient's transplant claim.

Using these codes is another way to ensure the integrity of the claims data submitted to CMS. We have included more information regarding use of these codes in Appendix B of this comment letter.

Guiding Principles for Making Changes to Determine CC/MCC Assignment

Last year, CMS proposed to change severity level assignments to diagnosis codes but decided to postpone finalization of this proposal until the Agency had obtained additional stakeholder input. NMDP appreciates CMS' request for input on the guiding principles it proposes to use in evaluating changes to severity level (CC and MCC) designations going forward based on input received from stakeholders and from its internal workgroup. CMS conducted a listening session on October 8, 2019 and convened an internal workgroup to consider public comments and develop guiding principles for evaluating changes to severity level designations.

We understand that, in addition to applying these principles (once finalized), CMS will also conduct claims data analyses. As a general comment, we believe CMS would benefit from assessing and describing the expected cost implications of each of these principles in order to help inform the eventual data analytics.

NMDP generally concurs that each of the following principles that CMS outlined is important in making a determination of whether a patient's diagnosis code should be complication and comorbidity (CC) or major complication and comorbidity (MCC):

- Represents end of life/near death or has reached an advanced stage associated with systemic physiologic decompensation and debility;
- Denotes organ system instability or failure;
- Involves a chronic illness with susceptibility to exacerbations or abrupt decline;
- Serves as a marker for advanced disease states across multiple different comorbid conditions;
- Reflects systemic impact;
- Post-operative condition/complication impacting recovery;
- Typically requires higher level of care (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length of stay, etc.);
- Impedes patient cooperation and/or management of care; and
- Recent (last 10 years) change in best practice, or in practice guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use.

NMDP has recommendations on several of these principles. First, with respect to "post-operative condition/complication impacting recovery," NMDP recommends that CMS revise the language used so that it more broadly includes "post-operative/*post-procedure* condition/complication impacting recovery." Stakeholders are likely to take the wording of this principle literally. NMDP notes that in this same NPRM, CMS proposes to move HSCT procedures to non-OR procedures. However, HSCT is a significant procedure and patients often experience complications such as graft-versus-host disease. Therefore, we believe significant procedures like HSCT should be included in this principle, even if they are not "operative" in nature. We also recommend that CMS define "recovery." This term is likely to indicate patients who require an increased length of stay or a change from routine to specialty care. We note, however, that numerous other costs increase with a complication or condition, including drugs, supplies, ancillary tests, etc. The term "recovery" is conceptually appropriate, so long as its use does not result in the exclusion of consideration of costs that may impact the patient stay.

Our second concern is about "Recent (last 10 years) change in best practice, or in practice guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use." CMS needs a method to assign CC and MCC status to new codes in advance of receiving claims data on those codes. Such cases include patients for whom a costly drug is administered to treat a complication that is reported with a new diagnosis code, and complications that may require ICU care or lengthier stays. This information may come from CMS' clinical advisors and/or from stakeholders' comments, given that the condition or treatment may be so new that peer-reviewed publications or research is unavailable. Certainly, claims data will not be available, since their availability lags for two years after new codes are released.

Chimeric Antigen Receptor T-Cell (CAR-T) Therapy

NMDP has a number of comments on CMS' proposals for CAR-T therapy reimbursement for FY 2021, new ICD-10-PCS codes for new CAR-T products, MS-DRG assignment for complications of CAR-T, and others. Our concerns are described below, organized by topic.

CAR-T Therapy Reimbursement via MS-DRG 018

NMDP supports CMS' proposal to create a new MS-DRG for CAR-T therapy. We have advocated for placing CAR-T cases and autologous HSCT cases in separate MS-DRGs, given that they are neither clinically nor resource homogeneous. We agree with the creation of MS-DRG 018 and with changing the name of MS-DRG 016 back to "autologous transplant." Finally, we recommend that CMS develop a new MS-DRG for the future assignment of new cell therapy cases that are not CAR-T cell therapies rather than defaulting once again to MS-DRG 016, or to the other transplant MS-DRGs.

Relative Weight Computation for MS-DRG 018

NMDP supports CMS' approach to rate-setting in creating the relative weight for MS-DRG 018. We agree with CMS that claims with the Z00.6 clinical trials diagnosis code should not be included in developing the relative weight for MS-DRG 018.

We also agree with CMS' proposal to remove claims that have standard drug charges less than $373,000 as these would be considered aberrant claims given the fact that both commercial CAR-T products on the market cost $373,000. However, CMS does not define "drug" charges in

the proposed rule. We assume that CMS is referring to the CAR-T product itself, and that CMS is defining "drug" charges as charges that are reported in revenue codes 025x, 026x, or 063x per the MedPAR data dictionary definition of pharmacy charges, or 0891.

We raise this issue because it is unclear whether CMS used revenue code 0891 charges for rate-setting purposes. The MedPAR data dictionary seems to indicate that revenue code 081x-089x charges are excluded from rate-setting. We have followed the MedPAR data dictionary definition for this closely for years, given that revenue code 0815 (formerly 0819) for donor search and cell acquisition charges falls in the range. As CMS knows, a process was created for including 0815 charges in rate-setting, rather than excluding them which would have been incorrect. Likewise, it would be incorrect for CMS to exclude revenue code 0891 charges, yet a similar workaround process to include these charges has not been described in the proposal. Therefore, we request that CMS address what is occurring with revenue code 0891 charges. We expect these charges to be included, since they would represent CAR-T product charges and because the NUBC created this revenue code as an extension of pharmacy revenue codes 025x and 063x to allow for the reporting of cell therapy charges separate from other drug charges.

Finally, we believe it is essential for CMS to address two issues that may resolve the issue of very low-dollar revenue code 0891 charges being reported: CMS' own outpatient billing instructions, and how expanded access cases are to be reported. First, CMS' outpatient billing instructions indicate that providers can report outpatient cell collection and cell processing charges on the inpatient claim, using revenue code 0891. We believe this is inappropriate for several reasons, including that these services are well outside the 3-day payment window. Instead, we once again urge CMS to work with the outpatient payment policy group to revise those instructions. Doing so will address some of the low dollar charges that are being reported with revenue code 0891.

Second, CMS must release clear reporting instructions for providers on how to report expanded access cases. These are cases where, although the CAR-T product does not meet the Food and Drug Administration's (FDA) labeled specification, it can be given to the patient under certain circumstances. In these cases, the hospital does not incur the product charge, and would report a token charge on revenue code 0891 on outpatient claims, but may or may not report the Z00.6 clinical trial diagnosis code due to uncertainty about whether it applies or not. NMDP requests that CMS release guidance on how providers should report expanded access cases so that future rate-setting is not compromised. With more cell therapy products coming to market, we anticipate expanded access use of products to continue. One recommendation is for CMS to require the use of value code 90, so CMS can definitively know whether the provider incurred a cost for the cell therapy product, separate from reporting the Z00.6 diagnosis code.

Finally, despite CMS' proposal for creating the relative weight for MS-DRG 018, the issue of charge compression remains. For rate-setting, CMS' proposal continues to use billed drug charges reduced to cost using the national pharmacy CCR of .191. As a result, only claims from providers that use appropriately high mark-ups (on the order of magnitude of three, four, or five times the product cost) will result in accurate calculation of CAR-T product costs for CMS' incorporation into the relative weight. While CMS proposes in this NPRM to migrate away from this type of rate-setting towards market-based pricing, it will be years before a new process is in place. In the meantime, we believe CMS must take steps now to mitigate charge compression.

One step is for CMS to create a new, dedicated cost center specific to this group of specialized, cell therapies. This would be no different than CMS' creation of cost center Line 77 in order to

more accurately capture donor search and cell acquisition costs reported through revenue code 0815 for allogeneic HSCT. Since cell therapy has a dedicated revenue code (0891) it would be straightforward for CMS to require a new, dedicated cost report line for cell therapy costs and for providers to set this up immediately. In time, CMS will have the ability to create a new national cost group to reduce billed charges reported on revenue code 0891 to costs for purposes of rate-setting. We recognize there will be a time lag before these data are available for use but believe that it is crucial to begin the process of data collection now.

Reduced Payment of CAR-T Clinical Trial Cases

NMDP agrees that if CMS excludes clinical trial cases from the development of MS-DRG 018's relative weight, then the Agency should pay a reduced amount for clinical trial cases. For the purposes of rate-setting, CMS defines a clinical trial case as one with a Z00.6 diagnosis code present on the claim or drug charges under $373,000. Yet, CMS will not use this same definition to identify clinical trial cases for payment purposes starting in FY 2021. NMDP requests CMS to provide its rationale for this; we believe that using only Z00.6 will result in potential over- and under-payment of CAR-T cases. Providers are likely to either inadvertently fail to report the Z00.6 code, or to not report it because they are unsure whether expanded access cases should be reported in this manner. As a result, CMS will inadvertently make the full MS-DRG 018 payment rather than a reduced payment. Moreover, CMS could under-pay providers that incur costs for the commercial CAR-T product but that participate in a clinical trial for a therapeutic drug (for example, a trial to address various CAR-T complications) and correctly report Z00.6 to flag the claim as a clinical trial claim.

We believe that a reduced MS-DRG 018 payment should be tightly linked to whether or not the provider incurred a cost for the commercially available CAR-T product rather than whether the claim uses the code Z00.6 which can represent many things. Therefore, we recommend that CMS require providers to report their actual cell acquisition cost in value code 90. This will more accurately help CMS determine whether to provide the full or reduced MS-DRG 018 payment and will help mitigate over- and under-payment issues likely to arise with the use only of diagnosis code Z00.6. Alternatively, CMS could use a similar "two-step" process whereby it looks for the presence of Z00.6 and drug charges reported in revenue codes 025x, 026x, 063x, or 0891 less than $373,000, or no Z00.6 code and drug charges reported in revenue code 025x, 063x, and 0891 less than $373,000, or zero dollars reported in Value Code 90 on the claim for reporting actual cell therapy acquisition cost, for the purposes of flagging claims for reduced payment in FY 2021.

Assignment of CRS Codes to MS-DRGs 814-816

NMDP recommends that CMS assign the new Cytokine Release Syndrome (CRS) codes to CC and MCC MS-DRGs within the MS-DRG 814-816 series. We believe that several of CMS' own guiding principles that are described in this NPRM provide sufficient rationale for such assignment. Once CRS becomes available in the claims data, CMS can re-evaluate this assignment.

ICD-10-PCS Coding for CAR-T Cases

NMDP is concerned that CMS has created a new coding table (XW2) for two new CAR-T codes and is not treating the existing CAR-T products (Yescarta and Kymriah) in the same manner; instead, the Agency has kept them in the existing XW0 table. It is unclear how or why four CAR-

T products can be considered two different things: blood and blood products in table XW2 and "not" as blood products in table XW0, given that the first two CAR-Ts products were added to the coding table in FY 2018.

NMDP recommends that CMS adhere to the principle of parity: for FY 2021, all four CAR-T products should be assigned to the same New Technology Coding table. Our preference is for the products to remain in the XW0 table. We believe this is reasonable, since both of the new products' manufacturers have asked for their codes to be in the XW0 table (albeit with a slightly different approach to the 6th character, where they wanted the products to be named).

We agree that visibility of the cell therapy product administered is critical but, given that CMS did not previously create this visibility, delaying any changes to the coding structure for a year will not cause any data problems. If CMS desires visibility as to the products, CMS should require that each of the four CAR-T products' National Drug Codes (NDCs) be reported on inpatient claims. This will allow the ICD-10-CM code for the procedure performed as well as detail concerning the specific cell therapy product administered. To the extent that new products are assigned NTAP, this process can help evaluate and generate appropriate NTAP payment and there is precedent for CMS using NDCs for the purpose of NTAP. Additionally, for products under trial, the same non-specific ICD-10-PCS autologous administration of CAR-T can be reported with the clinical trial number, the clinical trial diagnosis code Z00.6, and the condition code.

Finally, the FDA approved CAR-Ts and other cellular therapies as biologics. We believe they should continue to be designated this way (*i.e.,* name, label, code) until a broader stakeholder discussion can occur about the two existing CAR-Ts and those expected in FY 2021. This will enable the field to provide feedback on most appropriate coding convention for additional cell therapy products that will come to market over the next decade.

In summary, NMDP recommends CMS assign the two new CAR-T products to the existing ICD-10-PCS "XW0" codes currently in use for Kymriah and Yescarta and require the NDC be reported for all current and future CAR-T products using required revenue code 0891. An alternative is to create new CAR-T codes for all four products in the XW0 table and name each product using the 6th character of the respective new codes; this will foster coding and transparency parity for all four products.

New Technology Add-On Payment (NTAP)

NMDP asks that CMS modify the current NTAP process to allow for quarterly approvals of NTAP status for all approved applications, regardless of the approval pathway, and not have the quarterly approval process be limited solely for antimicrobial, antibacterial, and antifungal products as proposed at 42 CFR 412.87(d). NMDP believes the current NTAP process, which only allows for annual approvals, is much too limiting. Just as CMS recognizes the public health benefit for a quarterly approval process for antimicrobial, antibacterial, and antifungal products, it should have the same recognition for all other FDA-approved products seeking NTAP approval. CMS should review applications and issue a preliminary approval or non-approval to the manufacturer more frequently. For approved applications, CMS should recognize NTAP payment the first quarter after FDA approval.

It is in the beneficiary's best interest to have access to new therapies as soon as they are available. Our transplant centers should not have to decide whether to bear significant financial

losses simply because there was a timing “glitch” between the FDA’s approval date and CMS’ NTAP timing requirements. Currently, when the FDA is approving products on a faster timeframe, it seems important for CMS to establish a new process that enables NTAP reviews to occur more frequently. This will ensure that appropriate payment is available to hospitals at the earliest date possible after FDA approval.

Thank you again for providing us with the opportunity to provide comments on the notice of proposed rulemaking for the FY2021 Inpatient Prospective Payment System. We appreciate your ongoing collaboration, particularly with the implementation of Section 108. Please feel free to contact me with any questions at blindber@nmdp.org or (763) 406-8566.

With best regards,

Brian L. Lindberg, JD
Chief Policy Officer

Appendix A: Detailed Comments on Average Standard Charge Submitted 6/5/2020

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:

On behalf of National Marrow Donor Program® (NMDP)/Be The Match®, we thank you for the opportunity to provide our comments on the notice of proposed rulemaking (NPRM) for the FY2021 Inpatient Prospective Payment System.

For the thousands of Americans diagnosed every year with life-threatening blood cancers like leukemia and lymphoma, a cure exists. NMDP manages the largest and most diverse marrow registry in the world through a competitively-bid contract with the Health Resources and Services Administration (HRSA). Each year, Congress appropriates funds to operate this federal program, which is designated by Congress as the C.W. Bill Young Cell Transplantation Program (Program). Since the mid-1980s, Congress has reauthorized the Program with virtually unanimous support. Today, there are 22 million U.S. volunteers listed on the registry who are willing to donate, in addition to more than 300,000 cord blood units, making a transplant cure available for thousands of Americans each year.

NMDP is very excited that cost-based reimbursement of inpatient hematopoietic stem cell transplant (HSCT) donor search and cell acquisition cost is now imminent for our transplant center network. We are also very appreciative of the Agency taking time to collaborate with us and to carefully implement Section 108 of the Further Consolidation Act of 2019. We are still analyzing proposals in this Section and other proposals in the NPRM beyond Section 108 and will be submitting more comments prior to the deadline. There is, however, one topic of concern for our transplant centers that we wish to submit early to CMS to provide the maximum amount of time to consider and change the Agency's proposal.

CMS proposes that, when transplant centers submit claims to Medicare, the charge billed under revenue code 0815 for the donor search and cell acquisition services must be a standard charge based on the average of all of the centers HSCT donor search and acquisition services for all allogeneic HSCT recipients. The proposed regulation text would be at 42 CFR 412.113(e)(3). Much of the impetus for this legislation is CMS' treatment of donor costs for solid organ transplants, and NMDP believes that CMS' proposal to use a standard average charge is modeled on similar regulations for solid organs. However, this is one area where solid organ and stem cell transplants are not analogous, and there are no organ procurement agencies for HSCTs.

We ask CMS to view the proposed regulation language 42 CFR 412.113(e)(3) together with the existing Provider Reimbursement Manual Part 1, Section 2202.4 requirement that hospitals must uniformly apply a service charge to all patients—whether they be inpatient or outpatient, Medicare or non-Medicare patients. Transplant centers would have to follow both of these rules. Hence, if 42 CFR 412.113(e)(3) is finalized as proposed, transplant centers would

have to use the same average charge on all of their claims for transplants -- including claims for both commercial payer and Medicaid transplant cases not only on Medicare accounts, just as PRM1 2202.4 mandates.

Currently, CMS allows transplant centers to bill actual donor charges. Medicare's claims processing manual instructions in Chapter 3, Section 90.3.1 require transplant centers to hold all actual donor search and cell acquisition charges for each Medicare transplant recipient and report those charges under revenue code 0815 on the recipient's transplant claim. This existing and long-standing instruction allows transplant centers to bill all other payers their actual charges for various donor evaluation, testing, and other unrelated donor search and cell acquisition charges. If CMS finalizes its proposal, hospitals would no longer be able to report their actual charges to other payers; instead, they would be forced to report an average acquisition charge on all patient accounts. This would fundamentally and significantly impact how transplant centers bill commercial insurances for donor search and cell acquisition services. It is likely to change the payment terms of each transplant center's negotiated contracts, and ultimately the payment the centers receive.

We do not believe that CMS intended for this to be the case. We urge the agency to revise its proposal and instead allow transplant centers to continue reporting their actual charges, which will still fully facilitate implementation of Section 108 in the manner Congress intended.

NMDP recognizes that, under the new cost-based rules, Medicare will settle with each hospital annually and pay the actual Medicare recipient donor costs. Hence, the concept of a standard average charge, modeled off the way solid organ charges work, would not be of any concern IF Medicare were the only payer. That is not the case, however. Since no similar settlement opportunity exists with commercial payers, CMS' proposal will have a deeply concerning impact on hospitals with respect to their commercial payer cases.

Furthermore, many commercial payers accept claims for related donor evaluation and testing charges on separate claims in advance of the recipient's transplant claim. In the spirit of transparency and data collection, in August 2019, the NMDP requested new codes from the National Uniform Billing Committee (NUBC) to facilitate this reporting. We were pleased that the NUBC agreed with our requests (details provided in Appendix A) and released new value and condition codes for implementation on July 1, 2020. This commercial insurance billing practice would be complicated at best, or could not occur, at worst, if transplant centers are mandated to have one standard average charge for each transplant recipient.

In summary, the NMDP respectfully requests that CMS remove the standard charge language in this proposal. We urge the Agency, instead, to codify existing manual instructions that require transplant centers to hold their actual donor search and cell acquisition charges applicable to each Medicare transplant recipient's case, and include them all on the recipient's claim under revenue code 0815. The NMDP believes that continuing to allow transplant centers to report their actual charges—as has been the longstanding requirement—is the simplest approach. It will, moreover, accomplish appropriate implementation of Section 108 (e.g., paying reasonable cost for allogeneic donor search and cell acquisition) and allow transplant centers to continue billing their other payers in the manner to which they are accustomed, by reporting actual charges and using the new NUBC codes.

Thank you again for providing us with the opportunity to provide comments on the notice of proposed rulemaking. Please feel free to contact me with any questions at blindber@nmdp.org or (763) 406-8566.

With best regards,

Brian L. Lindberg, JD
Chief Policy Officer

Appendix B: New NUBC codes effective July 1, 2020

- **Condition code 88:** allogeneic HSCT related donor charges. This code is used on a claim submitted solely for separately billed charges for evaluating the suitability of HSCT donors, prior to the submission of the actual inpatient transplant claim.
- **Value code 88:** This value code indicates the number of related donors evaluated and is reported on the recipient's transplant claim. A zero is allowed for no related donors evaluated.
- **Value code 89:** this code is used to report the total charge amount for both related and unrelated donor services, including charges that were submitted on separate claims. This code would be reported on the recipient's transplant claim.

Example of Reporting

Type of Hospital Donor Services	Medicare	Medicaid & Commercial – Per Payer Requirement/Agreement
Related donor(s) services (e.g., evaluation, testing, cell collection, cell processing)	Held and reported on recipient transplant claim using revenue code 0815	**Option 1** = Held and reported on recipient transplant claim using revenue code 0815 or **Option 2** = billed on separate claim under recipient name using revenue code 0815, specific CPT/HCPCS codes, **and condition code 88**
Unrelated donor services (e.g., NMDP search, testing, cell purchase, cell processing)	Held and reported on recipient transplant claim using revenue code 0815	**Option 1** = Held and reported on recipient transplant claim using revenue code 0815 or **Option 2** = billed on separate claim under recipient name using revenue code 0815, specific CPT/HCPCS including 38204, **and condition code 88**

Transplant Recipient Claim	Medicare	Medicaid & Commercial – Per Payer Requirement/Agreement
Recipient Services (e.g., conditioning prior to SCT and hospital services to transplant and monitor patient (e.g., room charges, ICU, lab, imaging, drugs, etc.)	All previously held donor claims with cost of services summed and reported under revenue code 0815. Use 38204 if outpatient transplant. Value code 88 = Number of related donors evaluated; zero is acceptable for none Value code 89 = total charges for all related and/or unrelated donor charges. Should equal charges on revenue code 0815 line	If held, donor services reported under revenue code 0815 Value code 88 = Number of related donors evaluated; zero is acceptable for none Value code 89 = total charges for all related and/or unrelated donor charges including those reported on separate claims plus that reported with revenue code 0815 on recipient claim, if any