July 20, 2022

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted electronically at regulations.gov

Re: Revisions to Paperwork Reduction Act Revision of the Hospital and Health Care Complex Cost Report

Dear Administrator Brooks-LaSure:

On behalf of National Marrow Donor Program (NMDP), thank you for the opportunity to provide our comments on the Paperwork Reduction Act revision of the Hospital and Health Care Complex Cost Report; in particular, for the instructions regarding the hematopoietic stem cell transplant (HSCT) cost report line 77 for purchased donor search and cell acquisition costs and new worksheet (WS) D-6 to calculate the transplant center services directly furnished to donors to collect bone marrow and cells for HSCT. This comment letter is to recognize and thank CMS for their response to our questions, concerns, and recommendations related to the first draft instructions to implement section 108 of the Further Consolidated Appropriates Act 2020 outlined in our January 11, 2021, comment letter.

As operator of the C.W. Bill Young Cell Transplantation Program (Program), NMDP manages the most diverse marrow registry in the world through a competitively bid contract with the Health Resources and Services Administration (HRSA). Today, patients have access to more than 39 million potential donors worldwide in addition to more than 806,000 cord blood units, making the cure available through transplant a reality for thousands of Americans each year.

As the steward of this critical federal public health program, we work to identify and eliminate barriers faced by those patients in need of one of these life-saving transplants, and partner with nearly 200 hospital transplant programs in assisting them with efforts to protect access to transplant. It is because of this aspect of our role that we wish to provide comment on the revised instructions.

We believe the revised instructions, as proposed, recognize allogeneic stem cell donor acquisition costs for all types of transplant centers whether PPS or PPS-exempt which is important for accurate cost finding. As we stated in our prior comments, it is important to NMDP that the instructions fully implement Section 108 for PPS hospitals and it is also important that the instructions enable correct cost reporting for donor acquisition costs for all hospitals (i.e., PPS and non-PPS) including when the transplant recipient is

an outpatient. After completion of cost center 77 and WS D-6, costs flow to subsequent worksheets that enable calculation of Medicare inpatient and outpatient cost and then settlement, as appropriate, for each type of hospital.

NMDP is also pleased with modifications CMS made for line 78 and appreciates that CMS wants to understand the costs involved in furnishing cell therapy services. Again, we appreciate the consideration CMS made to our prior comments for this line.

Our objective regarding this comment letter is to suggest enhancements to CMS' instructions with an aim to improve clarity and to prevent any ambiguity or questions from transplant centers and Medicare Administrative Contractors (MACs) alike in the successful implementation of Section 108. We would be happy to discuss whether NMDP could be of assistance in collaborating with CMS regarding education of MACs and hospitals once the forms and instructions are finalized.

WS A-C, Line 77

As CMS is aware, correct cost reporting of donor acquisition costs for allogeneic stem cell transplants is complex. It is with this in mind that we suggest the following wording changes for additional clarity. We have added new blue italicized text in the draft instructions copied below as suggested changes for clarity.

Effective for services rendered on or after January 1, 2017, enter the hospital acquisition costs for allogeneic (stem cells obtained from a donor other than the recipient) hematopoietic stem cell transplants (HSCT) as defined in *42 CFR 412.113 (e),* CMS Pub. 100-04, chapter 3, §90.3.1, and CMS Pub. 100-04, chapter 4, §231.11. This includes *direct costs and* costs of services purchased under arrangements and registry fees for national donor registries (42 USC 274k), if applicable. Do not reclassify costs from the routine and ancillary cost centers; rather compute the acquisition costs on Worksheet D-6, Part I, including acquisition costs associated with services intended for transplant but not resulting in transplant, i.e., due to death of the intended recipient or other causes. Do not include costs *for recipient* allogeneic HSCT *services* on this line, *other than HLA typing*. *Time studies as described in Section 2314E may be used to determine direct staff time for services to donors.*

We suggest adding the Code of Federal Regulations citation as that is where the definition per Section 108 is codified and the manual citations are sub regulatory. We also ask that the instructions explicitly mention direct costs and time studies as we have had questions from our network centers about these issues.

Additionally, we suggest that the instructions for Worksheet C specify that the patient care gross charges for line 77 are solely for the donor purchased services costs and not the charges for donor services furnished by other departments as these charges should be included in the gross patient revenue of each of those department lines and will be used later to calculate donor costs of furnished services in Worksheet D-6.

WS D-6 for Donor Search and Cell Acquisition Costs

NMDP appreciates the revisions made to the draft WS D-6. The purpose of this WS is to calculate donor search and cell acquisition costs associated with related donor services rendered by transplant centers, including costs of cancelled transplants. The updated worksheet includes several important components including:

- costs of donor services when the recipient's transplant occurred and when it was cancelled due to death or other causes;
- costs of donor services whether the transplant was inpatient or outpatient;
- inclusion of teaching costs;
- determination of Medicare's share of donor costs; and
- transfer of Medicare's care of cost to settlement for both PPS and non-PPS hospitals.

For clarity and similar to our comment regarding Line 77, we ask that the last sentence of the opening paragraph be changed to read "Do not include costs for recipient allogeneic HSCT services ,except for HLA typing." Then we ask that the regulation citation 42 CFR 413.112(e) be added to the next paragraph with the manual citations.

WS A-C, Line 78 for CAR-T

With this proposal, CMS has clarified that the instructions for WS A line 78. Line 78 is being added to provide a specific cost center in which to record actual acquisition costs for procuring CAR-T cells from the manufacturer, including costs of provider services necessary to collect and process the cells used in the manufacture of these biologics. NMDP appreciates the revision and clarification.

Conclusion

Thank you for providing us with the opportunity to provide comments on these proposed revisions. We look forward to being a resource for CMS on any cellular therapy issues, particularly around Medicare beneficiary access to care. Please feel free to contact me with any questions at blindber@nmdp.org or (763) 406-8566.

Sincerely,

Brian L. Lindberg
Chief Policy Officer