



American Society for
Transplantation and Cellular Therapy

July 19, 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:

The American Society for Transplantation and Cellular Therapy (ASTCT) is pleased to offer comments on the Paperwork Reduction Act Revision of the Hospital and Health Care Complex Cost Report. The proposed revisions contain important instructions that will impact cellular therapy program centers that report costs for Chimeric Antigen Receptor T-cell (CAR-T) therapy, and also for hematopoietic stem cell transplants (HSCT).

ASTCT is a professional membership association of more than 3,000 physicians, scientists and other health care professionals promoting blood and marrow transplantation and cellular therapy through research, education, scholarly publication and clinical standards. The clinical teams in our society continue to develop and implement clinical care standards which advance the science of cellular therapy, which means we are very interested the second revision of proposed cost report instructions that implement Section 108 of the Further Consolidations Act of 2019 (Section 108).

ASTCT is very appreciative of the changes and additional clarification CMS has provided in its proposed instructions for cost Centers 77 and 78 and Worksheet D-6. We believe the instructions are much improved from the first draft and that the revisions will enable providers to submit more accurate information to CMS.

In this letter, we describe several additional areas for which ASTCT has recommendations and questions. First, ASTCT has a few questions related to cost center 78. Second, we provide some suggestions about reporting donor search and cell acquisition costs through Line 77 and WS D-6, which we believe will help improve clarity for transplant centers. Third, we have a recommendation about WS S-2 Line 123.

Finally, we note that the instructions for calculating donor acquisition and CAR-T costs are dependent upon understanding the differentiation in clinical services for autologous transplant, allogeneic transplant, donors, and recipients. As such, we expect CMS will need to educate the



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Medicare Administrative Contractors (MACs) about the different clinical services associated with these types of transplants and patients. ASTCT would welcome the opportunity to collaborate with CMS in developing and furnishing such education once the forms and instructions are finalized.

WS A, Line 78 Instructions

As we stated in our January 2021 comments on the first draft cost reporting instructions, ASTCT has long championed the need to capture the unique costs of CAR-T therapy through hospital cost reports. Thus, we are very appreciative of the Agency's proposal to establish new line 78, and the Agency's updated instructions clarifying that this cost center should include acquisition costs for procuring CAR-T from the manufacturer. Given the ongoing scientific and clinical advancements in this field, we have two additional requests for CMS to address in its final instructions that we believe will facilitate accurate provider reporting in the future.

First, ASTCT requests that CMS update the name of cost center 78 to reflect the rapidly evolving cellular immunotherapy space and include therapies that extend beyond CAR-T. In the time since cost center 78 was created, we have seen and expect to continue seeing rapid scientific developments occur in this space. As a result, ASTCT believes that broadening cost center 78's name will signal that its appropriate to use the cost center to report acquisition costs for products other than the current FDA-approved autologous cell therapy products. This means that both future FDA-approved allogeneic CAR-Ts and other cellular immunotherapy product acquisition costs should be reported in line 78. While this seems clear to us, it may not be to all providers, which is why we recommend that CMS clarify this issue for providers.

An example of a cellular immunotherapy product that is not a CAR-T is lifileucel, a tumor-infiltrating lymphocyte (TIL) product. At the beginning of FY22, CMS assigned lifileucel immunotherapy to MS-DRG 018, which is where CAR-T cases are also assigned. Unless CMS changes the name of cost center 78 and/or specifies that providers should use it to also report the TIL therapy's acquisition cost, providers may not do so consistently. ASTCT believes the best approach is for CMS to change the name of cost center 78 so that it is clear that product acquisition costs for *all* current and future cellular immunotherapy products reported in revenue code 0891 should be reported there; this is described further below.

Our second request is that CMS update cost center 78 instructions so that providers are directed to only report product acquisition costs for cellular immunotherapy products billed under revenue code 0891 in this cost center. This would parallel the precedent of using items billed under specific revenue codes as defined in the current cost reporting instructions for line 72, which is used solely for high-cost implantable devices with revenue codes established by the NUBC. By limiting cost center 78 to products charged under revenue code 0891, CMS would include current and future FDA-approved cellular immunotherapy products reported under this revenue code. It would also appropriately exclude non-product acquisition costs from the cost center (such as clinical costs associated with cell collection and cell lab processing services); if those costs are included in cost center 78, it could distort cost finding and complicate hospital



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reporting. ASTCT strongly believes that the costs associated with providing clinical services to patients or donors (e.g., pheresis versus surgical collection from a tumor) should remain in their natural cost centers. Therefore, ASTCT asks that CMS not to include these clinical services in cost center 78 or in WS D-6; the Agency should limit cost center 78 to acquisition costs only.

ASTCT understands that these therapies are evolving at a very rapid pace and strongly believes that these changes are an important step in ensuring that the cost of cellular immunotherapy products is appropriately segregated in the cost report. Doing so will ensure that the Agency has accurate information to inform future rate-setting and other payment policies. As a result, we would welcome the opportunity to meet with CMS to discuss the clinical and scientific developments we see in this space to ensure that the information captured in cost center 78 is appropriate.

WS A-C, Line 77 & WS D-6

We suggest that, with respect to AS A-C, Line 77 and WS D-6, CMS should:

- Provide the definition and accompanying citations for donor search and cell acquisition costs
 - Code of Federal Regulations citation (i.e., 42 CFR 412.113 (e));
 - CMS Pub. 100-04, chapter 3, §90.3.1, and CMS Pub. 100-04, chapter 4, §231.11, where Section 108 is codified, along with sub-regulatory citations in the manual.
- Explicitly mention the appropriateness of including direct costs, such as salaries and benefits of transplant coordinators who work with donors.
- Modify the instructions for Line 77 to add the following text provided in italics: “Do not include costs for *recipient* HSCT services, *other than HLA typing*.”
- Specify that the patient care gross charges for WS C, Line 77 are solely for the donor-purchased services costs—and not the charges for donor services furnished by other departments. The latter charges are included in the gross patient revenue of each of those department lines and will be used to calculate donor costs of furnished services in Worksheet D-6.

WS S-2 Line 123

ASTCT is concerned with the significant burden required for transplant hospitals to answer whether 50 percent or more of their purchased professional services for legal, tax, accounting and other similar services is furnished outside the hospital’s labor market. We ask CMS to not finalize this proposed modification.



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Conclusion

Thank you for the opportunity to provide these comments on the Revisions to Paperwork Reduction Act Revision of the Hospital and Health Care Complex Cost Report. ASTCT welcomes the opportunity to discuss these recommendations in more detail or to answer any questions you may have. Please contact Alycia Maloney, ASTCT's Director of Government Relations at amaloney@astct.org for any follow up issues.

Sincerely,

A handwritten signature in black ink, appearing to read "B. Sandmaier", with a long horizontal flourish extending to the right.

Brenda M. Sandmaier, M.D.
President, American Society for Transplantation and Cellular Therapy
Professor, Fred Hutchinson Cancer Center
Professor of Medicine, University of Washington