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adcc.org

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July 19, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2552-10
Room C4–26–05
7500 Security Boulevard
Baltimore, Maryland 21244–1850

Re: Agency Information Collection Activities: Proposed Collection; Comment Request

Dear Administrator Brooks-LaSure:

On behalf of the Alliance of Dedicated Cancer Centers (ADCC), I am writing to comment on CMS's proposed information collection through the Hospital and Health Care Complex Cost Report. The ADCC is comprised of the nation's premier cancer hospitals that are singularly focused on cancer. Our members also play an outsized role in delivering novel care, such as Chimeric Antigen Receptor (CAR) T-cell therapy, to patients, including Medicare patients.

The ADCC supports the agency's efforts to improve the health care system, keep costs down, and reduce provider burden through revisions to the Hospital and Hospital Health Care Complex Cost Report and related Provider Reimbursement Manual (PRM) guidance.

ADCC members are cancer hospitals paid under the Tax Equity and Fiscal Responsibility Act (TEFRA), which provides reimbursement based on historic costs to treat a cancer patient, subject to appeals that can last years to incorporate the costs of therapeutic advances.

We welcome the opportunity to provide comments regarding the agency's revisions intended to calculate and capture costs associated with CAR T-cell therapy, as well as hematopoietic stem cell transplant (HSCT) donor search and cell acquisition. We wish to acknowledge and apprciate CMS' attention to comments in our January 11, 2020 letter as the revisions proposed here address many of our questions and concerns.

As detailed further below, we request that CMS:

- Ensure that proposed changes to the cost report form and instructions are correctly interpreted by MACs and do not disrupt established adjustment methodology for CAR T-cell therapy reimbursement;

- Provide additional clarity regarding HSCT donor costs and the reclassification of CAR-T acquisition costs;

- Revising settlement worksheets for the revised direct graduate medical education resident caps pursuant to the outcome of the Milton S. Hershey Medical Center vs Becerra that U.S. District Court case; and

- Not finalize data collection on the percentage of purchased professional services outside the market area of the hospital.

Thank you for your consideration of our comments. Should you have any questions, please do not hesitate to contact me.

Sincerely,

Jack Kolosky
Executive Director
ADCC
Jack.Kolosky@ADCC.org

I. The agency should ensure that proposed changes to the cost report form and instructions are interpreted correctly by providing clarifying language to MACs (WS E-3, Part 1, Line 17 together with WS S-2, Lines 88 and 89)

The PRM's Chapter 40 revised instructions for WS E-3, part 1, line 17 did not change from what was previously proposed; it reads:

> *"Enter any other adjustments. (See CMS Pub. 15-1, chapter 21, §2146.4.) Specify the adjustment in the space provided. Do not report adjustments resulting from permanent or other adjustments to the TEFRA target amount per discharge on this line."*[1]

In last year's comments, we recommended that the agency add additional clarification by stating "Do not report adjustments resulting from permanent adjustments to the TEFRA target amount per discharge on this line," to avoid any confusion related to the term "other adjustments." We appreciate that the agency, while they did not change the language in this instruction, did add reference to PRM, Part 1, Chapter 30, §3004.2 in the WS S-2, Line 88 updated instructions to confirm that this line is appropriate for adjustments that are not permanent.

In addition to this clarification, we urge CMS to provide direct instruction and education to MACs to ensure that they understand how to differentiate permanent adjustments appropriate for WS S-2 lines 88 and 89 from other adjustments appropriate for WS E-3, Part 1, line 17 (such as those for CAR-T) which help maintain the seamless delivery of advanced therapies to Medicare patients. We ask that CMS take all necessary steps to ensure that PPS-exempt cancer hospitals and MACs correctly implement each of these distinct adjustments.

II. Instructions related to CAR-T acquisition (WS A, Line 78)

The ADCC appreciates CMS revisions to PRM's Chapter 40 revised instructions for WS A, line 78. It is now clear that this line is for direct and purchased cost of procuring, storing, processing and processing chimeric antigen receptor T-cells and acquiring the biologic from the manufacturer. CMS does not use the terms autologous or allogeneic, so our understanding is that this cost center would be used for costs of both types of cell therapy once allogeneic therapies are FDA approved.

ADCC requests that CMS add the words "cell collection" to "procuring, storing, and processing chimeric antigen receptor T-cells…" because cells are collected by centers more often than procured by an outside entity or other hospital. We also ask CMS to include in its instructions that this will require reclassification of the direct and purchased service costs in other cost centers to this line 78. In addition, CMS should specify that the gross patient charges for these services and the CAR-T biologic should be added to worksheet C for this line.

[1] PRM (Part II), CMS Pub. 15-2, §4033.1; Draft (Nov. 12, 2020) (emphasis added).

III. Instructions related to HSCT donor costs (WS D-6)

CMS proposes to use the new WS D-6 to calculate donor search and cell acquisition costs associated with donor services rendered to support Medicare recipient transplants, including transplants that are cancelled. ADCC was pleased to see the revisions to this WS to enable cost finding for donor costs for inpatient and outpatient transplants for all patients and that the Medicare share will appropriately transfer to Worksheet D-1, Part II, line 48.01 for TEFRA inpatient and to WS E, part B, line 2 outpatient with the modifications CMS has made.

We ask that CMS explicitly state in section 4029.8 Part III that PPS-exempt cancer hospital-outpatient costs require transfer to WS E, part B, line 2. CMS has appropriately and explicitly stated that this is required and included relevant instructions in the revision to WS E, part B, line 2, but not in the WS D-6 instructions. Including these instructions in WS D-6 line 10 would ensure that there is no confusion for cost report preparers and MACs. We therefore recommend adding this into the instructions for WS D-6 line 10, so that it is listed out just as the "TEFRA hospital – inpatient transfer to WS D-1, Part II, line 48.01" is listed. It should state "TEFRA hospital – outpatient – transfer to WS E, part B, line 2"

IV. Instructions related to HSCT donor costs (WS A-C, line 77)

The ADCC appreciates the clarity CMS has added to the line 77 instructions. Because of the complexities around donor acquisition costs for allogeneic stem cell transplants, ADCC asks that the instructions explicitly mention direct costs and time studies, which help hospitals capture costs devoted to donors as defined at 42 CFR 412.113(e).

ADCC also asks that instructions for Worksheet C reference the appropriate patient care gross charges for line 77. That is, line 77 should have patient charges for purchased donor services. Line 77 should not include charges for donor services furnished by departments, since these charges are included in each respective department's gross patient revenue lines, and are used to calculate donor costs of furnished services in Worksheet D-6. There are, however, gross charges for purchased donor services that are appropriate for line 77—it will be important that CMS' instructions reference these charges.

V. Need to modify instructions related to WS E-4, Line 9

ADCC asks that CMS review changes to the cost report form and instructions and associated software to ensure proper calculation of GME reimbursement for hospitals that are training residents at or above their cap limit as reported on WS E-4 Line 9 based on the outcome of the Milton S. Hershey Medical Center vs Becerra (No. 19-2680) case concerning counting residents when a hospital exceeds its cap. ADCC suggests the instructions for the calculations on line 9 should read as follows: "If Line 6 is less than Line 5 enter the amount from Line 8, otherwise multiply Line 8 times the result of Line 5 divided by the amount on Line 8, Column 3." We believe this change better reflects the revised calculations for PPS-exempt hospitals.

VI. Instructions related to WS S-2 Line 123

ADCC is concerned with the significant burden associated with asking all hospitals to address the question of whether 50 percent or more of purchased professional services for legal, tax, accounting and other similar services is furnished outside the labor marked of the hospital. We ask that CMS not finalize this proposed modification.