Advancing Transfusion and Cellular Therapies Worldwide

June 9, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1677–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: Proposed Rule; Medicare Hospital Inpatient Prospective Payment System and Long-Term Care Hospital Prospective Payment System FY 2018 (CMS–1677–P)

Dear Administrator Verma:

AABB is pleased to submit these comments to the Centers for Medicare & Medicaid Services (CMS) in response to the proposed rule related to the hospital inpatient prospective payment system and the long-term care hospital prospective payment system for FY 2018, which was published in the *Federal Register* on April 28, 2017.

AABB is an international, not-for-profit association representing institutions and individuals involved in transfusion medicine, cellular therapies and patient blood management. The association is committed to "making transfusion medicine and cellular therapies safe, available and effective worldwide." AABB works toward this vision by developing and delivering standards, accreditation and educational programs that focus on optimizing patient and donor care and safety. AABB membership includes physicians, nurses, scientists, researchers, administrators, medical technologists and other health care providers.

AABB's comments are focused on three discrete areas of CMS' proposed rule including:

(1) Payment policies for hematopoietic stem cell transplants (HCTs);
(2) Requiring accrediting organizations to make available on their public websites all final accreditation survey reports and plans of correction for deficiencies; and
(3) Requiring long-term care hospitals to report transfusions as a standardized patient assessment data element.

Payment Policies for Hematopoietic Stem Cell Transplants

Medicare beneficiaries with over 70 diseases, including leukemia and sickle cell disease, rely on HCTs as life-saving treatments. Unfortunately, Medicare beneficiaries' access to these vital treatments is threatened due to flawed payment policies. Current Medicare payment rates do

8101 Glenbrook Road
Bethesda, MD 20814-2749
301.907.6977 MAIN
301.907.6895 FAX
www.aabb.org

not adequately account for the cost of cell acquisition. In addition, AABB is concerned that CMS' proposal to recategorize ICD-10-PCS transfusion codes used in HCT from operating room (OR) to non-OR status will further jeopardize Medicare beneficiaries' access to HCTs by changing the current MS-DRG mapping. Thus, AABB urges CMS to: (1) pay for allogeneic HCT cell acquisition outside of the MS-DRG payment; and (2) reassign the identified ICD-10-PCS transplant transfusion codes back into the appropriate MS-DRGs following standard pre-MDC grouping logic.

AABB requests that Medicare pay for allogeneic HCT cell acquisition outside of the MS-DRG payment.

AABB encourages CMS to support Medicare beneficiaries' access to allogeneic HCTs by paying for cell acquisition outside of the MS-DRG payment. This proposed payment policy would be aligned with CMS' approach of paying for acquisition costs associated with obtaining solid organs (i.e., kidneys) from living donors.

Currently, Medicare provides a single MS-DRG payment for inpatient allogeneic HCTs, which is intended to include donor search and cell acquisition charges as well as the costs associated with the recipient's inpatient stay. The current base payment rate for MS-DRG-014 (allogeneic bone marrow transplant) is approximately $69,844. Cell acquisition costs vary and depend on clinical factors as well as the source of cells. For example, in 2016, the average cost of acquiring adult donor cells from marrow and peripheral blood stem cells (PBSC) was $48,436, while the average cost of cord blood was $65,117. Thus, due to the costs of acquiring the cells, there are insufficient funds from the MS-DRG payment to cover a patient's inpatient hospitalization, which averages 27.45 days. Therefore, transplant centers incur significant financial losses when treating Medicare patients using HCTs.

AABB is concerned that the financial losses incurred due to this flawed payment policy will reduce beneficiaries' access to medically necessary, life-saving care. We believe that CMS should ensure that HCTs remain accessible to Medicare beneficiaries by paying for cell acquisition outside of the MS-DRG payment.

AABB urges CMS to reassign the ICD-10-PCS codes used in HCT back into the appropriate MS-DRGs following standard pre-MDC grouping logic.

Although AABB agrees that it may be clinically appropriate to shift the ICD-10-PCS transfusion codes used in HCT from OR to non-OR status, the proposed change would result in the codes being inappropriately reassigned to different MS-DRGs with significantly lower payment rates. This is extremely problematic since even in the absence of this proposed coding change, the payment rates for allogeneic HCTs are inadequate. Thus, AABB is concerned that the coding change could further reduce Medicare beneficiaries' access to life-saving HCTs.

AABB believes that the ICD-10-PCS codes used in HCT should continue to flow into MS-DRG 014, 016 or 017, as determined by the type of transplant and associated complications or comorbidities. We encourage CMS to reassign the identified ICD-10-PCS transplant

transfusion codes back into the appropriate MS-DRGs following standard pre-MDC grouping logic.

AABB encourages CMS to rescind its proposal that national accrediting organizations disclose accreditation survey reports and plans of correction for deficiencies on their public websites.

AABB supports patient-centric transparency and activities that provide patients and their caregivers with useful information related to the quality of care. That said, AABB strongly opposes CMS' proposal that would require accrediting organizations (AOs) to publish final accreditation survey reports and plans of correction (PoC) for cited deficiencies on the AO's public website. We do not believe that CMS' proposal will achieve the agency's intended purpose of providing patients with useful information. Conversely, we are concerned that the proposed requirement could have damaging, unintended consequences. In addition, the proposed requirement would be an extremely burdensome, unfunded mandate for AOs.

Since 1995, AABB has served as a deemed accrediting organization for CMS for transfusion medicine, blood donor activity, immunohematology reference laboratories, molecular testing laboratories and cellular therapy services. AABB is proud of its stellar record as a deemed AO; since 1995, CMS has cited AABB with only one disparity. Although AABB does not believe that CMS' proposed rule directly applies to AOs with deeming authority under the Clinical Laboratory Improvement Amendment (CLIA), we are concerned that the policy could ultimately apply to all AOs.

AABB believes that CMS' proposal is flawed because accreditation survey reports and PoCs submitted for cited deficiencies are highly technical in nature and are not intended to convey useful information to patients and their caregivers. For instance, AABB's accreditation survey reports are intended to provide specific, technical information to individuals with expertise in transfusion medicine, blood donor activities, immunohematology reference laboratories, molecular testing laboratories or cellular therapy services. The survey reports cannot be reviewed in a vacuum by individuals who do not understand the applicable scientific requirements and who are not familiar with AABB's accreditation requirements and processes. AABB is concerned that typical patients, who do not have technical expertise and who are unfamiliar with AABB's accreditation requirements, will not be able to adequately evaluate the importance or relevance of cited deficiencies.

For example, one AABB accreditation survey report and related PoC may identify several areas of non-conformance, which are all minor and do not impact patient safety. However, an accreditation survey report and related PoC for a different organization may identify one area of non-conformance, which is significant and reduces patient safety. A patient may inadvertently select the lower quality facility based on this information due to not having sufficient technical knowledge to inform their interpretation of the accreditation survey report and the related PoC.

In addition, it is impossible for patients to compare accreditation survey reports for organizations that have been accredited by different AOs, since each AO has different

accreditation processes, requirements, standards and evaluation procedures. In addition, each AO has a different format for its accreditation survey reports and PoC submissions. Thus, AABB does not believe that making this detailed information publicly available will help patients identify high quality care. Rather, requiring AOs to publicly disclose the accreditation survey results and PoC submissions may cause the accredited organizations to cherry-pick the AO with the least rigorous standards and the least transparent survey reports, or to stop seeking voluntary accreditation altogether. The proposed disclosure requirements also may inadvertently disincentivize AOs from strengthening their standards or requiring organizations to satisfy requirements above the bare minimum. AABB believes that these possible outcomes would reduce the quality of care and have a negative impact on patients' health and safety.

Relatedly, the proposed disclosure requirements may result in reduced quality by having a chilling effect on the conversations that the accredited organizations have with their surveyors throughout the accreditation process, and the extent to which they cite non-conformances. These conversations and citations are integral to quality assurance and quality improvement activities, but will be stifled if the accredited organization is concerned about information being disclosed to the public.

Finally, the proposed requirements seem to run counter to the administration's focus on regulatory reform and reducing regulatory burdens. AOs would incur significant infrastructure and personnel costs if they are required to continuously update their websites with accreditation survey reports and related PoCs for each accredited organization. AABB does not believe there are sufficient benefits to justify this unfunded mandate. Rather, AABB's website currently provides a publicly accessible list of accredited facilities. Since an organization cannot be accredited without satisfying the applicable standards and assessment criteria, we believe that an organization's presence on such a list provides patients and the public with sufficient information to assess whether a provider satisfies important, technical safety requirements.

AABB believes that if CMS wants to require AOs to make additional information publicly available, CMS should first convene stakeholders, including AOs and patient representatives, to explore what information would be useful to patients and how the information can be conveyed to patients in a clear, uniform manner. CMS may also consider piloting a proposed disclosure process to ensure that the information and the manner in which it is conveyed is useful to patients and does not reduce the quality of care.

AABB commends CMS for proposing to require long-term care hospitals to report transfusions as a standardized patient assessment data element.

AABB supports CMS' proposal to include transfusions as a standardized patient assessment data element that will be reported by LTCHs as well as other post-acute care (PAC) providers. Safe, medically necessary transfusions are increasingly being conducted outside of the hospital setting of care. As CMS correctly recognizes,

> Blood transfusions are based on specific protocols, with multiple safety checks and monitoring required during and after the infusion in case of adverse events. Coordination with the provider's blood bank is necessary, as well as documentation by clinical staff to ensure compliance with regulatory requirements. In addition, the need for transfusions

signifies underlying patient complexity that is likely to require care coordination and patient monitoring, and impacts planning for transitions of care, as transfusions are not performed by all PAC providers.

AABB believes that requiring LTCHs and other PAC providers to report transfusions as a standardized patient assessment data element will contribute to higher quality, coordinated care for patients who rely on these life-saving treatments.

* * * * *

If you have any questions or need addition information, please contact Leah Stone, Director, Public Policy and Advocacy at 301-215-6554 or lmstone@aabb.org.

Sincerely,

Zbigniew "Ziggy" M. Szczepiorkowski, MD, PhD, FCAP
President
AABB