



Advancing Transfusion and  
Cellular Therapies Worldwide



June 17, 2019

Ms. Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1710-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**Re: Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2020 and Updates to the Inpatient Rehabilitation Facility Quality Reporting Program (CMS-1710-P)**

Dear Administrator Verma:

AABB (formerly known as the American Association of Blood Banks), America's Blood Centers and the American Red Cross appreciate the opportunity to submit comments in response to the proposed rule entitled, "Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2020 and Updates to the Inpatient Rehabilitation Facility Quality Reporting Program" (Proposed Rule), which was published in the *Federal Register* on April 24, 2019. Collectively, our organizations represent the nation's blood collection establishments, transfusion services, and transfusion medicine professionals.

We applaud CMS for proposing to include a transfusion data element as part of the standardized patient assessment data elements (SPADE). We agree with CMS' acknowledgement in "Proposed Specifications for IRF QRP Quality Measures and SPADE" that:

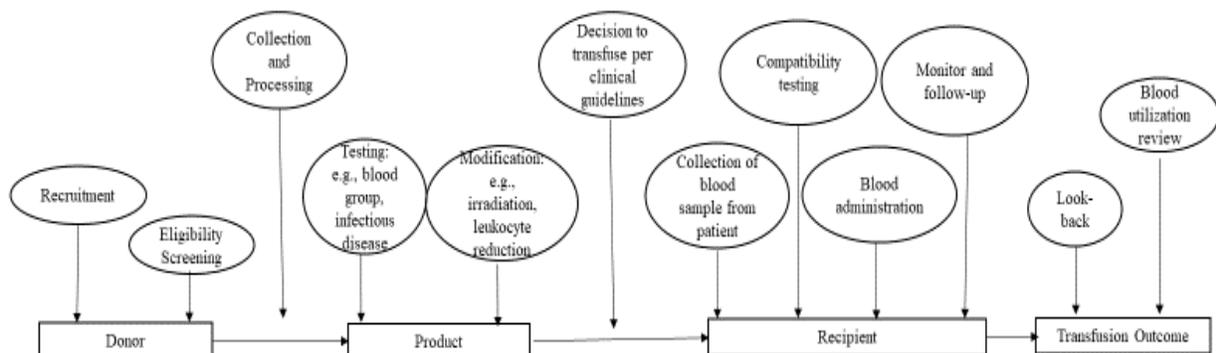
Transfusions are the administration of blood or blood products (e.g., platelets, synthetic blood products) into the bloodstream. Blood transfusions are highly protocolized, with multiple safety checks and monitoring required during and after the infusion to avoid adverse events. Coordination with the facility'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 additional nursing staff and care coordination, and impacts planning for transitions of care, as transfusions are not performed in all PAC settings. Receipt of transfusions is also important to assess for case mix adjustment due to the need for added resources and to the extent that receipt of transfusions indicates a more medically complex patient.

### *Relevance to IRFs*

Data regarding blood transfusions are not currently collected in the IRF-PAI. Key populations of IRF patients may benefit from blood transfusions during their rehabilitation stay. For example, patients with fractures of the lower extremity and major joint replacements of the lower extremity are IRF qualifying conditions and represent approximately 12 percent and approximately 8 percent of IRF cases annually, respectively. As in other settings, blood transfusions are resource-intensive, requiring laboratory testing, coordination with the blood bank, intensive bedside nursing care and monitoring, and can be associated with adverse reactions. Because need for and receipt of a blood transfusion can be a marker of clinical complexity and resource use, assessment of receipt of transfusions is warranted in the IRF setting. The standardized assessment of patients' receipt of transfusions would provide important information for care planning, clinical decision making, patient safety, care transitions, and resource use in IRFs.

As acknowledged by CMS in the “Proposed Specifications for IRF QRP Quality Measures and SPADE” and illustrated in Figure 1, blood transfusion is a complex, resource-intensive therapy. Specialized physicians, medical technologists, nurses and other support staff provide essential expertise throughout the transfusion process. The collection, processing, testing, storage, distribution and administration of blood components involves critical medical equipment and supplies. In addition, the transfusion process includes multiple safety measures and monitoring to avoid adverse events. AABB accredits blood collection establishments, transfusion services and out-of-hospital transfusion administration services to promote patient safety and quality, and to ensure compliance with AABB’s standards as well as federal regulations and guidances.

**Figure 1: Transfusion Process**



Our organizations applaud CMS for recognizing that blood transfusions should be available to patients in the most appropriate setting of care, including in IRFs and other post-acute care settings. We support CMS' proposal to adopt the transfusions data element as standardized patient assessment data for use in the IRF QRP. We believe that a standardized patient assessment data element will contribute to higher quality, coordinated care for patients who rely on these life-saving treatments.

AABB, America's Blood Centers and the American Red Cross respectfully request that CMS consider whether payments to IRFs are adequate to cover the cost of this resource-intensive, specialized service. Absent sufficient reimbursement, we are concerned that IRFs will not have the resources needed to provide patients with access to blood transfusions in that setting of care.

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If you have any questions or need additional information, please contact Leah Stone (301-215-6554 or [lmstone@aabb.org](mailto:lmstone@aabb.org)), Kate Fry (202-654-2911, [kfry@americasblood.org](mailto:kfry@americasblood.org)) or Liz Marcus (202-303-7980, [liz.marcus@redcross.org](mailto:liz.marcus@redcross.org)).

Sincerely,

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Chief Executive Officer  
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