January 4, 2019

Cynthia Hake, Director, CMS’ National Level II HCPCS Coding Program
Centers for Medicare and Medicaid Services
Mailstop: C5-09-14
7500 Security Blvd
Baltimore, Maryland 21244-1850

Re:  ESTABLISHMENT OF “MISCELLANEOUS/NOT OTHERWISE CLASSIFIED” HCPCS LEVEL II P-CODE FOR USE BY HOSPITALS TO BILL 3rd PARTY PAYERS FOR ANTICIPATED NEW BLOOD PRODUCTS

Dear Ms. Hake,

AABB (formerly known as the American Association of Blood Banks), America’s Blood Centers and the American Red Cross are submitting this letter to request that the Centers for Medicare & Medicaid Services (CMS) establish a HCPCS Level II “miscellaneous/not otherwise classified” code for blood products. Collectively, our organizations represent the nation’s transfusion services, transfusion medicine professionals and blood collection establishments.

As recognized by CMS, “the importance of miscellaneous codes is that they allow suppliers to begin billing immediately for a service or item as soon as it is allowed to be marketed by the Food and Drug Administration (FDA), even though there is no distinct code that describes the service or item.” 1 The group of HCPCS codes for blood products (i.e., P-codes) does not currently have a “not otherwise classified” code. This is different from other code sets; examples of existing “not otherwise classified” codes include J3490 (unclassified drugs), J3590 (unclassified biologics) and J7599 (immunosuppressive drug, NOC). Thus, unlike drugs, biologics and immunosuppressive drugs, there is no current mechanism to immediately begin billing for a new blood product or new technology that is not captured by any of the existing P-codes.

AABB, America’s Blood Centers and the American Red Cross strongly believe that the creation of a miscellaneous/not otherwise classified code for blood products is instrumental to facilitating the timely adoption of new products that may have the potential to result in improved clinical outcomes. As illustrated by the products highlighted on Table 1, a variety of new blood products are currently being evaluated in clinical trials, or are progressing toward clinical development, with the intention of seeking marketing approval from the U.S. Food and Drug

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Administration (FDA). Table 1 is not intended to be comprehensive, and there may be additional investigational blood products in development that are not included on this list.

Table 1: Examples of Investigational Blood Products Currently In Development

<table>
<thead>
<tr>
<th>Investigational Blood Product</th>
<th>Current Development Status</th>
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<tbody>
<tr>
<td>Freeze dried plasma (RePlas™)</td>
<td>Submission requesting FDA marketing approval anticipated in early 2019; clinical testing completed²</td>
</tr>
<tr>
<td>Psoralen-treated, pathogen reduced cryoprecipitate</td>
<td>Submission requesting FDA marketing approval anticipated in 2019³</td>
</tr>
<tr>
<td>Riboflavin-treated, pathogen reduced platelets</td>
<td>Currently in Phase 3 clinical testing⁴</td>
</tr>
<tr>
<td>Amustaline/glutathione-treated, pathogen reduced red blood cells</td>
<td>Currently in Phase 3 clinical testing⁵</td>
</tr>
<tr>
<td>Freeze dried, heat-treated platelets (Thrombosomes®)</td>
<td>Currently in Phase 1 clinical testing⁶</td>
</tr>
<tr>
<td>Spray dried plasma</td>
<td>Pre-clinical development⁷</td>
</tr>
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</table>

Since no “miscellaneous/not otherwise classified” HCPCS code currently exists for use by hospitals to bill third party payers during the interim period between FDA approval and establishment of a specific HCPCS Level II code, hospitals would find themselves unable to immediately bill third party payers for any of these currently investigational blood products in the event that one or more of them – or other future new blood products not adequately described by any existing P-code – receives FDA approval. Our organizations and others have previously recommended that CMS establish a miscellaneous/not otherwise classified HCPCS code for blood products to avoid this predicament and to accommodate new technologies and products.⁸

In order to enable providers to initiate immediate billing for new human blood products that may be approved by the FDA and become available in the near future, we formally request that the CMS HCPCS Workgroup revise the HCPCS Level II code set to establish a new “miscellaneous/not otherwise specified” HCPCS “P” code, under the Pathology and Laboratory Services section of the HCPCS code set, that is specific for human blood products.

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If you have any questions, please contact Leah Stone, Director, Public Policy and Advocacy, AABB (301-215-6554, lestone@aabb.org), Kate Fry, Chief Executive Officer, America’s Blood Centers (202-654-2911, kfry@americasblood.org) or Liz Marcus, Director, Hospital Sales and Marketing, American Red Cross (202-303-7980, liz.marcus@redcross.org).

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