Advancing Transfusion and
Cellular Therapies Worldwide

Association Bulletin #20-03

Date: April 8, 2020

To: AABB Members

From: Beth Shaz, MD – President
Debra BenAvram – Chief Executive Officer

Re: Emergent Standards to the 31st and 32nd editions of *Standards for Blood Banks and Transfusion Services*

Association Bulletins provide a mechanism for publication of documents that have been approved by the Board of Directors for distribution to individual and institutional members, such as:

- Standards that were adopted after publication of the most recent edition of *Standards*.
- Statements of AABB policy intended for distribution to members.
- Guidance, recommendations, and reports that have been developed by AABB Committees or National Office staff for distribution to members.

This bulletin describes updated requirements to Reference Standard 5.4.1A, Donor Qualification, in the 31st and 32nd editions of *Standards for Blood Banks and Transfusion Services* (*BB/TS Standards*.)

These changes fall into two categories:

1) Changing donor deferral requirements affected by the Food and Drug Administration (FDA) Statement released April 2, 2020, Coronavirus (COVID-19) Update: FDA Provides Updated Guidance to Address the Urgent Need for Blood During the Pandemic.

2) Discontinuing the use of the drug medication deferral list that appears in the 31st edition of *Standards*

1) <u>Summary of Changes to Donor Deferral Time Periods</u>

The updates in the reference standard communicated in this Association Bulletin adjust the deferral periods for several categories of prospective donors.

From indefinite to permanent:

- Donors who have a family history of genetic Creutzfeldt-Jakob disease
- Donors previously deferred for human growth hormone

From indefinite to as defined based on the FDA Guidance:

- Donors who have been deferred for a risk of vCJD are now deferred "in accordance with FDA Guidance", e.g., donors who spent time in certain European countries or on military

bases in Europe who previously were considered to be a potential risk for the transmission of vCJD.

From indefinite to 3 months:

- Donors who have had a needle used to administer nonprescription drugs
- Donors who have exchanged sex for money or drugs.

From 12 months to 3 months:

- Donors who have received blood, components or human tissue
- Donors who have had mucous membrane exposure to blood
- Donors who have recently received tattoos, ear or body piercings, or had permanent makeup applied. Exception: no deferral if the tattoo was applied by a state regulated entity with sterile needles and non-reused ink.
- Donors who have had nonsterile skin penetration with instruments or equipment contaminated blood or body fluids that are not their own e.g., needlestick or through contact with a wound or mucous membranes.
- Donors who have had sexual contact with an individual with HIV infection or an individual deemed to be at high risk of HIV infection, e.g., contact with male donors who have had sex with other males; female donors who have had sex with a male who had sex with a male; individuals who have paid for sex.
- Donors who have had a diagnosis of syphilis or gonorrhea and have completed treatment
- Donors who have traveled to an area where malaria is endemic, after departure from the malaria endemic areas
    - No deferral period for the collection of platelets or plasma that have been processed with an approved pathogen reduction device.

These changes to donor deferral periods are based on the following FDA Guidances:

- FDA Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products, (May 2010), (Updated January 2016), (Updated April 2020)
- FDA Guidance for Industry: Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products, (December 2015), (Updated April 2020)
- FDA Guidance for Industry: Recommendations for Donor Questioning, Deferral, Reentry and Product Management to Reduce the Risk for Transfusion-Transmitted Malaria (August 2013) (Updated August 2014) (Updated April 2020)

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2) Medication Deferral List

In addition to the updates noted above, the BB/TS Standards Committee wishes to implement a change to the 31st edition that appears in the forthcoming 32nd edition of *BB/TS Standards*. Effective immediately, AABB-accredited facilities are directed to use the current medication deferral list maintained and developed by AABB's Donor History Questionnaire Task Force. Accordingly, the list of medications in the 31st edition of *BB/TS Standards* should be implemented within six months of the date of this association bulletin.

The changes to Reference Standards 5.4.1A that appear below are emergent standards and may be implemented immediately. AABB-accredited facilities that wish to maintain stricter deferral periods may do so. The changes described in this Association Bulletin are reflected in the 31st and 32nd editions of *BB/TS Standards* and in the Standards Portal. The 32nd edition of *BB/TS Standards* will become effective July 1, 2020.

Please note, standards that have been edited are indicated by strike through and bold formatting.

Finally, please be advised that the footnotes to the reference standard have been updated to include the guidances noted above as well as 21 CFR 630.10(e)(1)(iv), which replaces a June 1995 FDA memorandum on blood donations by individuals incarcerated in correctional institutions.

Reference Standard 5.4.1A in the 31st and 32nd edition of Standards for Blood Banks and Transfusion Services

Reference Standard 5.4.1A – Requirements for Allogeneic Donor Qualification		
Category	Criteria/Description/Examples	Deferral Period
9) Drug Therapy	**The facility shall use the current version of the Medication Deferral List within 6 months of the list's effective date.**	**Defer according to the current version of the Medication Deferral List**
	• **Other medications**	**As defined by the facility's medical director**
10) Medical History and General Health	Family **genetic** history of Creutzfeldt-Jakob disease (CJD)[1]	**Permanent in accordance with FDA Guidance** ~~Indefinite deferral for risk of CJD~~
12) Receipt of Blood, Blood Component, or Human Tissue	• Receipt of **human cadaveric (**allogeneic**)** dura mater ~~or~~ **transplant** • **Donors previously deferred for**	Permanent **Permanent in accordance**

	~~pituitary~~ **human** growth hormone ~~of human origin~~	**with FDA Guidance**
	• Receipt of blood, components, or human tissue	**3 months** ~~12 months~~
15) Relevant Transfusion-Transmitted Infections [3]	• Use of a needle to administer nonprescription drugs	**3 months** ~~Indefinite~~
	• Mucous membrane exposure to blood	**3 months** ~~12 months~~
15) Relevant Transfusion-Transmitted Infections (continued) [3]	• Nonsterile skin penetration with instruments or equipment contaminated with blood or body fluids other than the donor's own. Includes tattoos or permanent make-up unless applied by a state regulated entity with sterile needles and ink that has not been reused.	**3 months** ~~12 months~~
	• Sexual contact with an individual with HIV infection or at high risk of HIV infection[9]	**3 months** ~~12 Months or as recommended by FDA~~
	• Syphilis or gonorrhea[~~11~~] a. Following the diagnosis of syphilis or gonorrhea. Must have completed treatment b. Donor who has reactive screening test for syphilis[**11**]	**3 months[9]** ~~12 months (in accordance with FDA Guidance)~~ Indefinite- Donor re-entry in accordance with FDA Guidance
	• Malaria[13] These deferral periods apply in non-endemic countries, irrespective of the receipt of antimalarial prophylaxis: d. Individuals who either: i. Traveled to an area where malaria is endemic; or	**d. Defer for 3 months from most recent date of departure from malaria-**

	ii. Lived longer than 5 consecutive years in countries considered malaria-endemic by the Malarial Branch, Centers for Disease Control and Prevention, US Department of Health and Human Services, who have traveled to an area where malaria is endemic after having lived at least 3 consecutive years in nonendemic country(ies)[14]	**endemic area(s) (deferral not required for platelets or plasma processed with an FDA or Competent Authority approved pathogen reduction device)** ~~d. Defer for 12 months after departure from malaria-endemic area(s) traveled to~~
16) Travel	• Donors recommended for deferral for risk of vCJD, as defined in most recent FDA Guidance[1]	**In accordance with FDA Guidance** ~~Indefinite~~