



ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2019 #33

September 27, 2019

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ABC, AABB, and ARC Comment on CMS Hospital Outpatient Prospective Payment System Proposed Rule

America’s Blood Centers (ABC), AABB, and the American Red Cross (ARC) have submitted joint comments to the Centers for Medicare and Medicaid Services (CMS) suggesting changes to the proposed rule for Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs for calendar year (CY) 2020 (CMS-1717-P).

The [letter](#) addresses the agency’s proposals related to laboratory date of service (DOS) policy and reimbursement for pathogen reduced platelets. It asks the agency to finalize the proposal to exclude from the laboratory DOS policy exception blood banks and blood centers and to clarify that all molecular testing performed by blood banks and blood centers is also excluded from the policy exception.

On June 28th, CMS extended the enforcement discretion period for six months until January 2, 2020 for the laboratory date of service exception policy (14-Day rule for Advanced Laboratory Tests). This was required following a 2019 CMS exception to the DOS policy that would have required a laboratory, including a blood center, to bill Medicare directly for advanced diagnostic laboratory tests (ADLTs) and molecular pathology tests under some circumstances. While some large labs wanted this change, blood centers needing to bill CMS was an unintended consequence of the billing change. The blood industry worked with CMS to delay enforcement until a workable solution could be established. The proposed OPPTS rule sets out three potential changes, which are not mutually exclusive, to address this issue:

- a test would be billable by the hospital if the ordering provider determines the results would impact a current or future hospital outpatient encounter. This section doesn’t specifically mention blood banks/ donor centers, but based on the later section it seems it likely would since the later use of blood (products) would most likely be in a hospital outpatient setting;
- remove molecular pathology tests from the DOS change. Blood banks/donor centers are specifically mentioned in this option; and
- exclude blood banks/donor centers from the DOS change.

Additionally, ABC, AABB, and ARC asked CMS to adjust the proposed reimbursement rate for pathogen reduced platelets (P9073) by continuing to crosswalk P9073 to P9037 (leukoreduced irradiated apheresis platelets) for 2020 and 2021 to help ensure that pathogen reduced platelets are reimbursed appropriately.

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ABC, AABB, ARC Submit OPPTS Joint Comments to CMS

Half of the 2019 data had already been collected before last year's proposed rule was released meaning the same erroneous data that CMS recognized as problematic last year is continued in this year's data.

The payment for Pathogen Reduced Platelets has historically been paid based on a crosswalk from another code [HCPCS code P9072 (Platelets, pheresis, pathogen reduced or rapid bacterial tested, each unit), the predecessor code to HCPCS code P9073 (Platelets, pheresis, pathogen-reduced, each unit) which was changed in CY16 because P9072 could be either PRT or rapid bacterial tested - two very different products in terms of cost). As is customary, the new code was paid based on a crosswalk from P9037 (Platelets, pheresis, leukocytes reduced, irradiated, each unit)]. Last year's proposed rule for CY2019 proposed payment was based on the claims data for the new code instead of the crosswalk, but the joint comments have expressed concern that the data was not reflective of the actual costs and the HCPCS code data still inappropriately included non-pathogen reduced products. CMS relented for CY2019 but for CY2020 is again proposing doing away with the crosswalk, which would result in a payment rate lower than the crosswalk rate.

Please contact ABC's Senior Director of Federal Government Affairs [Diane Calmus, JD](#) with any questions or concerns as we will report back with any new developments.

(Source: ABC, AABB, ARC Joint Comment [Letter](#) 9/26/19) 💧

ABC Supports Repeal of Medical Device Tax

ABC joined a coalition of more than 600 stakeholders that included patient advocacy groups, hospitals, and other organizations in the healthcare sector signing on to a coalition letter that supports a full repeal of the medical device tax before the end of 2019. The [letter](#) sent to Sen. Mitch McConnell (R-Ky.), Senate Minority Leader Sen. Charles Schumer (D-N.Y.), House Speaker Rep. Nancy Pelosi (D-Calif.), and House Minority Leader Rep. Kevin McCarthy (R-Calif.) described how the medical device tax negatively impacts the industry, “[u]nfortunately, when the medical device tax was in effect, it had an adverse impact on research and development investment and job creation, jeopardizing the U.S. position as a global leader in medical device innovation. U.S. Department of Commerce Census Data shows that the industry lost 29,000 jobs during the three years that the tax was in effect, and recent reports suggest that a reinstatement of the tax could result in an additional loss of 21,000 jobs. If this tax is not fully repealed, it will continue to force companies to make difficult decisions on whether to invest in manufacturing operations, research and development and other important investments, in communities across the U.S.”

(Sources: Medical Device Tax Repeal Coalition [Letter](#), 9/24/19) 💧

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ABC advocates for and advances policies that promote the role of independent blood centers in providing life-saving blood products and recognize the continuous need for a safe and robust blood supply. ABC exists to advocate for laws and regulations recognizing the essential role that independent blood centers play in the healthcare system; promote partnerships, policies and programs that increase awareness about the need for blood donation; and serve as a thought-leader in the advancement of evidence-based medical and scientific solutions related to health and safety.

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Houchin Community Blood Bank Joins ACTS

The Alliance for Community Transfusion Services (ACTS) announced that Houchin Community Blood Bank (Bakersfield, Calif.) has become the 12th community blood center to become a member of the organization. “We’re thrilled with the addition of Houchin Community Blood Bank to the ACTS Alliance,” said ACTS Chief Executive Officer Nelson Hellwig in a news [release](#). “With a history of great community support, and now under Brad Bryan’s, PhD, MBA leadership, the organization has become strong, successful, and fully committed to their hospital partners. We look forward to working with Houchin as we continue to help our blood centers become stronger and more successful in the communities they serve.” ACTS formed in 2010 to strengthen relationships between community blood centers and local hospitals. “I am very excited that Houchin Community Blood Bank is now a member of the ACTS Alliance,” said Houchin Chief Executive Officer Dr. Bryan in the release. “As a member of ACTS, we now have the product volume and purchasing advantages of a large blood center, while still keeping the strong community focus that our local donors have always appreciated.”

(Source: ACTS News [Release](#), 9/23/19)

REGULATORY NEWS

The Office of the Assistant Secretary for Health (OASH) in the U.S. Department of Health and Human Services (HHS) has [extended](#) the comment period to Oct. 10th at 5 p.m. eastern for the “[Request for Information: Regarding Revisions to the U.S. Public Health Service \(PHS\) Guideline for Reducing Human Immunodeficiency Virus \(HIV\), Hepatitis B Virus \(HBV\), and Hepatitis C Virus \(HCV\) Through Organ Transplantation.](#)” The agency is requesting review and public comments for proposed changes to the current Guideline that aimed to improve patient safety by reducing disease transmission through organ donation. In April, the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) made several recommendations to HHS regarding the Guideline. Based on the committee’s feedback, the agency is considering:

1. “Test all organ donors for HIV, HBV, and HCV using serological tests (including total antibody to hepatitis B core antigen [total anti-HBc], hepatitis B surface antigen [HBsAg], and hepatitis C antibody [anti-HCV]) and nucleic acid tests (NAT).
 - a) For living potential donors, testing should continue to be performed as close as possible to the surgery, but at least within the 7-day time period prior to organ recovery.
 - b) For deceased donors, the donor specimen should be collected within 72 hours prior to organ recovery with results of these screening tests available at the time of organ recovery. If the donor sample used for testing was collected more than 24 hours prior to organ recovery, an additional donor specimen should be collected in the immediate 24 hours prior to organ recovery and tested for HIV, HBV, and HCV by NAT. Results of these screening tests should be made available as soon as possible, even if these results might not be available at the time of organ recovery.
2. Regardless of donor risk profile for HIV, HBV, or HCV, transplant programs should test all organ recipients:
 - a) Before transplantation for HIV, HBV, and HCV using NAT and serologic tests including total anti-HBc, HBsAg, anti-HCV, and hepatitis B surface antibody (anti-HBs);
 - b) At 4-6 weeks following transplantation for HIV, HBV, and HCV (with NAT); and
 - c) At 12 months following transplantation for HBV (with NAT).
3. Organ Procurement Organizations (OPOs) should ascertain whether any of the following medical

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REGULATORY NEWS (continued from page 3)

or social risk criteria were present in potential organ donors within 30 days prior to organ recovery:

- a) Sex with a person known/suspected to be HIV, HBV, or HCV infected
 - b) Being a man who has had sex with another man
 - c) Sex in exchange for money/drugs
 - d) Non-medical drug injection
 - e) Sex with a person with history of non-medical drug injection
 - f) Incarceration for >72 consecutive hours
 - g) Child breastfed by a mother with HIV
 - h) Child born to a mother with HIV, HBV, or HCV
4. OPOs should identify donors for whom medical and social history is unknown at the time of organ recovery, which is also considered a risk criterion. When donors with ≥ 1 of the criteria as specified under #3 are identified, OPO's should communicate this information to the appropriate transplant centers. Transplant centers should discuss this information with transplant candidates and families as part of transplantation-related informed consent discussions. Transplant centers should make efforts to contextualize these discussions and should include the following:
- a) The risk of undetected HIV, HBV, or HCV infection is very low
 - b) Recipients are universally tested for HIV, HBV, and HCV after transplantation and should transmission occur, effective therapies are available
 - c) Recipients may have a higher chance of survival by accepting organs from donors with risk factors for HIV, HBV, and HCV compared with waiting for an organ from a donor without recognized risk factors
5. Remove any specific label (e.g., "increased risk donor") to describe donors with risk factors for undetected HIV, HBV, or HCV infection, with inclusion of additional strategies to enhance recipient safety.
6. No requirement for specific informed consent with recipients who are considering acceptance of these organs, though recipients would still be informed of certain donor risk factors.
7. All organ transplant candidates should be vaccinated for HBV per previous recommendations (<https://doi.org/10.1111/ctr.13563>).
8. HHS proposes no additional substantive changes to the following sections of the 2013 PHS Guideline:
- a) Collection and/or storage of donor and recipient specimens
 - b) Tracking and reporting of HIV, HBV, and HCV infection in donors or recipients."

(Sources: *Federal Register*, Comment Period Extension [Announcement](#), 9/20/19 *Federal Register*, RFI [Announcement](#) 8/27/19) ◆

We Welcome Your Letters

The *ABC Newsletter* welcomes letters from its readers on any blood-related topic that might be of interest to ABC members. Letters should be kept relatively short and to the point, preferably about a topic that has recently been covered in the *ABC Newsletter*. Letters are subject to editing for brevity and good taste and published after editorial review. Please send letters to the Editor at newsletter@americasblood.org or fax them to (202) 899-2621. Please include your correct title and organization as well as your phone number. The deadline for letters is Wednesday to make it into the next newsletter.



TACO Mitigation-Survey of AABB Standard Compliance

Contributed by Richard Gammon, MD, Medical Director at OneBlood

Please note: America's Blood Centers welcomes regular contributions or briefs from guest authors for scientific/medical peer-reviewed published papers. The views/comments expressed in submitted articles from external parties are those of the author(s) and are not to be interpreted as the viewpoint of America's Blood Centers. If you are interested in contributing an article for potential publication please contact us [here](#).

AABB Standard 5.19.7 (31st edition) for Blood Banks and Transfusion Services requires a policy for handling requests for blood components to patients identified as high-risk for transfusion-associated circulatory overload (TACO). This has been reported to occur in approximately 1 to 6 percent of transfused patients and has been identified as a leading cause of transfusion-related mortality reported to the U.S. Food and Drug Administration (FDA) 2016-17. A study published in *Transfusion* attempted to determine how many AABB accredited institutions adopted specific policies to comply with the TACO risk mitigation standard through a survey, due to the broad mandate of this Standard, and the clinical nature of the practice it was attempting to assist. A link to a Web-based survey was e-mailed to each AABB accredited hospital transfusion service/blood bank (n = 851) seeking details concerning how their institution was complying with this Standard and for general information on any TACO risk mitigation strategies in place. Of the 290 responses received (a 34 percent response rate), 282 met the criteria for analysis with a total of 174 of the 282 respondents (62 percent) who indicated that their institution had a formal policy for complying with the Standard. Institutions with a formal policy were significantly more likely than institutions without a formal policy to update patient charts for those who have experienced a prior TACO reaction, and to provide written advice to clinicians on mitigating the risk of TACO for patients who were clinically identified as being at high-risk (e.g., diuretics, slow infusion). The authors concluded by discovering that many, but not all AABB accredited institutions have policies to comply with the TACO risk mitigation Standard. Also, it was noted that the vast majority, including those that do not have a formal policy, conduct activities that could mitigate risk for TACO.

Citations: Yazer, M.H., Dunbar, N.M., Thomas J, *et al.* Transfusion-associated circulatory overload risk mitigation: survey on hospital policies for compliance with AABB Standard 5.9.17. *Transfusion*. 2019. Doi: [10.1111/trf15478](https://doi.org/10.1111/trf15478).

Differences in the Age of Blood Transfused Prehospital Vs. Emergency Department

Early transfusion strategies and their impact on the mortality of patients presenting in the emergency department (ED) is shifting to transfusion in the prehospital environment (e.g., helicopter, ambulance). The Pragmatic, Randomized, Optimal Platelet, and Plasma Ratios [PROPPR] study concluded that massively transfused patients who received at least 10 units of red blood cells (RBCs) had improved survival if they received those stored for less than 22 days as older RBCs increased the probability of death by five percent. A 24-month retrospective review of medical transport service transfusion records and a two-month, overlapping review of transfusions of uncrossmatched RBCs in the ED took place. This involved 5,203 medical flights of which transfusions were performed on 246 (4.7 percent). A total of 217 RBCs were issued to the ED, all were transfused. The mean storage age at the time of transfusion by helicopter was 20.3 days (range 3-40 days) compared with 14.3 days (range 5-38 days) for units transfused in the ED ($P < .0001$). Of the 379 units transfused on helicopters, 157 (41.4 percent) had been stored for 22 or more days at the time of transfusion compared to only 33 (15.2 percent) of units transfused in the ED ($P < .001$). From a blood bank inventory management perspective, it was believed that this difference was likely due to the perceived logistical difficulty involved with issuing and returning units. It was countered that it takes only 300 seconds for a blood bank to issue a unit of RBCs to a medical transport service and 120 seconds to receive a unit back into blood bank inventory. The authors felt that these short processing times should not prevent frequent replacement of helicopter inventory. They conclude that PROPPR was not intended to study the age

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Differences in the Age of Blood Transfused Prehospital (continued from page 5)

of blood, and the subanalysis that transfusion with older blood was associated with increased mortality should be treated with skepticism. The paper also recommends that transport programs and blood banks should jointly review their RBC inventory management programs and consider reasonable measures to ensure that blood transfused in the field does not have significantly different storage characteristics from blood transfused in the ED.

Citations: Gehrie, E.A., Szklarski, P.C., Nooner, K., *et al.* Storage Age of RBCs Transfused by a Prehospital Patient Transport Program vs the Hospital Emergency Department. *Am J Clin Pathol.* 2019. Doi: [10.1093/ajcp/aqz071](https://doi.org/10.1093/ajcp/aqz071). ♦

MEMBER NEWS

Héma-Québec recently took part in a series of testing simulations to assess the feasibility of drones being used to deliver medical supply such as blood products. The drones would potentially be called upon as an alternative form of transport to deliver supplies in disaster zones or remote areas. “This could be used in case of disaster, especially where the regular transportation routes for vehicles are unusable, because of a disaster,” [said](#) McGill University Health Centre (MUHC) Emergency Room Physician Valerie Homier, MD to CTV News. “If there’s too much traffic or there’s some reason why we can’t use the regular roads.” Renfrow, Ontario is currently the only location in Canada that emergency medical drones are in use.

(Source: CTV News, [Supplies in the skies: MUHC tests drone delivery of emergency medical equipment](#), 9/24/19)

LifeSouth Community Blood Centers (Gainesville, Fla.) and **MEDIC Regional Blood Center** (Knoxville, Tenn.) have concluded their annual blood donation competition. It coincides with the week of the University of Tennessee versus the University of Florida annual college football game, as MEDIC Regional Blood Center won this year’s contest with more than 1,700 units of blood and blood products collected.

(Source: WVLT CBS-8 Knoxville, [Vols beats Gators in race for blood donations to MEDIC](#), 9/19/19) ♦

BRIEFLY NOTED

The National Institutes of Health (NIH) announced the creation of the Blood and Immune Deficiency-Cellular Therapy Program (BID-CTP). It will deliver comprehensive treatments to individuals with rare blood and immune system diseases. “The BID-CTP has the potential to accelerate progress in the treatment of people with genetic diseases of the blood and immune system, which can be debilitating and even life-threatening,” said National Institute of Allergy and Infectious Diseases (NIAID) Director Anthony Fauci, MD in an agency news [release](#). “The close clinical and scientific collaboration within this program aims to foster advances that improve the lives of patients with these diseases.” The program will feature collaboration from immunologists, transplant specialists, geneticists, and hematologists applying a centralized approach to assessing, treating, and monitoring patients, as well as their outcomes.

(NIH, News [Release](#), 9/26/19)

The Centers for Disease Control and Prevention (CDC) has developed a multimedia [resource](#) page that contains podcasts and videos for sickle cell disease. The podcast highlights the need for African American blood donors to help sickle cell disease patients in need of a blood transfusion. It was produced as part of Sickle Cell Disease Awareness Month and is available for [listening](#) on the CDC website.

(CDC Multimedia [Resources](#), 9/25/19) ♦

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BRIEFLY NOTED (continued from page 6)

The Centers for Disease Control and Prevention (CDC) has awarded \$1.2 million in funding to help with the collection of data and development of systems at the state level that explore the issues encountered by individuals living with sickle cell disease. This round of funding will increase the total number of participating states from two to nine:

- Duke University (North Carolina);
- Georgia State University, University Foundation Inc. (Georgia);
- Indiana Hemophilia and Thrombosis Center (Indiana);
- Michigan Department of Health and Human Services (Michigan);
- Minnesota Department of Health (Minnesota);
- Public Health Institute (California);
- University of Alabama at Birmingham (Alabama);
- University of Tennessee Health Science Center (Tennessee); and
- Virginia Department of Health (Virginia).

“HHS is committed to normalizing the lives of people living with sickle cell within 10 years,” said the U.S. Department of Health and Human Services (HHS) Assistant Secretary for Health, Admiral Brett Giroir, MD, in an agency news [release](#). “Expanding the Sickle Cell Data Collection program is a critical first step toward reaching this goal.” CDC Director Robert Redfield, MD added, “[d]ata is vital to informing new treatments and clinical care that will improve the lives of people affected by sickle cell disease. This new funding expands CDC’s partner network across the country which will accelerate efforts to ensure sickle cell patients live longer and healthier lives.”

(Source: CDC News [Release](#), 9/25/19)

The CDC’s Center for Global Health has been recognized by the Pan American Health Organization (PAHO)/World Health Organization (WHO) as a collaborating Center for Biosafety and Biosecurity.

This four-year [designation](#) leverages the expertise of the agency to assist with international efforts in containing diseases such as Ebola. “Global laboratories provide data to drive public health action, inform programs, increase our knowledge base, and support solutions to global health problems,” said Kevin Karem, PhD, CDC Center for Global Health’s Associate Director for Laboratory Science in an agency news release. “In a world that is increasingly interconnected, our ability to prevent, identify, contain, and respond to biological threats—whether intentional or naturally occurring—is imperative to protect health and save lives.” According to the release, CDC will:

- provide global leadership to aid in the development of international recommendations and guidance for laboratory biosafety and biological risk management;
- support PAHO/WHO to use state-of-the-art training and technological innovations in laboratory science to fill knowledge gaps and address fundamental issues affecting safe laboratory operations; and
- continue to work to improve biosafety and biosecurity around the globe.

(CDC News [Release](#), 9/23/19) ◆

ABC Calendar of Events

ABC offers a variety of meetings, workshops and virtual opportunities for education and networking as well as participation in ABC business. The [calendar of events](#) includes annual and summer meetings, board meetings, workshops, and webinars, and details will be updated as confirmed. We look forward to your support and participation!



The programs and services described in the Inside ABC section are available to ABC member blood centers and their staff only, unless otherwise specified.

ABC Seeks Member Participation in 2019 Service Fee Survey

America’s Blood Centers has launched the annual survey of member service fees. Members are encouraged to participate by completing the online survey available in [MCN 19-065](#). The results from this survey are important in assisting ABC in its advocacy efforts on behalf of member blood centers for better reimbursement for blood products. Only aggregate data will be reported and no individual data or identifiable information from any center will be shared. A copy of the survey questions is also available in the MCN.

(Source: MCN [19-065](#), 9/19/19)

Member Response Requested for ABC Gender Identification Blood Collection Survey

The 2019 ABC Gender Identification Blood Collection Survey seeks to obtain more information on how a blood donor’s gender or sexual identification impacts blood collection at ABC member blood collection facilities. Members can find a link to the survey on ABC’s [Listserv](#). The data from this survey will be shared with the ABC membership and also used during a discussion of these issues at a workshop at the AABB meeting in San Antonio, Texas.

Questions have been raised recently regarding the donor history questions to be asked when donors decline to select the male or female gender options, the impact of nonbinary identification on TRALI mitigation efforts, and how to screen transgender potential donors for sexual risk factors for infection with HIV. This is in the context of appropriate blood donor screening and the most current guidance wherein, “FDA recommends that male or female gender be taken to be self-identified and self-reported.” Definitions for the purpose of this survey are found within the survey itself. Please complete the survey no later than October 2nd. If you have questions about the survey, please contact [Suchitra Pandey, MD](#) or [Louis Katz, MD](#).

(Source: ABC [Listserv](#), 9/19/19) 💧

ABC 2020 Meetings & Workshops				
Meeting/Workshop	Dates	Location	Hotel	Registration Dates & Fees
2020 ABC Annual Meeting	March 9 th -11 th	Washington, D.C.	Ritz-Carlton (Pentagon City)	More details coming soon!
ADRP 2020 Conference	May 19 th -21 st	Phoenix, Ariz.	Hyatt Regency	More details coming soon!
<p>Notes: For the most up-to-date information on all events, members of ABC may check the calendar on ABC’s Member Site. Non-members may attend all events; information will be updated on ABC’s Public Site.</p>				



GLOBAL NEWS

Progress continues on a state-of-the-art underground blood bank that will house Magen David Adom (MDA's), Israel's national supplier of blood and blood products. The \$130 million complex will consist of six floors and is designed to protect the nation's blood operations from missiles, chemical and biological attacks, and earthquakes. According to an article published by *The Times of Israel*, "[t]he top three floors will hold rooms for blood donations, a training center and the facility's administrative center. The lower three floors, underground, will be protected by special shielding to specifications from the Home Front Command and the National Security Agency; it is here that the blood will be stored and processed." The new facility is scheduled to be complete in 2020 and will be able to process 2,200 units of blood daily with capabilities of increasing up to 3,500 units in emergency situations. It will also more than double increase MDA's staff size from 184 to 374 reported the article. "[The new facility] will take us 20 years forward, with the technology we need," said Professor Eilat Shinar, who leads MDA, to *The Times of Israel*. MDA has currently raised \$100 million in support of the project with a majority of the funds having come from the group American Friends of Magen David Adom (AFMDA). "No blood center in the world will be as shielded as ours," added Moshe Noyovich, a senior Israeli representative of AFMDA.



Photo courtesy of *The Times of Israel*

(Source: *The Times of Israel*, [Israel to get state-of-art, missile-proof blood bank to meet growing demand](#), 9/25/19)

The Kenya National Blood Transfusion Service will lose all funding from the U.S. following cuts from the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). The lack of funds means that the U.S. will officially handover fiscal responsibility to the Kenyan government and other donors for sustaining operations of the country's blood supply. "It has always been clear the handover was coming," said a U.S. government official to *The STAR*, a daily Kenyan news publication. "In Africa, the transfer of responsibility to the country government in many countries has already happened. In Zambia it was after five years, in Kenya it was after 15 years." Overall funding had been steadily decreasing for the program, which has been provided 700 billion shillings in funding from PEPFAR over the past 15 years. The cuts have resulted in numerous layoffs for Kenyans that work at U.S. funded NGOs reported *The STAR*. "Government services have not been spared and the Kenya National Blood Transfusion Service will lose all funding, which is estimated at 2 billion shillings."

(Source: *The STAR*, [U.S. funding: hundreds lose jobs as PEPFAR budget cuts begin](#), 9/19/19) ♦

CALENDAR

Note to subscribers: Submissions for a free listing in this calendar (published in the last issue of each month) are welcome. Send information to Leslie Maundy by e-mail (lmaundy@americasblood.org) or by fax to (202) 393-1282. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)

2019

Oct. 15-16. **Biomedical Advanced Research and Development Authority Industry Day 2019, Washington, D.C.** More details available [here](#).

Nov. 12-14. **U.S. Food and Drug Administration Center for Drug Evaluation and Research Small Business and Industry Assistance Clinical Investigator Training Course, College Park, Md.** More details available [here](#).

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CALENDAR (continued from page 9)

2020

Jan. 14-15. **IPFA/EBA Workshop on Plasma Collection, Location to be announced.** More details available [here](#).

Mar. 9-11. **2020 ABC Annual Meeting, Washington, D.C.** More details coming soon.

Mar. 25-26. **IPFA 5th Asia Workshop on Plasma Quality and Supply, Thailand.** More details available [here](#).

April 14-15. **16th Annual U.S. Food and Drug Administration and the Changing Paradigm for HCT/P Regulation Conference, Washington D.C.** More details available [here](#).

May 13-14. **IPFA/PEI 27th International Workshop on “Surveillance and Screening of Blood-Borne Pathogens, Porto, Portugal.** More details available [here](#).

May 19-21. **2020 ADRP Conference, Phoenix, Ariz.** More details coming soon. 💧

CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC institutional members. There are charges for non-members: \$139 per placement for *ABC Newsletter* subscribers and \$279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, contact Leslie Maundy at the ABC office. Phone: (202) 654-2917; fax: (202) 899-2621; e-mail: hmaundy@americasblood.org.

POSITIONS

Senior Regulatory Affairs Officer (Macopharma USA). Responsibilities include: Develops appropriate regulatory strategy for bringing Macopharma Transfusion and Biotherapy products (Medical Devices and Drugs to the US). Identifies the status of the product according to the country (Medical Device, medicine). Sets the elements necessary for the compilation of files according to the regulations and regulatory guidelines. Collects data to assess compliance with the expectations of the authorities. Edits and submits the registration file to the competent authorities or notified bodies. Develop good relationships with the authorities. Keeps abreast of regulatory changes and analyse whether these changes have an impact on our business. Exchange with the service Materio/Pharmaco/ Biovigilance as part of risk management plans, the submission of periodic reports vigilance and change requests for medical information. Skills and requirements: Education and experience with FDA submissions/registrations for medical devices and drugs. Four years degree required in scientific field. Ability to multi-task effectively under tight deadlines. Expertise with Microsoft Package. Excellent organization and follow-up skills. High level accuracy and attention to detail. High level of discretion and confidentiality. Ability to communicate in a clear and articulate manner. By interest please forward your application to stephanie.ehrenberg@macopharma.de.

Assistant/Associate Director, Blood Transfusion Service (Massachusetts General Hospital, Harvard Medical School). The Blood Transfusion Service at the

Massachusetts General Hospital seeks a full-time, early- or mid-career, academically oriented transfusion medicine physician. The successful candidate will combine clinical and teaching activities with a research program in a field relevant to transfusion medicine, hematology or hemostasis. Our service encompasses an FDA-licensed donor center, therapeutic apheresis, an outpatient transfusion/infusion clinic, a transfusion service, and progenitor cell collection and processing. Service and teaching responsibilities will be shared with three other full and part-time staff physicians. Candidates must be BC/BE in Transfusion Medicine, with primary training in either Pathology or Hematology/Oncology (adult or pediatrics). Academic rank and salary will be based on experience and accomplishments. Please send a curriculum vitae and a description of interest to: Robert Makar, MD, PhD, GRJ233, Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02114-2696; or email to rmakar@mg.harvard.edu. The Massachusetts General Hospital is an equal opportunity/affirmative action employer.

Director of Collections (Full Time). We are looking for inspirational leader, customer-focused individuals who value integrity, accountability, collaboration and communication, to join our team as the Director of Collections. We are the sole blood bank for the State of Hawaii. We need people who are dependable, detail-oriented and comfortable following established procedures. For more

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**POSITIONS** (continued from page 10)

information about us, visit our website at <https://www.bbh.org/>. This position reports directly to the Chief Operating Officer and the ideal Director of Collections candidate is a highly motivated individual with exceptional customer service skills who is able to work independently while managing multiple priorities and provides effective leadership, supervision and direction to ensure excellent services and an adequate, safe, pure and potent blood supply for the operations of Collections. Must possess excellent written and verbal communication skills, be organized and creative, and have the ability to effectively evaluate and solve critical problems. Minimum of eight years' progressively responsible experience in a blood center, healthcare or other relevant environment with a minimum of five years' proven experience in positive management of multiple direct reports and budget experience. For complete job description and to apply, send resumes to hr@bbh.org.

Reference Laboratory Supervisor (Full Time). Blood Bank of Hawaii (BBH) is seeking a successful leader to oversee and coordinate all reference lab work and product quality control testing services. We are a nonprofit, community-based organization that provides blood components and clinical/technical services to hospitals, and patients throughout Hawaii. The ideal candidate will encompass a high standard for accuracy, follow-up and follow-through, and thrive in an environment where problem solving is a necessity. Will work with team members ensuring compliance at all times, and will also be responsible for the supervisory functions offering support and guidance to personnel. The incumbent will also serve as a technical resource to hospitals and other departments outside their primary responsibility. Minimum qualifications include baccalaureate degree in Medical Technology or in a related science from an accredited college or university; certified Medical Technologist by the ASCP. Previous work experience as an MT in hematology and immunohematology preferred. To apply, please submit a resume and cover letter to HR@bbh.org. BBH is an equal opportunity employer. We do not discriminate on the basis of age, race, sex, religion, color, national origin, ancestry, marital status, disability, sexual orientation, arrest and court record or any other protected category recognized by state and federal laws.

Assistant Manager of Component Laboratory. Innovative Blood Resources is seeking an Assistant Manager of Component Laboratory. Responsibilities: Supervise personnel and coordinate operations with the component evening lab. Ensure the lab's compliance and help with process improvement. Provide manufacturing support to staff when needed. Qualifications: Bachelor's degree: in Chemical, Physical, Biological Science, or Medical Technology. Two years component laboratory experience and one year supervisory. Experience with data management systems and Microsoft Suite. Apply today!

View full job descriptions on www.innovativebloodresources.org/careers/. Applicants must apply and submit a resume online to be considered.

Chief Operations Officer (Oklahoma City, OK). Oklahoma Blood Institute, America's largest, self-sufficient blood center seeks a seasoned, successful, and inspiring leader to direct its core blood production enterprise from donor recruitment through to product distribution. The position requires professional passion for system optimization, problem solving, project execution, personnel development, and mission delivery. Candidates should possess a diversity of progressively responsible experiences in blood center operations. They should also have a work history that evidences aptitudes for proactive innovation, team orientation, customer service, regulatory compliance, and financial discipline. Qualifications: Bachelor's degree from an accredited university, biologic sciences major preferred or graduate degree, management, administrative, or quantitative field preferred, 15 years of progressive responsibility in healthcare, having attained a senior executive position, 10 years or more blood center experience in a variety of operational areas, aptitude in budgeting, financial reporting, and economic decision making, self-starting mindset yielding proactive delivery of accountabilities with minimum direction, and residence within commuting distance of downtown Oklahoma City. Salary Range: Competitive salary, commission plan, and excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, and holiday pay. Visit <http://obi.org/careers/> to apply.

Outside Sales Representative/Event Planner (Wichita Falls, TX). Account Consultants must develop new partnerships with targeted decision makers in community organizations, educational and religious institutions and businesses to gain support in meeting the needs for volunteer blood donors. Responsibilities include organizing and promoting blood donation events; assessing, developing and implementing strategic/tactical plans to achieve recruitment objective/goals. She/he is expected to develop a customer-focused culture that will result in successful community partnerships and donation awareness. Identify opportunities for growth within current group base and facilitate a plan to achieve growth percentage for total unit collection within territory. Book recurring blood drives for the following year. Develop and maintain relationships with key accounts. Give presentations in order to promote blood collection. Identify and provide feedback on issues regarding customer needs/requirements, customer issues/concerns and satisfaction, competitor activities/strategies, etc. Interact effectively and professionally with team members and all internal/external contacts. Qualifications: Associate/Bachelor's degree preferred, one to three years sales

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related experience, public speaking/presentation experience preferred, excellent communication skills, and valid driver's license with access to vehicle. Salary Range: Competitive salary, commission plan, and excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, and holiday pay. Visit <http://txbi.org/careers/> to apply.

Clinical Lab Manager (San Francisco, CA; Req: 191475). Since 1941, Vitalant (formerly known as Blood Centers of the Pacific) has proudly served as a leader in the blood banking industry. We are a globally-recognized leader in blood transfusion medicine. Requirements: Bachelor's degree required. Master's degree preferred. Must satisfy CLIA requirements for High Complexity Testing required. Immunohematology Reference Laboratory (IRL). Specialist in Blood Banking (SBB) certification required. CA CLS/MT required. Seven years clinical laboratory experience required. To include: three years supervisory experience. Previous supervisory experience and experience in molecular techniques, immunohematology/ IRL techniques, auto-mated testing preferred. Please click [here](#) to apply. EOE

Senior Director of Donor Services. MEDIC Regional Blood Center, Knoxville, Tennessee, is seeking to fill the position of Senior Director of Donor Services. The ideal candidate would be a highly motivated individual with exceptional customer service skills and able to work independently while managing multiple priorities. Must possess excellent written and verbal communication skills, be organized and creative, and have the ability to effectively evaluate and solve critical problems. This position reports directly to the Chief Executive Officer and is responsible for defining the strategy, goals and objectives, and operational structure of Donor Services; provides management, supervision, and coordination of all day-to-day operations of fixed-site and mobile donor collections; key responsibilities include donor registration, eligibility screening, and phlebotomy for whole blood and apheresis donations. Specific duties consist of defining staffing needs, establishing hours of operation, monitoring of operational productivity, allocation of resources, ensuring the adherence to organization and departmental policies and procedures, and coordinating with other areas of operations. Qualifications: BSN required; (RN license in state of Tennessee); ten years of progressively responsible management experience and demonstrated ability to effectively manage multiple initiatives. Experience in blood banking preferred. For complete job description and to apply, send resumes to hr@medicblood.org.

Assistant Director Technical Services. Stanford Blood Center, a subsidiary of Stanford Health Care, is focused on connecting our communities to provide hope for healing. We lead the fields of transfusion and transplantation

medicine by advancing science and technology. For more information, visit <http://bloodcenter.stanford.edu/>. We are seeking a Technical Services Assistant Director. Under the direction of the Sr. Operations Director and the Medical Director, the Technical Services Assistant Director will set the strategy, goals, objectives and structure of Technical Services. Core Duties: Manage, supervise and coordinate the day-to-day operations and TS organizational structure which consists of five leaders and approximately 42 team members, and three distinct functions; Component manufacturing and distribution, Processing laboratory, and Product QC laboratory. In partnership with SBC Leaders, coordinate activities and goals of departments within the Blood Center. Manage implementation of policies and procedures, and ensure that employees understand and adhere to established policies and procedures. Qualifications: Four-year college degree and four years laboratory experience required. Four years of progressively responsible management experience and demonstrated ability to effectively supervise varied activities or functions required. Medical Technology (ASCP) license required. Must hold or qualify for California Clinical Laboratory Scientist (MTA) license. For complete job description and to apply, visit <https://www.stanfordhealthcarecareers.com/> and reference job #53404.

Outside Sales Representative/Event Planner (Oklahoma City, Okla.). Account Consultants must develop new partnerships with targeted decision makers in community organizations, educational and religious institutions and businesses to gain support in meeting the needs for volunteer blood donors. Responsibilities include organizing and promoting blood donation events; assessing, developing and implementing strategic/tactical plans to achieve recruitment objective/goals. She/he is expected to develop a customer-focused culture that will result in successful community partnerships and donation awareness. Identify opportunities for growth within current group base, and facilitate a plan to achieve growth percentage for total unit collection within territory. Book recurring blood drives for the following year. Develop and maintain relationships with key accounts. Give presentations in order to promote blood collection. Identify and provide feedback on issues regarding customer needs/requirements, customer issues/concerns and satisfaction, competitor activities/strategies, etc. Interact effectively and professionally with team members and all internal/external contacts. Qualifications: Associate/bachelor's degree preferred, one to three years sales related experience, public speaking/presentation experience preferred, excellent communication skills, and valid driver's license with access to vehicle. Salary Range: Competitive salary, commission plan, and excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, and holiday pay. Visit <http://obi.org/careers/> to apply.

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Medical Director. If you have a passion to join a team that is providing cutting-edge medical expertise in the areas of blood banking, transfusion medicine, immunohematology reference laboratories, therapeutic apheresis, cellular therapy and research, consider joining OneBlood as a Medical Director. Qualified candidates should possess a minimum of three years' experience and a M.D. or D.O. degree with board certification in Clinical Pathology, Internal Medicine or Hematology and subspecialty board certified in Blood Banking/Transfusion Medicine by a Board Registry recognized by the American Board of Medical Specialties. Appropriate state licenses will be required as needed. Must meet the eligibility requirements to obtain appointments at hospitals served by OneBlood. This position includes the option of free medical coverage with a competitive benefits package, 403(b) retirement plan with company contribution PLUS a company match, company vehicle lease/allowance, paid holidays, and much more. This position will be based out of the Ft. Lauderdale, Florida area, with some of the most gorgeous beaches in the nation! If you want to join our life saving mission and team of dedicated employees, visit our *Careers* page at www.oneblood.org to learn more. OneBlood, Inc., a proven leader in blood banking, is an Equal Opportunity Employer/Vet/Disability. ♦