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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2024 #11 **March 29, 2024**

INSIDE:

BPAC Publishes Meeting Materials Ahead of May 9th Meeting

The U.S. Food and Drug Administration (FDA) Blood Products Advisory Committee (BPAC) has released meeting materials for the committee's May 9th meeting. Included are a briefing document and meeting discussion questions.

The proposed strategies under consideration by the BPAC are:

- "selective testing strategy for individuals with a history of malaria;
- selective testing strategy for prior residents of malaria-endemic countries;
- selective testing strategy for residents of nonendemic countries who travel to malaria endemic areas in the past three months; [and]
- testing strategy for donations in regions of the U.S. with local, mosquito-borne malaria transmission."

The committee is specifically being asked to comment on:

- "FDA's proposed strategies for selectively testing blood donations from donors at risk for malaria using an FDA-licensed nucleic acid test (NAT); [and]
- FDA's proposal that blood establishments should implement time limited NAT screening of all donations collected in area(s) of the U.S. when a single case of local mosquito-borne malaria is reported by public health authorities."

The FDA explained in the briefing document that, "we support these selective NAT testing strategies to identify individuals who are carrying *Plasmodium* parasite nucleic acid and to reduce the number of unnecessary deferrals of healthy individuals based on screening questions, alone. We considered and rejected more complicated selective testing strategies because of the operational complexity and higher likelihood of error. We also considered and rejected universal testing of all donations in lieu of such selective testing strategies, because the disadvantages outweighed the advantages and would be unlikely to materially increase safety compared to a selective strategy. Universal testing of all donations would permit discontinuation of the malaria risk questions entirely and would address all three failure modes of current Donor History Questionnaire (DHQ) screening and deferral (staff error, nondisclosure of risk factors by the donor, and insufficient deferral periods to identify persistent, asymptomatic infection). While a universal testing strategy would simplify donor screening and donation testing algorithms and streamline operations, it would be at the expense of a greater testing burden and a larger number of donor deferrals associated with false positive test results."

(continued on page 2)

BPAC Meeting Materials (continued from page 1)

The FDA is proposing a deferral period, "for at least one year after a reactive NAT result for *Plasmodia spp*. and until completion of medical evaluation and all prescribed treatment. The reactive donation would be unsuitable and must not be released for transfusion or further manufacturing (21 CFR 630.30). Blood establishments would be required to perform further testing using an FDA cleared diagnostic test to provide additional information concerning the donor's infection status (21 CFR 610.40 (e)). At this time, we do not have sufficient information to propose a testing algorithm for reentering a donor before the one-year deferral period if false-positive screening test results are suspected. Therefore, all donors with reactive NAT results would become eligible again only after the one-year deferral and medical evaluation. The donation may or may not be tested again based on selective testing strategy."

(Source: FDA BPAC Meeting Materials, 3/27/24)

CMS Hospice Proposed Rule Includes RFI Regarding Blood Transfusions

The Centers for Medicare & Medicaid Services (CMS) has announced the pending publication of the fiscal year (FY) 2025 hospice payment rate proposed rule on April 4th. An unpublished version of the proposed rule is available in the *Federal Register* after being filed on March 28th.

Of interest to the blood community, the proposed rule titled, "FY 2025 Hospice Wage Index and Payment Rate, Hospice Conditions of Participation, and Hospice Quality Reporting Program Requirements" solicits comments regarding potential implementation of a separate payment mechanism to account for high intensity palliative care services, including blood transfusions. This request for information (RFI) explains that CMS is considering a major potential shift away from a closed hospice bundled payment to allow for patient access to services like blood transfusions.

The RFI builds on last year's rule which asked about palliative services that were unavailable to patients enrolled in hospice or that retention of these services dissuaded or delayed enrollment in hospice. ABC joined the blood community in responding in accordance with our advocacy agenda ask regarding expanding access to palliative blood transfusions for patients at the end-of-life desiring hospice services.

Specifically, CMS is seeking comments on the following questions in the RFI:

- "[w]hat could eliminate the financial risk commenters previously noted when providing complex palliative treatments and higher intensity levels of hospice care?
- What specific financial risks or costs are of particular concern to hospices that would prevent the provision of higher-cost palliative treatments when appropriate for some beneficiaries? Are there individual cost barriers which may prevent a hospice from providing higher-cost palliative care services? For example, is there a cost barrier related to obtaining the appropriate equipment (for example, dialysis machine)? Or is there a cost barrier related to the treatment itself (for example, obtaining the necessary drugs or access to specialized staff)?
- Should there be any parameters around when palliative treatments should qualify for a different type of payment? For example, we are interested in understanding from hospices who do provide these types of palliative treatments whether the patient is generally in a higher level of care (CHC, GIP) when the decision is made to furnish a higher-cost palliative treatment? Should an additional payment only be applicable when the patient is in RHC?
- Under the hospice benefit, palliative care is defined as patient and family centered care that optimizes quality of life by anticipating, preventing, and treating suffering (§ 418.3). In addition to this definition of palliative care, should CMS consider defining palliative services, specifically regarding high-cost treatments? Note, CMS is not seeking a change to the definition of palliative care, but rather should CMS consider defining palliative services with regard to high-cost treatments?

(continued on page 3)

CMS Hospice Proposed Rule (continued from page 2)

- Should there be documentation that all other palliative measures have been exhausted prior to billing for a payment for a higher-cost treatment? If so, would that continue to be a barrier for hospices?
- Should there be separate payments for different types of higher-cost palliative treatments or one standard payment for any higher-cost treatment that would exceed the per diem rate?"

Comments on the proposed rule are due May 28th. ABC intends to submit comments and encourages member blood centers to contact ABC Senior Director of Government Affairs Diane Calmus, JD with any input.

(Source: CMS Proposed Rule, 3/28/24)

Puerto Rico Declares Public Health Emergency Amid Dengue Surge

Officials in Puerto Rico declared a public health emergency (PHE) on March 25th due to increased cases of dengue. From January 1st to March 21st the island's department of health reported 549 cases of dengue, a 140 percent increase over the same period from the previous year according to *ABC News*. The news outlet also stated that, "the PHE order will remain in place for 90 days. The department [of health] says its response will include early detection, epidemiological surveillance and providing educational material on dengue…A dengue vaccine is approved for children between ages 9 and 16 who have a laboratory-confirmed previous dengue virus infection and who live in areas where dengue is endemic, according to the Centers for Disease Control and Prevention (CDC). It is available in Puerto Rico and is part of the territory's routine childhood immunization schedule, the CDC said [to *ABC News*]." The agency explained that, "dengue viruses are spread through bites from infected *Aedes* species mosquitoes, mostly found in tropical and subtropical regions of the world. These mosquitoes are also responsible for spreading Zika and chikungunya viruses." Dr. Carlos Mellado López, the secretary of the Puerto Rico Department of Health, said in a statement to *ABC News*, "[t]his year, dengue cases have exceeded historical figures. The teams have been working on the integrated plan for prevention and control in response to arbovirus and we are going to expand the implemented response. It is important to note that the increase in cases has not only been reflected in Puerto Rico, but we have seen it throughout the region of the Americas."

(Source: *ABC News*, "Puerto Rico declares public health emergency as dengue fever cases rise," 3/27/24)

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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 recognizes 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 health care 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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ABC Asks California Legislators for Exemption for Blood Collection Supplies in DEHP Proposed Bill

America's Blood Centers (ABC) sent a letter to the California General Assembly's Health Committee's Chair and Vice-Chair in support of an exemption to exclude human blood and blood product collection, processing, and storage bags, including integral tubing, and apheresis and cell therapy collection kits and bags from a recently introduced bill regarding di-(2-ethylhexyl) phthalate (DEHP) in medical devices. In the letter, ABC explained that, "[w]e recognize the purpose of the bill is to eliminate DEHP in medical products as soon as feasible. However, while manufacturers are moving towards DEHP-free alternatives for blood collections and storage, if AB 2300 does not include an exemption for blood collection supplies, sufficient alternatives would be unavailable, leaving blood collectors without compliant options." The letter also noted that, "once new materials are identified, the process for [U.S.] Food and Drug Administration (FDA) approval and adoption by blood centers are time consuming. Indeed, while the European Union initially granted multiple years for the transition away from DEHP, they have had to push the implementation date further from 2026 to 2030. The protracted timeframe required for FDA approval to allow new products to enter the U.S. market is then followed by FDA required validations and modifications of blood center procedures, all of which could not be completed within the timeframe set out in AB 2300. While blood centers have begun moving to DEHP-free products when good replacement products are available, a complete transition is not currently possible with the products available in the U.S. market."

The proposed legislation, AB-2300, would, "prohibit a person or entity from manufacturing, selling, or distributing into commerce in the [s]tate of California intravenous solution containers made with intentionally added DEHP. The bill would, commencing January 1st, 2031, prohibit a person or entity from manufacturing, selling, or distributing into commerce in the [s]tate of California intravenous tubing made with intentionally added DEHP for use in neonatal intensive care units, nutrition infusions, or oncology treatment infusions. The bill would [also] prohibit a person or entity from replacing DEHP for revised or new products with other specified ortho-phthalates." A committee hearing is scheduled for April 2nd. ABC will continue to provide updates on the bill and its advocacy efforts with Blood Centers of California.

(Sources: ABC Letter, 3/27/24; AB-2300, 2/12/24)

WORD IN WASHINGTON

The U.S. Government Accountability Office (GAO) has published a March 25th report titled "Clinical Research: FDA Should Evaluate Its Efforts to Recruit and Retain Its Inspection Workforce." According to the agency, the report describes, "inspections [that] the U.S. Food and Drug Administration (FDA) conducted from fiscal years 2012 through 2023; [the] frequency with which FDA identified serious deficiencies during inspections; and examines FDA's efforts to maintain its investigator workforce." GAO reviewed data and documents and interviewed officials at the FDA as part of the report. Based on this research, the agency determined that, "[f]rom fiscal years 2012 through 2020, FDA classified 3 percent of clinical research inspections as having serious deficiencies that would warrant regulatory actions. Investigators GAO spoke with were frustrated that problems they identified (e.g., failure to follow research protocols) did not result in more serious classifications. FDA is limited in its ability to cite serious deficiencies for a common type of study supporting generic drugs. Specifically, the regulations for these studies do not include certain requirements for basic study conduct, such as record retention and following study protocols. FDA has started the process of revising these regulations. Having effective requirements will be important to help ensure high-quality research. FDA has faced challenges recruiting and retaining investigators, resulting in fewer inspections and a less experienced workforce." GAO is recommending that, "FDA evaluate its recruitment and retention efforts to determine their effectiveness and incorporate results, as appropriate, to help ensure the agency is using the most appropriate tools to maintain its investigator workforce. The U.S. Department of Health and Human Services (HHS), of which FDA is a part, agreed with GAO's recommendation."

(Source: GAO Report, 3/25/24)

BRIEFLY NOTED

Facebook recently informed America's Blood Centers of a pending change to its blood donation tool. Starting April 1st, the blood donation tool will no longer be available on the Facebook app. Blood centers will have the option to create and manage a WhatsApp Channel as a one-way broadcasting tool to share updates with followers and communicate the need for blood donations in their area. Details on creating a WhatsApp channel are available here. Please contact Stephanie Sasser from Meta's Social Impact Partnerships team with questions regarding the transition.

(Source: MCN 24-018, 3/21/24)

The Centers for Disease Control and Prevention (CDC) has announced the next event in their Virtual Thalassemia Grand Rounds Series. The next virtual forum, titled "Hemoglobin H Disease: Treatment Update," will take place on April 18th at 2 p.m. eastern. Registration is open and the forum will feature Ashutosh Lal, MD and Jennifer Yu, MD as speakers. The learning objectives for attendees are listed as:

- "[d]escribe genetics and pathophysiology of hemoglobin H disease;
- [l]ist clinical manifestations and complications associated with hemoglobin H disease; [and]
- [d]escribe the recommended monitoring and treatment plan for hemoglobin H disease."

(Source: CDC Announcement, 2/2/24)

RESEARCH IN BRIEF

RBC Directed Autoimmunity as Post-Transfusion Risk. A study in *British Journal Haematology* sought to, "quantify the association between red blood cell-directed autoimmunity as determined by direct antiglobulin test (DAT) positivity and transfusion-induced red blood cell alloimmuni[z]ation, considering important alloimmunization risk modulators." The authors noted that, "[the] cohort constitutes all newly transfused, previously non-alloimmuni[z]ed patients who received their first and subsequent red blood cell transfusion(s) in six Dutch hospitals between January 2005 and January 2019." The paper explained that, "DAT positivity was defined as at least one positive monospecific DAT preceding at least one red blood cell transfusion and followed by subsequent alloantibody screening…[T]he control group comprised all patients with negative DAT results." The study featured, "[a]mong newly transfused patients, 47,825 patients fulfilled all inclusion criteria…Red blood cell alloimmuni[z]ation occurred in 1,127 (2.4 percent) patients, who formed a total of 1,280 alloantibodies, including 876 (68.4 percent) directed against Rh/K…DATs were performed in 4,456 (9.3 percent) [of] patients…Of those, 380 (0.8 percent) had positive results for IgG and/or C3d." The researchers found that, "[i]n general, cumulative red blood cell alloimmunization incidences were comparable between patients with and without positive DAT results, that is, 4.5 percent (95 percent confidence interval [CI] 2.5–8.2) as compared to 4.2 percent (CI 3.9–4.5, p = 0.88) after 10 units received." Additionally, the authors reported that, "[n]oticeably, the use of immunosuppressants was higher among alloimmune[z]ed as compared to non-alloimmuni[z]ed patients (42.4 percent vs. 30.9 percent)…After adjusting for clinical confounders, DAT-positive patients demonstrated a 1.7-fold increased risk for red blood cell alloimmune[z]ation (RR 1.7 [95 percent CI 1.1–2.8]." The authors concluded that, "DAT positivity is associated with an intrinsically increased red blood cell alloimmune response. Despite this, but explained by counteracting co-existing immune conditions, overall alloimmuni[z]ation incidences among DAT-positive patients are comparable to patients lacking DAT testing, while patients with a negative DAT result exhibit particularly low incidences of alloimmuni[z]ation…Taken together, in [the authors'] opinion, DAT positivity does not warrant extensive red blood cell matching."

Citation: Oud, J.A., de Haas, M., de Vooght, K.M.K., *et al*. "Challenging the dogma: Red blood cell-directed autoimmunity as risk factor for red blood cell alloimmunisation after blood transfusion." *Br J Haematol*. 2024.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

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INSIDE ABC

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

Special Members Meeting and Bylaws Vote Set for April 10th

America's Blood Centers (ABC) is holding a special Members Meeting on April 10th at 3 p.m. EDT to electronically vote on proposed changes to the ABC Bylaws. Additional details regarding the meeting are available in MCN 24-019. Attachments accompanying the MCN included:

- ABC's current Bylaws with redline proposed changes;
- an overview of the proposed changes as presented at the ABC Members Meeting on March 5th;
- a proxy ballot for any member voting representative (MVR) unable to attend the call (please complete and return no later than April 9th); and
- a ballot for designated MVRs attending the call.

The results of the vote will be announced by 12 p.m. EDT on April 11th. Please contact ABC Chief Executive Officer Kate Fry, MBA, CAE with questions or to receive the attachments.

(Source: MCN 24-019, 3/21/24)

ABC Economic Outlook Survey Open

ABC recently launched of the Economic Outlook Survey. This new resource consolidates what were formerly known as the ABC Financial Ratio and Median Service Fee surveys while offering a comprehensive look at blood center finances, including 19 of the most frequently used ratios for benchmarking the financial health of an organization as well as median service fees for 30 different blood products and blood center procedures.

The aggregate data of this survey is important to both members and ABC as we advocate for fair and accurate reimbursement policies. Survey results are anonymized and aggregated. The ability to download final trend reports and create customized reports based on selected filters will be available to participants via ABC's benchmarking portal in early May and are complimentary to all survey participants. Non-participants may purchase the report here. The survey will remain open until April 19th. Please contact us with questions.

Meet Us in St. Louis for the ABC 2024 Quality and Technical Workshop!

Registration remains open for the 2024 America's Blood Centers (ABC) Quality and Technical Workshop. Check out our program as this year's workshop is centered around highlighting collaboration amongst blood banking professionals to allow for an exchange of innovative ideas and best practices. Sessions have been developed to emphasize the important topics that are affecting you and your blood center. The workshop will feature experts in their field presenting topics that include implementation of new devices and blood products, regulatory and licensure round tables, and peer to peer strategic discussions to name a few. Don't miss the opportunity to network with your peers and gain greater insights into the challenges that the blood industry is facing now.

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Schedule Available 2024 ADRP Annual Conference

The schedule is available for the 2024 ADRP Annual Conference. Register today! Join more than 400 blood center professionals in St. Louis, Mo. May 14th-16th at The St. Louis Union Station Hotel. This year's conference will feature keynotes Jason Kotecki, an expert at helping people "Escape Adulthood" in order to beat burnout and become more innovative and creative by breaking rules that do not exist, and Candy Whirley, a recognized motivational speaker, leadership, and team building expert. The 2024 ADRP Annual Conference is your opportunity to gain insights into industry trends, exchange ideas, and share information with your peers, while taking advantage of networking opportunities. Attendees will be able to participate in pre-conference workshops, educational sessions, roundtables, and have access to an expansive exhibit hall. Learn more about available exhibitor and sponsorship opportunities. Remember to book your hotel room by April 19th for the discounted rate. Please contact us with questions.

PEOPLE

Gretchen Jameson, EdD has joined Versiti, Inc. as the new executive vice president and chief marketing officer beginning April 1st. According to a Versiti news release, "Dr. Jameson will lead portfolio, field, and corporate marketing; business development across service lines; marketing insights and operations; public relations; and the Versiti customer center of excellence. Her team will further develop and communicate Versiti's strategic direction, inspire stakeholders to become advocates for the mission, and ensure alignment to deliver exceptional experiences for customers and donors throughout the organization's multi-state footprint." Chris Miskel, MBA, president and chief executive officer of Versiti, added in the news release, "Gretchen brings an unwavering commitment to brand excellence, marketing communications, and change leadership. She understands the intricacies behind a brand's success, evolution, and transformative potential; we are thrilled to land a talent of her caliber." Dr. Jameson stated in the news release, "I am thrilled to join Versiti and contribute to the organization's mission of enhancing lives through discovery, diagnosis, and treatment. Throughout my career, my passion has centered on empowering people to uncover and champion their unique purposes for the betterment of all," said Jameson. "I am truly excited to work alongside the talented team at Versiti to drive impactful marketing initiatives that resonate with our communities and advance patient health with compassion and purpose." She most recently served as, "chief learning and experience officer for RippleWorx, a Software as a service firm recently named among the INC5000 fastest growing tech firms in the U.S. She has also held a variety of leadership positions for both Kacmarcik Enterprises and Concordia University Wisconsin and Ann Arbor, earning national recognition for excellence in strategic design and outcomes…Dr. Jameson is a graduate of Concordia University Nebraska with a degree in education. She later earned a Master of Arts in Public Relations from Webster University and her Doctorate in Organizational Change Leadership from the University of Southern California."

(Source: Versiti, Inc. News Release, 3/26/24)

INFECTIOUS DISEASE UPDATES

DENGUE

The Pan American Health Organization (PAHO) has issued a warning regarding a surge in cases of dengue across the Americas. According to March 26th data released by the organization, "over 3.5 million cases and more than 1,000 deaths have been reported in the region…While dengue is on the rise throughout Latin America and the Caribbean, the hardest-hit countries are Brazil (83 percent), Paraguay (5.3 percent), and Argentina (3.7 percent), which account for 92 percent of cases and 87 percent of deaths. This increase is attributed to the higher transmission season in the southern hemisphere, when the *Aedes aegypti* mosquito vector of dengue thrives due to warm and rainy weather." PAHO Director Jarbas Barbosa explained during a press conference that, "[t]his is cause for concern, as it represents three times more cases than those reported for the same period in 2023, a record year with more than 4.5 million cases reported in the region." Dr. Barbosa added that, "we are also seeing an uptick in cases in countries such as Barbados, Costa Rica, Guadeloupe, Guatemala, Martinique and Mexico, where transmission is usually higher in the second half of the year." According to PAHO, "[t]he presence of all four dengue serotypes in the region increases the risk of epidemics and severe forms of the disease. The simultaneous circulation of two or more dengue serotypes has been observed in 21 countries and territories of the Americas." Dr. Barbosa also stated that, "despite the record increase in cases in 2023, the dengue case fatality rate in the region remained below 0.05 percent. [This] is very encouraging, considering the spikes in cases we have seen since then."

(Source: PAHO News Release, 3/28/24)

MEMBER NEWS

LifeSouth Community Blood Centers is officially celebrating its 50th anniversary and kicked off the festivities by opening a new Gainesville, Fla. donor center on March 20th. According to blood center news release, the event included, "representatives from local hospitals, the Greater Gainesville Chamber of Commerce, community leaders, elected officials, blood donors and LifeSouth Board Members." Kim Kinsell, JD, president and chief executive officer (CEO) of LifeSouth and vice president of the America's Blood Centers Board, added in the news release, "[w]e are excited to celebrate our 50th year of serving the Gainesville community and the grand opening of our new donor center. We were founded here in 1974 at the request of local hospitals, and we continue to grow to meet the needs of the communities and hospitals we serve."

(Source: LifeSouth Community Blood Centers News Release, 3/27/24)

Pictured left to right: LifeSouth COO JD Pettyjohn, LifeSouth Board Member Ron Spitznagel, LifeSouth Board Member Carl Smith, LifeSouth President and CEO Kim Kinsell, LifeSouth Board Emeritus Member Will Shafer, LifeSouth CFO Dan Galasso, and LifeSouth Board Member Rick Staab.

The Blood Connection (TBC) has expanded its operations to Roanoke, Va. as part of its partnership with Carilion Clinic. According to a report from WSLS NBC-10, TBC held a celebration event with a ribbon cutting ceremony in front of a bloodmobile to commemorate the expansion. Plans to open a donor center in the area are currently underway. "Since the pandemic, the amount of blood available has decreased dramatically so the need has increased exponentially — so this partnership is going to help us just take even better care of our patients," said Brandon Jones, assistant patient experience manager at Carilion Clinic, according to WSLS NBC-10.

(Source: WSLS NBC-10, "New blood donation center, 'The Blood Connection' opens," 3/27/24)

GLOBAL NEWS

The World Health Organization (WHO) has developed CoViNet, which aims to be a global network for coronaviruses. A WHO news release stated that the network aims, "to facilitate and coordinate global expertise and capacities for early and accurate detection, monitoring, and assessment of SARS-CoV-2, MERS-CoV, and novel coronaviruses of public health importance. CoViNet expands on the WHO COVID-19 reference laboratory network established during the early days of the pandemic. Initially, the lab network was focused on SARS-CoV-2, the virus that causes COVID-19, but will now address a broader range of coronaviruses." Currently, CoViNet includes, "36 laboratories from 21 countries in all 6 WHO regions…Representatives of the laboratories met in Geneva on March 26th-27th to finalize an action plan for 2024-2025 so that WHO Member States are better equipped for early detection, risk assessment, and response to coronavirus-related health challenges." The WHO also explained in the news release that, "[d]ata generated through CoViNet' s efforts will guide the work of WHO's Technical Advisory Groups on Viral Evolution (TAG-VE) and Vaccine Composition (TAG-CO-VAC) and others, ensuring global health policies and tools are based on the latest scientific information."

(Source: WHO News Release, 3/27/24)

COMPANY NEWS

The U.S. Food and Drug Administration (FDA) has extended the shelf life of **Cerus Corp.**'s Intercept Platelet Processing Sets. According to a company announcement, "FDA has granted approval of 12-month shelf life for INTERCEPT Platelet Processing Sets, from the date of manufacture, effective immediately. This approval extends the set shelf life by six months from the existing six-month shelf life that took effect following a set component change last year. All Intercept Platelet Processing Sets in both customer and Cerus inventories are now eligible for this six-month extension. This shelf-life extension applies to all sizes of Intercept Platelet Processing Sets currently available in the U.S. "Cerus also added in the news release that, "[the company] is continuing to generate additional data to pursue potential shelf-life extension from the FDA beyond 12 months for the Intercept Platelet Processing Sets.

(Source: Cerus Corp. News Release, 3/26/24)

BioBridge Global recently opened its first stand-alone cell therapy testing laboratory. A March 1st ribbon cutting ceremony celebrating the milestone included more than 50 employees according to a company news release. The expanded lab will, "focus on safety, potency, and purity testing, identifying and characterizing therapies fighting a range of ailments, from wounds to cancer. [It] also can help with the testing of starting materials used in the earliest stages of advanced therapy development. [The lab] currently serves 31 clients and approximately 100 different products." The news release also stated that, [t]he new, extended lab will begin with a team of five and with plans to add two additional scientists this year."

(Source: BioBridge Global News Release, 3/6/24)

Valneva SE has announced the "initiation" of a phase I trial, "to investigate the safety and immunogenicity [of its] second-generation adjuvanted inactivated vaccine candidate against the Zika virus (ZIKV)." According to a company news release, "the randomized, placebo-controlled, phase I trial is planned to enroll approximately 150 participants aged 18 to 49 years in the U.S. Participants will receive a low, medium, or high dose of [the vaccine candidate] In addition, the low dose of [the vaccine candidate] will be evaluated with

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COMPANY NEWS (continued from page 9)

an additional adjuvant, either the CpG 1018® adjuvant from Dynavax Technologies Corporation or 3M-052-AF adjuvant from the Access to Advanced Health Institute (AAHI). Topline data from the trial are expected in the first half of 2025." Valneva also explained in the news release that, "[the vaccine candidate-is being developed on the original manufacturing platform of Valneva's licensed Japanese encephalitis (JE) vaccine IXIARO®, which was further optimized to develop the [c]ompany's inactivated, adjuvanted COVID-19 vaccine VLA2001, the first COVID-19 vaccine to receive a standard marketing authorization in Europe. Phase 1 results from Valneva's first-generation Zika vaccine candidate were reported in 2018 showing a favorable safety profile and immunogenicity in all tested doses and schedules…There are currently no preventive vaccines or effective treatments available against ZIKV."

(Source: Valneva SE News Release, 3/26/24) ♦

NEW on Coll*ABO*rate

COLLABORATE

SHARE STRATEGIC ADVICE | SOLVE CHALLENGES | DEVELOP NEW APPROACHES

Recent discussion topics on the ABC Coll*ABO*rate Online Member Community include:

- Low-volume RBCs (QUALITY BYTES)
- Phlebotomy Start Times (COLLECTIONS & DONOR SERVICES)
- Adverse Reaction Time of Departure (ALL MEMBER FORUM)
- Abnormal Kleihauer Betke Staining (ALL MEMBER FORUM)
- Electronic Young Donor Parental Consent (MEMBER RESOURCES)
- Freeze Dried Plasma (MEDICAL ISSUES)
- Type A Liquid Plasma (MEDICAL ISSUES)
- Testosterone and Aromatase Inhibitors (MEDICAL ISSUES)
- Tracking Blood Center Equipment (QUALITY BYTES)
- New Hire Supports (EMPLOYEE TRAINING and DEVELOPMENT)

CALENDAR

Note to subscribers: *Submissions for a free listing in this calendar (published weekly) are welcome. Send information to newsletter@americasblood.org. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)*

2024

Apil 10. **ABC Special Members Meeting (Virtual).** More information available to ABC members in MCN 24-019 including a link to registration.

April 11-12. **International Haemoviglance Network Symposium. Athens, Greece.** Registration is open. More information available here.

April 12-13. **BEST Meeting. Amsterdam, Netherlands.** More information is coming soon.

April 16-17. **International Plasma Protein Congress. Athens, Greece.** Registration is open. More information available here.

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CALENDAR (continued from page 10)

April 17. **ADRP Webinar: Conference 2024 "Know Before You Go."** Registration is open. More information available here.

April 17-18. **ABC Quality and Technical Workshop. St. Louis, Mo.** Registration is open. More information available here.

May 3-4. **California Blood Bank Society (CBBS) Annual Meeting.** More information is coming soon.

May 14-16. **2024 ADRP Annual Conference. St. Louis, Mo.** Registration is open. More information available here.

May 15-16. **International Plasma and Fractionation Association/Paul-Ehrlich Institut[e] 30th International Workshop on Surveillance and Screening of Blood-borne Pathogens. Aarhus, Denmark.** Registration is open. More information available here.

June 7-8. **2024 South Central Association of Blood Banks (SCABB) Annual Meeting and Exhibit Show. Orlando, Fla.** More information is coming soon.

June 23-27. **38th International Society of Blood Transfusion (ISBT) Congress. Barcelona, Spain.** Registration is open. More information available here.

Sept. 4-6. **American Society for Clinical Pathology (ASCP) Annual Metting. Chicago, Ill.** Registration is open. More information is available here.

Sept. 18-19. **2024 ADRP Master Class.** More information is coming soon.

Sept. 30-Oct. 3. **American Association of Tissue Banks (AATB) Annual Meeting. Denver, Colo.** More information is coming soon.

Oct. 19-22. **Association for the Advancement of Blood & Biotherapies (AABB) Annual Meeting. Houston, Texas.** More information is coming soon.

Nov. 6-7 **ABC Women's Executive Leadership Community (WELC) Workshop. San Antonio Texas.** More information is coming soon.

2025

May 20-21. **International Plasma Protein Congress. Warsaw, Poland.** More information is coming soon.

Oct. 12-15. **AATB Annual Meeting. Atlanta, Ga.** More information is coming soon.

Oct. 25-28. **AABB Annual Meeting. San Diego, Calif.** More information is 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 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, e-mail: newsletter@americasblood.org

POSITIONS

Lab Technical Director. The Central California Blood Center (CCBC) is seeking a Laboratory Technical Director for our operations based out of Fresno, California. This position provides exceptional, mission-focused leadership to the blood component manufacturing, testing lab, research, and immunohematology reference laboratory and assures cost-effective, lean operations and

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compliance with all regulatory agencies and best practices as defined in AABB Standards and AABB Technical Manual. Assures that the department strives for optimal performance by providing the necessary resources and developing a highly competent team. This position works in close collaboration with CCBC senior leadership and the Medical Director, who holds the CLIA licensure for the organization. The ideal candidate must have a current California Clinical Laboratory Scientist (CLS) license or eligible, a minimum of six (6) years of experience working in a blood center, and a minimum of three (3) years of direct supervisory experience managing teams and assets. Certified as an SBB/BB or equivalent is preferred. We offer a generous benefits package including a great 401k matching program, PTO, paid sick leave, medical, dental, vision, electronic vehicle charging, wellness program, and employee assistance program (EAP). Prospective candidates may be eligible for relocation assistance. For full description and to apply click here. The Central California Blood Center is an Equal Opportunity Employer.

Regulatory and Audit Compliance Specialist. The Regulatory and Audit Compliance Specialist ("Specialist") is responsible for developing and maintaining a risk-based quality auditing program for the New York Blood Center Enterprise division. The Specialist monitors and evaluates divisional compliance with regulatory requirements, professional accreditation standards and internal policies and procedures to ensure the ongoing quality and safety of products and services. Manages Audits: The Specialist manages the quality audit program for the division, including planning, risk assessment, scheduling, executing, and reporting on audits of the organization's facilities and operations. The auditor makes recommendations on areas of improvement based on audit observations and findings. Advises on Compliance: The Specialist represents the division as a direct liaison to regulators, managing communications, Biologics License Applications (BLA) submissions, regulatory reporting, and ongoing compliance matters, including the filing of Biological Product Deviation Reports (BPDRs). The incumbent serves as a subject matter expert, advising divisional leadership of new or changed regulations and standards, and providing interpretation for successful implementation. Please click here to view the full job description and apply.

Vice President, Quality & Regulatory Affairs (VPQRA). The Vice President, Quality & Regulatory Affairs (VPQRA) leads the Organization's adherence to regulations and standards established by governing agencies (AABB, FDA, CLIA, State, OSHA, NRC, EU, etc.). Kentucky Blood Center is seeking qualified candidates to fill this key executive leadership role which is responsible for our Quality Assurance (QA) program and regulatory compliance activities. The position has oversight of the QA department and team, and reports to the CEO. Qualifications include MLS/CLS (ASCP) with preference given to candidates with a graduate degree, and blood banking experience. Relocation to the Lexington, Kentucky area required (assistance provided). For more information or to apply, visit https://www.kybloodcenter.org/about-us/careers.

Quality and Regulatory Services Manager. The Quality and Regulatory Services Manager reports to the Director of QRS and is responsible for the quality and regulatory affairs, duties, and responsibilities by reviewing department procedures, forms, training documents, product and equipment quality control (QC), change control processes, and validations, and assist with the development, as necessary. Reviews applicable regulations and standards from FDA, AABB, CLIA, OSHA, NRC, State of Tennessee, and manufacturers to ensure compliance. Personnel Training: Perform Good Manufacturing Practice (cGMP) and safety training and assist in inter-departmental training and competency evaluation. Maintain compliance by enforcing applicable regulations and standards set by regulatory agencies and submit appropriate reports when required. Document Control: Maintain proficiency in Document Control within MediaLab. Able to revise and create SOPs, Forms, and Job Aids. Create, perform, and review validations. Manage the overall deviation management program to include investigation, root cause, analysis, corrective and preventative actions, and documentation. Responsible for developing, tracking, monitoring, and reporting quality indicators. Monitor and conduct trend analysis of quality indicators. Process improvement, including change control and corrective/preventative actions. Please click here to view the full job description and apply.

Cord Blood Operations Supervisor. LifeSouth Community Blood Centers is looking for a leader with a passion for making a difference to join our Cellular Therapies team at our headquarters in Gainesville, FL. This position is responsible for supporting and supervising the Cord Blood (CB) program's supply, records, logistics and communication activities. This position is also responsible for supervision and training of the cord blood logistics staff and for coordinating and managing all activities related to orders and shipments of biological products. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!

Cellular Therapy Scientist. LifeSouth Community Blood Centers is looking for an experienced laboratory scientist, with a passion for making a difference, to join our Cellular Therapies team at our headquarters in Gainesville, FL. The Cellular Therapy Scientist is responsible for performing and developing testing,

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processes, troubleshooting, and investigation related to cellular therapy and manufactured biologics. Duties and projects may relate to products intended for research, commercial, and clinical use. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!

District Director. LifeSouth Community Blood Centers is seeking a highly skilled leader with proven management experience and a passion for making a difference. The District Director at our Jacksonville, FL location is responsible for managing and directing the operations within the assigned district to ensure blood donation goals are achieved. They will work closely with local hospitals to ensure blood products are available as needed and all service needs are met appropriately. The District Director also ensures local operations are managed appropriately, in accordance with all procedural requirements and are in line with organizational values. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!

Manager of Donor Resources. The Blood Connection is seeking a Manager of Donor Resources for our operations based out of Augusta, GA. This position will be responsible for monitoring progress to goal proactively, and effectively coaching and managing their team to success. The ideal candidate for this position possesses strong leadership and organizational skills with a proven ability to meet organizational goals. We offer a generous benefits package including a substantial 401k, 30 days PTO, potential company bonuses, cell phone stipend, and tuition reimbursement. Join our team and help create a positive change in your community! *Prospective candidates may be eligible for relocation assistance*. How to apply: Manager of Donor Resources – Augusta, GA.

Manager of Donor Services. The Blood Connection is seeking a Manager of Donor Services for our operations based out of Raleigh, NC and Rock Hill, SC. These positions will oversee donor collection operations within their assigned divisional territory. These positions provide leadership and discipline to direct reports, interviews, and hire staff, and ensure staff are appropriately trained. We offer a generous benefits package including a substantial 401k, 30 days PTO, potential company bonuses, cell phone stipend, and tuition reimbursement. Join our team and help create a positive change in your community! *Prospective candidates may be eligible for relocation assistance*. How to apply: Manager of Donor Services – Raleigh, NC. Manager of Donor Services – Rock Hill, SC.

Director, Quality Assurance & Regulatory Affairs (Hoxworth Blood Center). The University of Cincinnati College of Medicine (COM) has a reputation for training best-in-class health care professionals and developing cutting-edge procedures and research that improves the health and clinical care of patients. Hoxworth Blood Center (HBC) is located within the College of Medicine and is the only Regional Blood Center owned and operated by a University in United States. The HBC is seeking a **Director of Quality Assurance & Regulatory Affairs**. This position will oversee and direct the coordination of quality assurance and regulatory compliance for the Cellular Therapy, Therapeutic Apheresis, and Transplantation Immunology divisions. Required Education & Experience: Bachelor's degree in Medical Technology, Biology, Chemistry, or related field. Seven (7) years of experience in a clinical laboratory, blood banking or other related experience. Additional Qualifications Considered: Previous experience in a FACT, AABB and HCT/P (21 CFR 1271) and GMP (21 CFR 211) for Phase I/II clinical manufacturing, Regenerative Medicines, Cleanrooms, and Aseptic Processing is ideal. Understanding of CAP requirements for histocompatibility (HLA) laboratories which includes disciplines of sequencing, molecular, serological, immunology, flow cytometry, and cellular analysis is preferred. For full description and to apply, visit https://bit.ly/489l7Gl. The University of Cincinnati is an Equal Opportunity Employer.

Division Director, Core Operations (Hoxworth Blood Center). Hoxworth Blood Center is recruiting for Division Director, Core Operations, to provide leadership, vision, and oversight of programs related to donor center core operations, including Biomedical Engineering, Materials Management, Physical Operations, and computer software informational systems. Experience in daily production of cleanroom environments, as well as recruitment and training of new employees with knowledge in cleanroom environment and regulatory framework in accordance with cGMP, FDA, and ISO regulations pertinent to the environmental control in ISO7/8 facilities is crucial. Enforce current strategic planning initiatives; develop new activities and establish goals in support of blood center strategic plans. Direct and facilitate cross functional activities that support the interdepartmental communications, productivity, and quality between various operating units. Develop innovative processes for monitoring operations to ensure high quality customer service and successful delivery of outputs. Required Education and Experience: Bachelor's Degree in related field of healthcare, biological or computer sciences. Seven (7) years of relevant experience in equipment management, computer and software information systems, blood banking, biotherapies, transfusion medicine, or scientific research. Three (3) years of direct

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supervisory experience managing employees, teams, and assets. For full description and to apply, visit: https://bit.ly/3OHlZet. The University of Cincinnati is an Equal Opportunity Employer.