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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2024 #18 **May 24, 2024**

INSIDE:

Please Note: The *ABC Newsletter* will not be published on May 31st. We will resume regular publication on June 7th. Thank you for your continued interest.

Blood Community Response to 2025 CMS Hospice Proposed Rule & RFI

America's Blood Centers (ABC), the Association for the Advancement of Blood & Biotherapies (AABB), and the American Red Cross (ARC) have submitted joint comments to the Centers for Medicare & Medicaid Services (CMS) fiscal year (FY) 2025 proposed rule titled, "Hospice Wage Index and Payment Rate, Hospice Conditions of Participation Updates, and Hospice Quality Reporting Program Requirements." Specifically, the blood community comments, "urge CMS to improve Medicare beneficiaries' access to end-of-life care by providing incremental, separate payments, leveraging the established blood product HCPCS code sets and associated rates for palliative blood transfusions furnished under the Medicare hospice benefit."

The proposed rule solicited comments regarding potential implementation of a separate payment mechanism to account for high intensity palliative care services, including blood transfusions. It also included a request for information (RFI) explaining that CMS is considering a major potential shift away from a closed hospice bundled payment to allow patient access to services like blood transfusions.

The blood community comments noted that, "[o]ur organizations commend CMS for the focused attention on removing barriers and expanding access to palliative blood transfusions for Medicare beneficiaries under the hospice benefit. Palliative blood transfusions relieve debilitating symptoms that negatively impact patients' quality of life. Recognizing and explicitly acknowledging the coverage of palliative blood transfusions under the hospice benefit constitutes a crucial step forward in enhancing access to this essential therapy. However, to truly optimize access to palliative blood transfusions, revisions to Medicare's payment policy are imperative."

ABC, AABB, and the American Red Cross explained that few hospice organizations offer blood transfusions due to the Medicare per diem payment amount being, "far too low to cover costly yet helpful palliative interventions, such as blood transfusions." The comments stated that, "hospice providers lack accurate data on the number of patients who would benefit from palliative transfusions, as many of these patients never even contact the hospice provider after being told by their treating physician that transfusions will be unavailable. This uncertainty further complicates

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Blood Community RFI Response to 2025 Hospice Proposed Rule (continued from page 1)

the justification for the infrastructure and staffing costs required to provide blood transfusions. As a result, Medicare beneficiaries reliant on blood transfusions may experience delays in hospice enrollment, premature exit from hospice care, or frequent transitions in and out of hospice settings. Such outcomes not only compromise the quality of care but also contribute to increased overall costs."

The blood community concluded the comments by stating that, "with continued education about the availability of blood transfusions under the hospice benefit, carving out payments for blood transfusions from the per-diem payment will remove a substantial barrier to care and improve end of life care for patients and their families."

(Source: Blood Community Comments Regarding Hospice Proposed Rule, 5/23/24)

Summer of Giving Campaign Kicks Off Tuesday, May 28th

America's Blood Centers (ABC) and GLAAD, the largest LGBTQ media advocacy organization worldwide, have officially announced the "Summer of Giving" initiative publicly. In the May 22nd news release, the organizations described the campaign as, "[an] initiative [that] aims to encourage businesses to host blood drives and all eligible individuals to donate blood in support of recent [U.S. Food and Drug Administration] (FDA) eligibility changes that promote fairness and inclusivity in the donation process while maintaining the safety of the blood supply. The campaign will run from Tuesday, May 28th through National Blood Donation Day on Wednesday, September 4th, 2024, in recognition of the critical need for blood donations during the summer months. Despite the ongoing demand for blood products, donations typically decline during this period due to travel and the lack of school-based blood drives."

GLAAD President and Chief Executive Officer (CEO) Sarah Kate Ellis stated in the news release, "[t]he 'Summer of Giving' is a celebration of the LGBTQ community and decades of work to remove the stigma too many potential donors have endured. Removing discriminatory barriers and following facts and science will ease the critical national blood shortage. LGBTQ donors should be treated the same as any other donor when they walk into their local blood donation center. This campaign sends a long-needed message that LGBTQ people are welcome and can generously contribute to their communities to help save lives." ABC CEO Kate Fry, MBA, CAE added in the news release, "ABC is proud to team up with GLAAD to promote the facts about this new change in blood donor eligibility, which prioritizes the safety of the blood supply while bringing more equality to the donation process. The 'Summer of Giving' campaign is a unique opportunity for individuals and businesses to donate blood and host blood drives in support of a new era of blood donor eligibility. Together, we can help save lives during a time of critical need for the blood community."

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The *ABC Newsletter* (ISSN #1092-0412) is published by America's Blood Centers® and distributed by e-mail.

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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"Summer of Giving" Campaign Kicks Off Tuesday, May 28th (continued from page 2)

ABC members have access to several resources to promote the campaign including a "Summer of Giving" Frequently Asked Questions (FAQ) Document, "Summer of Giving" One Pager, "Summer of Giving" Post-card to FDA encouraging the agency to continue updating eligibility criteria based on scientific evidence in order to broaden the pool of potential blood donors, "Summer of Giving" Logo, Summer of Giving Public Service Announcement (PSA), and "Summer of Giving" Video and Audio Files. *(**Please note if you are an ABC member blood center and would like individual copies of the video and audio files, please contact us.**)*

ABC member blood centers may reach out to ABC Director of Strategic Communications and National Partnerships Jeff Gohringer for more information or with questions about the "Summer of Giving" initiative.

(Source: "Summer of Giving" News Release, 5/2/24)

REGULATORY NEWS

The U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) has published its 2023 annual summary of Biological Product and Human Cells, Tissues, and Cellular Tissue-based Product (HCT/P) Deviation Report. Deviations potentially affecting "safety, purity, or potency," as well as unexpected events that occur during the manufacturing of blood and blood products must be reported to CBER in accordance with 21 CFR 606.171 or 1271.350(b). In addition, manufacturers of non-reproductive HCT/Ps regulated by FDA are "required to submit [deviation] reports" involving distributed products if "the deviation or the unexpected event is related to a core Current Good Tissue Practice requirement and related to the prevention of communicable disease transmission or HCT/P contamination." The annual summary provides an overview of the reports FDA received during the most recent fiscal year, including detailed information regarding the number and types of deviation reports received. FDA combined data received over the last three fiscal years to compare data and highlight changes. During fiscal year 2023, Oct. 1, 2022 to Sept. 30, 2023, CBER entered 16,258 deviation reports into its database, an 8 percent increase from FY 2022. "The total number of reporting establishments increased from 2,276 in FY 2022 to 2,475 in FY 2023. Compared to FY 2022, there were 203 more blood and [s]ource [p]lasma establishments, 10 fewer manufacturers of licensed biological products other than blood and blood components, and six more 361 HCT/P manufacturers reporting in FY 2023."

(Source: CBER Biological Product and HCT/P Deviation Reports – Fiscal Year 2023, 5/10/24)

The FDA has issued a communication titled, "Information for Human Cell, Tissue, and Cellular and Tissue-Based Product (HCT/P) Establishments Regarding FDA's Determination that Zika Virus is no Longer a Relevant Communicable Disease Agent or Disease." According to the May 20th notice, the agency explained that, "FDA has determined Zika virus (ZIKV) is no longer a relevant communicable disease agent or disease (RCDAD) under FDA's regulations because [the available] evidence demonstrates that ZIKV no longer has sufficient incidence and/or prevalence to affect the potential HCT/P donor population. [Thus,] FDA is withdrawing the guidance titled, "Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products," dated May 2018. Because ZIKV is no longer an RCDAD, HCT/P establishments may discontinue screening donors for ZIKV and revise their relevant procedures to reflect this change. FDA will continue to monitor ZIKV epidemiology in the United States (U.S.) and worldwide. If there is a change in epidemiology that leads FDA to conclude that ZIKV again may have "sufficient incidence and/or prevalence to affect the potential HCT/P donor population," then FDA may again determine that ZIKV is an RCDAD and issue guidance with recommendations to reduce the risk of transmission of ZIKV by HCT/Ps."

(Source: FDA Communication, 5/20/24)

WORD IN WASHINGTON

The National Institutes of Health's (NIH) National Heart, Lung, and Blood Institute (NHLBI) is hosting the "Annual Sickle Disease Research Meeting" Aust 12th–14th. The meeting is taking place in Bethesda, Md. and will have a hybrid virtual option for those who cannot attend in-person. Registration officially opens on May 29th. In-person registration closes on July 22nd and virtual registration closes on August 5th. According to NHLBI, the meeting will, "provide a unique platform for researchers, healthcare providers, and other stakeholders to discuss the latest research findings and innovations in sickle cell disease. [It] will feature engaging presentations and discussions about ongoing research and new developments in the scientific and clinical aspects of the disease. The event will also allow participants to interact with other investigators and NHLBI program staff to exchange ideas, collaborate, and network."

(Source: NHLBI Announcement, 5/22/24)

The Administration released new tariffs on products as part of President Biden's effort to, "Protect American Workers and Businesses from China's Unfair Trade Practices." The tariffs announced on May 14th include certain medical products, "[t]he tariff rates on syringes and needles will increase from 0 percent to 50 percent in 2024. For certain personal protective equipment (PPE), including certain respirators and face masks, the tariff rates will increase from 0–7.5 percent to 25 percent in 2024. Tariffs on rubber medical and surgical gloves will increase from 7.5 percent to 25 percent in 2026." The Administration explained that, "[t]hese tariff rate increases will help support and sustain a strong domestic industrial base for medical supplies that were essential to the COVID-19 pandemic response, and continue to be used daily in every hospital across the country to deliver essential care. The federal government and the private sector have made substantial investments to build domestic manufacturing for these and other medical products to ensure American health care workers and patients have access to critical medical products when they need them. American businesses are now struggling to compete with underpriced Chinese-made supplies dumped on the market, sometimes of such poor quality that they may raise safety concerns for health care workers and patients. Today's announcement reflects President Biden's commitment to always have the back of American workers. When faced with anticompetitive, unfair practices from abroad, the President will deploy any and all tools necessary to protect American workers and industry."

(Source: White House Announcement, 5/14/24)

PEOPLE

Katie Marchik has been named chief operating officer at ImpactLife as of July 1st. She most recently served as the senior vice president and chief financial officer (CFO) of UnityPoint Health in the Quad Cities market. In her new role, Ms. Marchik will, "report to the chief executive officer (CEO) and will have direct oversight of Donor & Patient Services, Technical Services, and Donor Relations & Marketing." ImpactLife CEO Mike Parejko stated in the news release, "Katie is a proven, dynamic leader who brings more than 20 years of hospital leadership experience to ImpactLife. We are fortunate to attract a candidate with such extensive financial and operational leadership expertise as well as a strong commitment to serving our community, demonstrated throughout her tenure with UnityPoint Health. We look forward to welcoming Katie to the executive management team at ImpactLife." Ms. Marchik earned her, "Bachelor of Arts in accounting from the University of Northern Iowa [and] began her career as an Audit Associate with RSM (formerly McGladrey & Pullen, LLP). [She] moved to UnityPoint Health in 2004 as [d]irector of Finance. She then served in Finance, Treasury, and Supply Management roles at UnityPoint Health Corporate Services before being named the organization's CFO for the Quad Cities Market in 2016."

(Source: ImpactLife News Release, 5/13/24)

RECENT REVIEWS

Transfusion Outcomes and Safety of ABO-Nonidentical Platelets. A systematic review published in *Transfusion and Apheresis Science*, "evaluate[d] the transfusion outcomes and safety of ABO-identical platelets transfusions compared to ABO-nonidentical." The authors explained that, "[t]he primary indicator that [the study] considered was transfusion outcomes [and] safety was the secondary outcome." For the review and meta-analysis, they included, "[a] total of 11 retrospective cohort studies and seven prospective cohort studies with a sample size of 104,359 platelets transfusions." The reviewers noted that, "[t]here was [a] significant difference in transfusion effectiveness between the ABO-identical and ABO-nonidentical platelets transfusions (RR 1.20, 95 percent CI 1.11-1.38, P＜0.00001, I^2=21 percent)." Additionally, they found in the review that, "there was significant difference in transfusion effectiveness between the ABO-compatible and ABO incompatible ones (RR 1.28, 95 percent CI 1.11-1.48, P=0.0006, I^2=0 percent)." The authors explained that, "when compared to the major ABO-incompatible platelets transfusion, minor ABO-incompatible platelets transfusion had more significant clinical transfusion response rate (RR 1.22, 95 percent CI 1.05-1.41, P=0.008, I^2=0 percent). For ABO-identical platelets versus minor ABO-incompatible transfusion, it did not have significant difference in improving transfusion efficacy (RR 1.04, 95 percent CI 0.90-1.20, P=0.56, I^2=53 percent). In the same way, [the study] compared ABO-identical and major ABO incompatible platelets transfusion, it showed significant difference (RR 1.30, 95 percent CI 1.14-1.48, P=0.0001, I^2=0 percent)." The reviewers noted that the, "24h corrected count increment (CCI) was mean difference (MD) 0.34, 95 percent CI -0.01-0.70, P=0.06, I^2=0 percent. It was true that ABO-identical platelets transfusions had higher mean post-transfusions 24h CCI compared to the ABO-nonidentical ones, but it was not statistically significant." The authors also explained that, "[o]nly three acute intravascular hemolyses were observed in one study, two of these occurred with minor ABO-incompatible transfusions, and one occurred in a bidirectional ABO-incompatible transfusions…Allergy occurred more than often in ABO-nonidentical platelets transfusions (RR 0.63, 95 percent CI 0.41-0.96, P=0.03, I^2=0 percent)…Fever was more common in patients who received ABO-nonidentical platelets transfusions (RR 0.59, 95 percent CI 0.37-0.94, P=0.03, I^2=31 percent)." The review found that when comparing, "mortality in patients who received multiple platelets transfusions, [>2, ABO-identical platelets] there was no significant difference about mortality (RR 0.93, 95 percent CI 0.72-1.20, P=0.59, I^2=32 percent)." In patients who received <2 or fewer ABO-identical platelets, "there was no significant difference about mortality (RR 0.74, 95 percent CI 0.52-1.06, P=0.10, I2=47 percent)." The authors concluded that, "ABO-nonidentical platelets transfusions are acceptable in the case of platelets shortage…Although ABO-identical transfusions may be ideal, lack of platelets availability makes this approach impractical for most transfusion services."

Citation: Cheng, Z., Kong, Y., Lin, Y., *et al*. "Transfusion outcomes and clinical safety of ABO-nonidentical platelets transfusion: a systematic review and meta-analysis." *Transfusion and Apheresis Science*. 2024.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

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:

- Scholarship Program Sponsored by Blood Center (MEMBER RESOURCES)
- Epi Pens (MEMBER RESOURCES)
- Product Testing (MEDICAL ISSUES)
- Water Baths (QUALITY BYTES)
- B Medical Systems Plasma Freezer (ALL MEMBER FORUM)

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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.

SAVE THE DATE: Blood Advocacy Week Briefing Set for May 29th

America's Blood Centers (ABC) is inviting all member blood centers and Blood Advocacy Week partners to take part in a Blood Advocacy Week Briefing on Wednesday, May 29th at 2 p.m. EDT. The webinar will provide an overview of Blood Advocacy Week events as ABC discusses the ways blood centers and partners can participate and advocate for policies that promote the value of blood to patients and communities while strengthening the resilience of the U.S. blood supply. A link to register for the webinar is available to ABC members in MCN 24-034. During Blood Advocacy Week, ABC, member blood centers, and Blood Advocacy Week partners will collectively advance the ABC 2024 Advocacy Agenda, focused on expanding access to blood products and increasing the donor base. This year's Blood Advocacy Week events will also include Hill briefings, senior level meetings between Congress, federal agencies and ABC leadership, media outreach, and grassroots action. Thanks to the funding from the ABC Corporate Partner Council, ABC will be expanding its reach this year to include a politics and policy section takeover on *Axios* site during Blood Advocacy Week providing the opportunity to highlight the work of ABC, its member blood centers and Blood Advocacy Week partners. Please contact ABC Vice President of Government Affairs Diane Calmus, JD with questions.

ABC Hosting Prehospital Blood Transfusion Programs Webinar June 18th

The ABC Education Committee will be hosting a Prehospital Blood Transfusion Programs Webinar on June 18th at 3 p.m. EDT. Registration is open. The webinar will feature Chief Adam Hagar and Daniela Hermelin, MD sharing their experiences in implementing and maintaining a prehospital blood transfusion program. Chief Hagar serves as battalion chief-EMS at Mehlville Fire Protection District in St. Louis. Dr. Hermelin is the chief medical officer at ImpactLife and an assistant professor of Pathology at the St. Louis University School of Medicine. A link to registration is available to ABC members in MCN 24-035. Please contact ABC Director of Scientific and Technical Operations Betzy Gonzalez, MS BB(ASCP) with questions.

ADRP Marketing Survey Launched

ADRP, The Association for Blood Donor Professionals has launched the first-ever ADRP Marketing Survey to serve as a tool to enhance your blood center's marketing strategy. The anonymized data from this resource can be used to benchmark your blood center's marketing spend and marketing activities to your peers. This survey will also provide participants with key information and insights to drive future decision-making including:

- appointment acquisitions and donor retention;
- spend allocation through various marketing channels; and
- paid advertising, donor incentives, and social media activity.

The deadline to complete the survey is June 14th. Only blood centers who participate in the survey will receive a report of the survey findings. Data is always anonymized, and no raw data will be provided. ADRP recommends that your marketing team complete this brief survey. A webinar will be hosted by ADRP in July to review the findings and key insights. Please contact us with any questions.

MEMBER NEWS

New York Blood Center Enterprises (NYBCe) is partnering with Thermo Fisher Scientific as the organizations, "co-develop the Applied Biosystems™ Axiom™ BloodGenomiX™ Array and BloodGenomiX Reporter Software that provides a high-throughput solution for more precise blood matching to enable safer transfusions." According to a news release, "[t]he array is a first-of-its-kind solution for more precise blood genotyping. The new array detects common, extended, and rare blood groups, tissue (HLA) and platelet (HPA) types in a single, high-throughput assay, supporting future advancements in donor and patient blood group matching for blood transfusion." Connie Westhoff, SBB, PhD, representing the National Cener for Blood Group Genomics at NYBCe, explained in the news release, "[w]e have an amazing team working together to reshape the future of blood typing. Our goal is to develop an affordable and scalable solution that can one day be embedded across labs globally. Our vision is to one day make comprehensive blood typing for all donors and patients the standard of care." Dr. Westhoff is deputy chair of the Blood transfusion Genomics Consortium (BGC), "an international partnership of blood services, research institutions and industry leaders that aims to improve the safety and efficacy of blood and platelet transfusion. The array was developed in partnership with BGC, Thermo Fisher Scientific and NYBCe."

(Source: NYBCe News Release, 5/15/24)

Blood Assurance has received a grant from the Commonwealth Transfusion Foundation to advance their cellular therapy work. The grant will be used to, "add equipment to analyze the cells in these products and freeze them for preservation." Blood Assurance developed a cellular therapy division last year, according to the news release. Liz Culler, MD, chief executive officer (CEO) of Blood Assurance, stated in the news release, "[r]eceiving this grant from Commonwealth Transfusion Foundation is a milestone for us. This equipment will be used to prepare products for shipment to researchers, prepare treatments for patients and to train future laboratory cell therapy technicians." Robert Carden, PhD, president and CEO of the Commonwealth Transfusion Foundation added, "[t]he developments in cellular therapy are redefining what's possible in terms of patient care. We are thrilled to support research that will help create more personalized healthcare, which will ultimately improve patient outcomes and save lives."

(Source: Blood Assurance News Release, 4/15/24)

GLOBAL NEWS

The European Blood Alliance (EBA) is hosting a June 6th webinar titled, "Innovation in Medicine: Exploring the Potential of Human Platelet Lysate" from 1 p.m. CEST – 2:30 p.m. CEST (7 a.m. EDT – 8:30 a.m. EDT). Registration is limited to blood centers and open to America's Blood Centers (ABC) member blood centers (please reference that you are an ABC member when registering). The webinar, "will dive into the significant role that human platelet lysate plays in modern medical practices and research. [It will include] expert insights from leaders in the field, including Ólafur Eysteinn Sigurjónsson, Hendrik Feys, Katharina Schallmoser, Erja Kerkelä, and David Lundy. Topics will cover the standardization of human platelet lysate, regulatory considerations, good manufacturing practices for advanced therapy medicinal product (ATMP) manufacturing, and innovative treatments for hypoxic injuries."

(Source: EBA Announcement, 5/14/24)

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GLOBAL NEWS (continued from page 7)

The World Health Organization (WHO) has announced publication of new data that indicates an increase in sexually transmitted infections (STIs) worldwide. The data appears in the WHO report titled, "Implementing the global health sector strategies on HIV, viral hepatitis and sexually transmitted infections, 2022–2030." According to the agency, "[i]n 2022, WHO Member States set out an ambitious target of reducing the annual number of adult syphilis infections by ten-fold by 2030, from 7.1 million to 0.71 million. Yet, new syphilis cases among adults aged 15-49 years increased by over 1 million in 2022 reaching 8 million. The highest increases occurred in the Region for the Americas and the African Region. Combined with insufficient decline seen in the reduction of new HIV and viral hepatitis infections, the report flags threats to the attainment of the related targets of the Sustainable Development Goals (SDGs) by 2030…In 2022, around 1.2 million new hepatitis B cases and nearly 1 million new hepatitis C cases were recorded. The estimated number of deaths from viral hepatitis rose from 1.1 million in 2019 to 1.3 million in 2022 despite effective prevention, diagnosis, and treatment tools. New HIV infections only reduced from 1.5 million in 2020 to 1.3 million in 2022. Five key population groups — men who have sex with men, people who inject drugs, sex workers, transgender individuals, and individuals in prisons and other closed settings — still experience significantly higher HIV prevalence rates than the general population. An estimated 55 percent of new HIV infections occur among these populations and their partners. HIV-related deaths continue to be high. In 2022, there were 630 000 HIV related deaths, 13 percent of these occurring in children under the age of 15 years." Strategies recommended by the WHO to mitigate the increase in STIs include:

- "implement policy and financing dialogues to develop cross-cutting investment cases and national-level sustainability plans;
- further consolidate and align disease-specific guidance, plans, and implementation support within a primary health care approach;
- accelerate efforts to address ongoing criminalization, stigma, and discrimination within health settings, particularly against populations most affected by HIV, viral hepatitis, and STIs;
- expand multi-disease elimination approaches and packages, drawing from lessons learned from the triple elimination of mother-to-child transmission; and
- strengthen the focus on primary prevention, diagnosis, and treatment across the diseases to raise awareness especially for hepatitis and STIs."

(Source: WHO Report, 5/21/24)

The United Kingdom's (UK) "Infected Blood Inquiry" report has been published. The inquiry examined the crisis in the 1970s and 1980s that resulted in more 30,000 individuals being infected with HIV and hepatitis C from contaminated blood products. The report includes:

- [an] overview and recommendations;
- what happened and why; and
- the response of government and public bodies.

UK Prime Minister Rishi Sunak issued a statement apologizing to the victims and their families following the release of the report.

(Sources: UK Infected Blood Inquiry Report, 5/20/24; PM Rishi Sunak Statement, 5/20/24)

COMPANY NEWS

Blood Centers of America (BCA) and **Galapagos NV** have announced a partnership for, "decentralized manufacturing of Galapagos' CAR-T cell therapies through BCA's network [of blood centers] in the U.S." According to a news release describing the strategic collaboration, "Galapagos will leverage BCA's net

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COMPANY NEWS (continued from page 8)

work to initiate technology transfer to multiple sites in parallel for the decentralized manufacturing of its CAR-T product candidates, close to cancer treatment centers, while also accessing apheresis capacity at BCA sites when required. In addition, BCA will play a crucial coordinating role by supporting site initiation and onboarding to accelerate Galapagos' efforts and ensure consistent quality." BCA Board Chair Delisa English explained in the news release, "[w]e are very pleased to partner with Galapagos in expanding their nationwide CAR-T manufacturing network. Our decades of experience and advanced capabilities in regulatory compliant biologic processing across the U.S. will facilitate seamless technology transfer across multiple sites. We strongly believe that the combination of Galapagos' decentralized manufacturing platform and our national cell therapy manufacturing footprint will ultimately benefit patients by providing convenient access to our local facilities for apheresis and local healthcare providers within their communities."

(Source: Galapagos NV News Release, 5/15/24)

Valneva SE has reported additional data from a phase III trial of their single-shot chikungunya vaccine. In the latest findings, the company stated, "the most recent analysis [evaluated] the safety and immunogenicity six months (Day 180) after vaccination with a single dose of the vaccine. The Day 180 results confirm the initial positive immunogenicity and safety data Valneva reported previously, and are intended to support filing for potential label extension for use in adolescents aged 12 to 17 years. The data are also expected to support licensure of [the vaccine] (Ixchiq) in Brazil, which would be the first potential approval for use in endemic populations. [The] data [also] confirmed that a single-dose vaccination [induced] a high, sustained immune response with a seroresponse rate of 99.1 percent (232 out of 234 participants) at Day 180 compared to 98.8 percent (248 out of 251 participants) at Day 29 in an immunogenicity subset of individuals who were chikungunya virus negative at baseline. Geometric mean antibody titers (GMTs) consistently surpassed the seroresponse threshold defined with the U.S. Food and Drug Administration (FDA) as the surrogate of protection in baseline seronegative participants who received a single dose of [the vaccine]. Additionally, the Day 180 data confirmed that a single dose of the vaccine was generally safe and well tolerated in adolescents receiving [the vaccine], irrespective of previous infection with the chikungunya virus. Throughout the trial, an Independent Data Safety Monitoring Board (IDSMB) consistently assessed safety data and found no safety issues." Ixchiq is the first and only licensed chikungunya virus vaccine.

(Source: Valneva SE News Release, 5/13/24) ♦

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

May 29. **America's Blood Centers (ABC) Blood Advocacy Week Partners Briefing (Virtual).** More information and link to registration available to ABC members here.

May 29-30. **U.S. Food and Drug Administration (FDA) Regulatory Education for Industry (Redl) Annual Conference 2024: Innovation in Medical Product Development (Hybrid).** More information available here.

June 4. **U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) Office of Therapeutic Products (OTP) Town Hall: Chemistry, Manufacturing, and Controls (CMC) Readiness for Gene Therapy Biologics License Applications (BLAs) (Virtual).** More information available here.

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CALENDAR (continued from page 9)

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

June 13. **FDA Public Meeting: Optimizing FDA's Use of and Processes for Advisory Committees (Virtual).** Registration is open. More information available here.

June 18. **ABC Prehospital Blood Transfusion Programs Webinar.** More information and link to registration available to ABC members here.

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

Aug. 12-14. **National Institutes of Health (NIH) National Heart, Lung, and Blood Institute's (NHLBI) Annual Sickle Cell Disease Research Meeting. (Hybrid) Bethesda, Md.** More information available here.

Sept. 3-6. **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: Bring in the Coach — The Path to Effective Leadership (Virtual).** Registration is open. More information available here.

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

Mar. 10-12. **ABC Annual Meeting. Arlington, Va.** More information is coming soon.

May 6-8. **2025 ADRP Annual Conference. Oklahoma City, O.K.** More information is coming soon.

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

Director of Quality Assurance. Shepeard Community Blood Center in Augusta, Georgia, seeks an ambitious leader to promote product safety and compliance. A generous benefits package, including up to a 9 percent employer 401(k) contribution, relocation expenses, and ample PTO, are available for a successful candidate. Shepeard serves several communities in rapidly growing communities in Georgia and South Carolina. The ideal candidate will have at least six years of experience in blood banking, quality assurance, or compliance. Responsibilities include serving as the subject matter expert in regulatory compliance; working with operational leaders to help advance Shepeard's strategic plan; and overseeing the review and implementation of SOPs, validations, maintenance, reporting, and other related processes. The person selected for this role must see themselves as an integral member of the Shepeard leadership team and dedicated to furthering the organization's long-term goals. Those interested can apply at shepeard-blood.org.

Donor Services Operations Director (Our Blood Institute, Fort Smith, AR). This position will provide leadership and direction over all aspects of the Donor Services collection team for both mobile and fixed site operations. It is responsible for assessing, developing, and implementing strategic plans to achieve donor services objectives and goals. Create a friendly competitive environment to motivate staff to achieve high system wide standings on all key performance metrics (loss rates, errors, 2RBC conversion, Global Blood Fund, etc.). Conduct routine meetings to communicate organizational vision, updates, and changes and recognize outstanding staff performance keeping morale high. Maintain adequate staffing levels. Make frequent visits to both fixed and mobile collection sites. Actively participate in internal and external assessments/inspections including corrective action plans and effectiveness checks as needed. Track and monitor inventory and collection goals, which include whole blood, automation rates, and WB conversion data. Analyze data and make adjustments to increase productivity. This includes working closely with recruitment to ensure projections are met. Prepare and manage department annual budgets. Qualifications: Bachelor's degree in management or medical field. Minimum of five years' leadership/management experience, and valid driver's license. Salary: Competitive salary and excellent benefits package. How to apply: http://obi.org/careers/.

Operations Coordinator – Mobile Collections (Carter BloodCare). Principal Accountability: The Operations Coordinator-Mobile Collections position is crucial within the Collection Management team. Key responsibilities include ensuring daily production objectives and standards are met, maintaining high levels of compliance and customer service, and serving as the primary contact and acting manager in the manager's absence. Duties also involve hiring collection staff, conducting investigations, fostering employee development, and providing feedback on termination decisions. The role requires promoting team spirit within the department and collaborating with all CBC personnel to ensure maximum efficiency. Education: High School diploma or equivalent. College degree preferred. Bilingual skills are a plus. Special licensure such as CDL driver a plus. Experience: Two (2) years of supervisory/management experience. Background in a highly regulated field. Previous blood banking or apheresis experience required. Equal Opportunity Employer: Disability/Veteran. Apply at www.carterbloodcare.org, click Careers & search for job **Ops Coord Mobiles**.

Senior Vice President (SVP). Reporting to the Chief Operating Officer, the Senior Vice President (SVP) will function as the top executive leader of Enterprise Laboratory Services and will be responsible for overseeing the day-to-day operations, developing strategy, implementing business plans, managing the department's P&L (including revenue and operating margins), developing budgets and financial plans, and fostering a high-performance, customer-oriented culture. Education: BS/MS/PhD in Medical Technology or Applied Science, or MD with background in transfusion medicine, medical laboratory, or related specialty. An assorted business degree (MBA, MPA, MHA or equivalent) is highly desirable. Experience: Ten (10) years of blood banking or comprehensive laboratory experience, with five years at managerial level. Relevant published research in peer reviewed journals is highly desirable. For applicants who will perform this position in New York City or Westchester County, the proposed annual salary is $ 350,000.00 p/yr. to $375,000.00 p/yr. For applicants who will perform this position outside of New York City or Westchester County, salary will reflect local market rates and be commensurate with the applicant's skills, job-related knowledge, and experience. Please click here to apply.

Transfusion Lab Supervisor Needed! Join Florida's leading blood center, **OneBlood,** as a Blood Bank Lab Supervisor in Lakeland, FL. Bring your leadership, technical expertise, and management experience to support the transfusion testing procedures on patient and/or donor samples. Qualified candidates should possess three (3) or more years' experience in a clinical laboratory, preferably blood banking environment, including one (1) or more years' experience in supervision and management experience, as well as a valid and current Florida Clinical Laboratory Technologist license in Immunohematology or Blood Banking; Supervisor license strongly preferred. To apply and view a complete Job Description of this Lab Supervisor position, visit www.oneblood.org/careers. OneBlood, Inc. is an Equal Opportunity Employer/Vet/Disability.

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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. We collaborate closely with clinical colleagues in bone marrow and solid organ transplantation, CAR-T cell therapy, cardiac surgery, trauma and critical care, neurology, and pediatrics. Our faculty also work closely with transfusion medicine faculty within the MGB network. Service and teaching responsibilities will be shared with two full and several 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, GRJ148, Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02114-2696; or email to rmakar@mgh.harvard.edu. The Massachusetts General Hospital is an equal opportunity/affirmative action employer.

Director, Division of Cellular Therapies (Hoxworth Blood Center, University of Cincinnati). Hoxworth Blood Center (HBC) is seeking a Stem Cell Transplant/Cellular Therapies Medical Director and Processing Facility Director. This is an open rank/track, faculty position, with opportunities for collaborative clinical and basic research, and an active clinical trials program in stem cell transplantation and immunotherapies, supporting four different stem cell transplantation programs in Ohio. Candidates with expertise in transfusion medicine, hematology, hematopoietic biology and therapy, immunology and/or immunotherapies could use this opportunity to build a translational/clinical research program. HBC has established connections with world-class research departments that offer access to a wide variety of shared facilities. Minimum Requirements: Applicants must have an MD or DO to be considered as the processing facility director and processing facility medical director, and licensed or eligible for unrestricted license in the State of Ohio. Applicants must have a PhD to be considered solely as the processing facility director. Position and track will depend on academic accomplishments and programmatic expectations. At least two years' relevant experience in the preparation and clinical use of cellular therapy products is required. For full description and to apply, visit https://bit.ly/3woC42L. The University of Cincinnati is an Equal Opportunity Employer.

Associate Director – Process Excellence Design and Field Support. This position is charged with eliminating waste and standardizing operations to enable optimization of the collection staff and donor experience across Enterprise Divisions allowing for improved efficiency and productivity. The position will own and drive projects to completion, have the ability to build complex models for the validation of new procedures and technology that inform decision-making in donor and product management and support all other pillars of the Enterprise Collections Center of Excellence (ECCOE) in the identification of metrics for performance management. The position interacts with multiple verticals within the Enterprise Collections Center of Excellence departments and other departments within New York Blood Center Enterprise such as Information Technology, Laboratories, Quality/Regulatory Affairs, Recruitment, and Logistics. Candidates must be able to report into one of the following NYBCe locations: New York City, NY; Kansas City, Missouri; St. Paul, Minnesota; Providence, RI and Newark, DE. For applicants who will perform this position in New York City or Westchester County, the proposed annual salary is $130,000.00 to $140,000.00. For applicants who will perform this position outside of New York City or Westchester County, salary will reflect local market rates and be commensurate with the applicant's skills, job-related knowledge, and experience. Click here to view the full job description and apply.

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

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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.

Immunohematology Reference Laboratory Manager. LifeSouth Community Blood Centers is looking for a leader with a passion for making a difference to join our Immunohematology Reference Laboratory team in Atlanta, GA. This position is responsible for providing mentorship and leadership to laboratory staff. The IRL Manager is expected to provide onsite day-to-day supervision of testing personnel and reporting of test results under the direction of the Laboratory Director. This position is also responsible for performing laboratory procedures and reporting of test results, ensuring compliance with company policies and procedures, ensuring compliance with regulatory requirements from agencies such as CLIA, FDA, AABB, and HIPAA. 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!

Immunohematology Reference Lab Medical Technologist. LifeSouth Community Blood Centers is looking for an experienced Laboratory Medical Technologist, with a passion for making a difference, to join our Immunohematology Reference Laboratory team in Birmingham, AL. The position is responsible for following established policies and procedures, identifying problems that may adversely affect test performance or reporting of test results, and either correct the problems or immediately notify a supervisor, manager, or director. The IRL Medical Technologist will resolve complex immunohematology and compatibility problems to provide the safest donor blood for the patients in our community. We focus on providing the best possible customer service. 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!

Immunohematology Reference Lab Medical Technologist. LifeSouth Community Blood Centers is looking for an experienced Laboratory Medical Technologist, with a passion for making a difference, to join our Immunohematology Reference Laboratory team in Atlanta, GA. The position is responsible for following established policies and procedures, identifying problems that may adversely affect test performance or reporting of test results, and either correct the problems or immediately notify a supervisor, manager, or director. The IRL Medical Technologist will resolve complex immunohematology and compatibility problems to provide the safest donor blood for the patients in our community. We focus on providing the best possible customer service. 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!

Immunohematology Reference Lab Medical Technologist. LifeSouth Community Blood Centers is looking for an experienced Laboratory Medical Technologist, with a passion for making a difference, to join our Immunohematology Reference Laboratory team in Jacksonville, FL. The position is responsible for following established policies and procedures, identifying problems that may adversely affect test performance or reporting of test results, and either correct the problems or immediately notify a supervisor, manager, or director. The IRL Medical Technologist will resolve complex immunohematology and compatibility problems to provide the safest donor blood for the patients in our community. We focus on providing the best possible customer service. 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!

Director, Donor Marketing. The Director, Donor Marketing is a pivotal leadership role within New York Blood Center Enterprises (NYBCe), overseeing a team of seasoned marketing professionals tasked with driving donor engagement and donor acquisition across various Blood Operations divisions. Working closely with divisional Donor Recruitment and Collections teams to ensure alignment with overarching marketing strategies. As the senior-most authority in donor marketing, the Director, Donor Marketing operationalizes Enterprise Donor Engagement strategies at the local level, guiding and empowering divisional marketing managers to execute targeted initiatives that meet product and service objectives across all divisions. Reporting directly to the Executive Director, Strategy and Planning, Donor Engagement, this role carries significant responsibility in steering local marketing efforts in line with enterprise goals. Candidates must be able to report into one of the following NYBCe locations: New York City, NY; Providence, RI and Newark, DE. New York Location: For applicants who will perform this position in New York City or Westchester County, the proposed annual salary is $160,00.00 p/yr. to $170,00.00 p/yr. Rhode Island Location: For applicants reporting into Rhode Island, the proposed annual salary is $150,00.00 p/yr. to $160,00.00 p/yr. Click here to apply.

Donor Recruitment Manager. Blood Assurance is seeking a Donor Recruitment Manager to lead field recruitment efforts that build new and existing business in our Chattanooga and North Georgia region. Primary responsibilities include direct leadership of Account

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Managers in expanding blood drive activity on mobiles primarily, and in facilities as needed, based on growth strategy in a specific type of blood product recruitment and collection. Assist in developing long-term community business partnerships and coordinating internally with all leadership levels to support or expand Blood Assurance recruitment efforts. Work closely with Donor Services leadership to ensure recruitment and collection teams are working together toward meeting overall product collection goals. Qualified applicants will have: Bachelor's degree-preferably in business, marketing, or related field. Seven to 10 years sales experience, preferably in blood banking. Three to five years sales staff management. Advanced communication skills. Public presentation and networking skills. Advanced organizational, customer service and teamwork skills. We offer many benefits including: Health/Dental/Vision Insurance, Flexible Spending Account, Employee Assistance Program for you and your family, Paid Time Off, 401K, a Wellness Program, and Relocation Assistance. Qualified candidates are encouraged to submit an online application for consideration at www.bloodassurance.org. Blood Assurance is an Equal Opportunity Employer and a Tobacco-Free Environment.

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.