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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2024 #24 **July 26, 2024**

INSIDE:

CMS 2025 OPPS Proposed Rule Available

The Centers for Medicare & Medicaid Services (CMS) has published the, "Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center (ASC) Payment Systems" proposed rule for calendar year 2025. It contains a market basket increase of 2.6 percent.

Unlike inpatient care where blood is included in a bundled payment of services, CMS makes separate payments for blood and blood products in outpatient care. CMS is proposing to continue the methodology used since calendar year 2005 to set the rates for blood and blood products. Within the proposed OPPS rule, CMS seeks comments on several items of note to the blood community:

- payments for certain cell and gene therapies including, "a Chimeric Antigen Receptor (CAR) T-cell therapy administration C-APC, with which the CAR-T or gene therapy would be integral, ancillary, supportive, dependent, or adjunctive to the primary C-APC service;"
- a recommendation of service improvement requirements for OB emergencies. The proposed rule does not require blood specifically, though it is suggested;
- an emergency services Condition of Participation (CoP) to improve readiness for hospitals with Emergency Departments that would require blood and blood products commonly used in lifesaving procedures "be kept in the hospital and be readily available for treating emergency cases." It is noted that the requirement is flexible and does not require any specific items, but rather anticipates that each facility will determine what is needed based on their particular facility and patient population."

Comments on the proposed rule are due September 9th. America's Blood Centers (ABC) continues to review the proposed rule regarding its implications for community blood centers and will submit comments to CMS. Please contact ABC Vice President of Government Affairs Diane Calmus, JD with questions or feedback that you would like included in ABC's comments. ABC will continue to provide updates on its advocacy efforts.

(Source: CMS Proposed Rule, 7/22/24)

FDA Releases Blood Pressure and Pulse Donor Eligibility Requirements – Compliance Policy Guidance

On July 17th, the U.S. Food and Drug Administration (FDA) published the guidance titled, "Blood Pressure and Pulse Donor Eligibility Requirements – Compliance Policy." According to the agency, "the guidance addresses the regulatory requirements for determining donor eligibility that apply to establishments that collect blood and blood components (blood establishments) for transfusion or for further manufacturing use, including Source Plasma." FDA describes the circumstances in which, "[it] does not intend to take regulatory action for a blood establishment's failure to comply with certain regulations for determining the eligibility of blood donors with blood pressure or pulse measurements outside of the specified limits."

Blood Pressure. The guidance states that, for a donor with blood pressure measurements outside of the specified limits (90-180 mm Hg systolic or 50-100 mm Hg diastolic), FDA does not intend to take regulatory action with respect to the requirement in 21 CFR 630.10(f)(2) that the donor may be permitted to donate only when the responsible physician examines the donor. FDA intends to apply this compliance policy when the responsible physician conducts a telephonic or other offsite consultation (e.g., telemedicine), and determines and documents that the health of the donor would not be adversely affected by donating.

Pulse. For a donor with a pulse measurement below 50 bpm who self-reports being a healthy athlete, FDA does not intend to take regulatory action with respect to the requirement in 21 CFR 630.10(f)(4) that the donor may be permitted to donate only when the responsible physician determines and documents that the health of the donor would not be adversely affected by donating, and the requirements in 21 CFR 630.5(b)(1)(i)(B) and 21 CFR 630.5(c)(1)(i)(A)(2) that the responsible physician must not delegate this determination of the donor's health. FDA will apply this compliance policy, as long as the blood establishment maintains SOPs that:

- are approved by the responsible physician of the blood establishment; and
- allow for donation by a donor with a pulse measurement below 50 bpm who self-reports at each donation being a healthy athlete without consultation with the responsible physician.

For a donor with an irregular pulse, FDA does not intend to take regulatory action with respect to the requirement in 21 CFR 630.10(f)(4) that the donor may be permitted to donate only when the responsible physician determines and documents that the health of the donor would not be adversely affected by donating, and the requirements in 21 CFR 630.5(b)(1)(i)(B) and 21 CFR 630.5(c)(1)(i)(A)(2) that the responsible

(continued on page 3)

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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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FDA Blood Pressure and Pulse Donor Eligibility Requirements Guidance (continued from page 2)

physician must not delegate this determination of the donor's health, as long as the blood establishment maintains SOPs that:

- are approved by the responsible physician of the blood establishment; and
- define medical criteria for donation by a donor with an irregular pulse without consultation with the responsible physician.

Implementation. Blood establishments that intend to implement changes described in this guidance must report changes to their SOPs made to reflect the compliance policy in this guidance as Changes Being Effected (CBE) supplements under 21 CFR 601.12(c)(5) (see 21 CFR 601.12(a)(3). Please contact ABC Director of Regulatory Affairs and Public Policy Justine Coffey, JD, LLM with questions or comments.

(Source: FDA Guidance, 7/17/24)

REGULATORY NEWS

The U.S. Food and Drug Administration (FDA) has published a guidance titled, "Recommendations for Investigational and Licensed COVID-19 Convalescent Plasma." According the agency, the guidance provides, "FDA's recommendations to blood establishments for the submission of a Biologics License Application (BLA) for the manufacture of COVID-19 convalescent plasma for transfusion intended to treat patients with immunosuppressive disease or receiving immunosuppressive treatment in either the outpatient or inpatient setting. The guidance also provides FDA's recommendations for Investigational New Drug applications (INDs) for investigational COVID-19 convalescent plasma for transfusion." The agency explained in the guidance that, "[b]ased on current knowledge and available evidence supporting efficacy and safety of COVID-19 convalescent plasma in the treatment of COVID-19 in patients with immunosuppressive disease or receiving immunosuppressive treatment, FDA expects that blood establishments intending to manufacture and market COVID-19 convalescent plasma will submit a BLA for licensure. If FDA determines that there are adequate, available, approved alternatives to the COVID-19 convalescent plasma provided through emergency use (or if FDA determines that other criteria for issuance of the EUA are no longer satisfied), FDA may determine that it is appropriate to revoke the EUA. Absent an EUA, blood establishments must only manufacture and distribute COVID-19 convalescent plasma under an approved BLA or an IND in effect."

(Source: FDA Guidance, 7/21/24)

The U.S. Department of Health and Huiman Services (HHS) Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) will hold its next public meeting September 4th (9 a.m. – 4 p.m. EDT) and September 5th (9 a.m. – 1 p.m. EDT). During the meeting, the committee will, "discuss and vote on recommendations related to tissue biovigilance [and] also hear presentations and updates on recent committee work related to blood and organ safety," according to the notice published in the *Federal Register*. The public may participate in the meeting via a webcast [and] will [also], "have an opportunity to present their views to the ACBTSA by submitting a written public comment or providing a verbal public comment during the meeting. Comments should be pertinent to the meeting discussion. Persons who wish to provide written or verbal public comment should review instructions and respond by midnight August 27th EDT." Additional information including the agenda and presentations will be available on the ACBTSA website prior to the meeting.

(Source: *Federal Register* Notice, 7/16/24)

(continued on page 4)

REGULATORY NEWS (continued from page 3)

The FDA issued a July 23rd communication that provided an updated table of licensed donor screening tests for, "Testing Human Cells, Tissues, and Cellular and Tissue-Based Product (HCT/P) Donors for Relevant Communicable Disease Agents and Diseases." The document now includes updated licenses (STNs) for seven infectious disease marker tests:

- Elecsys HBsAg II and HBsAg II Auto Confirm;
- Elecsys Anti-HBc II;
- Elecsys Anti-HCV II;
- Elecsys HIV Duo;
- Elecsys HTLV-I/II;
- Elecsys Anti-CMV; [and]
- Elecsys Syphilis.

(Source: FDA Communication, 7/23/24)

RESEARCH IN BRIEF

Providers Perceptions of Bleeding in Acute Leukemia Patients. Authors of a study published in *Transfusion Medicine* explained that the, "objective was to identify, from the healthcare providers' (HCPs) perspective, the components of clinically significant bleed (CSB) in the acute leuk[e]mia (AL) population undergoing induction chemotherapy." The researchers noted that the study, "recruited physicians, nurse practitioners (NP), and registered nurses (RN) who provide care to AL patients in Canada." Participants in the study, "were asked open-ended questions about their perceptions and clinical knowledge of bleeding in AL patients…Nineteen HCPs, including 12 physicians, four NPs, and three RNs from eight hospital cent[ers] participated." The authors stated that, "[p]articipants based their assessment of whether a bleed was clinically significant on characteristics, which included the amount of blood loss, the duration and ability to gain control of the bleeding, the level of intervention required, the impact on vital signs, changes or persistently low h[e]moglobin and platelet counts, and the location of the bleed in areas that posed a risk to the individual's life...They stated [that] changes in vital signs, the use of interventions including specialist consultations, uncontrolled and prolonged bleeding, the amount of blood loss, overt bleeding and the potential damage to other organs were characteristics of significant bleeding." The researchers explained that, "[p]articipants had varying opinions on the characteristics and clinical significance of certain bleeds resulting in the creation of a 'could evolve into a clinically significant bleed' category. Some believed that bleeds, such as melena, petechiae, mucosal bleeding, epistaxis, moderate bruising and h[e]maturia, could potentially predispose individuals to CSB, while others felt that notwithstanding predisposition to more serious bleeding these bleeds sufficiently met the criteria for a CSB." They noted that,"[t]here was a consensus among participants that minor bruising, h[e]morrhoidal bleeding, cutaneous bleeding, such as superficial skin manifestations, subconjunctival bleeding, self-limited epistaxis or gingival bleeding that resolved on its own was not clinically significant… [HCPs] explained that predicting whether a bleed could escalate was closely linked to the assessment of the patient's condition and bleeding characteristics but was also influenced by a certain level of randomness or unpredictability. Some participants mentioned relying on their clinical intuition, formed from past knowledge and experience, as part of their prediction and assessment strategies." The authors stated that their, "analysis led to the creation of three categories to differentiate bleeds based on their clinical significance: those that were clinically significant, those that could evolve into a CSB and required vigilance and those that lacked clinical significance."

Citation: Taneja, S., Heddle, N.M., Hillis, C., *et al*. "Healthcare provider's perceptions of bleeding in patients with acute leukaemia undergoing induction chemotherapy: A qualitative study." *Transfusion Medicine*. 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.

ABC WELC Rise & Lead Workshop Registration Opens

Register today for the ABC Women's Executive Leadership Community's (WELC) Rise & Lead Workshop. This is event will take place November 6th-7th in San Antonio, Texas at the Hyatt Regency Hill Country Resort. The workshop will ignite meaningful conversations and cultivate diverse perspectives. This event goes beyond traditional conferences by encouraging dynamic conversations that spark connections and drive personal and professional growth. At the Rise & Lead Workshop, you will delve into topics that matter, participate in interactive networking sessions, and walk away with tangible, real-life strategies to become a more resilient leader in today's ever-evolving world. Elevate your leadership journey with us! A preliminary agenda is available. Book your room by October 9th to secure the group rate. Stay tuned for an email formally launching the ABC WELC Rise & Lead Workshop registration next week.

SMT Journal Club Webinar Set for August 16th

The next ABC Scientific, Medical, and Technical Journal Club Webinar will occur on August 16th at 12 p.m. EDT. The webinar will feature a review of the following articles:

- Traumatic subcutaneous emphysema following blood donation: A case report (*Transfusion*);
- Survey of policies at U.S. hospitals on the selection of RhD type of low-titer O whole blood for use in trauma resuscitation (*Transfusion*); and
- Clinical outcomes, blood utilization, and ethical considerations for pediatric patients in a bloodless medicine and surgery program (*Anesthesia & Analgesia*).

This webinar is eligible for 1.0 continuing medical education (CME) credit hour upon completion of the activity and evaluation. Additional information including the articles and a link to registration are available to ABC members here. Contact us with any questions.

ABC Economic Outlook Survey Report Available

The ABC Economic Outlook Survey results are in! ABC member blood centers that participated in the survey can access the results and have the ability to download final trend reports and create customized reports based on selected filters. This survey is a new resource that consolidated the previous 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. ABC member blood centers that were non-participants may purchase the report here. Please contact us with questions.

Rise & Lead
A WOMEN'S LEADERSHIP WORKSHOP

WORD IN WASHINGTON

The U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) Director Jeff Shuren MD, JD is retiring after close to 15 years leading CDRH, according to a report from the Regulatory Affairs Professionals Society (RAPS). "Michelle Tarver, deputy center director for transformation, will take on the role of CDRH acting director. During a CDRH all-hands meeting on July 23rd, Dr. Shuren announced his plan to retire from [the] FDA. On July 28th, he plans to transfer to the commissioner's office as center director emeritus to allow Ms. Tarver to take the reins and the center transition to a new permanent center director. Dr. Shuren told staff he had achieved several key goals over the years, which led him to consider leaving the agency in 2020. He noted that since he took the reins in 2009, new medical devices authorized in the U.S. increased five-fold, and between 50 and 70 percent of novel devices come to the U.S. or in parallel with other major markets. However, his plans were thwarted when the COVID-19 pandemic hit. 'I have been considering this decision for several months in order to think it through, plan it out, and finish some actions I needed to see to the end, such as issuing our final regulation on laboratory developed tests. Back in 2018 I thought we would achieve our vision by the end of 2020, or thereabouts, and that then would be a good time for me to depart. However, COVID-19 hit, and we had a job to do. As you well know because you were there with me, too, we cannot abandon our posts in a time of crisis. Today, the pandemic is in our rearview mirror, our Center is not only back on track, but I think better positioned and stronger than ever before, and our current vision has been achieved.'"

(Source: RAPS, "Shuren to leave FDA after 15 years as CDRH director," 7/23/24)

The FDA's Centers for Biologics Evaluation and Research (CBER) Office of Therapeutic Products (OTP) has published a notice in the *Federal Register* titled, "Cellular and Gene Therapies Interactive Site Tours Program for Regulatory Project Managers and Reviewers; Information Available to Industry." According to the agency, the program is, "intended to give CBER regulatory project managers and/or reviewers an opportunity to tour biotechnology manufacturing facilities developing cellular and gene therapy products, and to exchange regulatory experiences with their industry counterparts. With this program, CBER intends to enhance review efficiency and quality by providing CBER staff with a better understanding of the biotechnology manufacturing industry and its operations. The purpose of this notice is to invite companies developing cellular and gene therapy products interested in participating in this program to contact OTP for more information." The stated goals of the program are to provide:

- "firsthand exposure to industry's product development processes; and
- a venue for sharing information about project management best practices (but not product-specific information) with industry representatives."

(Source: *Federal Register* Notice, 7/15/24)

The Centers for Disease Control and Prevention (CDC) has published a Health Alert Network (HAN) Health Advisory regarding, "a critical shortage of Becton Dickinson (BD) BACTEC™ blood culture media bottles. This shortage has the potential to disrupt patient care by leading to delays in diagnosis, misdiagnosis, or other challenges in the clinical management of patients with certain infectious diseases. Healthcare providers, laboratory professionals, healthcare facility administrators, and state, tribal, local, and territorial health departments affected by this shortage should immediately begin to assess their situations and develop plans and options to mitigate the potential impact of the shortage on patient care."

(Source: CDC HAN Health Advisory, 7/23/24)

PEOPLE

Carter BloodCare (Bedford, Texas) has announced the retirement of **Merlyn Sayers, MBBCh, PHD** as president and chief executive officer (CEO). A blood center news release stated that Dr. Sayers has led the blood center for close to 30 years, joining the blood center in 1996. Under his leadership, the blood center has, "grown to become one of the largest blood centers in Texas, supporting transfusion-dependent patients in more than 200 north, central and east Texas hospitals and medical facilities."

Carter BloodCare has named **Barbara Bryant, MD, FCAP, FASCP** as CEO effective September 23rd. "Dr. Bryant previously served as chief medical officer (CMO) and executive vice president at Versiti. Her prior experience includes appointment as chief [of the] Department of Transfusion Medicine and Center for Cellular Engineering, at the National Institutes of Health. In addition, [She] has held faculty positions at the University of Texas Medical Branch at Galveston. [Dr. Bryant] is widely published and serves on a number of international, national, and regional committees involved in blood banking accreditation, teaching, research, and patient management."

(Source: Carter BloodCare News Release, 7/17/24)

Versiti, Inc. has announced "the promotion of **Matthew Anderson, MD, PhD** to executive vice president and CMO. According to the July 23rd news release, Dr Anderson is, "[c]urrently serving as Vice President and Medical Director of Versiti's Diagnostic Labs, Dr. Anderson will now lead the organization's Medical Sciences Institute (MSI), providing strategic leadership and guiding innovative research and clinical programs…He will assume his new role on July 29th ensuring a smooth transition and continued momentum of Versiti's life-saving mission. A native of California, Dr. Anderson graduated from the University of California (UC) San Diego. He pursued an MD/PhD at the Medical College of Wisconsin, conducting his PhD research at the Versiti Blood Research Institute. He completed programs in anatomic pathology and hematopathology at Stanford University, followed by fellowships in molecular pathology and histocompatibility. In 2011, Dr. Anderson joined the Stanford faculty as an assistant professor and assistant director of the Histocompatibility, Immunogenetics, and Disease Profiling Laboratory. Dr. Anderson returned to Versiti in 2013 as the medical director for the Wisconsin Diagnostic Laboratories. He was promoted to vice president in 2017, expanding his leadership to include Cenetron Diagnostics and Salus IRB." Versiti President and CEO Chris Miskel, MBA added in the news release, "[w]e are thrilled to promote Matt into this role. His career trajectory, starting at our Versiti Blood Research Institute, highlights our commitment to intentional leadership succession and development. Matt's diverse experience, reputation in the industry, and collaborative approach to leading teams and enhancing patient care make him an ideal fit to further Versiti's mission." Dr. Anderson stated in the news release, "[a]s blood health innovators, we are passionate about advancing scientific knowledge and clinical practice in transfusion medicine, hematology, and transplantation, I am excited to have the opportunity to lead our medical science teams in creating new innovative solutions for patient care."

(Source: Versiti, Inc. News Release, 7/23/24)

MEMBER NEWS

Gulf Coast Regional Blood Center (Houston, Texas) has joined the National Blood Collaborative (NBC) becoming the organization's 9th member. "We are excited to welcome the Gulf Coast Regional Blood Center into our group of affiliated blood centers from across the nation," explained Doug Morton, chair of the NBC Board of Directors and chief executive officer (CEO) of San Diego Blood Bank, in the NBC news release. "We look forward to working closely with their leadership on our strategic objective to create groundbreaking initiatives and innovations to support hospitals and local communities." According to the news release, NBC is, "a national network of leading blood centers working together to respond to the increasing economic demands of hospitals and healthcare systems. The organization delivers blood management services through local and not-for-profit, community-based centers. It [is comprised of blood centers] that collect, process, and distribute more than one million blood components every year, serving hospital customers in 36 states." Nikhil Nayak, MBA, president and CEO of Gulf Coast Regional Blood Center, added in the news release, "membership in this organization aligns us with like-minded leaders. Together, we can work towards solving some of today's most difficult challenges as blood operators and embrace innovation and the future of our industry." Other members of NBC include:

- **Kentucky Blood Center** (Lexington, Ky.);
- **LifeServe Blood Center** (Johnston, Iowa);
- **LifeSouth Community Blood Centers** (Gainesville, Fla.);
- **ImpactLife** (Davenport, Iowa);
- **Rock River Valley Blood Center** (Rockford, Ill.);
- **San Diego Blood Bank** (San Diego, Calif.);
- **Stanford Blood Center** (Palo Alto, Calif.); and
- **The Blood Center** (New Orleans, La.).

(Source: NBC News Release, 7/11/24)

New York Blood Center (New York, N.Y.) (NYBC) recently unveiled, "new-state-of-the-art 'Blood Donation Pods,'" according to a report from *Patch*. The news organization reported that, "[t]he portable and sustainable Pods are designed to provide a more comfortable, efficient, and convenient donation experience…The Blood Donation Pods are portable donor centers equipped with donor beds, a climate-controlled environment, and entertainment options, including access to streaming services and music…Given the limited number of donor centers, only 19 in the region, the NYBC said the portable Pods will serve as convenient, mobile donor centers, making it easier for communities far from established centers to participate. Municipalities and organizations can host a Pod in their communities from a few days to multiple weeks, providing flexible access to blood donation." NYBC's Andrea Cefarelli explained to *Patch*, "[a]s we celebrate 60 years of lifesaving innovation, we're thrilled to introduce this new and innovative portable donor center and improved donor experience to blood donors in New York. Our goal is to make blood donation as comfortable and convenient as possible, and we believe these Pods will help us attract new blood donors and ultimately save more lives."

Photo courtesy of Patch.

(Source: *Patch*, "NY Blood Center unveils new high-tech portable blood donation pods," 7/24/24)

GLOBAL NEWS

NHS Blood and Transplant (NHSBT), the national blood provider for England and transplant services for the United Kingdom (UK), are partnering with Marvel Studios to promote blood donation as part of this week's release of the film *Deadpool & Wolverine*. Co-stars of the movie Ryan Reynolds and Hugh Jackman encouraged individuals to schedule an appointment to give blood in a video as part of the campaign. Mark Chambers, director of Donor Experience for NHSBT added in a news release, "[w]e are delighted to team up with Marvel Studios' Deadpool & Wolverine and have the incredible support of Ryan Reynolds and Hugh Jackman to highlight the lifesaving power of blood donation. Deadpool saves the day, but blood donors save lives. We hope film fans will be inspired to become a hero in their own story by giving blood. Right now, the NHS needs more young people to become the donors of the future. And we urgently need more donors of Black heritage to help patients who need ethnically matched blood. Giving blood is quick and easy and each donation saves up to three lives. Please register today and book an appointment to donate. After all, not all heroes wear capes and saving lives is more impressive than any superpower out there." This collaboration is, "NHSBT's fourth blood donation film partnership with Disney [including] Free Guy in 2021, Doctor Strange in the Multiverse of Madness, and Black Panther: Wakanda Forever in 2022."

(Source: NHSBT News Release, 7/15/24)

The European Commission (EC) announced the publication of, "the new Regulation on standards of quality and safety for substances of human origin intended for human application," in the Official Journal of the European Union (EU) on July 17th. Earlier this year, the EC announced that the European Parliament had adopted, "new rules to increase the safety and quality of substances of human origin (SoHO)." The regulation explains that, "[t]he use of financial incentives for SoHO donations can have an impact on the quality and safety of SoHO, posing risks to the health of both SoHO donors and recipients and therefore to the protection of human health. Without affecting the responsibilities of the Member States for the definition of their health policy, and for the organization and delivery of health services and medical care, SoHO donation should be voluntary and unpaid, and be founded on the principles of altruism of the SoHO donor and solidarity between donor and recipient." However the regulation does allow for compensation that fits the definition of financial neutrality, "compensation to remove any such risk is deemed appropriate as long as it endeavors to guarantee financial neutrality and does not result in a financial gain for the SoHO donor or constitute an incentive that would cause a SoHO donor to not disclose relevant aspects of their medical or behavioral history or to donate in any way that could pose risks to their own health and to that of prospective recipients, in particular by donating more frequently than is allowed. It should be possible for compensation to consist of the reimbursement of expenses incurred in connection with SoHO donation or of making good of any losses, preferably based on quantifiable criteria, associated with the donation of SoHO. Whatever the form of compensation, including through financial and nonfinancial means, compensation schemes should not result in competition between SoHO entities for SoHO donors, including cross-border competition and in particular between SoHO entities collecting SoHO for different purposes, such as the manufacture of medicinal products versus human application as a SoHO preparation. The setting of an upper limit for compensation at national level and the application of compensation that is financially neutral for the SoHO donor have the effect of removing any incentive for SoHO donors to donate to one SoHO entity rather than another, significantly mitigating the risk that compensation differences might result in competition between SoHO entities, in particular between public and private sectors."

(Source: *Official Journal of the EU* SoHO Regulation, 7/17/24)

(continued on page 10)

GLOBAL NEWS (continued from page 9)

The UK has published data from its annual Serious Hazards of Transfusion (SHOT) Report. The SHOT Report is the annual United Kingdom (UK) hemovigilance report that describes transfusion-related adverse events across the UK. Key takeaways from the available data include:

- "errors (including near miss) continue to account for the vast majority of reports. In 2023, 3,184/3,833 (83.1 percent) of all reports were due to errors with a substantial increase (24.1 percent) in laboratory errors where the error was not detected prior to transfusion (transfused errors);
- a steep increase in the transfused laboratory errors in the IBCT-WCT (65.1 percent) and IBCT-SRNM (43.1 percent) categories in comparison to 2022 is concerning and warrants urgent action. Staffing issues, gaps in staff knowledge, poor skill mix, lone working, ineffective information technology (IT), communication issues and poor safety culture have been reported as contributory factors in these incidents;
- near miss events continue to account for a large proportion, 1,420/3,833 (37.0 percent) of the incidents reported to SHOT;
- an increase in the febrile allergic, and hypotensive reactions was noted as compared to previous years. No changes were evident in the number of h[e]molytic reactions reported to SHOT. All staff involved in transfusions must be competent and confident in recogni[z]ing and appropriately managing transfusion reactions in recipients;
- transfusion delays and pulmonary complications (transfusion-associated circulatory overload (TACO) and non-TACO) continue to be the leading causes of transfusion-related deaths in the UK. These two categories together accounted for 29/38 deaths reported (76.3 percent);
- the risk of death related to transfusion in the UK is approximately 1 in 58,000 components issued and the risk of serious harm is approximately 1 in 11,000 components issued. This includes solvent-detergent fresh frozen plasma (SD-FFP) data; [and]
- ABO-incompatible red cell transfusions continue to occur as a result of suboptimal safety checks throughout the process. Using a patient side pre-administration checklist correctly can prevent incorrect transfusions in most cases."

Previous SHOT Reports can be accessed here. "Since 1996 SHOT has been collecting and analy[z]ing anonymi[z]ed information on adverse events and reactions in blood transfusion from all healthcare organi[z]ations that are involved in the transfusion of blood and blood components in the UK. Where risks and problems are identified, SHOT produces recommendations to improve patient safety. The recommendations are put into its annual report which is then circulated widely and to all of the reporting hospitals. As h[e]movigilance is an ongoing exercise, SHOT can also monitor the effect of the implementation of its recommendations."

(Source: UK 2023 SHOT Report, 7/9/24) ♦

COMPANY NEWS

Moderna, Inc. has been awarded $176 million to assist with accelerated development of m-RNA-based vaccines for pandemic influenza. According to a company news release, the funding from the Rapid Response Partnership Vehicle (RRPV), "a Consortium funded by the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS). [Specifically, the] project award will support late-stage development for an mRNA-based vaccine to enable the licensure of a pre-pandemic vaccine against H5 influenza virus. This subtype of influenza virus causes a highly infectious, severe disease in birds called avian influenza and poses a risk for spillover into the human population. The agreement also includes additional options to prepare and accelerate a response to future public health threats." Last

(continued on page 11)

COMPANY NEWS (continued from page 10)

year, Moderna began a phase I/II study, "to generate safety and immunogenicity data of investigational pandemic influenza vaccine (mRNA-1018) in healthy adults 18 years of age and older. The study includes vaccine candidates against H5 and H7 avian influenza viruses. Results from the study are expected in 2024 and will inform Phase III development plans."

(Source: Moderna, Inc. News Release, 7/2/24)

60 Degrees Pharmaceuticals, Inc. recently announced that three clinical trials have been chosen for, "world's first randomized, double-blind, placebo-controlled clinical trial evaluating the efficacy and safety of tafenoquine, [malaria prophylaxis], in treating human babesiosis patients." According to the company, the trial comes in the wake of a study published in May 2024 in *Clinical Infectious Diseases* that, "suggested that tafenoquine combined with standard-of-care treatment exhibits a high cure rate in immunosuppressed patients who have relapsing babesiosis and for whom prior treatment has failed." The clinical trial aims to enroll, "[a]t least 24, and potentially up to 33, hospitalized patients diagnosed with relapsing babesiosis [with] interim results anticipated by September 2025." Last month, the company's investigational tafenoquine candidate [received the] orphan drug designation for the treatment of patients with acute babesiosis [from the U.S. Food and Drug Administration.]

(Source: 60 Degrees Pharmaceuticals, Inc. News Release, 7/19/24)

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

July 28-Aug. 1. **National Alliance of Sickle Cell Centers Annual Meeting and Consensus Conference. Minneapolis, Minn.** 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.

Aug. 16. **America's Blood Centers (ABC) Scientific, Medical, and Technical (SMT) Journal Club Webinar.** More information and a link to registration available here.

Aug. 21. **ADRP Webinar — Riding the Wave: Political Partnerships and State Legislation.** Registration is open. More information available here.

Aug. 29. **ADRP Webinar Sponsored by Terumo Blood and Cell Technologies — Empowering Lifesavers: Innovations in Blood Donor Recruitment and Retention.** More information coming soon.

Sept. 3-6. **American Society for Clinical Pathology (ASCP) Annual Meeting. Chicago, Ill.** Registration is open. More information is available here.

Sept. 5. **U.S Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (CBER) Office of Therapeutic Products (OTP) Town Hall: Cell Therapy Chemistry, Manufacturing, and Controls (CMC) Readiness for Late-Stage Investigational New Drug Applications (INDs) (Virtual).** Registration is open. More information is available here.

(continued on page 12)

CALENDAR (continued from page 11)

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 26. **ABC Women's Executive Leadership Community (WELC) Webinar.** More information coming soon.

Sept. 30-Oct. 3. **American Association of Tissue Banks (AATB) Annual Meeting. Denver, Colo.** Registration is open. More information available here.

Oct. 16-17. **Biomedical Excellence for Safer Transfusion (BEST) Fall Meeting. Galveston, Texas.** More information available here.

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

Nov. 6-7. **ABC Women's Executive Leadership Community (WELC) Workshop. San Antonio, Texas.** Registration is open. More information is available here.

Nov 19-20. **Plasma Protein Forum. Washington, D.C.** More information available here.

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

IRL Supervisor. Bloodworks Northwest, a recognized leader in transfusion medicine, currently has an opening for an IRL Supervisor in the Immunohematology Reference Laboratory. Key responsibilities include supervising departmental staff, ensuring the management of departmental projects, and participating in interdepartmental projects according to established priorities and timelines. Coordinating quality review and management of errors. Providing technical expertise in IRL testing and the development and implementation of new methods and as needed and perform clinical laboratory testing. Requirements include: Must qualify as General Supervisor, High Complexity Testing, under CLIA personnel requirements found in Subpart M of the Code of Federal Regulations. Certification as a Specialist in Blood Banking (SBB) is required. Certification as a Medical Laboratory Scientist (MLS) is preferred. Five years of laboratory technical experience with at two years of experience in immunohematology reference testing is required or an equivalent combination of education and experience. Three years of laboratory supervisor or Lead experience is preferred. Demonstrated expertise in immunohematology reference testing. Basic knowledge of molecular techniques is preferred. We offer competitive benefits: Medical, dental, vision, life insurance, retirement plan, subsidized back-up childcare program, subsidized transit program, educational reimbursement and more! Interested candidates should apply directly on our website at www.bloodworksnw.org/careers

(continued on page 13)

POSITIONS (continued from page 12)

Manager, Blood Services. ARUP Laboratories is looking for a result driven Manager to lead our Donor Centers. ARUP is a national nonprofit and academic reference laboratory at the forefront of diagnostic medicine. We are a CAP, ISO 15189, and CLIA-certified diagnostic lab with 40 years of experience supporting clients through unparalleled quality and service. This is a unique manager opportunity that will provide leadership and direction over all aspects of recruitment, mobile and in-center whole blood and platelet collections and component processing and distribution. This position will drive strategic planning, navigate challenges, and lead an already strong leadership team to achieve goals and objectives. Meeting the future growth needs of our health system will be a driving force for this position. Incumbent should have strong leadership skills, be experienced in a blood center, and demonstrate a passion for commitment to organizational goals. In addition, incumbent will formulate strategic goals, develop, and manage budgets, and effectively coach and manage their teams to success. We offer exceptional benefits, competitive pay, and beautiful facilities to work in. Prospective candidates may be eligible for applicable relocation assistance. Interested candidates can apply at www.aruplab.com/careers

Executive Director. The National Blood Collaborative (NBC) is seeking an experienced and dynamic Executive Director to lead our organization. This role reports directly to the Board of Directors. NBC, established in 2012, is a unique collaboration owned by nine independent blood centers, focusing on innovation in the blood and biotherapies industry. Visit www.nationalbloodcollaborative.org for more info. As the Executive Director, you will be responsible for the strategic direction and operational leadership of NBC. This role requires a self-directed individual capable of developing operational plans and implementing sales strategies, marketing communications, and public relations functions with minimal direction from the Board of Directors. Join us and lead NBC to new heights in the blood products and cellular therapies industry! Email your resume to dmorton@nationalbloodcollaborative.org with your salary requirements. Resumes are confidential. NBC is an EOE/AAE.

Marketing Executive. LifeSouth Community Blood Centers is looking for a highly skilled leader with a solid understanding of marketing principles and techniques, a data-driven approach, and a passion for innovation, to join the team as Marketing Executive in Gainesville, FL. This position is responsible for the overall marketing strategy across the organization. This position requires active communication with executive leadership and department directors within the organization to ensure adequate planning and execution of strategic marketing plans. This position is dedicated to advancing the organization's objectives in blood donation, cord blood services, cellular therapy, new business development, and meeting patient needs. 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!

Laboratory Education Coordinator. LifeSouth Community Blood Centers is looking for a team-oriented, goal-driven individual with a passion for education to join the team as a Laboratory Education Coordinator in Gainesville, FL. This position is responsible for the overall execution and development of LifeSouth's Blood Banking and Transfusion Medical education programs. Additional responsibilities include assisting with the training of laboratory employees, assessing competencies, and maintaining training materials. 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!

Supervisor, Immunohematology Reference Lab (San Diego Blood Bank). The San Diego Blood Bank is currently seeking a motivated, knowledgeable professional to lead the Immunohematology Reference Lab. This person will oversee the daily operation of the department as well as support the greater Lab Management Team following safety, cGMP, and Quality Plan. Additionally, the ideal candidate will supervise the flow of samples, blood, and blood components through the department from satellite centers, mobile collection vehicles, hospitals, blood banks, and laboratories. **Qualifications** include a minimum of 2 years in blood bank related fields to include leadership experience and IRL experience. **Certification/Licensure** required include MLS(ASCP)CM/MT(ASCP) or equivalent experience and a California Clinical Laboratory Scientist License (CLS). Certification as a Specialist in Blood Bank (SBB) or equivalent is preferred. For a full description of this job posting and to apply, visit: Careers | San Diego Blood Bank (recruitingbypaycor.com)

Immunohematology Reference Laboratory CLS (San Diego Blood Bank). Under the direction of the department leadership, the Medical Laboratory Scientist I will assist the Immunohematology Reference Laboratory in daily operations according to cGMP compliant policies and Standard Operating Procedures implemented by the San Diego Blood Bank (SDBB). The ideal candidate will successfully complete/pass an initial training program resulting in the ability to provide guidance and expertise for the laboratory to meet the needs of SDBB customers, in accordance with accepted standards and regulations. Requirements: Bachelor's degree, MLS/MT (ASCP)CM or equivalent experience, Clinical Laboratory Scientist (CLS). Certification as a Specialist in Blood Banking (SBB) preferred. For a full description of this job posting

(continued on page 14)

POSITIONS (continued from page 13)

and to apply, visit: Careers | San Diego Blood Bank (recruitingbypaycor.com)

Immunohematology Reference Laboratory Manager (Oklahoma City, OK). The Our Blood Institute, a large, successful blood center servicing Oklahoma, Arkansas, Texas and beyond, seeks qualified candidates for the position of **Immunohematology Reference Laboratory Manager**. Successful applicants must have a Bachelor of Science degree with a MT/MLS training program, ASCP or equivalent. The position will manage the AABB accredited Immunohematology Reference Laboratory and ensure compliance with all regulatory requirements. Be the on-site Immunohematology subject matter expert and provide consultation services for resolution of complex serological problems. Manage the IRL team of laboratory technologists, laboratory technicians, and lab associates, to include hiring, scheduling, training and competency, disciplinary actions, and performance evaluations. Manage the OBI rare donor red cell unit inventory and ensure appropriate use of the rare donor inventory. Manage processes within the Ref Lab to prevent errors and increase efficiency. Salary Range: Competitive salary with excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, and holiday pay. How to apply: https://obi.org/about/careers/.

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 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. This individual 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 of Operations. Rock River Valley Blood Center, based in Rockford IL, is seeking a Director of Operations. Lead daily operations in recruitment, collections, and special services, ensuring organizational objectives are met, including collection and recruitment targets. Implement strategies for a balanced inventory aligned with organizational and hospital needs. Additionally, this position will oversee all aspects of Special Services, including cell therapy and therapeutic phlebotomy programs. This role requires strong leadership, operational expertise, and a commitment to quality and compliance. Qualifications include: bachelor's degree in business administration or related field, seven plus years progressive management experience, proven track record of meeting production goals, and management experience in blood center operations or non-profit preferred. Please visit our careers site online to apply https://www.rrvbc.org/careers/.

Massachusetts General Hospital
Founding Member, Mass General Brigham

Assistant/Associate Director, Blood Transfusion Service (Massachusetts General Hospital; Boston, Massachusetts). The Department of Pathology at the Massachusetts General Hospital (MGH), a founding hospital of Mass General Brigham, and a major teaching affiliate of the Harvard Medical School, 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. The Blood Transfusion Service at MGH 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 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 pediatric). Academic rank as Associate Professor, Assistant Professor or Instructor and salary will be commensurate with experience

(continued on page 15)

POSITIONS (continued from page 14)

and accomplishments. Interested candidates should send a personal statement with research interest, three potential referees and Curriculum Vitae to: Dr. Robert Makar; Director, Blood Transfusion Service; Department of Pathology; Massachusetts General Hospital; 55 Fruit Street, GRJ 148; Boston, MA 02114. Email: rmakar@mgh.harvard.edu C/O Diane Savickas dsavickas@mgb.org. We are an equal opportunity employer, and all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, disability status, protected veteran status, gender identity, sexual orientation, pregnancy and pregnancy-related conditions or any other characteristic protected by law.

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