

# A B C N E W S L E T T E R CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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#### 2025 #14

#### April 21, 2025

#### **CMS Releases Proposed Rule for Hospital IPPS**

The Centers for Medicare & Medicaid Services (CMS) has <u>released</u> the fiscal year (FY) 2026 <u>proposed rule</u> for Hospital Inpatient Prospective Payment Systems (IPPS). The proposed rule includes a 2.4 percent payment rate increase for hospitals over FY 2025. Each year, CMS must reassess the payment rate to reflect hospital reporting of the price of goods and services used to treat all Medicare patients (known as the market basket).

The proposed rule started a discussion noting, "Octapharma USA, Inc. submitted an application for new technology add-on payments for FIBRYGA® for FY 2026. According to the applicant, FIBRYGA® is a concentrated form of human fibrinogen, indicated for fibrinogen supplementation in bleeding patients with acquired fibrinogen deficiency and the treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia." The discussion compares FIBRYGA with INTERCEPT Fibrinogen Complex.

In the hospice payment rule, CMS did not address the potential implementation of a separate payment mechanism to account for high intensity palliative care services, including blood transfusions. The agency has previously expressed interest regarding this issue and it remains a priority of the <u>2025 ABC Advocacy Agenda</u>. The <u>published version</u> of the proposed rule will be available in the *Federal Register* on April 30<sup>th</sup>. CMS is accepting comments on the proposed rule until June 10<sup>th</sup>.

Member blood centers are encouraged to provide any feedback, comments, or questions to ABC Vice President of Government Affairs <u>Diane Calmus</u>, JD. ABC will continue to provide updates on its advocacy efforts as they become available.

(Source: CMS IPPS <u>Proposed Rule</u>, 4/11/25)

#### A Personal View Published in The Lancet Planetary Health on the Impact of Climate Change on the Global Blood Supply Garners National Media Attention

Authors of a *Personal View* <u>published</u> in *The Lancet Planetary Health* examines the, "effect of climate change on blood supply chains" in hopes of developing, "resilient strategies to ensure the continuous availability of safe blood, even among climatic disruptions." The paper received media coverage in the publications such as the <u>New York Times</u>. As part of their methodology, the authors, "defined the different aspects of health and wellbeing that can be directly and indirectly associated

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## Impact of Climate Change on the Global Blood Supply Garners National Media Attention (continued from page 1)

with blood safety [and] defined the various stages of the blood supply chain potentially affected by climate change." Additionally, they noted the potential for, "[c]limate change [to] trigger various risks, particularly concerning infectious diseases, and [the expectation for it] to further increase the transmission of vectorborne diseases in both existing and new regions." The authors expressed that, "integrating pathogen inactivation alongside other mitigation strategies will be crucial in maintaining a resilient and adaptive blood supply system, [while acknowledging the potential for] climate change-induced health impacts, including increased chronic conditions, mental health challenges, and displacement, [to] strain health-care systems, leading to reduced donor participation, challenges in maintaining a stable blood supply, and increased demand for medical resources."

The paper also highlighted the potential role that climate change could play in future extreme weather events causing transportation and logistical disruptions to the global blood supply chain, stating that, "[d]istribution to recipients might face additional hurdles from supply chain disruptions and increased workloads, requiring efficient emergency protocols to prioriti[z]e crucial needs." They hypothesized that, "the rising burden of climate-sensitive health conditions, such as cardiovascular diseases, respiratory disorders, and trauma-related injuries from extreme weather events, is expected to increase transfusion demand. This convergence of factors highlights the need for adaptive, integrated strategies that not only reinforce the resilience of the blood supply chain, but also proactively address the cascading effects of climate change on both donors and recipients."

Their recommendations to build a resilient global blood supply include, "[p]reparedness in blood collection must [account for risks by maintaining] flexible and adaptive emergency plans. [Additionally, robust] modeling and forecasting are crucial for navigating the complexities of climate change and [prioritization of] serosurveillance." They concluded by stressing the need for, "dynamic and region-specific approaches to disease surveillance and risk mitigation that supports a reliable blood supply chain [and noting that] further studies are essential to fully understand the magnitude of these potential effects and develop targeted mitigation strategies.

**Citation**: Viennet, E., Dean, M.M., Kircher, J., *et al.* "<u>Blood under pressure: how climate change threatens</u> blood safety and supply chains." *The Lancet Planetary Health*. 2025

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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. America's Blood Centers Chief Executive Officer: Kate Fry Chief Medical Officer: Jed Gorlin Editor: Mack Benton Subscriptions Manager: Leslie Maundy Annual Subscription Rate: \$420

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#### PEOPLE



Vitalant has <u>announced</u> the expansion of the role of **Rob Van Tuyle**, chief operating officer (COO), to now include president of the organization. Mr. Van Tuyle, past president of the America's Blood Center Board of Directors, will now be, "responsible for stewarding and deploying Vitalant's organizational strategy to fulfill its lifesaving mission [overseeing] all aspects of Vitalant's operations, including blood services, biotherapies, laboratory and clinical services, information technology, supply chain, and marketing and sales," according to a Vitalant announcement. David R. Green, chief executive officer (CEO) of Vitalant, added, "Rob's strategic vision, operational expertise, and unwavering dedication to our mission are invaluable to Vitalant. This promotion

recognizes his significant contributions and reflects our confidence in his ability to lead our operational teams and drive continued growth and impact across the communities we serve. Mr. Van Tuyle stated in the announcement, "I am honored and excited to take on this new role at Vitalant. I am deeply passionate about our mission and the vital role we play in healthcare. I look forward to working closely with our dedicated teams across the country to further enhance our operations, strengthen our partnerships, and ultimately save and improve more lives."

(Source: Vitalant <u>Announcement</u>, 4/14/25)

**Patrick Daly** has been <u>named</u> chief business officer of Terumo Blood and Cell Technologies (Terumo BCT). A news release noted that he has more than, "30 years of business and healthcare industry experience, both domestically and internationally. Most recently, he built the medical technology global data franchise at IQVIA, a provider of technology solutions to the life sciences industry. Mr. Daly has spent his career building commercial capabilities to deliver organic and inorganic growth. Before joining IQVIA, he was president and CEO of Cohera Medical, and he remains an independent Board Director for BioStem Technologies. He has held successive senior leadership roles in strategic marketing, sales, and business development across various



regions and businesses of Johnson & Johnson. [Mr. Daly] earned his B.S. in Foreign Area Studies from the U.S. Military Academy at West Point." Terumo BCT President and CEO Antoinette Gawin added, "Patrick's experience acquiring capital and building strategic partnerships complements his experience monetizing data and solutions. This uniquely positions him to integrate our offerings and drive innovation across our business models and go-to-market strategies. His diverse experience will help accelerate our ambitions for double-digit growth."

(Source: Terumo BCT <u>News Release</u>, 4/16/25)

#### **STATE ADVOCACY BRIEFS**

The Washington State Legislature has passed <u>Senate Bill (SB) 5641</u> "AN ACT Relating to public school instruction in awareness of blood donation; amending RCW 28A.210.430; and creating a new section." The legislation integrates, "blood donation awareness into existing [curriculum for students to] gain knowledge about the life-saving impact of blood donation, eligibility requirements, and opportunities to participate in donation programs. The legislature intends for this instruction to complement existing health education requirements and increase opportunities for students to engage in civic and community health initiatives." America's Blood Centers (ABC) member Bloodworks Northwest has been advocating and actively working with state legislators to get this legislation passed. The bill is awaiting the governor's signature into law.

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#### STATE ADVOCACY BRIEFS (continued from page 3)

The Washington State Legislature has also passed <u>SB5689</u>, "An Act Relating to Adding Blood Type Information to Drivers' Licenses and Identification Cards." The bill provides," individuals the option to voluntarily include their blood type on their state-issued identification documents." Bloodworks Northwest has been advocating for this bill and testified at a February 20<sup>th</sup> hearing which also included testimony from ABC's Vice President of Government Affairs Diane Calmus, JD, "in strong support of SB 5689 [explaining that] adding blood type to Washington driver's licenses is a simple, low-cost, life-saving measure." The bill is awaiting the governor's signature into law as well. ♦

#### WORD IN WASHINGTON

U.S. Food and Drug Administration (FDA) Commissioner Martin A. Makary, MD, MPH has announced a new policy directive regarding individuals serving on FDA advisory committees. According to the agency news release, the policy directive, "limits individuals employed at companies regulated by the (FDA), such as pharmaceutical companies, from serving as official members on FDA advisory committees, where statutorily allowed. As part of this effort, the agency will prioritize and elevate the role of patients and caregivers, strengthening the voices of their communities. [Additionally,] the directive will not preclude employees of regulated companies from attending or presenting their views at advisory committee meetings or serving as representative members of the committee when required by statute. Also, exceptions can be made in rare circumstances (i.e., when the scientific expertise in an area is only available from an employee of an FDA-regulated company) provided that the official strictly complies with the applicable ethics requirements. By limiting employees of FDA-regulated companies from serving as officials, the FDA aims to boost public trust in its decisions and improve how its advisory committees operate." FDA Commissioner Makary added, "[w]hile FDA should be partnering with industry to ensure a user-friendly review process, the scientific evaluation of new products should be independent. Industry employees are welcome to attend FDA advisory committee meetings, along with the rest of the American public, but having industry employees serve as official members of FDA advisory committee members represents a cozy relationship that is concerning to many Americans. In fact, the FDA has a history of being influenced unduly by corporate interests. Public trust in the healthcare-industrial complex is at an all-time low. We need to restore impeccable integrity to the process and avoid potential conflicts of interest."

(Source: FDA News Release, 4/17/25)

The Cybersecurity & Infrastructure Security Agency (CISA) <u>published</u> an alert providing, "Guidance on Credential Risks Associated with Potential Legacy Oracle Cloud Compromise." According to the agency, they are aware of, "public reporting regarding potential unauthorized access to a legacy Oracle cloud environment. While the scope and impact remain unconfirmed, the nature of the reported activity presents potential risk to organizations and individuals, particularly where credential material may be exposed, reused across separate, unaffiliated systems, or embedded (i.e., hardcoded into scripts, applications, infrastructure templates, or automation tools). When credential material is embedded, it is difficult to discover and can enable long-term unauthorized access if exposed." CISA recommends that organizations:

- "[r]eset passwords for any known affected users across enterprise services, particularly where local credentials may not be federated through enterprise identity solutions;
- [r]eview source code, infrastructure-as-code templates, automation scripts, and configuration files for hardcoded or embedded credentials and replace them with secure authentication methods supported by centralized secret management;
- [m]onitor authentication logs for anomalous activity, especially involving privileged, service, or federated identity accounts, and assess whether additional credentials (such as API keys and shared accounts) may be associated with any known impacted identities;

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#### WORD IN WASHINGTON (continued from page 4)

- [e]nforce phishing-resistant multi-factor authentication (MFA) for all user and administrator accounts wherever technically feasible; and
- [f]or additional information for or on Cloud security best practices please review the following Cybersecurity Information Sheets: <u>CISA and NSA Release Cybersecurity Information Sheets on Cloud</u> <u>Security Best Practices</u>."

(Source: CISA <u>Alert</u>, 4/16/25)

**FDA** has <u>announced</u> that the agency is, "taking a groundbreaking step to advance public health by replacing animal testing in the development of monoclonal antibody therapies and other drugs with more effective, human-relevant methods." The FDA explained in a news release that the new approach, "is designed to improve drug safety and accelerate the evaluation process, while reducing animal experimentation, lowering research and development (R&D) costs, and ultimately, drug prices. [Implementation of] he regimen will begin immediately for investigational new drug (IND) applications, where inclusion of New Approach Methodologies (NAMs or NAMs data) is encouraged, and is <u>outlined in a roadmap</u> also being released. To make determinations of efficacy, the agency will also begin use pre-existing, real-world safety data from other countries, with comparable regulatory standards, where the drug has already been studied in humans."

(Source: FDA <u>News Release</u>, 4/10/25) ♦

### **INFECTIOUS DISEASE UPDATES**

#### Mpox

The World Health Organization (WHO) and the Africa Cent[ers] for Disease Control and Prevention (CDC) have announced that the joint Continental Response Plan for the mpox emergency has been updated, "as the disease continues to affect new areas." According to the agencies, "the revised strategy focuses on controlling outbreaks, while expanding vaccination coverage and transitioning toward a longer-term, sustainable response. [Additionally,] the updated Continental Response Plan calls for intensified efforts to bring outbreaks under control, while also taking concrete actions to integrate mpox into routine health services. Along with the Continental Response Plan for Africa, WHO has updated the global strategic plan to curb - and where feasible, to stop - human-to-human transmission of mpox. In the first two months of 2025, 60 countries reported mpox, with the majority of cases and deaths reported from the African continent. The joint Continental Response Plan is aligned with the global strategy." The U.S. Food and Drug Administration (FDA) previously published a communication in August 2022 titled, "Information for Blood Establishments Regarding the [Mpox] Virus and Blood Donation," in which the agency explained that, "[w]orldwide, there have been no reports of transmission of [mpox] virus through blood transfusion and the risk of transfusion-transmission remains theoretical. The levels of virus in the blood of an infected or exposed individual have not been well characterized. Routine measures used to determine blood donor eligibility prevent individuals with symptomatic infections from donating blood. [Also,] given he robustness of the existing safeguards for blood safety FDA does not recommend that blood establishments ask donors additional, specific questions about possible exposure to monkeypox virus. Further, FDA does not recommend using laboratory diagnostic tests to screen blood donors for [mpox] virus. FDA will continue to monitor cases of monkeypox in the U.S. and worldwide and the available information about potential risk of transfusion-transmitted [mpox] virus."

(Source: WHO and Africa CDC <u>News Release</u>, 4/17/25)

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#### **INFECTIOUS DISEASE UPDATES** (continued from page 5)

#### Avian Influenza A(H5N1)

The International Health Regulations (IHR) National Focal Point (NFP) for Mexico recently <u>notified</u> the WHO of nation's first laboratory-confirmed human infection and death of avian influenza A(H5N1) virus. According to the agency, the individual was child under the age of 10 who, "did not have any underlying medical conditions, had not received seasonal influenza vaccination, and had no history of travel. [The source] of infection remains under investigation. During contact tracing, 91 individuals were identified, including 21 household contacts, 60 healthcare workers, and 10 individuals from a childcare center. [No further] cases of human infection with influenza A(H5N1) linked to this case have been identified." Transfusion-transmission of A(H5N1) has never been documented in humans though according to the Association for the Advancement of Blood & Biotherapies (AABB) Transfusion-Transmitted Diseases (TTD) Committee's Emerging Infectious Diseases (EID) Fact Sheet, "[a] small study published in 2014 found dose-dependent transmission and mortality from [Influenza] A(H5N1-VN.1203.04) from ferrets infected by the respiratory route to recipients of their blood."

(Sources: WHO Disease Outbreak News Update, 4/17/25; AABB TTD EID Fact Sheet, 1/14/25)

#### **MEMBER NEWS**

**LifeShare Blood Center** has <u>launched</u> LifeShare Biologics. The new division will be, "committed to expanding the organization's mission by delivering a robust line of cellular products to communities across Louisiana and beyond [and makes LifeShare] the first blood center in their service area to strategically pursue a comprehensive biologics initiative, signaling a major milestone in its continued evolution to meet the future of medicine head-on," according to the news release. Additionally, the announcement explained that LifeShare is appointing Monica Kalvelage to lead the new division as chief operating officer (COO) [and] Geri Venable will now serve as COO of Blood Services at LifeShare.

(Source: LifeShare Blood Center <u>News Release</u>, 4/16/25)

**Carter BloodCare** <u>opened</u> a new fixed-site location today (April 21<sup>st</sup>) in Burleson, Texas. A blood center announcement noted that this is the organization's 26<sup>th</sup> donor center. Andrea Sign, director of Marketing, Communications, and Donor Relations at Carter BloodCare, noted in the news release, "[o]ur North Texas population is one of the fastest growing in the United States (U.S.), with the U.S. Census reporting an average daily increase of nearly 500 residents in the Dallas-Fort Worth area. Our new donor center in Burleson is an important resource to support Texas' increased health needs for local patients who urgently require lifesaving transfusions."

(Source: Carter BloodCare <u>News Release</u>, 4/15/25)





**ABC** Newsletter

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

#### **Register for the ABC Advocacy Summit**

<u>Registration</u> is open for America's Blood Centers (ABC) <u>Advocacy Summit</u>. This event will take place in Washington, D.C. at the Hamilton Hotel June 10<sup>th</sup>-11<sup>th</sup>. <u>Book your room</u> before Thursday, May 15th to take advantage of the discounted rate. The <u>full agenda</u> is available and don't miss this opportunity to let your voice be heard as this event connects the blood community with national leaders in public policy and advocacy including meetings with members of Congress and their staff. Join us for a full day of advocacy training and group preparations for meetings with congressional offices on June 10<sup>th</sup> before heading to Capitol Hill on June 11<sup>th</sup> for group meetings with members of Congress and their staff. ABC will coordinate and schedule meetings on behalf of all attendees and conclude the day with a reception for all attendees. The training will feature insights from former members of Congress, seasoned lobbyists, and public policy staff from partner organizations, and ABC's government affairs team. Please <u>contact us</u> with questions.

#### Nominations Are Open for HOSA Partnership Recognition

ABC encourages member blood centers to <u>submit nominations</u> recognizing the HOSA-Future Health Professionals chapters that they are partnering with. The submission deadline is May 15<sup>th</sup> as the nominationbased categories highlight outstanding contributions from HOSA chapters and state associations in strengthening the nation's blood supply during times of critical need and/or through support of blood donation or a blood drive. The winning HOSA chapters will be honored at the <u>HOSA International Leadership</u> <u>Conference</u> in June. More information is available <u>here</u>. Also, please remind your HOSA student partners to <u>upload</u> their blood donation data for the 2024-25 school year by May 15<sup>th</sup>. The goal is to surpass last year's <u>33,000 donor record</u>, and your support is crucial in achieving this. For more information on data submission and our HOSA partnership, please visit <u>www.AmericasBlood.org/HOSA</u>.

### Deadline Extension: Participate in the ABC Economic Outlook Survey

The <u>ABC Economic Outlook Survey</u> deadline has been extended to May 2<sup>nd</sup>. This resource provides a comprehensive look at blood center finances, including 19 of the most frequently used ratios for benchmarking the financial health of an organization as well as median service fees for 30 different blood products and blood center procedures. The aggregate data from this survey is important to both members and ABC as we advocate for fair and accurate reimbursement policies. Survey results are anonymized and aggregated, and all reporting complies with antitrust requirements. The ability to download final trend reports and create customized reports based on selected filters will be available to participants via ABC's benchmarking portal. Please <u>contact us</u> with questions.

#### 2025 ADRP Annual Conference Room Block Closing April 22<sup>nd</sup>

<u>Register now</u> for the <u>2025 ADRP Annual Conference</u> in Oklahoma City, Oklahoma, from May 6th to 8th at the Omni Oklahoma City Hotel. Remember to <u>book your hotel room</u> by April 22<sup>nd</sup> for the discounted rate. This conference offers a chance to learn about industry trends, share ideas, and connect with other

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donor recruitment, donor services, collections, marketing, and communications professionals. Join more than 400 of your peers by participating in pre-conference workshops, attending compelling educational sessions, engaging in roundtable discussions, and exploring an expansive exhibit hall filled with innovative solutions. Seize this extraordinary opportunity to learn, share, and grow within the blood community.

#### **RESEARCH IN BRIEF**

Blood Donation Time and Adverse Donor Reactions. Authors of a study published in Vox Sanguinis "evaluated the effect of time exposure of a whole blood donor during the proper blood donation stage, donor counse[1]ing, and adverse donor reactions (ADRs)." The paper explained that, "[d]ata used for this study were gathered from a 24-month experimental study carried out at the Bafoussam Regional Hospital Blood Bank, West Region of Cameroon. [Participants consisted of] counse[1]ed and non-counse[1]ed eligible blood donors [ages 18-65 years]." The authors noted that there were "252 whole blood donors [200 (79.4 percent) male], 125 counse[1]ed, and 127 noncounse[1]ed participants. [The age range of] 18-32 years was the most represented, with 172 (68.3 percent). Overall, 35 of 252 (13.9 percent) participants experienced ADR, the majority being local complications (19 of 35 [54.3 percent]). The common local complications recorded were numbness and hematomas associated with re-puncture." The paper explained that, "[h]ematoma associated with re-puncture (17 of 35 [36.1 percent]) were notified as the highest undesirable sign and symptom, followed by the systemic complication, dizziness (10 of 35 [28.57 percent]). Though not statistically significant, the risk of developing ADR was high in female donors (relative risk [RR]; 1.1x), replacement (RR;1.5x), multiple donors (RR; 1.3x) and donors with a previous ADR history (RR; 2.1x) compared with their counterparts. Participants between the ages of 47-60 years witnessed the highest (28.6 percent) undesirable effects. With respect to bleed duration, ADR was 28.9 percent (13 of 45) for donors with bleed duration exceeding 10 min as compared with 10.6 percent (22 of 207) for those who bled within 10 min (p=0.003). Whether counse[l]ed or not, no significant difference was found between intervention and the occurrence of ADR." The authors concluded that, "the study identified prolonged bleeding duration as a novel predisposing factor for ADRs, with local complications as the most prevalent compared with the systematic. The high prevalence of hematomas associated with re-puncture, which is an erroneous phlebotomist act, is the probable cause. Hence, it is necessary to acquire digital vein detector devices in blood banks to curb adverse donor events, scale up blood donation and reduce the gap in the blood supply."

**Citation**: Gesu Ngunyi, C., Noubom, M., Enoh, J.E., Njukeng, P., Tagny, C.T., Gesu, N., *et al.* "Evaluation of bleed duration and adverse donor reactions during the blood donation process." *Vox Sanguinis*. 2025

Contributed by Richard Gammon, MD 🍐

### **GLOBAL NEWS**

Researchers in the United Kingdom (UK) have <u>announced</u> a clinical trial that is examining, "if routinely taking iron supplements during pregnancy can prevent an[e]mia, reducing the risk of stillbirth, pre-term birth, postnatal depression, h[e]morrhage after delivery, and the need for blood transfusions." The study known as "Primary prevention of maternal AN[e]mia to avoid preterm Delivery and other Adverse outcomes (PANDA)" will include women, "who are in the first 16 weeks of pregnancy," according to a news release. "Those who join will be given either iron supplements or placebo tablets, to take every day throughout their pregnancy and until six weeks after birth. Researchers will assess several factors within both groups, including the numbers of pre-term births, stillbirths, neonatal deaths and babies deemed small for their gestational age, as well as the proportion of women developing an[e]mia during pregnancy, any changes in red cell counts in the blood during pregnancy, any changes in red cell counts in the blood during <u>GLOBAL NEWS</u> (continued from page 8)

pregnancy and the proportion of women with bleeding after giving birth. Longer term, the study will also link with other organi[z]ations to collect data to understand the effects of giving iron supplements during pregnancy on a child's development; it is known that iron plays an important role in a baby's neurodevelopment." NHS Blood and Transplant (NHSBT), the national blood provider for England and transplant services for the UK, and the University of Oxford will lead the PANDA study with funding from the National Institute for Health and Care Research (NIHR).

(Source: University of Oxford <u>News Release</u>, 4/7/25)

The World Health Organization (WHO) Intergovernmental Negotiating Body (INB) has <u>drafted</u> a pandemic agreement, "to strengthen global collaboration on prevention, preparedness and response to future pandemic threats." The agency announcement explained that, "[p]roposals within the text developed by the INB include:

- establishing a pathogen access and benefit sharing system;
- taking concrete measures on pandemic prevention, including through a One Health approach;
- building geographically diverse research and development capacities;
- facilitating the transfer of technology and related knowledge, skills, and expertise for the production of pandemic-related health products;
- mobilizing a skilled, trained, and multidisciplinary national and global health emergency workforce;
- setting up a coordinating financial mechanism;
- taking concrete measures to strengthen preparedness, readiness and health system functions and resilience; and
- establishing a global supply chain and logistics network."

The INB formed in December 2021 to, "draft and negotiate a convention, agreement or other international instrument, under the WHO Constitution, to strengthen pandemic prevention, preparedness and response." The proposal will be presented and considered during the 78<sup>th</sup> World Health Assembly in May.

#### (WHO <u>News Release</u>, 4/16/25)

The Brazilian regulatory authority (ANVISA) has "granted marketing authorization" to Valneva SE for the company's single-dose chikungunya vaccine (Ixchiq®). A company news release explained that the vaccine is approved for, "the prevention of disease caused by the chikungunya virus in individuals 18 years of age and older [and] is approved for the prevention of disease caused by the chikungunya virus in people aged 12 years and older in the EU, and in people aged 18 years and older in the United States (U.S.), Canada and the United Kingdom (U.K.). [The approval] in Brazil, "primarily enables initiation of large-scale clinical trials of Ixchiq® in Brazil, including the committed Phase IV clinical trials supporting Ixchiq's® approval by the U.S. Food and Drug Administration (FDA) and the European Commission to generate additional data on vaccine effectiveness. The Coalition for Epidemic Preparedness Innovations (CEPI) is providing funding support to these trials."

(Source: Valneva SE <u>News Release</u>, 4/14/25) •





### COMPANY NEWS

**ABC** Newsletter

Abbott and the **Big Ten Conference** recently <u>honored</u> the University of Nebraska-Lincoln during an April 17<sup>th</sup> celebration for winning "<u>The We Give Blood Drive</u>." According to *Nebraska Today*, "[t]he April 17 event was held to honor the thousands of Nebraskans who stepped up to donate blood and help strengthen the nation's supply during a time of critical need — saving nearly 12,000 lives through Husker donations alone." The school received a \$1 million contribution from Abbott which will be used by the school for, "to fund grants supporting health and wellness programs at the University of Nebraska–Lincoln and expand access to health services throughout the state." Last year was the inaugural year of the initiative which inspired, "[n]early 20,000 Big Ten students, alumni, and fans across the country donated blood as part of the competition," according to an Abbott <u>news release</u>. "With each donation saving up to three lives, the competition helped save as many as 60,000 lives. The competition did its part to help alleviate current nationwide blood shortages and educate people about the need for blood while inspiring blood donations across the country" The blood drive competition aimed to, "help build the next generation of blood donors during a time when the nation is experiencing one of the biggest blood short-ages in a generation and has seen the rate of donors between 19- and 24-years-old drop by nearly a third in recent years. More than half of donors at 'The We Give Blood Drive' campus blood drives donated blood for the first time."

(Source: Nebraska Today, "Health, wellness grants available through \$1M 'We Give Blood' prize," 4/18/25)

**Precision BioSciences** <u>announced</u> that the U.S. Food and Drug Administration has granted the "Fast Track" designation for its investigational gene therapy to trat hepatitis B virus (HBV). Specifically, a company news release explained that the therapy is designed to, "[potentially] cure chronic hepatitis B by eliminating covalently closed circular DNA (cccDNA), the key source of replicating HBV, and inactivating integrated HBV DNA in hepatocytes." The investigational gene therapy is being evaluated in an, "ongoing global Phase 1 ELIMINATE-B trial, with clinical investigation in the United States, Moldova, Hong Kong, New Zealand, and the United Kingdom. The company anticipates sharing updates on the full low-dose cohort, including multiple dose administrations, and data from higher dose levels throughout 2025. Fast Track designation is designed to facilitate development and expedite the review of drugs that are intended to treat serious or life-threatening conditions and address an unmet medical need."

(Source: Precision BioSciences <u>News Release</u>, 4/15/24)

#### CALENDAR

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

#### 2025

May 6-8. 2025 ADRP Annual Conference. Oklahoma City, Okla. Registration is open. More information available here.

May 14-15. International Plasma and Fractionation Association (IPFA)/Paul-Ehrlich Institut[e] (PEI) 30<sup>th</sup> International Workshop on Surveillance and Screening of Blood-borne Pathogens. Heidelberg, Germany. <u>Registration</u> is open. More information available <u>here</u>.

May 20-21. International Plasma Protein Congress. Warsaw, Poland. Registration is open.

June 1-4. International Society of Blood Transfusion (ISBT) 35<sup>th</sup> Regional Congress. Milan, Italy. <u>Registration</u> is open. More information available <u>here</u>.

CALENDAR (continued from page 10)

June 10-11. ABC Advocacy Workshop. Washington, D.C. More information is coming soon.

June 25-26. HHS OIDP TBDAIC Community Engagement Meeting (Hybrid). Portland, Maine. More information is coming soon.

Sept. 24-25. **2025 ADRP Master Class: "Building Brighter Experiences: Empowering Customers, Engaging Employ**ees (Virtual). More information is coming soon.

Oct. 12-15. American Association of Tissue Banks (AATB) Annual Meeting. Atlanta, Ga. More information is coming soon.

Oct. 14-15. International Protein Forum. Old Town Alexandria, Va. Registration opens in July.

Oct. 25-28. AABB Annual Meeting. San Diego, Calif. More information is coming soon.

Oct. 26-29. Blood 2025 and the ISBT 36th Regional Congress. Perth, Australia. More information available here.

Nov. 17-20. American Society for Clinical Pathology (ASCP) Annual Meeting. Atlanta, Ga. <u>Registration</u> is open. More information available <u>here</u>.

#### 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: <a href="mailto:newsletter@americasblood.org">newsletter@americasblood.org</a>

#### POSITIONS

Vice President of Technical Operations (Oklahoma City, OK). Our Blood Institute is looking for a VICE PRESIDENT OF TECHNICAL OPERATIONS who will provide strategic planning, operational management, budgeting, and leadership to the OBI and provide technical and leadership support to the Testing Lab, Quality Control Lab, Manufacturing Operations, Logistics/Inventory Management, and Technical Operations Systems departments. Overseeing the day-to-day operations, implementing business plans, managing the department's P&L, and fostering high performance, customer-oriented culture. Successful applicants must have a Bachelor of Science degree in Medical Technology and a Master's degree is strongly preferred. Position requires ASCP certification as a Medical Technologist and Specialist in Blood Banking is preferred. Position requires a minimum of ten years progressive management in a related medical industry. 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/

**Technical Director, Manufacturing & Distribution.** Mississippi Blood Services (MBS) is seeking a dynamic and flexible Technical Director to join our team. Since 1979, MBS has been committed to making a difference in the lives of patients in Mississippi hospitals. We offer an excellent working environment and great benefits. The ideal candidate will be confident, self-disciplined, and innovative, with strong problem-solving Responsibilities include overseeing seroconversion lookback investigations, liaising with hospital labs, mentoring team members, ensuring compliance with FDA and regulatory guidelines, administering patient antibody letters, managing lab records, and assisting with inspections. A bachelor's degree and MT(ASCP) certification are required; MT(ASCP)BB or SBB preferred. This role requires flexibility, leadership, and the ability to work in a fast-paced environment. If you're ready to make a meaningful impact, visit <u>www.msblood.com</u> to apply online.

**Director, Quality Assurance/Regulatory Affairs.** Hoxworth Blood Center (HBC) was founded in 1938 and serves more than 30 hospitals in 18 counties in Ohio, Kentucky, and Indiana. Annually, HBC collects more than 100,000 units of blood from local donors to help save the lives of patients in area hospitals. HBC is located within the University of Cincinnati (UC), College of Medicine, and is seeking a full-time Director, to oversee and direct the coordination of quality assurance and regulatory compliance for the collection, manufacture, storage and distribution of licensed and unlicensed blood and blood components, and for the testing of donor and



#### POSITIONS (continued from page 11)

patient samples. **Essential Functions:** Direct the coordination of regulatory compliance with the Food & Drug Administration (FDA), e.g., review of changes to regulations & guidance documents, submission of biological product deviation reports & response to observations/findings from FDA inspections. Support the Division Director in the preparation of license applications, annual report of minor changes & correspondence with the FDA. Manage the quality programs for maintaining applicable licensure and accreditation, e.g. internal and external audits, supplier qualifications, change control, deviation management, document control and record retention. **Minimum Requirements:** Bachelor's Degree and seven (7) years' experience. **Click** <u>HERE</u> for the full job description and apply. EOE

Associate Medical Director/Medical Director (Versiti Blood Center of Ohio). Serve as the physician face of Versiti and Versiti Ohio, translating complex medical issues to educate other physicians, support staff and the public. Opportunities in educational initiatives and clinical/applied research are available within Versiti and with our affiliated health systems. As part of the Versiti physician team you will have the opportunity to participate in clinical research projects with investigators at our world-renowned diagnostic laboratory and blood research institute. Joining our Medical Science Institute transfusion medicine physician team will provide you with a uniquely diverse and collaborative experience. Requirements: MD or DO Degree. Board certified/eligible in Blood Banking/Transfusion Medicine. At least three years of experience in blood center/transfusion medicine practice preferred. Licensed or eligible for an Ohio and Indiana; other state licenses may be required. Driver's License in good standing. Please click here to read the full job description and apply.