America's Blood Centers
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NEWSLETTER

A weekly chronicle of events and issues impacting the blood community

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FDA Updates Two Final Guidances to Require Blood Establishments to Report SOP Changes in Their Annual Report

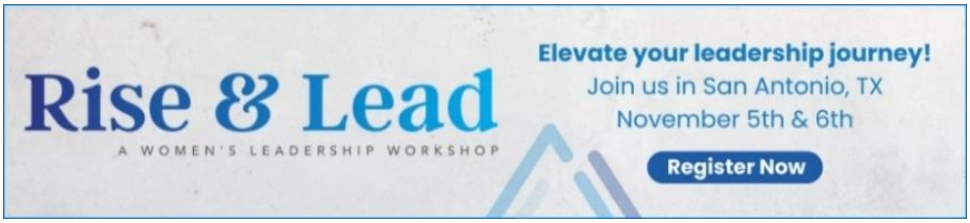
The U.S. Food and Drug Administration (FDA) has updated a final guidance on October 14th titled "Compliance Policy Regarding Blood and Blood Component Donation Suitability, Donor Eligibility and Source Plasma Quarantine Hold Requirements." The guidance explains, "the conditions under which FDA does not intend to take regulatory action for a blood establishment's failure to comply with certain requirements in Title 21 of the Code of Federal Regulations 630.30 (21 CFR 630.30) regarding donation suitability; 21 CFR 630.10(c)(2) regarding donor eligibility; and 21 CFR 640.69(f) regarding quarantine hold for Source Plasma."

Specifically, the updated agency guidance publishes, "[r]evisions issued under Level 2 guidance procedures (21 CFR 10.115(g)(4)), [updating] Section IV to require licensed establishments to report changes to their standard operating procedures (SOPs) in their Annual Report under 21 CFR 601.12(d)."

The FDA also updated the final guidance titled, "Blood Pressure and Pulse Donor Eligibility Requirements — Compliance Policy." This guidance addresses, "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."

The updated Blood Pressure and Pulse Donor Eligibility Requirements guidance specifically publishes, "[r]evisions issued under Level 2 guidance procedures (21 CFR 10.115(g)(4)), [updating] to Section V to require licensed establishments to report changes to their SOPs in their Annual Report under 21 CFR 601.12(d)."

(Sources: FDA Blood Donation Suitability Guidance, 10/14/26; FDA Blood Pressure and Pulse Donor Eligibility Requirements Guidance, 10/14/26)



REGULATORY NEWS

The Centers for Medicare & Medicaid Services (CMS) has published a proposed rule titled, "Clinical Laboratory Improvement Amendments of 1988 (CLIA); Virtual Access, Gynecologic Cytology Proficiency Testing (PT), Personnel Qualifications, and Other Changes." The proposed rule would formally incorporate "virtual access" into the CLIA regulations, allowing qualified laboratory personnel to, "remotely review digital laboratory data, digital results, live imaging, and digital images under the CLIA certificate of the primary testing laboratory that generated the data." This proposal would codify flexibilities that CMS previously permitted through enforcement discretion during and after the COVID-19 Public Health Emergency. Cytology remains excluded because federal statute requires cytology screening to occur on the premises of a CLIA-certified cytology laboratory. The laboratory director remains responsible for all testing and reporting activities performed through virtual access. The proposed rule also contains revisions to personnel requirements that were substantially revised in the 2023 CLIA final rule and became effective in December 2024. Following implementation, stakeholders reported that several new requirements were overly burdensome and potentially exacerbated workforce shortages. CMS subsequently exercised enforcement discretion in 2025 and is now proposing permanent regulatory revisions. The proposed regulation would also remove the requirement to report SARS-CoV-2 test results. CMS noted that these requirements were tied to authority provided under the CARES Act and expired when the federal COVID-19 Public Health Emergency ended on May 11th, 2023.

(Source: CMS Proposed Rule, 10/8/26)

WORD IN WASHINGTON

The Defense Department's Defense Advanced Research Projects Agency (DARPA) has awarded the University of Colorado (CU) Anschutz up to $120 million over three years to, "accelerate the evaluation and advancement of emerging technologies designed to improve care for patients experiencing severe hemorrhage [including] blood and blood-like products and diagnostic technologies." A news release explained that, "CU Anschutz will independently verify and validate multiple emerging technologies and therapeutics, helping determine which products meet the safety and performance requirements needed to advance from laboratory and translational research into clinical trials and ultimately FDA review and approval. The campus expects to evaluate as many as 11 products over the next three years. These may

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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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WORD IN WASHINGTON (continued from page 2)

include novel blood or blood-like products, such as oxygen carriers, plasma- and platelet-based products, and diagnostic technologies designed to help detect hemorrhage and guide treatment. [Rather than] focusing on a single technology, CU Anschutz will serve as an independent research institution across multiple products, evaluating them through successive stages of development and providing DARPA with objective data to guide decisions about which technologies should continue moving forward. [CU Anschutz] will assess products against established safety and performance requirements, allowing promising approaches to advance while identifying technologies that do not meet those benchmarks. This process will help DARPA rapidly determine which technologies warrant continued investment, development, and advancement. The program will be carried out through an Other Transaction agreement, a flexible federal contracting mechanism that allows DARPA and CU Anschutz to adapt the scope of the work as technologies and program priorities evolve. [More shelf-stable] and readily manufacturable blood products could also help address challenges associated with the nation's blood supply. By providing alternatives or complements to conventional blood products, these technologies could give clinicians additional tools while reducing reliance on donated blood."

(Source: University of Colorado Anschutz News Release, 10/13/26)

BRIEFLY NOTED

On October 13th, Kaufman Hall released its most recent National Hospital Flash Report containing August 2026 data. Key takeaways from the report included:

- "[c]onverging pressures strain hospital performance. August was notably weaker for hospital performance than the prior four months, with year-to-date operating margins dipping to 2.5% when including allocations. Mounting financial challenges from increasing bad debt and charity care, payer mix erosion, and rising expenses may prompt hospitals to strengthen enterprise margin preservation efforts;
- [n]on-labor expenses are a major pain point. Non-labor expense per adjusted discharge rose 6% year-to-date compared with 2025, and supply and drug expenses rose 5% and 6%, respectively, compounded by inflation in food and energy costs. Health systems could mitigate the cost pressures from persistent expense growth by sharpening supply chain optimization and expense management strategies; [and]
- [n]early half of hospitals are in the red. Roughly 43% of hospitals are currently operating at a loss, compared with roughly 33% before the COVID-19 pandemic. As hospitals seek greater long-term financial sustainability, continued financial pressures may accelerate strategic repositioning and portfolio optimization efforts through partnerships.

(Source: Kaufman Hall National Hospital Flash Report, 10/13/26)

Authors of a research letter published in *JAMA* titled "Longitudinal Trends and Characteristics of Hospital Closures and Openings" provided an analysis of, "hospital closures and openings from 2010-2025 to characterize net changes in hospitals and hospital beds, the factors associated with closures and openings, and changes in distance to the nearest hospital after the closures." The researchers noted that, "[a]mong 4,962 hospitals observed, 432 (8.7%) closed and 216 (4.4%) opened, a net loss of 216 hospitals (4.7% of 2010 hospitals) and 24,399 beds (3.3% of 2010 beds). Hospital closures increased by 4.0% year over year (95% CI, 0.3% to 7.9%; p = .05), whereas openings decreased by 3.0% year over year (95% CI, −5.3% to −0.6%, p = .03). Of 432 hospital closures, 315 closed completely and 117 retained outpatient services, including 45 rural emergency hospitals. For-profit hospitals closed more than 3 times as often as

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BRIEFLY NOTED (continued from page 3)

nonprofit hospitals (21.4% vs 6.0%, respectively, $p < .001$). Safety net, nonteaching, and smaller hospitals closed more often. Critical access hospitals closed less often. Closure rates did not differ between urban and rural hospitals (9.1% vs 8.3%, respectively, $p = .29$), though there were more closures in the most socially vulnerable counties and in states that never expanded Medicaid. Openings were concentrated among urban, for-profit, and small hospitals. Safety net hospitals and those serving a high number of Medicaid patients rarely opened." Limitations of the research acknowledged by the authors included, "[the study's] observational design and the self-reported nature of the American Hospital Association annual survey, though manual verification of hospital openings and closures reduces misclassification. Measuring hospitals at the level of Centers for Medicare & Medicaid Services certification number means closures within multihospital systems are not always observable. Measuring hospital characteristics at the last observed year may introduce bias if characteristics systematically changed over time. In addition, hospital closure–associated characteristics should not be interpreted as causal." The authors concluded that, "[a]s health reforms reshape hospital financing, monitoring acute care access across urban and rural areas will be essential."

Citation: Calianos, J.E., Song, J.H., Orav, J.E., *et al*. "Longitudinal Trends and Characteristics of Hospital Closures and Openings." *JAMA*. 2026.

PEOPLE



Meghan Delaney, DO, MPH has been appointed as the next president and chief executive officer (CEO) of New York Blood Center Enterprises (NYBCe) by the Board of Trustees effective January 4th, 2027, according to an NYBCe announcement. Dr. Delaney currently is the, "Associate Chief Clinical Officer, Division Chief of Pathology and Laboratory Medicine, and Director of Transfusion Medicine at Children's National in Washington, D.C. She is also a Professor of Pathology and Pediatrics at the George Washington University School of Medicine and Health Sciences and serves on the Board of Directors of the Association for the Advancement of Blood & Biotherapies (AABB)." She stated in the announcement, "I am honored to have been selected as the next President and CEO of New York Blood Center Enterprises and look forward to building on its exceptional history of service, scientific excellence, and innovation. NYBCe plays a vital role in patient care, public health, scientific discovery, and the future of blood and cellular therapies. I am excited to work alongside its talented and dedicated employees, partners, and the communities we serve to embrace new opportunities and expand our impact for generations to come." Dr. Delaney will succeed **Christopher D. Hillyer, MD**, "who has led the organization since 2009. Dr. Hillyer will transition to the role of Special Advisor to NYBCe's Board of Trustees. In this capacity, he will work closely with Dr. Delaney to support a smooth and successful transition while continuing to provide strategic guidance to the Board and NYBCe leadership, ensuring the organization continues to benefit from his experience, expertise, and deep institutional knowledge. During his 17-year tenure, Dr. Hillyer transformed NYBCe from a regional blood center and research institution into an internationally recognized life sciences enterprise serving 16 states and more than 550 hospitals. Under his leadership, NYBCe expanded the work of its Lindsley F. Kimball Research Institute (LFKRI) and advanced its capabilities in genomics, cellular therapies, and biomanufacturing. Key milestones included the FDA approval of HemaCord, the



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first FDA-licensed hematopoietic progenitor cell therapy product; the establishment of Comprehensive Cell Solutions; the founding of NYBC Ventures, a $50 million life sciences investment fund; and the opening of NYBCe's new Rye Master Campus, consolidating blood operations, research, and cell therapy manufacturing under one roof." Dr. Hillyer said in the announcement, "[i]t has been a distinct honor and privilege to lead NYBCe for the better part of two decades. I am incredibly proud of what we have accomplished together and deeply grateful to the extraordinary people who make this organization what it is today. I look forward to welcoming Dr. Delaney and supporting her success as NYBCe continues to grow, innovate, and advance its lifesaving mission."

(Source: NYBCe Announcement, 10/12/26)

INFECTIOUS DISEASES UPDATE

DENGUE & CHIKUNGUNYA

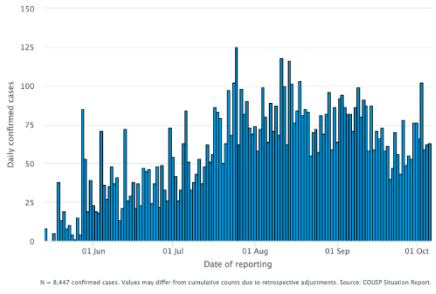
The Pan American Health Organization (PAHO) has published a communication titled "Epidemiological Update: Dengue and Chikungunya in the Americas Region." The agency explained in the update that it is raising awareness, "[g]iven the increase in dengue cases observed in some countries of the Andean, Central American, and Caribbean subregions of the Americas Region, as well as the increase in chikungunya cases experienced between late 2025 and 2026, accompanied by the resurgence of chikungunya transmission in countries and territories of the Region where no viral circulation had been recorded for several years, the anticipated intensification of the El Niño phenomenon over the coming months, and the approaching peak season for dengue and chikungunya transmission in South America. [PAHO and the] World Health Organization (WHO) [urge] Member States to maintain and strengthen epidemiological, virological, and entomological surveillance, as well as to strengthen diagnostic capacity, to ensure early detection and timely clinical management of cases, and to consolidate integrated vector management efforts, with the aim of limiting transmission and reducing morbidity and mortality associated with dengue, chikungunya, and other arboviral diseases." The communication noted that, "[i]n the Americas Region, during 2026 as of epidemiological week (EW) 37, 1,692,937 suspected cases of dengue and 523,102 confirmed cases of dengue were reported to the Health Information Platform for the Americas (PLISA) of PAHO. Of this total, 3,413 (0.2%) were classified as severe dengue, and there were 571 deaths (case fatality rate [CFR] of 0.034%). [Regarding] the trend analysis, a comparison of cases reported through PLISA in 2026 with the numbers in 2025 during the same period show a 58% decrease; a comparison of the 2026 data with the last five-year average, shows a 64% decrease, given that 2024 saw the highest number of dengue cases in the past 10 years (n=13,123,659 cases). [Between late 2025 and 2026,] there has been an increase in chikungunya cases in several countries and territories in the Americas Region, as well as the resurgence of indigenous transmission in countries and territories that had not reported viral circulation for several years. [Between EW 1] and EW 38 of 2026, a total of 213,919 suspected cases of chikungunya were reported, including 78,481 confirmed cases and 88 deaths, with a case fatality rate of 0.041%, in 20 countries and territories of the Americas Region. Although this figure is lower than that observed during the same period in 2025, transmission shows a greater potential for expansion into new areas where *Aedes aegypti* mosquitoes are present, the occurrence of outbreaks outside of historical seasons, longer transmission periods, and an increase in more severe clinical forms."

(Source: PAHO Communication, 10/20/26)

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INFECTIOUS DISEASES UPDATE (continued from page 5)

EBOLA



On October 8th, the World Health Organization (WHO) updated the status of the Ebola disease outbreak in the Democratic Republic of the Congo (DRC). As of October 5th, "the outbreak has spread to 64 health zones [in the region] across 7 of 26 provinces of the country." On October 6th, the WHO noted that, "[a total] of 8,728 confirmed cases, including 4,205 deaths, have been reported corresponding to a crude case fatality ratio (CFR) of 48.2 percent. At the national level, transmission remains intense, although the burden is unevenly distributed. In some areas, there are clear signs that the epidemic is slowing down, although in others it continues to grow. Over the past three completed epidemiological weeks, new weekly cases nationwide have increased by 2.5% from 475 to 487, while new weekly deaths remain stable at 224 compared to 222. The persistently high mortality, together with the large number of deaths occurring outside treatment cent[ers], continues to point to delays in identifying illness and reaching appropriate care." In May, the WHO declared the Ebola disease outbreak in the DRC and Uganda caused by Bundibugyo virus a, "public health emergency of international concern (PHEIC), but [noted that it] does not meet the criteria of pandemic emergency, as defined in the International Health Regulations (2005) (IHR)." The U.S. Centers for Disease Control and Prevention (CDC) published an update on October 21st stating that the U.S. "is responding to an outbreak of Ebola disease in remote areas of the DRC. To date, no cases of Ebola disease have been confirmed in the United States because of this outbreak. The overall risk to the American public and travelers remains low." On May 18th, the CDC announced that it had, "enhanced travel screening, entry restrictions, and public health measures to prevent Ebola virus disease from entering the United States amid ongoing outbreaks in East and Central Africa." The CDC has not classified the affected region as having "widespread transmission of Ebola virus," which would trigger donor interventions in the U.S. The Food and Drug Administration (FDA) updated its guidance document on June 29th and published a communication explaining that"[b]ecause of the severity of [Ebola disease] and the potential risk of transmission by blood and blood components, Ebola disease meets the definition of transfusion-transmitted infection 21 CFR 630.3(l); however, transmission of Ebola disease by blood transfusion has not been reported. Routine measures used to screen every blood donor effectively prevent individuals with symptomatic Ebola disease from donating blood. [Considering] the current Ebola disease outbreak in the DRC and Uganda, we refer blood establishments to the recommendations in our guidance document to update their donor eligibility processes accordingly, including asking donors about residency or travel to DRC and Uganda."

(Source: WHO Update, 10/8/26; CDC Update, 10/21/26)

MEASLES

PAHO issued a communication on October 9th, "urging countries in the Americas, to strengthen vaccination, surveillance and rapid response measures as the risk of measles spread across the region remains very high, [with] several religious mass gatherings in South America expected to increase national and international travel across the Americas in the coming months. The warning comes in a new PAHO regional risk assessment released amid ongoing outbreaks, persistent gaps in vaccination coverage and the detection of measles cases in new geographic areas. [According to] the latest PAHO data, 55,792 confirmed measles cases and 77 deaths were reported in 17 countries and territories in the region between January 4th and October 3rd. This represents a 4.8-fold increase in cases compared with the same period in 2025." Transfusion-transmission of measles has never been demonstrated, and any risk to the blood supply is believed to be theoretical.

(Source: PAHO Communication, 10/9/26) ♦

INSIDE ABC

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

ABC Executive Fellows Program Call for Applicants Is Open

Apply to participate in the 2027-2028 America's Blood Centers (ABC) Executive Fellows Program (EFP) before November 7th. ABC is partnering with Vanderbilt University's Owen School of Management. This groundbreaking initiative offers industry-specific, best-in-class leadership training to blood community executives, elevating individuals, organizations, and the nation's blood supply. The program will accept an annual cohort of up to 25 fellows who will participate in:

- "a week-long leadership residency at Vanderbilt;
- three additional in-person learning immersions;
- virtual seminars taught by Vanderbilt faculty;
- a 360-leadership assessment;
- individual executive coaching; and
- a capstone project presented at the 2028 ABC Annual Meeting."

The EFP strives to accept participants from a wide variety of backgrounds and leadership roles. Final selections for the 2027-2028 cohort will occur by December 2026. An independent selection committee is responsible for choosing each year's cohort. Senior leaders from ABC member blood centers, hospital-associate members, affiliate organizations, and industry partners are encouraged to apply. The Foundation for America's Blood Centers (FABC) is pleased to announce a limited number of partial scholarships available for individuals employed by ABC active member blood centers. Additional information regarding tuition rates is available here.

ABC Executive Compensation Survey Is Open

ABC has launched the Executive Compensation Survey. Authorized individuals from ABC member blood centers have received an email with additional details and instructions for accessing the survey. The deadline to complete a submission is October 30th. The Executive Compensation Survey serves as a resource for blood center chief executive officers (CEOs) and their boards in setting executive salaries/benefits, as well as meeting the Internal Revenue Service (IRS) Form 990 requirements to demonstrate comparability of executive compensation. Please contact us with any questions.

September *Blood Bulletin* Is Available

The latest edition of *Blood Bulletin*, titled "Platelet Products in Clinical Practice: Manufacturing, Dose, and Safety Considerations" has been published. This issue of *Blood Bulletin* was written by: Theresa Nester, MD, Co-Chief Medical Officer at Bloodworks Northwest; Kirsten Alcorn, MD, Co-Chief Medical Officer at Bloodworks Northwest; Roni J. Bollag, MD, PhD, Laboratory Medical Director, National Blood Testing Collaborative and Augusta University Blood Bank; Ruchika Goel, MD, MPH, CABP, Medical Director, Research, Carter BloodCare; Daniela Hermelin, MD, Chief Medical Officer at ImpactLife; Courtney Hopkins, DO, Vice President, Corporate Medical Director, Vitalant; Kathleen Hopping, MS, Senior Director

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Regulatory Affairs, Vitalant; Cyril Jacquot, MD, PhD, Medical Director, Children's National Hospital; and D. Kip Kuttner, DO, Vice President and Medical Director at Miller-Keystone Blood Center. The authors of this publication disclosed no conflicts. *Blood Bulletin* is reviewed and edited by the ABC Scientific, Medical, and Technical Publications Committee.

Registration Is Open for the Rise & Lead Workshop

Register for the ABC Women's Executive Leadership Community (WELC) Rise & Lead Workshop taking place in San Antonio, Texas November 5th-6th at The Westin Riverwalk, San Antonio. Join blood community professionals and industry partners for a dynamic leadership experience focused on Executive Presence and Personal Brand to develop the skills needed to increase your visibility, strengthen your influence, and confidently communicate your value while building meaningful connections with peers and industry leaders. For chief executive officers (CEOs) seeking a more intimate leadership experience, an optional CEO Retreat on November 4th offers a dedicated opportunity to connect with fellow executives, discuss shared challenges, and engage in meaningful peer-to-peer conversations before the workshop begins. WELC empowers leaders throughout the blood community through networking and professional development. Whether you are an emerging leader, experienced manager, or seasoned executive, the workshop creates space for meaningful conversations, shared learning, and the development of lasting professional relationships. Please contact us with any questions.

Register for the November ABC Webinar: "Risk Assessment for Blood Centers"

The ABC Educational Webinar Committee is hosting a November 17th webinar at 3 p.m. EST titled "Risk Assessment for Blood Centers." Registration is open and ABC members may contact us for a link to register. Featured speakers include:

- Loretta Olamigoke, PhD, CLS Quality Assurance Manager at Gulf Coast Blood; and
- Dana Knight, Director of Quality Assurance at Versiti.

The event will provide attendees with:

- valuable perspectives on the importance of having a robust risk assessment program;
- help exploring challenges and opportunities; and
- the opportunity to connect with subject-matter experts to ask questions and exchange ideas.

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INSIDE ABC (continued from page 8)

Join us for the 2026 ADRP International Showcase on November 4th



Registration is open and complimentary for the 2026 ADRP International Showcase taking place on November 4th from 1 to 2:30 p.m. EST! This year's theme is "Extreme Weather and Disruption: Building a Climate-Resilient Donor Program." The 2026 ADRP International Showcase will provide lessons in resilience from blood centers around the world. Hear how extreme heat, floods, storms, wildfires, severe winter weather, transportation challenges, or other climate-related events affected donor recruitment, collection operations, and how the responses were evaluated. While these challenges vary by region, the lessons learned are applicable and can be shared. Discover how peers from ADRP's global community prepared, adapted, and recovered which can help you strengthen your preparedness and respond more effectively when disruption occurs. Please contact us with any questions.

MEMBER NEWS



San Diego Blood Bank (SDBB), a **Vitalant** organization recently received recognition as part of the 39th Annual County of Los Angeles Productivity and Quality Awards Program for LA-DROP, a prehospital blood transfusion pilot partnership with the County of Los Angeles Fire Department, LA Health Services (EMS Agency and Harbor-UCLA Medical Center), Compton Fire Department, and SDBB. The pilot program was a co-winner of the Bronze Eagle Award. The County of Los Angeles Productivity and Quality Awards Program honors, "departmental productivity and quality improvement efforts deserving recognition. Ninety-five entries representing $425 million dollars in cost savings, revenue, cost avoidance, and improved services to the community were submitted for awards consideration." The award announcement noted that, "[s]ince launching in April 2025, LA-DROP has transfused 60 patients, with approximately 75% surviving through hospital discharge. The program established a safe, sustainable system for blood storage, transportation, warming, administration, and documentation while meeting regulatory requirements and minimizing blood waste. Supported by a $380,000 Productivity Investment Fund grant from the Quality and Productivity Commission, LA-DROP demonstrates how innovative collaboration can expand emergency medical capabilities, strengthen equitable access to advanced care, and potentially save lives."

(Source: SDBB Announcement, 10/12/26)

ADVANCED THERAPIES NEWS



Vitalant has launched, "its analytics lab at the Phoenix Bioscience Core, expanding its cell and gene therapy (CGT) analytical capabilities for developers of allogeneic cell therapies." An announcement from the organization explained that, "[t]he new laboratory will support cell-based analytics, providing enhanced characterization of allogeneic donors and immune profiling, and offering flexible support for assay development across cell-based analytics platforms. This latest facility with specialized equipment is designed to serve biotech and

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ADVANCED THERAPIES NEWS (continued from page 9)

pharmaceutical therapy developers and other teams seeking access to scientific expertise and broader donor datasets. The analytics lab, which supports a wide range of immunomodulatory drug developers, is part of Vitalant's integrated clinical, production and testing network organized around centers of excellence, creating community access across Vitalant's national footprint. The lab is anchored within the Phoenix Bioscience Core, a 30-acre life sciences innovation district in the heart of downtown Phoenix and part of Vitalant's flagship presence in the city. This summer, Vitalant also unveiled new investigative and diagnostic analytical capabilities through its expanded coagulation laboratory in Pittsburgh, Pa. [The analytics lab] supports the growth of Vitalant's characterized allogeneic donor base and nationwide collection infrastructure. By expanding characterization capabilities, Vitalant aims to help developers evaluate source material more effectively and, over time, explore data-driven approaches to therapy selection based on patient-cell characteristics."

(Source: Vitalant Announcement, 10/5/26)

ARPA-H, an agency within the U.S. Department of Health and Human Services (HHS), has awarded, "[four contracts] through its BioStabilization Systems (BoSS) program, funding three teams to develop new methods to produce, store, and transport cell-based biologic medicines at room temperature." The news release noted that, "[t]he BoSS program also awarded one independent verification and validation (IV&V) partner to provide test materials and performance assessments at critical junctures throughout the program. [The awards] mark a major step toward the program's goal of taking the '200-degree leap,' from ultra-cold storage (around -196°C) to close to room temperature (around 21°C). This technology would end the reliance on the cold chain for some of medicine's most promising treatments and unlock the future of regenerative medicine. [Medicines] manufactured from living cells or organisms (including cell- and gene-based therapies), called biologics, are a rapidly growing class of therapeutics with the promise of treating—and even curing—cancers, chronic autoimmune disorders, and other rare diseases. However, these therapies can be prohibitively expensive for the average American patient. This is in part due to the logistical requirement to store fragile biologics in an unbroken cold chain of ultra-cold storage, from the manufacturing site to the hospital. A single dose worth hundreds of thousands of dollars can be ruined by a shipping delay or cryogenic container failure. The reliance on frozen storage adds tens of billions of dollars annually and represents a significant logistical barrier to innovation and access. All BoSS performers will be working with transition partners to apply their technology developments to a cell therapy towards the end of the project. The selected BoSS performer teams will work across two technical areas: interventions to stabilize and restore cells, and the creation of novel processing systems that mitigate chemical and physical stress to cells during manufacturing."

(Source: ARPA-H News Release, 9/25/26)

Terumo Blood and Cell Technologies (Terumo BCT) has announced a research collaboration with TrAMPoline Pharma and Eduardo Davila, PhD, at the University of Colorado to, "develop an automated manufacturing approach for tumor-infiltrating lymphocyte (TIL) therapies targeting solid tumors. The automated approach is intended to support manufacturing of TrAMPoline Pharma's lead therapeutic candidate, MightyTIL, as the company scales up for clinical trials." The news release noted that, "[b]ecause TILs are derived from immune cells that have already infiltrated the tumor microenvironment, they are being explored as a promising approach for solid tumors, an area where traditional CAR-T therapies have faced biological and manufacturing challenges. [By automating] key processes on Terumo BCT's Quantum Flex™ Cell Expansion System, the partners aim to improve consistency, reduce labor requirements and reagent consumption and support clinical-scale production of genetically modified TILs for solid tumor therapies."

(Source: Terumo BCT News Release, 10/5/26) ♦

GLOBAL NEWS

Australian Red Cross Lifeblood and the University of Queensland are partnering on research that will explore, "manufacturing techniques to increase production and reduce costs [of lab-grown blood]," according to a report from the *Australian Broadcasting Corporation*. The article noted that, "Lifeblood scientists can already grow fully functional red blood cells from donor stem cells in the lab for research purposes, but it takes three weeks to produce a teaspoonful, and the process is prohibitively expensive. Producing a unit of lab-grown blood costs about $1 million." The $2.5 million research initiative between the two organizations, "is being developed through the Solutions and Manufacturing Advanced Regenerative Therapies Co-operative Research Centre (SMART CRC). [While the lab-grown blood] would never replace human donations, [if it] could be grown efficiently and at scale, it could save lives through being able to produce red blood cells for people with ultra-rare blood types. [Within the next four years, researchers hope that,] they will be able to produce bigger yields of lab-grown blood at a reasonable cost that could then be tested in clinical trials."

(Source: *Australian Broadcasting Corporation*, "Lab-grown blood offering hope for Queensland family with ultra-rare grouping," 9/28/26)

Saudi Crown Prince Mohammed bin Salman recently donated blood as part of, "launching the kingdom's annual national donation campaign for this year," according to *The National*. The news organizations explained that, "[t]he campaign aims to promote regular voluntary blood donation and increase public awareness of its importance, while helping secure sufficient supplies of blood and blood products for patients, including those with cancer, blood disorders and critical or emergency medical conditions. [Last year's] campaign, also launched by Prince Mohammed, helped quadruple the number of donors and recorded more than 65,000, the highest figure in the history of Saudi blood banks. All donations recorded during the campaign were voluntary, with more than 85 percent coming from first-time donors."

(Source: *The National*, "Saudi Crown Prince Mohammed bin Salman gives blood to launch country's donation drive," 10/7/26)

The World Health Organization (WHO) has launched, "a new five-year strategy for its Hub for Pandemic and Epidemic Intelligence, charting a path towards a world where every country can detect and understand emerging health threats within 24 hours of their appearance by 2030." A news release explained that, "[t]he Hub's strategy aims to equip every country with the capabilities needed to rapidly identify and understand emerging health threats, thus supporting them in developing the systems, capacities, and partnerships necessary to prevent outbreaks from escalating into epidemics or pandemics. [Under] the next five-year strategy, the Hub will build on the achievements and deliver its work through five priority initiatives:

- *Epidemic Intelligence from Open Sources (EIOS)* uses artificial intelligence to scan thousands of publicly available sources in real time each day to identify signals of potential health threats. It brings together a global community of over 4,000 experts and is being used by over 125 Member States and 30 regional and international organizations;
- [t]he *International Pathogen Surveillance Network (IPSN)* strengthens capacities in genomic sequencing and bioinformatics to identify and understand emerging pathogens. This helps accelerate the development of tests, treatments, and vaccines;
- [t]he *Collaboratory* connects more than 2,000 experts in modeling and data science who can be rapidly mobilized when new threats emerge;
- [t]he *Collaborative Surveillance Initiative*, which is being implemented in more than 83 countries, supports national institutions, systems, and workforces to detect health threats through a One Health approach; [and]

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GLOBAL NEWS (continued from page 11)

- [t]he *Digital Enablers for Public Health Intelligence Initiative*, a new progra[m], will develop secure digital systems that enable countries and partners to share, analyze, and use data while supporting the responsible adoption of artificial intelligence."

(Source: WHO News Release, 10/12/26)

COMPANY NEWS

Valneva SE recently announced that, "following a further benefit-risk assessment of IXCHIQ® for travelers by the United Kingdom's (UK) Commission on Human Medicines (CHM), the UK marketing authorization for IXCHIQ® has been revoked by the Medicines and Healthcare products Regulatory Agency (MHRA)." According to a company news release, "[t]he decision was based on a review of previous safety data and was not associated with any newly identified safety signal. It does not affect the product licenses for IXCHIQ® in the EU, Canada, Brazil, or other territories where IXCHIQ® is currently marketed. IXCHIQ® was launched in the UK in mid-2025. Due to low sales amongst travelers, Valneva has not actively distributed IXCHIQ® in the UK for several months." Valneva SE further explained in the news release that it, "considers the benefit-risk profile of IXCHIQ® favorable when used in accordance with the approved indication, contraindications, warnings, and precautions. This is further supported by the emerging post-marketing evidence, including the ongoing pilot vaccination strategy (PVS) in Brazil, where more than 61,000 people aged 18-59 years have been vaccinated to date with no new safety concerns identified. Similar safety reviews were concluded recently by the European Medicines Agency (EMA) and by Health Canada, which maintained the marketing authorizations for IXCHIQ®, with updated product information. To date, approximately 187,000 doses of IXCHIQ® have been administered globally. While the Company disagrees with CHM's and MHRA's conclusion, Valneva has decided not to appeal the decision, given its immaterial financial and commercial impact, and in line with the Company's strategic focus on expanding access to IXCHIQ® in endemic territories, where the risk of chikungunya virus infection is highest."

(Source: Valneva SE News Release, 10/7/26)

The **Plasma Protein Therapeutics Association (PPTA)** has shared results from a global survey of more than 1,100 caregivers, healthcare providers and patient advocates who reported that they, "found high confidence in plasma-derived medicines and deep gratitude for the donors who make them possible." The results of the survey were "formally" analyzed by SSRS and revealed that:

- "[a]bout two in three respondents reported that they, or someone they care for, receive treatment at least once a month, including 41% who receive treatment weekly;
- [n]early half of survey respondents shared that they, or someone they care for, receive plasma-derived medicines for an immunodeficiency, 18% for a bleeding or blood disorder, 16% for a neurological condition, and 15% for a lung-related illness;
- [t]he age at which treatment began varied, but the largest share (49%) said they, or someone they care for, first received a plasma-derived medicine between the ages of 36 and 64; [and]
- [m]any respondents reported noticing a change in health relatively quickly after treatment began. More than two-thirds (69%) noticed a change in their health, or the health of someone they care for, within a few months of beginning a plasma-derived medicine, including 26% who noticed a change within just a few days."

(Source: PPTA News Release, 10/5/26)

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COMPANY NEWS (continued from page 12)

The **American Hospital Association (AHA)** has published a report prepared by **Kaufman Hall**, at the request of AHA, titled "A New Approach to Hospital Mergers & Acquisitions: Supporting Healthy, Competitive Hospital Markets." The report comes in the wake of, "merger and acquisition (M&A) activity among hospitals and health systems [coming] under increased scrutiny by federal antitrust enforcement agencies in recent years. [It aims to provide a,] "more comprehensive analysis of hospital merger and acquisition (M&A) transactions, one that considers impacts on all patients served, broadens the focus to impacts beyond pricing, and considers the consequences if an M&A transaction is not permitted to proceed, [while ensuring] not only competitive but also healthy hospital markets that can continue to provide the fullest possible range of services."

(Source: AHA and Kaufman Hall Report, 9/14/26)

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.)*

2026

November 3-4. **Plasma Protein Therapeutics Association (PPTA) Plasma Protein Forum Alexandria, Va.** Registration is open. More information is available here.

November 4. **2026 ADRP International Showcase (Virtual).** Registration is open. More information is available here.

November 5-6. **2026 ABC Women's Executive Leadership Community (WELC) *Rise &* Lead Workshop. San Antonio, Texas.** Registration is open. More information is available here.

November 17. **ABC Educational Committee Webinar: Risk Assessment for Blood Centers (Virtual).** ABC members can contact us for more information including a link to registration.

November 17. **NHTSA Office of EMS Prehospital Blood Transfusion Policies, Protocols Guidelines & Training Webinar (Virtual).** Registration is open. More information is available here.

November. 17-20. **American Society for Clinical Pathology (ASCP) and Canadian Association of Pathologists- Association Canadienne des Pathologistes (CAP-ACP) Joint Annual Meeting. Montreal, QC.** Registration is open. More information available here.

December 15. **NHTSA Office of EMS Prehospital Blood Transfusion: Tracking Success & Improvement Webinar (Virtual).** Registration is open. More information is available here.

2027

March 2-4. **Eugene Springfield Fire "Pacific Northwest Whole Blood Summit."** Eugene, Ore. Col. More information is available here.

March 8-11. **2027 ABC Annual Meeting. Atlanta, Ga.** More information is coming soon.

April 20-21. **PPTA International Plasma Protein Congress (IPPC). Barcelona, Spain.** More information is available here.

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CALENDAR (continued from page 13)

May 11-13. **2027 ADRP: The Association for Blood Donor Professionals Annual Conference. Columbus, Ohio.** More information is coming soon.

September 15-16. **2027 ADRP: The Association for Blood Donor Professionals Master Class (Virtual).** 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

Finance Manager. LifeSouth Community Blood Centers is seeking an experienced **Finance Manager** to lead our Business Office operations at our headquarters in Gainesville, Florida. This is an opportunity to put your financial expertise and leadership skills to work for a nonprofit organization with a lifesaving mission. **Position Highlights:** Lead and develop a team supporting essential financial and accounting operations. Oversee functions including payroll, accounts payable, revenue cycle, fixed assets, and expense reporting. Promote accuracy, accountability, operational efficiency, and exceptional service across the organization. Identify opportunities for process improvement and strengthen financial operations. **What We're Looking For:** Progressive accounting or finance experience with demonstrated supervisory experience. Strong knowledge of accounting principles, financial controls, and business operations. Proven leadership, organizational, and communication skills. Bachelor's degree in Accounting, Finance, or a related field (equivalent education, training, and experience may be considered). **Location:** Gainesville, FL (fully on-site). **Starting Salary:** Negotiable based on relevant experience and qualifications. **Interested?** Learn more about the position and apply using the link below. **To be considered for this opportunity, candidates must submit an application through LifeSouth's official careers website.** APPLY HERE

Blood Services Medical Director (Milwaukee, WI - Hybrid). Versiti is seeking a physician leader to serve as **Blood Services Medical Director**, providing medical oversight and strategic leadership for blood collection, manufacturing, testing, distribution, and transfusion medicine services across Wisconsin and the broader Versiti network. This role offers the opportunity to influence patient care, donor safety, regulatory excellence, and innovation within one of the nation's leading blood health organizations. Working closely with physicians, laboratory teams, operational leaders, hospital partners, and community stakeholders, you will support quality systems, regulatory compliance, donor eligibility programs, adverse event management, investigations, product lookbacks, and public health reporting. You will also provide transfusion medicine consultation to hospital clients, support Special Patient Services, participate in physician on-call coverage, and collaborate across the organization to advance standardized practices, education, research, and continuous improvement initiatives. **Qualifications:** M.D. or D.O. degree. Board certified or board eligible in Blood Banking/Transfusion Medicine. Board certification or eligibility in Pathology, Internal Medicine, or Pediatrics with transfusion medicine specialization. Eligibility for Wisconsin medical licensure and multi-state licensure within Versiti's service area. Qualifications to serve as a CLIA Laboratory Director. Join Versiti's nonprofit organization and help advance blood health through trusted medical leadership. This hybrid role requires onsite presence three days per week, **while supporting innovation, collaboration, and operational excellence.** Click **here** to apply.

Chief Operating Officer. National Blood Testing Cooperative (NBTC) is seeking a strategic **Chief Operating Officer (COO)** to lead and scale the operations of our blood testing laboratory services, located in Stone Mountain, Georgia. The COO is a senior executive responsible for overseeing laboratory operations and operational support functions, providing service to 20 blood centers. The COO ensures the organization consistently delivers accurate, timely, and reliable testing services while advancing NBTC's mission to provide exceptional value to its member blood centers. The COO partners with senior leadership to translate the organization's strategic goals into reliable, compliant, efficient, day-to-day execution across laboratory operations, quality systems, personnel, technology, client interactions, facilities, and financial performance. The COO is responsible for defining, monitoring, and reporting key performance indicators (KPIs) to drive accountability, operational efficiency, and continuous improvement across laboratory functions. **Qualifications:** Bachelor's degree in clinical laboratory

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POSITIONS (continued from page 14)

science or related life science required. MLS/ASCP, MT/ASCP, or equivalent certification required. Minimum five years of senior management experience and 10 years of progressive leadership experience within clinical laboratory setting, transfusion medicine or diagnostic testing operations required. Must have demonstrated success leading complex, high-volume, regulated laboratory operations. Experience managing multiple operational departments and cross-functional teams. Proven record of driving operational excellence and organizational performance improvements. Strong capability to lead organizational change and with extensive knowledge of laboratory operations, quality systems, and regulatory compliance. Experience with FDA-regulated laboratory operations is required; CAP and CLIA expertise is preferred. Click here to apply.

Manager, Immunohematology Reference Lab (Gulf Coast Blood). Take your laboratory leadership career to the next level with Gulf Coast Blood, one of the nation's largest community blood centers serving more than 170 hospitals across Texas. In this impactful role, you'll lead the daily operations of the Immunohematology Reference Lab, ensuring the delivery of safe, accurate, and timely laboratory services while overseeing quality, regulatory compliance, staff development, and continuous improvement initiatives. This opportunity is ideal for experienced blood banking and transfusion medicine professionals who are passionate about mentoring teams, solving complex immunohematology challenges, and collaborating with hospitals, physicians, and laboratory leaders to support lifesaving patient care. **Required Qualifications:** Bachelor's degree in Medical Laboratory Science, Clinical Laboratory Science, Biomedical Science, Biology, or a related scientific/healthcare field. Six to 10 years of progressive laboratory experience, preferably in blood banking, transfusion services, reference laboratories, or similar regulated environments. Demonstrated leadership or supervisory experience managing laboratory operations and personnel. Strong knowledge of laboratory quality systems, regulatory compliance, and accreditation standards. Current certification as a Specialist in Blood Banking (SBB) or international equivalent. Join a mission driven organization where your expertise directly contributes to saving and sustaining lives! Apply Now: Manager, Immunohematology Reference Lab - Gulf Coast Blood.

Donor Services Collections Operations Manager (Ada, OK). Our Blood Institute is looking for a Donor Services Collections Operations Manager. This position will play a vital role in ensuring successful blood collection operations throughout our mobile blood drive program. In this leadership position, you'll guide and support supervisors and donor services staff while helping us achieve our collection, quality, financial, compliance, and customer service goals. This is an exciting opportunity for an experienced leader who enjoys working with people, using data to drive improvement, and creating efficient, high-performing teams-all while contributing to a mission that saves lives. This position requires a minimum of three (3) years of supervisory or management experience; blood banking experience preferred. **Salary Range:** Competitive compensation and comprehensive benefits package, including Health, Dental and Vision insurance, Life Insurance, Long-Term Disability, Flexible Spending Plan, 401(k) retirement plan, Paid Time Off, Holiday Pay, and Tuition Reimbursement along with tenure bonuses ($500 bonus after 6 months, $1,000 bonus after 1 year, and $1,500 bonus after 3 years). **How to apply:** https://ourbloodinstitute.org/about/careers/

Process Optimization Program Manager (Orlando, FL). OneBlood is seeking a Process Optimization Program Manager to lead initiatives that enhance efficiency, improve donor experience, and strengthen blood supply operations. In this highly visible role, you will partner with teams across Collections, Recruitment, Manufacturing, and Quality to identify opportunities, implement solutions, and drive measurable operational improvements. The ideal candidate is a strategic problem solver with expertise in process improvement, data analysis, and change management. You will lead cross-functional projects focused on reducing product waste, minimizing donor deferrals, improving collection accuracy, and aligning blood collections with organizational demand. Qualified candidates should have a bachelor's degree and relevant experience in business operations, industrial engineering, or process improvement, with knowledge of Lean Six Sigma and continuous improvement methodologies preferred. This is a hybrid position offering the opportunity to make a meaningful impact on OneBlood's mission to save lives. Apply Here.