



ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

Visit ABC's Web site at: www.americasblood.org

2018 #2

January 19, 2018

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FDA DoD Introduce Workplan for Prioritized Review of Medical Products

In November, the Department of Defense (DoD) and the U.S. Food and Drug Administration (FDA) reached agreement on a provision within the National Defense Authorization Act (NDAA) that allowed the FDA the ability to authorize medical treatments that haven't been approved by the agency for temporary use in emergencies and expedites product review. The compromise between DoD and FDA paved the way for Congress to pass legislation authorizing defense agencies and funding.

This week, DoD's Office of Health Affairs and FDA announced in a [news release](#) the "launch of a joint program to prioritize the efficient development of safe and effective medical products intended to save the lives of American military personnel." The workplan is in accordance with the framework identified in [H.R. 4374](#). "The FDA is fully committed to working closely with our federal partners in the DoD to expedite availability of medical products essential to the health of our military service members, particularly those products used to treat injuries in battlefield settings," said FDA Commissioner Scott Gottlieb, MD in the news release. "Ensuring our Nation's warfighters have safe and effective medical products is a top priority for the agency. By standing up a collaborative program with DoD, we hope to address DoD's immediate product priorities and ensure these products are developed and made available in the most expeditious manner possible."

To help expedite the review process, FDA's Center for Biologics Evaluation and Research (CBER) and DoD's Office of Health Affairs will meet regularly. The initial phase of the program covers the transfusion of blood products on the battlefield such as freeze-dried plasma, cold-stored platelets, and cryopreserved platelets. The FDA also issued a [guidance](#) that included provisions for vouchers that expedite the approval process of products that are "intended to diagnose, prevent, or treat diseases or conditions associated with chemical, biological, radiological, and nuclear threats and emerging infectious diseases." The guidance also allows the agency to grant emergency use authorizations to entities such as the military for medical products and medical countermeasures through provisions. "This partnership reflects the invaluable collaboration between [DoD's Office of] Health Affairs and the FDA to equip U.S. warfighters with the best possible military medical support as we work to achieve a safer, more secure world," said Tom McCaffery, acting Assistant Secretary of Defense for [DoD's Office of] Health Affairs. "Expeditious access to life-saving medical products for U.S. troops on the battlefield is part and parcel to ensuring our shared priority of operational readiness. The Department of Defense looks forward to working with the FDA on this important program to ensure delivery of critical battlefield medicine to our service members downrange."

(Source: Food and Drug Administration [News Release](#), 1/16/18) ♦



OUR SPACE

Sameer Ughade, Director, Information Technology & Business Intelligence, ABC

Onward and Upward—Journey to the Cloud

Cloud computing is bringing us closer to the utility information technology (IT) model: functionality on-demand, elasticity to increase or decrease resources as needed, and accessibility—the ability to access it from connected devices in any location. Deployment models can be private (services from internal hardware), public (services from a public provider), or a hybrid (services delivered by a combination of both). Service delivery models include Infrastructure as a Service (IaaS), Platform as a Service (PaaS), and Software as a Service (SaaS), each with unique characteristics chosen for your needs. In simple terms, IaaS refers to getting your IT infrastructure needs for computing, storage, and networking from external providers, while PaaS is providing a software platform for developing custom software applications. SaaS refers to obtaining completely developed software application(s) from providers.

Cloud computing increases reliance on third party providers, hence partnering and deciding the correct vendor is critical. Providers should be selected based on your current and future business needs, technologies and services roadmap, reliability and performance, and financial sustainability. The benefits of using cloud are numerous, including increased agility in delivering products to market, reduced capital expenditures, and increased data security. For all the promise that cloud demonstrates, organizations must be vigilant in proper implementation and tracking to avoid increased operating costs. To realize the enhanced benefit of improved data security, the various security features and tools must be configured and utilized. Investments should be made in attaining the appropriate training and knowledge to perform configuration management, change management, migration between multiple service providers, security audits, billing, and service level agreement management for cloud.

Recognizing the desired business outcomes is critical to selecting business and technical specifications and defining cloud strategy, which involves governance and control, vendor due-diligence, contingency planning using a multi-cloud approach, and developing cloud talent within organizations. In my opinion, a hybrid cloud strategy that uses existing infrastructure and cloud together remains the best approach. We are still many years away from an “All-Cloud” strategy in the healthcare industry, mainly due to the unique challenges of regulatory changes, our multi-application environments, legacy systems, and nascent vendor adoption. A more practical approach for community blood centers is to migrate non-core applications and use a cloud-first approach for any systems that will be implemented moving forward. Based on a recent ABC IT survey, blood centers are implementing applications with cloud computing capabilities such as Office 365, WebEx, file storage, customer relationship management, and software version control systems. Also, 78 percent of participating member blood centers are using at least one Software as a Service (SaaS) product and 32 percent are using at least one Infrastructure as a Service (IaaS) product. The ABC office will migrate file storage, the phone system, and the endpoint protection tool to cloud as part of our virtual office conversion. Cloud continues to play a big role in increasing innovation—allowing organizations to embrace agility, create new products or services at a faster pace without substantial capital investment. It is here to stay, and we must adopt and use this technology to our advantage. ♦

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ABC is an association of not-for-profit, independent community blood centers that helps its members provide excellence in transfusion medicine and related health services. ABC provides leadership in donor advocacy, education, national policy, quality, and safety; and in finding efficiencies for the benefit of donors, patients, and healthcare facilities by encouraging collaboration among blood organizations and by acting as a forum for sharing information and best practices.

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Correction: Israeli Pilot Program Allowing MSM to Donate

Last week, *ABC Newsletter* [Issue #1](#) covered the Israeli Health Ministry's plan to adopt a system for a two-year trial, which allows males who have sex with other males (MSM) to donate without being celibate. In the article, the *Israeli Times* quoted Magen David Adom's Professor Eilat Shinar, director of blood services, as stating that testing of the blood product would occur "once at donation and a second time before infusion."

ABC reached out to Professor Shinar for further clarification. She stated that "an initial donation will be frozen as fresh frozen plasma for four months, and if a second donation is made and is negative on necessary tests, the first unit can be released and the second stored." A more in-depth piece on the pilot program is [available](#) via the *Jerusalem Post* according to Professor Shinar.

We regret any confusion and the lack of initial clarity caused by publication of the quote last week.

NEJM Publishes Responses to Blood Sustainability Sounding Board

Last November, the *New England Journal of Medicine* distributed the "[Crisis in the Sustainability of the U.S. Blood System](#)" Sounding Board (Klein, H., *et. al.*). Responses in the form of letters to the editor from Stephen Nightingale, MD, a former senior medical adviser for Blood Safety to the Assistant Secretary for Health and the Surgeon General, and Bill Block, president and CEO of Blood Centers of America (BCA), Inc. were published. Dr. Nightingale comments on the efficacy of blood substitutes to help alleviate concerns of sustainability, "The availability of safe, effective, and affordable blood substitutes would obviate these concerns. Unfortunately, scientific and economic obstacles continue to impede progress in this area." Mr. Block indicated that BCA "appreciate[s] the authors' call for an improved reimbursement system for blood components," and adds "that the dire financial picture presented in the article is overstated— or, at minimum, not consistent across the industry." He presents supporting data from BCA members that show "profitable operations" for most BCA members with 43 percent showing "increased net incomes in 2016."

The Sounding Board authors, Jay Epstein, MD, from the U.S. Food and Drug Administration, Harvey Klein, MD, from the National Institutes of Health, and Chris Hrouda, from the American Red Cross responded to both letters noting that, "[w]e disagree with [Dr.] Nightingale about the practical potential for blood substitutes to solve this problem. Oxygen-carrying solutions are unlikely to replace blood transfusions." They also disagreed with Mr. Block noting that, "[t]he 43% increase in income since 2016 that [Mr.] Block reports can be a misleading statistic without information about the revenues (or losses) in the previous year. If the BCA survey is accurate, then more than 20% of BCA members did not report profitable operations, which hardly inspires confidence in system stability."

The letters in their entirety and the authors' response are [accessible](#). ABC's [response](#) to the Sounding Board addressed policy development, competition, and reimbursement for blood and blood products expressing the need for all stakeholders to be included in contributing solutions, "[t]he following core principles must be heeded in considering changes to the system. First, policy must be rooted in evidence and formal risk-based decision-making before promulgating public health and safety mandates. Second, hyper-competition must be addressed. Last, reimbursement for blood must capture the full costs of safety and technology initiatives and preparedness for unprecedented disaster scenarios to which the Department of Health and Human Services (HHS) expects blood centers to respond." The full statement is available [here](#).

Citation: Nightingale, S., Block, B., Epstein, J. Crisis in the sustainability of the U.S. blood system. *New England Journal of Medicine*. 2018. [doi:10.1056/NEJMc1714807](https://doi.org/10.1056/NEJMc1714807). ♦



America's Blood Centers®
It's About *Life.*

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.

2017 Compensation and Benefits Survey Results Now Available

The results from ABC's 2017 Compensation and Benefits survey are available. Highlights include current trends in compensation and benefit programs of ABC member blood centers, with data effective as of October 1, 2017, along with salary data collected by individual incumbent, rather than the organizational averages. This methodology allows the survey to present data that is more accurate, detailed and far more reflective of the actual market. Thirty-six ABC member blood centers participated in the benefit survey, while 37 member blood centers participated in the compensation survey, which includes data representative of more than 10,500 employees and 67 positions. Participants can purchase the results for \$450. Non-participant pricing is \$900. This second-tier management survey was designed by Gallagher Surveys, in collaboration with ABC's Human Resources Committee. To place your order, please [e-mail](#) Annmarie Flaherty. For blood centers that have already ordered the survey, an e-mail with the results has been sent.

(Source: ABC [MCN 18-001](#))

Reminder: Complete ABC 2017 Service Fee Survey

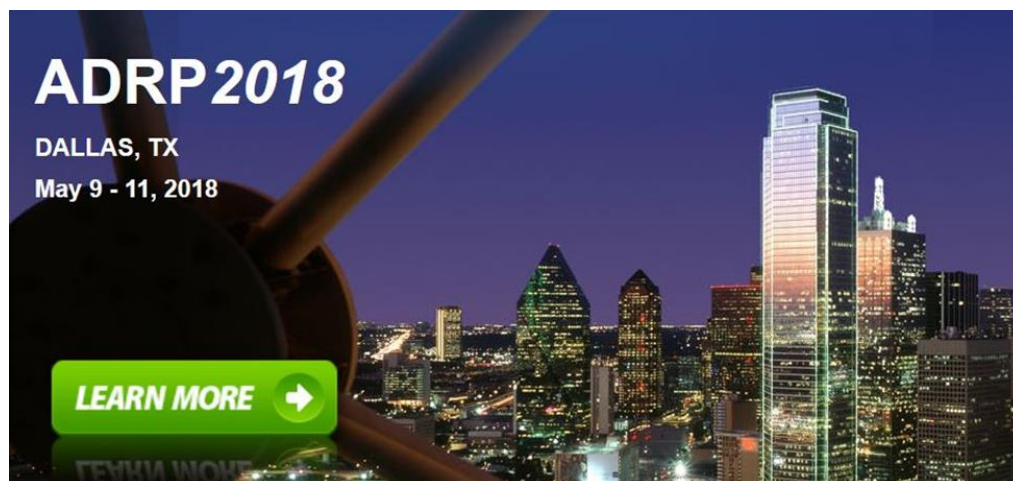
ABC is conducting its annual survey of member service fees. The results from this survey play a vital role in ABC's advocacy efforts to obtain better reimbursements for blood products on behalf of its member blood centers. The data in this report will only be reported in aggregate. No individual data from a member blood center will be displayed or shared. Please respond by January 31, 2018. Contact [Sameer Ughade](#) with any questions or to receive a link to the online survey distributed earlier this week.

SAVE THE DATE

**ABC Quality Education presents
Process Improvement Test Cases—
Best Bang for Your Bucks Webinar**

February 20, 2017 at 3 PM ET

Additional details coming soon!



(continued on page 5)



INSIDE ABC (continued from page 4)

56th ABC Annual Meeting Registration

[Registration](#) is open for America's Blood Centers (ABC) 56th Annual Meeting in Scottsdale, Ariz. March 17th – 19th at the Scottsdale Plaza Resort. Don't miss an exclusive opportunity for blood community leaders to experience peer-to-peer collaboration, while discussing the latest trends impacting community blood centers. The meeting will feature the Celso Bianco, MD Lectureship, the Scientific, Medical, Technical Forum, and the 21st Annual *Awards of Excellence*. Additionally, ABC member Blood Systems Inc. will host a networking event at the [Musical Instrument Museum](#). Please make your hotel reservations by February 23rd to ensure best availability and the group rate. Click [here](#) for additional details. Contact [Leslie Maundy](#) for available sponsorship opportunities. ♦



AMERICA'S BLOOD CENTERS'

56TH ANNUAL MEETING

March 17-19, 2018 | Scottsdale, AZ

2018 ANNUAL MEETING SCHEDULE

Saturday, March 17	ABC Board Meeting Opening Session
Sunday, March 18	ABC Members Meeting SMT Forum & Celso Bianco Lectureship Host Event by Blood Systems
Monday, March 19	General Session 21st Annual Awards of Excellence
Tuesday, March 20	NBF Leadership Forum

Hotel Information
Scottsdale Plaza Resort
Hotel room rate:
\$219 Single/Double

For registration information, visit http://bit.ly/abc_annual_meeting.




For sponsorship opportunities, please contact Leslie Maundy at lmaundy@americasblood.org.

“ I look forward to welcoming America's Blood Centers back to Scottsdale, where the organization began more than 55 years ago. Along with opportunities to discuss emerging issues in our field, the Annual Meeting is a great forum for exchanging ideas and developing collaborations. The more who attend – the greater the value to all involved! ”



Blood Systems — Dave Green, MSA, President and CEO
Blood Systems, Inc.



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RESEARCH IN BRIEF

New studies may help clarify and quantify the links between Zika virus and microcephaly in Northeast Brazil. The apparent association of Zika infection with microcephaly and other serious fetal morbidity was an important driver of public health responses to the epidemic, including that required in the blood community. A case-control study from Brazilian and U.S. Centers for Disease Control and Prevention authors in *The Lancet Child and Adolescent Health* suggests that of 164 original microcephaly reports, 43 had microcephaly on follow-up (26 percent), and of those, 35-87 percent were actually linked to Zika infection.

(continued on page 6)



RESEARCH IN BRIEF (continued from page 5)

The higher original reports of microcephaly may be related to a sensitive, but not specific, surveillance definition. These numbers confirm an association with Zika in Northeast Brazil, albeit at lower rates than originally reported. Microcephalic infants were 22 times more likely than controls to have serological evidence of infection and six-fold more likely to have been delivered by a mother with Zika symptoms in the first trimester. A second study reports an increased risk of microcephaly in poorer districts of Recife (also in Northeast Brazil), but unmeasured confounders make any detailed conclusions about why this may be true difficult.

Citations: Krow-Lucal, E.R., de Andrade, M.R., Cananéa, J.N.A *et al.* Association and birth prevalence of microcephaly attributable to Zika virus infection among infants in Paraíba, Brazil, in 2015–16: a case-control study. *The Lancet Child & Adolescent Health*. 2018. [http://dx.doi.org/10.1016/S2352-4642\(18\)30020-8](http://dx.doi.org/10.1016/S2352-4642(18)30020-8).

De Souza, W.V., de Albuquerque, M., Vazquez, E. *et al.* Microcephaly epidemic related to the Zika virus and living conditions in Recife, Northeast Brazil. *BMC Public Health*. 2018. <https://doi.org/10.1186/s12889-018-5039-z>.

Papers in *Transfusion* and *Vox Sanguinis* find INTERCEPT® processes for red blood cells (RBCs), platelets, and plasma are effective against clinically relevant levels of Chikungunya virus(CHIKV). Both studies included investigators from Cerus Corp., the manufacturer of the processes. In a study with French and French Polynesian scientists, the red blood cell (RBC) process (amustaline with glutathione) was found to inactivate $5.81 \pm 0.18 \log_{10}$ 50 percent tissue culture infective doses of spiked virus. The second study, from the company and Kansas State University evaluated the U.S. Food and Drug Administration-licensed platelet and plasma process using amotosalen and ultraviolet light as well as the RBC process. They found no residual tissue culture infectivity after treatment, corresponding to inactivation of $>6.5 \log_{10}$ and $>7.1 \log_{10}$ plaque forming units, respectively. CHIKV viremia is detectable in acute infections. Transmission by transfusion is theoretically possible, but has been neither documented nor alleged despite millions of infections since the virus became widespread, and eventually pandemic, beginning in 2005.

Citations: Aubry, M., Laughhunn, A., Santa Maria, F. *et al.* Amustaline (S-303) treatment inactivates high levels of Chikungunya virus in red-blood-cell components. *Vox Sanguinis*. 2018. [doi: 10.1111/vox.12626](https://doi.org/10.1111/vox.12626).

Laughnunn, A., Huang, Y-J.S., Vanlandingham, D.L. *et al.* Inactivation of chikungunya virus in blood components treated with amotosalen/ultraviolet A light or amustaline/glutathione. *Transfusion*. 2018. [doi:10.1111/trf.14442](https://doi.org/10.1111/trf.14442). ♦

RECENT REVIEWS

A patient blood management (PBM) paper from Johns Hopkins, the Cleveland Clinic, and New York University was recently published. The authors of this paper describe not only the evidence in support of recent transfusion guidelines, but place them in the context of several professional societies’ “Choosing Wisely” campaigns aimed at promoting high value care. They provide their “blueprint” for development of a PBM program that includes building organizational support, the use of authoritative transfusion guidelines, development of educational outreach and clinical decision support, use of data dashboards, audit and reporting, and the role of blood conservation methods beyond restrictive transfusion. The importance of the use of clinical judgement, beyond simple laboratory triggers, is emphasized.

Citation: Sadana, D., Pratzler, A., Scher, L.J. *et al.* Promoting high-value practice by reducing unnecessary transfusions with a patient blood management program. *JAMA Internal Medicine*. 2018. [178:116-22](https://doi.org/10.1001/jamaintern.2018.1162).



BRIEFLY NOTED

The National Institutes of Health (NIH) issued a call for ideas utilizing the “use case” online tool for projects to be included in the “[All of Us](#)” Research Program. “*All of Us*” is part of the Precision Medicine Initiative, which materialized in 2016 when former President Barack Obama allocated \$130 million to NIH with the stated goal of bringing precision medicine to all in the U.S. through applying “more individualized approaches to healthcare,” according to the announcement. Interested parties can find additional information or submit their or their organization’s ideas to NIH directly via the [NIH website](#) through February 23rd. “The information you provide will be used at the “*All of Us*” Research Priorities Workshop March 21st – 23rd, to identify key research priorities and requirements (such as data types and methods) for future versions of the “*All of Us*” protocol.” Contact AoURPW@nih.gov with questions.

(Source: National Institutes of Health [Announcement](#), 12/19/17)

The “[2016 Global Status Report on Blood Safety and Availability](#)” is available from the World Health Organization (WHO). This document provides an overview of the status of the global supply of blood components for transfusion and plasma-derived medicinal products regarding safety and availability. “The report is primarily based on data for the year 2013, which were reported by 156 of 195 Member States to the World Health Organization (WHO) Global Database on Blood Safety” that was created in 1998 “to address global concerns about the availability, safety, and accessibility of blood for transfusion.” Highlights include: estimates on worldwide collections and variability in availability, the proportion of blood made into components, arrangements for plasma fractionation, data on fractionation volumes, information of the level of dependence of volunteer vs. replacement or paid donors, and levels of self-sufficiency with Immune globulin intravenous 💧

(Source: World Health Organization [2016 Global Status Report on Blood Safety and Availability](#))

REGULATORY NEWS

The U.S. Food and Drug Administration’s (FDA) Centers for Biologics Evaluation and Research published the list of its 2017 Biologics License Application Approvals. A full list is available on the FDA’s [website](#).

(Source: U.S. Food and Drug Administration Announcement, 12/21/17)

This week, the U.S. Department of Health and Human Services and 15 other government agencies and departments announced a [six month delay](#) of the “Federal Policy for the Protection of Human Subjects,” or Common Rule. It governs most human-research financed by the federal government and was scheduled to take effect on January 19th after being published in the *Federal Register* a year earlier. The Interim Final Rule (IFR) provides a delay until July 19th. The notice stated that, “regulated entities will be required to comply with the pre-2018 Common Rule as published in the 2016 edition of the Code of Federal Regulations (i.e., the Federal Policy for the Protection of Human Subjects, originally published on June 18, 1991, and subsequently amended on June 23, 2005) that can be accessed [here](#). This means that before July 19, 2018, institutions may only begin implementing provisions of the revised Common Rule that do not conflict with the pre-2018 Common Rule.” A notice of proposed rulemaking will be forthcoming from the agencies and departments listed in the IFR. The published version of the IVR will be [available](#) on January 22nd. 💧

(Source: [Interim Final Rule](#), 1/17/18)

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REGULATORY NEWS (continued from page 7)

The U.S. Food and Drug administration (FDA) published an industry [guidance](#) entitled “Emergency Use Authorization of Medical Products and Related Authorities.” It outlines the framework for the agency to “support emergency preparedness and response and foster the development and availability of medical products for use in [emergencies],” according to the [guidance](#). Additionally, it references medical products and medical countermeasures including “drugs (e.g., antivirals and antidotes), biological products (e.g., vaccines, blood products, and biological therapeutics), and devices (e.g., in vitro diagnostics and personal protective equipment).” Provisions for vouchers that expedite the approval process of products that are “intended to diagnose, prevent, or treat diseases or conditions associated with chemical, biological, radiological, and nuclear threats and emerging infectious diseases,” are described in addition to the provisions for FDA to grant emergency use authorizations to entities such as the military for medical products and countermeasures. “This [guidance](#) finalizes the draft guidance, Emergency Use Authorization of Medical Products and Related Authorities (April 2016) and replaces the following two guidance documents, Emergency Use Authorization of Medical Products (July 2007) and Emergency Use Authorization Questions and Answers (April 2009).”

(Source: FDA [Guidance](#)) ♦

Learn ♦ Grow ♦ Lead

Shed Light on Your Future



This Month's Featured API Resources

1. Jerry Haarmann Leadership Program
Six courses on leading teams

“This course gave me many ideas on how to work with the team in my department as well as working with other teams outside my department.”

- API pilot participant

2. Strategic Leadership Program
Six courses on change management and communication challenges

Effective Leadership: How Do You Rate?

Check your leadership effectiveness by answering yes or no to the following questions:

- Do you know exactly what you want employees to understand, think, and do in response to your communications?
- Are trust and commitment part of your team's DNA?
- Do you know what motivates your employees?



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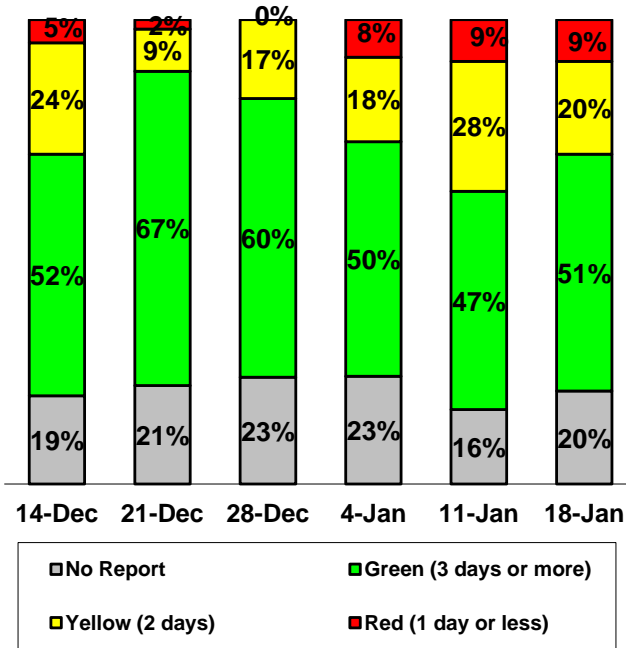
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Log on at: www.americasblood.org/education

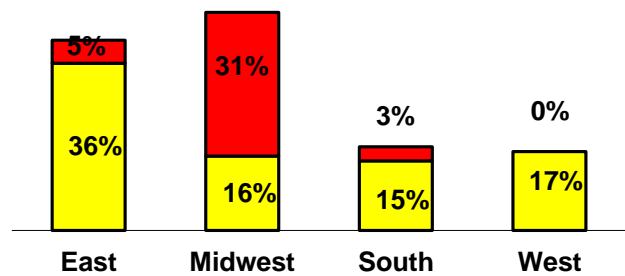


STOPLIGHT®: Status of America’s Blood Centers’ Blood Supply

Total ABC Red Cell Inventory



Percent of Regional Inventory at 2 Days Supply or Less, January 18, 2018



Percent of Total ABC Blood Supply Contributed by Each Region
 East: 20%; Midwest: 25%; South: 24%; West: 31%

Daily updates are available at:
www.AmericasBlood.org

WORD IN WASHINGTON

The House approved a short-term spending bill extending funding for the federal government through February 16th. The stopgap measure, aimed at preventing a government shutdown, included a six year extension for the Children’s Health Insurance Program (CHIP) and a two year moratorium on the medical device tax, which ABC supported [repealing](#) and cosigned a [joint letter](#) from the Advanced Medical Technology Association (AdvaMed). Earlier this week, the Internal Revenue Service (IRS) [announced](#) that it plans to waive late payment penalties for the tax deposits due if the medical device tax moratorium is not extended, “[i]n consideration of the short time frame between the end of the moratorium period and the due date of the first deposit and in the interest of sound tax administration, the IRS and the Treasury Dept. have decided to provide temporary relief from the §6656 penalty for the first three calendar quarters of 2018.” The battle shifted to the Senate, as Senate Democrats have indicated that they are unlikely to support the House bill without concessions from their Republican counterparts, “that reflect their [Democrats] priorities on immigration, government spending, and other issues,” according to the *Washington Post*. If the Senate fails to pass the short-term spending bill, government funding would end at midnight Friday. Prospects for the bill’s passage do not look promising as the Senate Republicans currently lack the 60 votes needed to advance the bill for a full Senate vote as of Friday morning.

(Source: *Washington Post*, [House approves bill to keep government open as Senate Democrats take heat for threatening to block it](#), 1/18/18; IRS [Notice](#), 1/17/18)

(continued on page 11)

WORD IN WASHINGTON (continued from page 10)

The Senate Finance Committee voted in favor of advancing Alex Azar to a full Senate vote. Mr. Azar is the President's nominee for the next Secretary of the Department of Health and Human Services (HHS) and would lead the organization if confirmed. According to *Politico*, “[t]he full Senate vote has not yet been scheduled, but multiple people close to the process said Republicans are hoping to confirm Azar by the end of the month. At least three Senate Democrats, including [Sen. Tom] Carper (D-Del.), have indicated they will join Republicans in supporting [Mr.] Azar during the final floor vote.” Mr. Azar has worked both as a pharmaceutical executive and previously within the administration of former President George W. Bush. He would fill the role formerly held by Tom Price, MD.

(Source: *Politico*, [Senate committee advances Trump's nominee for HHS secretary](#), 1/17/18)

The Senate Health, Education, Labor and Pensions Committee held a [hearing](#) to reauthorize the Pandemic and All-Hazards Preparedness Act (PAHPA), which promotes hospital and public health emergency preparedness agreements. The U.S. Food and Drug Administration (FDA) published a guidance this week that included provisions for vouchers that expedite the approval process of products that are “intended to diagnose, prevent, or treat diseases or conditions associated with chemical, biological, radiological, and nuclear threats and emerging infectious diseases,” along with the provisions for the agency to grant emergency use authorizations to entities such as the military for medical products and medical countermeasures. PAHPA also authorizes programs such as the Strategic National Stockpile. FDA Commissioner Scott Gottlieb, MD testified during the hearing that “FDA plays a critical role in facilitating preparedness for and response to chemical, biological, radiological, and nuclear (CBRN) and emerging infectious disease threats. These threats can and often emerge without warning as was the case with the anthrax attacks of 2001, the 2009 H1N1 influenza pandemic, the 2014 Ebola outbreak in West Africa, as well as in the ongoing Zika virus outbreak. FDA’s role in facilitating preparedness for, and response to, CBRN and emerging infectious disease threats focuses largely on facilitating the development and availability of medical countermeasures—such as vaccines, therapeutics, and diagnostic tests—to respond to these threats. FDA works closely with the Department of Health and Human Services and other U.S. government partners through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), as well as with regulated industry and non-governmental organizations (NGOs), to build and sustain the medical countermeasure programs necessary to effectively respond to public health emergencies.” A recording of the hearing is [available](#). PAHPA is slated to end on October 1st. A second hearing is scheduled for next week.

(Source: Senate Health, Education, Labor and Pensions Committee [Hearing](#), 1/17/18)

Brett Giroir, MD was advanced by the Senate Health, Education, Labor and Pensions Committee. His nomination for the position of Assistant Secretary of the U.S. Department of Health and Human Services had previously been on hold, preventing a vote on the Senate Floor. Dr. Giroir has served is the president and CEO of ViraCyte a biopharmaceutical company. ♦

We Welcome Your Letters

The *ABC Newsletter* welcomes letters from its readers on any blood-related topic that might be of interest to ABC members. Letters should be kept relatively short and to the point, preferably about a topic that has recently been covered in the *ABC Newsletter*. Letters are subject to editing for brevity and good taste. Please send letters to the Editor at newsletter@americasblood.org or fax them to (202) 393-1282. Please include your correct title and organization as well as your phone number. The deadline for letters is Wednesday to make it into the next newsletter.

MEMBER NEWS

San Diego Blood Bank held the inaugural “[San Diego Cares: It’s in our Blood](#)” drive last month. The single day blood drive replaced the annual Chargers Blood Drive, a community staple for 38 years that resulted in the collection of more than 74,000 pints, following the National Football League team’s move to Los Angeles. “When the Chargers announced they were leaving, we were immediately contacted by the Padres, the Gulls, the Holiday Bowl, and other community leaders, who have all committed to making sure this critical need during the holiday season [was] met,” said David Wellis, PhD, Chief Executive Officer of San Diego Blood Bank in a news release. The drive featured live entertainment and local sports celebrities including former Chargers players. It resulted in the collection of more than 700 pints. “We would like to thank all of the members of the local sports community, especially Ron Fowler and the Padres, and Rolf Benirschke for all of their hard work to make this blood drive a tremendous success... We appreciate the support of the entire community, especially the donors. We can’t do it without them.”



Left to Right: Former San Diego Chargers defensive end Jacques Cesaire, poses for a photo with Kidan Good during the drive. *Photo courtesy of The San Diego-Union-Tribune.*


(Source: San Diego Blood Bank [News Release](#), 11/30/17; San Diego Blood Bank [News Release](#), 12/16/17)



CALENDAR

Note to subscribers: Submissions for a free listing in this calendar (published in the last issue of each month) are welcome. Send information to Leslie Maundy by e-mail (Imaundy@americasblood.org) or by fax to (202) 393-1282. (For a more detailed announcement in the weekly “Meetings” section of the newsletter, please include program information.)

2018

- Feb. 5-7. **14th Annual FDA and the Changing Paradigm for HCT/P Regulation., Alexandria, Va.** Register [here](#).
- Feb. 21. **SCABB Regional Symposium: General Topics for Blood Bankers in Clinical Laboratory Medicine, Orlando, Fla.** For more information, contact [Nancy Benitez](#).
- Mar. 17-19. **ABC Annual Meeting, America’s Blood Centers, Scottsdale, Ariz.** More details available [here](#).
- Mar. 20. **National Blood Foundation Leadership Forum, Scottsdale, Ariz.** More details available [here](#).
- Mar. 21-22. **IPFA 3rd Asia Workshop on Plasma Quality and Supply, Kuala Lumpur, Malaysia.** More details available [here](#).
- May 8-10. **ABC Human Resources and Training/Development Workshop, Dallas, Texas.** More details available [here](#).
- May 9-11. **ADRP Conference & Expo, Dallas, Texas.** More details available [here](#).
- May 15. **2018 NJABBP Spring Seminar & Annual Conference, Woodbridge, NJ.** [Join](#) NJABBP by March 15th to be eligible to receive benefits. More details available [here](#).
- May 16-17. **IPFA/PEI 25th Workshop on “Surveillance and Screening of Blood-borne Pathogens,” Athens, Greece.** More details available [here](#). 

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 institutional 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, contact Leslie Maundy at the ABC office. Phone: (202) 654-2917; fax: (202) 393-1282; e-mail: lmaundy@americasblood.org.

POSITIONS

Manager of Clinical Apheresis. Responsible for departmental goals, objectives, and managing daily operations/business activities. Meet the needs of hospital and clinical accounts to ensure excellent customer service and quality patient care. Responsible for staffing field assignments, performing procedures in the field to assist in training or as staffing indicates, and remaining competent in all procedures and equipment utilized. The manager is responsible for maintaining statistics, quality indicators of procedures and records of preventative or responsive maintenance, and quality control of supplies and equipment. Regular attendance during office hours. RN active licensure in the State of Texas, HP credentialing preferred. Five year's apheresis experience - three year's therapeutic/PBSC apheresis. Carter BloodCare (CBC) is an EEO/Affirmative Action employer. CBC provides equal employment opportunities (EEO) to all employees and applicants and will not discriminate due to an employee's or applicant's race, color, religion, sex, sexual orientation, gender identity, age, national origin, genetic, and veteran or disability status. In addition to federal law requirements, Carter BloodCare complies with applicable state and local laws governing nondiscrimination in employment in every location in which the company has facilities. For more information or to apply, please visit www.carterbloodcare.org. CBC is a Pro Disabled & Veteran Employer. We maintain a drug-free workplace and perform pre-employment substance abuse testing.

Director of Client Services. Blood Bank Computer Systems (BBCS) is seeking qualified candidates for a Director of Client Services in Auburn, WA. This position is responsible for all aspects of client related services and support as well as the implementation of all products and services. The role's responsibilities include: implementation of BBCS products, training for clients, project management, technical support, marketing and demonstration materials, ensuring IT needs of the organization are met and managing all corporate and marketing events. The individual must demonstrate a high level of understanding of the technical aspects of BBCS products, services, training materials and documentation. Required skills include: strong customer service orientation, oral and written communication skills, analytical and problem solving, public speaking skills, ability to handle multiple projects concurrently, function in a fast-paced environment, and ability to understand new technologies quickly. Desired skills include: experience working in a software development environment, regulatory and/or medical device experience. A BA/BS or equivalent healthcare

industry experience is required. Candidate must be located in WA or be willing to relocate. Click [here](#) to apply.

Assistant Vice President, Quality & Regulatory Affairs. Kentucky Blood Center, located in Lexington, Kentucky, is seeking a proactive professional to assist the Vice President, Quality & Regulatory Affairs (VPQRA) in coordination of institutional adherence to standards and guidelines issued by regulatory agencies and accrediting organizations by designing, implementing, and monitoring the quality assurance program plan. This position is responsible for assisting the VPQRA in regulatory oversight of quality and operational activities to ensure KBC compliance with all regulations and standards issued by regulatory agencies and accrediting organizations, including AABB, FDA, CLIA, State, OSHA, NRC, EU, and Short-Supply Agreement requirements. Qualified applicants must have a Bachelors of Arts or Science, Medical Technologist MT(ASCP) or equivalent, and CQA(ASQ) or equivalent preferred. A minimum of seven years blood banking experience or demonstrate understanding of all federal, state and regulatory agency requirements/guidelines and five years' experience in management. Must have good communication skills, computer skills, and have the ability to perform and interpret statistical analyses and reports. Competitive salary, comprehensive benefits including health, dental, vision, life, STD, LTD, paid time off/holidays, EAP, and 401(k) retirement savings plan. Relocation provided. For more information or to apply online, please visit www.kybloodcenter.org. Drug-free and EOE/AAP.

Manufacturing and Hospital Services Manager. Kentucky Blood Center (KBC), located in Lexington, KY is seeking a resourceful, self-motivated individual to oversee Technical Services second shift blood component processing from receipt of units through distribution, including inventory management. The successful candidate will ensure excellent customer service is provided to all KBC blood component customers; ensure Quality System Essentials are implemented, audited, and in compliance within Technical Services; develop and monitor department budgets; and will ensure acceptable validation and implementation of new or revised processes, equipment, computer programs and SOPs. This is a second shift position, 2:00 pm – 10:30 pm. Bachelors of Arts or Science, Medical Technologist MT(ASCP) or

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POSITIONS (continued from page 12)

Clinical Laboratory Sciences, or experience deemed equivalent. Three years of management experience in an organization regulated by good manufacturing practices, FDA, AABB or equivalent. Two or more years' experience in a blood center managing blood components distribution, inventory, and customer relations preferred. Must have excellent leadership, problem solving, and communication skills. Competitive salary, comprehensive benefits including health, dental, vision, life, STD, LTD, paid time off/holidays, EAP, and 401(k) retirement savings plan. Relocation provided. For more information or to apply online, please visit www.kybloodcenter.org. Drug-free and EOE/AAP.

Vice President, Clinical Services Administration. Blood Systems, headquartered in Scottsdale Arizona, is one of the nation's largest comprehensive transfusion medicine organizations. Our blood centers provide blood, blood components and special services to patients in over 1,000 hospitals across the country. We are seeking a Vice President, Clinical Services Administration for the Corporate Division. This position is responsible for fostering enterprise-wide collaboration among Blood Systems' immunohematology reference and centralized transfusion clinical services, promoting cost-saving standardization and enacting approved changes to provide impeccable laboratory and transfusion services for the patients served by our hospital partners. The ideal candidate will have extensive supervisory experience in immunohematology. Experience: Eight years of related experience required, to include five years' supervisory experience. Knowledge/Education: Bachelor's degree required. Master's degree preferred. Knowledge of large system operations management including fiscal policies, human resource management, and strategic planning required. Knowledge of federal, state, and local regulations that affect business operations required. Licenses/Certifications: SBB or equivalent preferred. To view the job description and apply for this position, please click [here](#).

Human Resources (HR) Training Specialist (Greenville, SC). The Blood Connection (TBC) seeks qualified applicants for its Human Resources (HR) Training Specialist position. The role of the HR Training Specialist is to oversee all professional development and regulatory training within TBC. HR Training Specialist responsibilities include understanding regulatory training requirements and communicating with executives and managers to identify training needs and mapping out development plans for teams and individuals. The HR Training Specialist is responsible for managing, designing, developing, coordinating and facilitating all training programs. Bachelor's degree in education, human resources, or related field with four years training experience or a bachelor's degree in any field with eight years training experience preferred. This position reports

to Vice President of Business and Administration/VPBOA. The Blood Connection is an Equal Opportunity Employer. EEO/Minority/Female/Disability/Vets. To apply please go to <http://thebloodconnection.org/everify/>.

Manager of Operations. The Blood Connection (TBC) seeks qualified applicants for its Manager of Operations position in Western North Carolina. This position is responsible for operational oversight of The Blood Connection's collections, and donor recruiting in the Western NC Region. Supervises staff in Western NC Region with guidance from the TBC Executive team. Monitors performance in the areas of productivity, proficiency, efficiency, and customer service. Advanced communications skills preferred with working knowledge of blood center practices, regulations, and equipment requirements. Must be an effective leader and have the ability to adapt to change. Excellent salary and benefits including relocation packages. Bachelor's degree required. Demonstrated experience in territory management skills, superb leadership and team building skills, excellent verbal and written communication and public speaking skills, computer literate. Five years related experience required with at least three years' supervisory experience. Successful candidate must demonstrate ability to work closely with Executive team to facilitate efficient and effective blood drives. This position reports to Executive Vice President Operations/COO. The Blood Connection (TBC) is an Equal Opportunity Employer. EEO/Minority/Female/Disability/Vets. To apply please go to <http://thebloodconnection.org/everify/>.

Chief Financial Officer (CFO). LifeShare Blood Center is looking for a Chief Financial Officer (CFO) with responsibilities for directing, organizing, leading and managing the following departments: Fiscal Services, Central Supply, and Properties. Additionally, the CFO provides overall reporting to the President & CEO and the Board of Trustees on all financial aspects of the Corporation. The CFO serves as Secretary/Treasurer of the Corporation, prepares annual budget, prepares and analyzes financial statements in accordance with GAAP and monitors the financial position of the Corporation at all times. The CFO manages Corporate investments, monitors cash flow information to ensure adequate availability to monies needed for daily operations, reviews and approves expense reports, coordinates annual audit, reviews and files all 990's, and files all annual reports with appropriate bodies. The CFO reviews and approves all expenditures and monitors all property and liability insurance contracts. A bachelor's degree in business, finance, accounting or other application degree is required. Master's degree preferred. Certified Public Accountant (CPA) certification must be current and maintained or have the ability to obtain within two years of hire. Ten

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POSITIONS (continued from page 13)

plus years' work experience in public or private accounting, or business finances. Experience working in a not-for-profit organization helpful. Interested applicants may apply through company website at www.lifeshare.org/careers. ♦