



# ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2019 #38

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## CMS Publishes CY 2020 OPPTS Final Rule

The Centers for Medicare and Medicaid Services (CMS) has issued the calendar year (CY) 2020 Hospital Outpatient Prospective Payment System (OPPS) [final rule](#). It addresses payment to hospital outpatient departments and ambulatory surgical centers (ASCs), including payment rates for blood components.

**Laboratory date of service (DOS) exception policy.** The rule finalized the categorical exemption of blood centers from the Medicare laboratory Date of Service (DOS) policy, clarifying that blood centers do not have to bill Medicare directly for molecular tests. This was required following a 2019 CMS exception to the DOS policy that would have required a laboratory, including a blood center, to bill Medicare directly for advanced diagnostic laboratory tests (ADLTs) and molecular pathology tests under some circumstances. Following extensive advocacy by America's Blood Centers (ABC) and other blood industry stakeholders, CMS has been exercising enforcement discretion of the DOS policy for blood centers with an extension that lasts until January 2, 2020. The exclusion of blood centers from the laboratory DOS policy is a substantial victory for blood centers and was achieved following a year-long effort by ABC and other blood community stakeholders.

**Payment Policies.** CMS is continuing the cost-to-charge methodology in use since 2005 for blood and blood products.

The agency is using claims data instead of a crosswalk from another code to pay for pathogen reduced platelets despite receiving multiple comments highlighting accuracy concerns with the underlying claims data. The result is about a two percent reduction in payment from \$624.93 in CY2019 to \$611.94 for CY2020. The payment for pathogen reduced platelets had been paid based on a crosswalk from another code [Healthcare Common Procedure Coding System (HCPCS) code P9072 (Platelets, pheresis, pathogen reduced or rapid bacterial tested, each unit), the predecessor code to HCPCS code P9073 (Platelets, pheresis, pathogen-reduced, each unit) which was changed in CY2016 because P9072 could be either pathogen reduction technology or rapid bacterial tested, two very different products in terms of costs). As is customary, the new code was paid based on a crosswalk from P9037 (Platelets, pheresis, leukocytes reduced, irradiated, each unit)]. Last year's proposed rule for CY2019 recommended payment based on the claims data for the new code instead of the crosswalk, but industry commenters expressed concern that the data was not reflecting the costs and the HCPCS code data still inappropriately included non-pathogen reduced products.

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CMS Publishes OPSS (continued from page 1)

CMS finalized the proposed increase in payment for pathogen testing for platelets (HCPCS P9100), the two approved bacterial detection tests for seven-day platelets by assigning these tests to a higher level of 1D (\$31-40) with a payment rate of \$35.50 resulting from claims data reflecting a higher cost, an increase from the CY2019 rate of \$25.50 which had been based on a new technology level 1C (\$21-\$30).

CMS created a new HCPCS code, P9099 Blood component/product noc. This new code is the result of advocacy efforts of ABC along with AABB and the American Red Cross (ARC) for the establishment of a level II P-code for use by hospitals to bill third party payers for anticipated new blood products. This code was discussed at a June 12<sup>th</sup>, 2019 meeting and was not included in the proposed rule as the CMS HCPCS Public Meeting Agenda for Durable Medical Equipment (DME) and Accessories; Orthotics and Prosthetics (O & P); Supplies and Other. Previously, a “not otherwise classified code” did not exist for blood products, a barrier to the timely adoption of new products that may have the potential to result in improved clinical outcomes. This code was created with a status indicator of E2, Items and Services for which pricing information and claims data are not available. ABC, along with AABB and ARC, is working to ensure this code facilitates the collection of claims data to inform future decisions to include specific new products and to ensure the correct status indicator is assigned.

The full listing of payment rates can be found in [Addendum B](#) of the file rule. The blood codes are listed below in the CY2019 rate for comparison. 💧

HCPCS Code	Short Descriptor	CY2019 Final Payment Rate	CY2020 Final Payment Rate	Percentage Change
P9010	Whole blood for transfusion	\$111.18	\$127.19	14.40%
P9011	Blood split unit	\$126.06	\$134.46	6.66%
P9012	Cryoprecipitate each unit	\$49.40	\$50.43	2.09%
P9016	Rbc leukocytes reduced	\$184.78	\$188.33	1.92%
P9017	Plasma 1 donor frz w/in 8 hr	\$71.53	\$83.74	17.07%
P9019	Platelets, each unit	\$107.96	\$108.02	0.06%
P9020	Platelet rich plasma unit	\$125.23	\$141.22	12.77%
P9021	Red blood cells unit	\$140.12	\$139.75	-0.26%
P9022	Washed red blood cells unit	\$355.93	\$379.68	6.67%

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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 recognize 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 healthcare system; promote partnerships, policies and programs that increase awareness about the need for blood donation; and serve as a thought-leader in the advancement of evidence-based medical and scientific solutions related to health and safety.

**America’s Blood Centers**

Chief Executive Officer: Kate Fry  
 Chief Medical Officer: Rita Reik  
 Editor: Mack Benton  
 Subscriptions Manager: Leslie Maundy  
**Annual Subscription Rate: \$390**

Send subscription queries to [lmaundy@americasblood.org](mailto:lmaundy@americasblood.org)

America’s Blood Centers  
 1717 K St. NW, Suite 900, Washington, DC 20006  
 Phone: (202) 393-5725

Send news tips to [newsletter@americasblood.org](mailto:newsletter@americasblood.org).

CMS Publishes OPPS (continued from page 2)

P9023	Frozen plasma, pooled, sd	\$75.96	\$80.13	5.49%
P9031	Platelets leukocytes reduced	\$136.61	\$126.34	-7.52%
P9032	Platelets, irradiated	\$171.91	\$139.64	-18.77%
P9033	Platelets leukoreduced irradi	\$167.14	\$217.10	29.89%
P9034	Platelets, pheresis	\$337.08	\$323.98	-3.89%
P9035	Platelet pheres leukoreduced	\$486.30	\$499.55	2.72%
P9036	Platelet pheresis irradiated	\$552.91	\$692.30	25.21%
P9037	Plate pheres leukoredu irradi	\$624.93	\$634.62	1.55%
P9038	Rbc irradiated	\$221.36	\$190.80	-13.81%
P9039	Rbc deglycerolized	\$331.14	\$320.42	-3.24%
P9040	Rbc leukoreduced irradiated	\$255.58	\$262.73	2.80%
P9041	Albumin (human),5%, 50ml	\$10.490	\$10.490	0.00%
P9043	Plasma protein fract,5%,50ml	\$26.95	\$18.43	-31.61%
P9044	Cryoprecipitatereducedplasma	\$88.73	\$91.40	3.01%
P9045	Albumin (human), 5%, 250 ml	\$52.450	\$52.450	0.00%
P9046	Albumin (human), 25%, 20 ml	\$20.980	\$20.980	0.00%
P9047	Albumin (human), 25%, 50ml	\$52.450	\$52.450	0.00%
P9048	Plasmaprotein fract,5%,250ml	\$76.98	\$111.68	45.08%
P9050	Granulocytes, pheresis unit			
P9051	Blood, l/r, cmv-neg	\$175.94	\$188.09	6.91%
P9052	Platelets, hla-m, l/r, unit	\$844.83	\$854.32	1.12%
P9053	Plt, pher, l/r cmv-neg, irr	\$492.31	\$502.19	2.01%
P9054	Blood, l/r, froz/degly/wash	\$298.37	\$281.07	-5.80%
P9055	Plt, aph/pher, l/r, cmv-neg	\$445.06	\$485.12	9.00%
P9056	Blood, l/r, irradiated	\$225.47	\$203.31	-9.83%
P9057	Rbc, frz/deg/wsh, l/r, irradi	\$224.51	\$241.62	7.62%
P9058	Rbc, l/r, cmv-neg, irradi	\$229.29	\$246.78	7.63%
P9059	Plasma, frz between 8-24hour	\$76.66	\$75.90	-0.99%
P9060	Fr frz plasma donor retested	\$62.81	\$49.98	-20.43%
P9070	Pathogen reduced plasma pool	\$41.43	\$32.30	-22.04%
P9071	Pathogen reduced plasma sing	\$78.35	\$80.10	2.23%
P9073	Platelets pheresis path redu	\$624.93	\$611.94	-2.08%
P9100	Pathogen test for platelets	\$25.50	\$35.50	39.33%





## REGULATORY NEWS

The U.S. Food and Drug Administration's (FDA) Blood Products Advisory Committee (BPAC) has published the meeting [materials](#) for their next public meeting on November 22<sup>nd</sup> including the meeting [agenda](#), committee [roster](#), and [summary](#) of the topic, cold stored platelets. The meeting will include discussions and scientific considerations for the safety and efficacy of transfusing cold stored platelets products including:

- product characterization;
- duration of storage; and
- clinical indications for use.

Additionally, there will be discussion of the clinical studies needed to support extending expiration of cold stored platelets beyond three days. The meeting will take place at the [Tommy Douglas Conference Center](#) in Silver Spring, Md from 8:30 a.m. to 4:45 p.m. eastern. A webcast will be available for those unable to attend. ABC is requesting input from member blood centers in preparing a statement committee on behalf of independent community blood centers. Please complete this [survey](#) by Wednesday, November 13<sup>th</sup> and contact [Ruth Sylvester](#) with any questions.

(Source: Blood Products Advisory Committee Meeting [Materials](#), 11/7/19; [Notice](#), 10/2/19)

The U.S. Department of Health and Human Services (HHS) announced that Assistant Secretary for Health, Admiral Brett Giroir, MD will take on the delegable duties of the FDA Commissioner at the request of HHS Secretary Alex Azar, who assumed duties and authorities of the role, pending the confirmation of Stephen Hahn, MD, nominated by President Trump last week. "Under Dr. Sharpless's leadership for the past seven months, FDA has forged ahead in its essential work of protecting the public health," said Secretary Azar in an agency news [release](#). "Dr. Sharpless's willingness to step into the role of Acting Commissioner, and to lead the team at FDA with a steady hand, ensured that the agency did not miss a beat in advancing its vital mission. With Dr. Sharpless at the helm, the FDA has executed on its core responsibilities while also making progress on key priorities, such as lowering the price of prescription drugs and tackling the growing epidemic of youth use of tobacco products. I am very grateful to have had Dr. Sharpless as a partner in these efforts...Admiral Giroir, MD has been an indispensable leader for HHS on a number of public health priorities. As Assistant Secretary for Health, whose authorities include overseeing the U.S. Public Health Service, he will be able to assume the delegable duties of the Commissioner at this time and ensure the FDA's work continues to move forward." Dr. Sharpless will return to his previous role as National Cancer Institute Director.

(Source: HHS News [Release](#), 11/1/19) 💧

### Upcoming ABC Webinars – Don't Miss Out!

- **Staffing Success & Challengers at Blood Centers Webinar** – November 19<sup>th</sup> from 3 - 4:30 p.m. (ET). More details including a link to join the webinar available to ABC Members in [MCN 19-075](#).
- **SMT Journal Club Webinar** – December 5<sup>th</sup> from 12 – 1 p.m. (ET). Additional details coming soon.
- **Irradiator Replacement at Blood Centers Webinar** – January 21<sup>st</sup> from 3 – 4:30 p.m. (ET). Additional details coming soon.

### ABC Calendar of Events

ABC offers a variety of meetings, workshops and virtual opportunities for education and networking as well as participation in ABC business. The [calendar of events](#) includes annual and summer meetings, board meetings, workshops, and webinars, and details will be updated as confirmed. We look forward to your support and participation!



## Fibrinogen Concentrate vs. Cryoprecipitate—How Do They Compare for Cardiac Surgery Patients?

Contributed by Richard Gammon, MD, Medical Director at OneBlood

*\*\*Please note: America's Blood Centers welcomes regular contributions or briefs from guest authors for scientific/medical peer-reviewed published papers. The views/comments expressed in submitted articles from external parties are those of the author(s) and are not to be interpreted as the viewpoint of America's Blood Centers. If you are interested in contributing an article for potential publication please contact us [here](#).\*\**

Excessive bleeding is a common complication of cardiac surgery. An important cause of bleeding is acquired hypofibrinogenemia (fibrinogen level <150 -200 mg/dL) for which published guidelines recommend fibrinogen replacement with cryoprecipitate or fibrinogen concentrate. Cryoprecipitate's fibrinogen content varies widely (30-300 mg/dL per unit) and it has a limited shelf life after thawing (four to six hours) that can lead to wastage. Fibrinogen concentrates are pathogen-reduced, have standardized fibrinogen content (200 mg/dL) and lyophilized allowing for easy storage, reconstitution, and administration; and have longer shelf life after reconstitution (up to 24 hours), which may reduce wastage. The two products have important differences, but comparative clinical data are lacking. The Effect of Fibrinogen Concentrate vs. Cryoprecipitate on Blood Component Transfusion After Cardiac Surgery (FIBRES study) published in *JAMA* was conducted to determine if fibrinogen concentrate was noninferior to cryoprecipitate for treatment of bleeding related to hypofibrinogenemia after cardiac surgery.

This was a randomized clinical trial at 11 Canadian hospitals enrolling adult patients experiencing clinically significant bleeding and hypofibrinogenemia (<200 mg/dL) after cardiac surgery during an approximately 20-month period. Patients in the fibrinogen concentrate group received 4.0 g of fibrinogen concentrate infused over 10 minutes, and those in the cryoprecipitate group received 10 units of cryoprecipitate infused according to local practice. Patients were to only receive the allocated product for 24-hours after cardiopulmonary bypass, after which only cryoprecipitate was used. The primary outcome was cumulative blood components administered for 24-hours after cardiopulmonary bypass. Secondary outcomes included individual blood component units administered for 24-hours after cardiopulmonary bypass, all transfusions from beginning of surgery to postoperative day seven, bleeding severity during the 24 hours after cardiopulmonary bypass, and pre- and post-treatment fibrinogen levels.

There were 735 patients treated (372 fibrinogen concentrate, 363 cryoprecipitate). The mean 24-hour post-bypass cumulative blood transfusions were 16.3 units in the fibrinogen concentrate group and 17.0 units in the cryoprecipitate group ( $P < .001$  for noninferiority). Noninferiority was also observed for the secondary outcomes of individual 24-hour and cumulative seven-day blood component transfusions as well with cumulative transfusions from product administration to 24 hours after cardiopulmonary bypass [mean units, 8.6 in the fibrinogen concentrate group vs 8.9 in the cryoprecipitate group ( $P = .003$  for noninferiority)]. Timing and number of doses of product were similar between groups. Fibrinogen response was slightly greater in the fibrinogen concentrate group [(median increase, 90 mg/dL vs 70 mg/dL) ( $P < .001$ )].

The authors concluded that in patients undergoing cardiac surgery who developed clinically significant bleeding and hypofibrinogenemia after cardiopulmonary bypass, fibrinogen concentrate was noninferior to cryoprecipitate with regard to number of blood components transfused in a 24-hour period post bypass. They also stated that use of fibrinogen concentrate may be considered for management of bleeding in patients with acquired hypofibrinogenemia in cardiac surgery.

**Citation:** Callum, J., Farkouh, M.E., Scales, D.C., *et al.* Effect of Fibrinogen Concentrate vs Cryoprecipitate on Blood Component Transfusion After Cardiac Surgery-The FIBRES Randomized Clinical Trial. *JAMA* 2019. Doi: [10.1001/jama.2019.17312](https://doi.org/10.1001/jama.2019.17312). ♦





## RECENT REVIEWS

A systemic review published in the *Canadian Journal of Anesthesia* examined the impact, if any, on blood product transfusion, patient mortality, and length of hospital stay, from performing point-of-care viscoelastic tests (e.g. thromboelastography (TEG) and rotational thromboelastometry (ROTEM) in cardiac surgery patients). The authors' research discovered 1,917 records, from 11 trials (one multi-center and 10 single center) that included 8,294 patients from 1999-2006 that matched their identified criteria, randomized controlled trials with patients over the age of 18 with a minimum of 80 percent of the patients undergoing cardiac surgery that required cardiopulmonary bypass. They found that, "the use of point-of-care viscoelastic testing was not associated with a difference in the proportion of patients transfused with any blood product (RR, 0.90; 95 percent CI, 0.79 to 1.02;  $I^2 = 51$  percent; four trials, 7,623 patients) or mortality at the longest follow up ((RR, 0.73; 95 percent CI, 0.47 to 1.13;  $I^2 = 5$  percent; six trials, 7,931 patients). We found no difference in proportion of patients transfused with any blood product or all-cause mortality across all subgroups examined, including risk of bias, funding source, procedure urgency, and complexity." They conclude that the benefits of viscoelastic testing "are not sufficiently robust" enough to universally recommend implementation for adult cardiac surgery patients.

**Citation:** Lowdewyks, C., Heinrichs, J., *et al.* [Point-of-care viscoelastic hemostatic testing in cardiac surgery patients: a systematic review and meta-analysis](#). *Canadian Journal of Anesthesia*. 2018. ♦

## RESEARCH IN BRIEF

**Researchers at Abbott have reported the discovery of a new strain of HIV and believe it is detectable by their current screening methods.** The findings have been [published](#) in the *Journal of Acquired Immune Deficiency Syndromes*. "[HIV-I group M subtype L] is the first new subtype classification identified since the nomenclature guidelines were established in 2000," explained the authors. The specimens were obtained in the Democratic Republic of the Congo (DRC) in 1983, 1990, and 2001 and frozen due to testing limitations at the time. The latter specimen had "low viral load (<4 log<sub>10</sub> copies/ml) and limited sample volume, which have now been overcome," according to the study. The authors conclude "[f]urthermore, our identification of CG-0018a-01 decades after the first subtype L strain was collected also suggests that ongoing transmission of subtype L is likely, albeit poorly sampled. Although CG-0018a-01 was one of 172 specimens sequenced in this study, we expect the prevalence of subtype L is much lower than was found in this small cohort. While subtype L is currently restricted to the DRC, it remains possible that future sequence analyses that include this clade as a reference may identify more subtype L infections in DRC or elsewhere. Continued molecular surveillance will be essential to determining the true prevalence of subtype L and other rare or emerging strains of HIV."

**Citation:** Yamaguchi, J., McArthur, C., *et al.* Complete genome sequence of CG-0018a-01 HIV-I subtype L. *Journal of Acquired Immune Deficiency Syndromes*. 2019. Doi: [10.1097/QAI.0000000000002246](#). ♦

## BRIEFLY NOTED

**The U.S. Food and Drug Administration (FDA) is encouraging regulatory alignment to improve consistency in regulations in the U.S., Europe, and Canada.** In remarks delivered by FDA Center of Biologics Evaluation and Research (CBER) Director Peter Marks, MD, PhD during a policy summit for the American Society for Gene and Cell Therapy, he [discussed](#) that agency's efforts to improve access to new and innovative gene therapies, "[w]e really want to see the delivery of safe and effective gene therapies, not just in high income countries but across the globe," said Dr. Marks according to *Bloomberg*. "Hopefully

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**BRIEFLY NOTED** (continued from page 6)

that could facilitate commercial availability and the use of gene therapy in low- and middle-income countries.” The agency believes that increasing regulatory consistency will remove accessibility barriers and promote the ability and availability of gene therapies to improve public health. “As part of that effort, the FDA will allow regulators from other nations to sit in on early-stage development meetings with gene therapy developers and the U.S. agency,” reported *Bloomberg*.

(Source: *Bloomberg*, [FDA Official Urges Wealthy Nations to Align Gene Therapy Rules](#), 11/4/19)

**The *Washington Post* published an article examining the impact of immune globulin shortages on patients and the factors contributing to the shortage.** It includes statements from the patient’s, physician’s, manufacturer’s, and regulator’s perspectives citing immune globulin’s increasing use as a therapy for patients with certain health disorders as a primary reason for the ongoing shortage despite efforts by manufacturers to increase production. “[D]espite increased supply of immune globulin products in recent years, the demand for IG products has also increased over the same time and there is an ongoing shortage,” said the FDA in an August statement referencing the shortage. The article also explores mitigation strategies that plasma collection facilities are implementing such as the addition of more collections facilities and maximizing the efficiency of manufacturing process, “efforts to optimize both plasma collecting and manufacturing capacity, opening more collection centers, and more recently investing in a new manufacturing facility in the U.S.,” said Katie Joyce, a spokesperson for manufacturer Takeda Pharmaceuticals.

(Source: *Washington Post*, [A severe shortage hits a drug used for cancer, immune disorders, epilepsy, causing canceled treatments and rationing](#), 11/4/19) ◆

**WORD IN WASHINGTON**

**Members of the Senate Health, Education, Labor, and Pensions (HELP) Committee have expressed concern over the U.S. Food and Drug Administration’s plan for a progressive approval pathway for medical devices.** According to a news [release](#), Sens. Elizabeth Warren (D-Mass.) and Patty Murray (D-Wash.) sent a [letter](#) to the agency that stated “We are disappointed by FDA’s clarification that the agency no longer fully stands by former-Commissioner Gottlieb’s commitment that the ‘FDA does not believe this...pathway would be suitable for human medical products.’ [W]e continue to have questions regarding the eligibility criteria the FDA envisions for this proposal; the FDA’s ability to ensure the quality and completeness of post-market data collection; and the agency’s ability to exercise its authority to remove medical products from the market once they have been approved under an accelerated approval pathway.” According to the news release, the senators feel such a system could potentially compromise patient safety by allowing device manufacturers to introduce products to the market prior to proving them be both safe and effective. “Whether ‘progressive,’ ‘provisional,’ or ‘conditional,’ the proposal is particularly alarming, given the FDA’s already-lenient regulatory framework guiding medical device approval standards. While new drug sponsors must show ‘substantial evidence [of effectiveness],’ new device sponsors must only show a reasonable assurance of ...safety and effectiveness.

(Source: Sen. Elizabeth Warren News [Release](#), 11/5/19)

**The Senate passed a minibus spending bill that would include funding for the FDA.** The bill would increase the FDA’s discretionary funding to \$3 billion, \$80 million more than 2019 funding levels, but more than \$100 million less than the increase approved by the House earlier this year. The House version of the bill includes \$20 million for pathogen reduction technology, while the Senate version includes \$10

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WORD IN WASHINGTON (continued from page 7)

million. Now the two sides will attempt to reconcile differences in their bills in conference in hopes of agreeing on a unified bill by November 21<sup>st</sup> when the temporary continuing resolution to fund the government is set to expire.

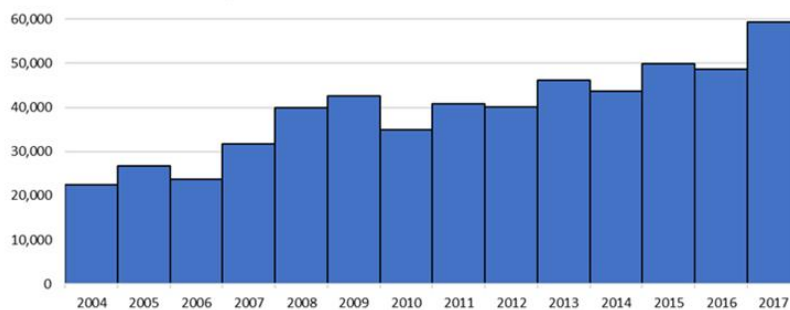
(Source: *Politico*, [Senate succeeds — then stumbles — on spending bills amid border wall fight](#), 10/31/19)

**The Senate Health, Education, Labor, and Pensions (HELP) Committee has advanced the Kay Hagan Tick Act (S. 1657).** The bill, introduced by Sens. Susan Collins (R-Maine) and Tina Smith (D-Minn.), aims to address the increasing incidence of tick and vector-borne diseases and disorders. “I want to express my condolences to the family of our former colleague and friend, Sen. Kay Hagan (D-N.C.), who passed away this week from complications of the Powassan virus [a tick-borne disease],” said Sen. Collins in a news [release](#). “Tick-borne diseases like Lyme have become a major public health concern, with the incidence exploding over the past 15 years. The Tick Act takes a comprehensive approach to address Lyme and other tick and vector-borne diseases. I am pleased that our bipartisan bill was approved by the Senate Health Committee today, and I urge all of my colleagues to support this important legislation to reverse this burgeoning public health crisis.” The legislation would:

- require the U.S. Department of Health and Human Services to create a national strategy to promote research, better testing, and encourage interagency coordination from the federal government;
- reauthorize \$50 million in funding over five years for Regional Centers of Excellence in Vector-Borne Disease; and
- allow the Centers for Disease Control and Prevention to issue \$20 million dollars annually in grants to state health departments to improve the collection of data, surveillance efforts, treatment, and awareness of vector-borne diseases.

“Several of the bills we are moving forward today will help us better understand and address the public health challenges that we face to keep our families safe, like the Tick Act—which I want to thank Sens. Collins and Smith,” said Senate HELP Committee Ranking Member Sen. Patty Murray (D-Wash.) in the news release. “They have been great leaders on this, and this is a bill, as they will describe to you, that will create a national strategy and take other important steps to address vector borne diseases like Lyme disease.”

Total Reported Cases of Tickborne Disease, 2004–2017



Reported cases of confirmed and probable Lyme disease, anaplasmosis/ehrlichiosis, spotted fever rickettsiosis (including Rocky Mountain spotted fever), babesiosis, tularemia, and Powassan virus disease all increased between 2016 and 2017.

*Centers for Disease Control and Prevention’s Tickborne Disease Surveillance Data Summary*

(Source: Sen. Susan Collins News [Release](#), 10/31/19) 💧





## GLOBAL NEWS

The U.S. Agency for International Development (USAID) recently took part in a ribbon cutting [ceremony](#) for new headquarters for the **National Blood Bank Services of Ethiopia**. Approximately \$65 million in funding has been provided by both USAID and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) over the past five years to improve healthcare facilities throughout Ethiopia, including \$5 million for National Blood Bank Services headquarters. The facility will allow the National Blood Bank Services to collect, process, and screen blood donations with improved efficiency and increased capacity.



Photo courtesy of the U.S. Embassy in Addis Ababa.

(Source: Borkena Ethiopian News, [United States and Ministry of Health inaugurate National Blood Bank](#), 10/26/19)

The European Medicines Agency has approved the refined drug product manufacturing specifications for bluebird bio's gene therapy treatment (ZYNTGLO™) for patients that are 12 years of age and older with transfusion-dependent beta thalassemia (TDT) according to the announcement from bluebird bio. "We look forward to serving TDT patients with ZYNTGLO™ and providing a treatment option that offers the possibility of a transfusion-free future," said Alison Finger, chief commercial officer of bluebird bio in the news [release](#). "This is one step along the commercial journey as we advance our ongoing launch and market access activities on a country-by-country basis, with the goal of enrolling our first commercial patient in 2019." ZYNTGLO™ is a one-time gene therapy treatment for TDT patients that would otherwise rely on hematopoietic stem cell (HSC) transplantation but are unable to find a human leukocyte antigen (HLA)-matched related HSC donor.

(Source: bluebird bio, News [Release](#), 10/22/19)



Photo courtesy of Terumo BCT.

Terumo BCT and the Organization for First Ladies for Development (OAFLAD) held a panel discussion entitled "The Importance of Blood for Africa's Mothers" with the goal of raising awareness of the importance of having and maintaining a safe and sustainable blood supply for sub-Saharan Africa. "Saving lives is our joint responsibility, requiring commitment, expertise, and capacity to support the United Nations (UN) Sustainable Development Goal 3 (SDG3) targets, particularly relating to maternal mortality," said Terumo BCT President and CEO Antoinette Gawin in a news [release](#). "Our panel is a call to action for all stakeholders to do more. Terumo BCT is committed to building the capacity of communi-

ties to ensure an adequate, safe, and sustainable blood supply." H.E. Auxillia Mngangwa, the First Lady of Zimbabwe added, "The First Ladies of Africa continue to work tirelessly towards reducing the high rates of maternal, neonatal, and child mortality across our continent. We recognize that a lack of infrastructure and equipment for collection and processing of blood components are key impediments to achieving public health goals in Africa – particularly those related to maternal and child health. Our hope is that this discussion will result in concrete and actionable solutions to address blood safety and maternal health issues in Africa."

(Source: Terumo BCT News [Release](#), 9/25/19) 💧



**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.*

### **ABC Awards of Excellence Call for Nominations Now Open**

ABC members are encouraged to nominate blood donation sponsors, corporations, and advocates for the 23<sup>rd</sup> Annual Awards of Excellence. This year's ceremony on Tuesday, March 10<sup>th</sup> will be in Washington, D.C. during ABC's 58th Annual Meeting at the Ritz-Carlton (Pentagon City). Nominations are currently open until Wednesday, December 4th. Additional details are available in [MCN 19-072](#) for ABC member blood centers. The online submission form is available [here](#). ABC members are permitted to submit up to three nominations per category. The following awards will be presented during the awards ceremony and are currently open for nominations:

- ABC Outstanding Blood Drive of the Year
- Outstanding Public Relations Campaign
- Corporation of the Year Award
- Larry Frederick Award (jointly presented by ABC and ADRP)
- William Coenen President's Award
- Blood Community Advocate of the Year Award
- Thomas F. Zuck Lifetime Achievement Award

A complete description of each award is available [here](#). Please direct any questions about nominations or the awards ceremony to [memberservices@americasblood.org](mailto:memberservices@americasblood.org).

(Source: MCN [19-072](#), 10/30/19)

### **2020 ADRP Award Nominations Available**

Each year, ADRP honors individuals and organizations that have demonstrated outstanding service, accomplishments or leadership in blood banking. Blood centers are encouraged to [nominate](#) individuals and organizations. In addition to a complimentary conference registration, winners receive a commemorative award and recognition in the ADRP newsletter and website. The nomination deadline is December 31, 2019. This year's award categories are:

#### Individual Awards

- Donor Recruiter of the Year
- Collections Team Member (Recruitment and Collections)
- Rolf Kovenetsky Leader of the Year
- Ron Franzmeier Lifetime Achievement
- Ronald O. Gilcher, MD

#### Organization Awards

- Media Partner
- Humanitarian Service

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- Blood Drive (Most Creative and Most Productive)
- School Blood Drive (HS or College)

Additional information on the ADRP awards is available on the ADRP [website](#).

(Source: ADRP Awards [Announcement](#), 10/29/19)

## 2020 ADRP Annual Conference Now Accepting Abstracts

ADRP, an international division of America's Blood Centers, is encouraging donor collections, donor recruitment, and marketing or communications professionals to consider sharing their knowledge at the 2020 ADRP Annual Conference by being a presenter. The call for speaker abstracts is [open](#) until December 31<sup>st</sup>. Topics that have been the most requested by attendees include:

- **Leadership and team development:**
  - Critical thinking
  - Time management
  - Staff adequacy and talent level
  - Managing change
- **Blood Type Management:**
  - Collecting correct units based on blood type
  - Maintaining inventory during time of need
  - Rebooking donors and drives with emphasis on time of need
- **Donor and sponsor communication strategies:**
  - Diversification of the donor base
  - Addressing donor apathy
  - Communications strategies

As the industry's leading conference for donor facing professionals in the areas of collections, communications, marketing and recruitment, this year's focus, Charting the Course to Excellence, will delve into each step of the donor journey and provide proven solutions for how staff from all aspects of the blood center can work together to achieve the best possible outcomes. Additional information about the conference is available on ADRP's [website](#).

(Source: ADRP [Announcement](#), 10/10/19)

## 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 [newsletter@americasblood.org](mailto:newsletter@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.)*

### 2019

Nov. 12-14. **U.S. Food and Drug Administration Center for Drug Evaluation and Research Small Business and Industry Assistance Clinical Investigator Training Course, College Park, Md.** More details available [here](#).

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CALENDAR (continued from page 11)

Nov. 22. **U.S. Food and Drug Administration Blood Product Advisory Committee Meeting, Silver Spring, Md.** More details available [here](#).

**2020**

Jan. 14-15. **IPFA/EBA Workshop on Plasma Collection, Amsterdam, the Netherlands.** More details available [here](#).

Mar. 9-11. **2020 ABC Annual Meeting, Washington, D.C.** More details coming soon.

Mar. 25-26. **IPFA 5<sup>th</sup> Asia Workshop on Plasma Quality and Supply, Chonburi, Thailand.** More details available [here](#).

April 14-15. **16<sup>th</sup> Annual U.S. Food and Drug Administration and the Changing Paradigm for HCT/P Regulation Conference, Washington D.C.** More details available [here](#).

May 13-14. **IPFA/PEI 27th International Workshop on “Surveillance and Screening of Blood-Borne Pathogens, Porto, Portugal.** More details available [here](#).

May 19-21. **2020 ADRP Conference, Phoenix, Ariz.** More details coming soon.

July 21-23. **2020 ABC Medical Directors Workshop and Summer Summit, Cleveland, Ohio.** More details coming soon.



<b>ABC 2020 Meetings &amp; Workshops</b>				
<b>Meeting/Workshop</b>	<b>Dates</b>	<b>Location</b>	<b>Hotel</b>	<b>Registration Dates &amp; Fees</b>
2020 ABC Annual Meeting	March 9 <sup>th</sup> -11 <sup>th</sup>	Washington, D.C.	Ritz-Carlton (Pentagon City)	More details coming soon!
ADRP 2020 Conference	May 19 <sup>th</sup> -21 <sup>st</sup>	Phoenix, Ariz.	Hyatt Regency	More details coming soon!
2020 ABC Medical Directors Workshop and Summer Summit	July 21 <sup>st</sup> -23 <sup>rd</sup>	Cleveland, Ohio	Westin Downtown	More details coming soon!
<b>Notes:</b>				
For the most up-to-date information on all events, members of ABC may check the <a href="#">calendar</a> on ABC’s Member Site.				
Non-members may attend all events; information will be updated on ABC’s <a href="#">Public Site</a> .				

**EQUIPMENT AVAILABLE**

**For Sale.** 50 Genesis Mixers Model CM375A and 22 Ohaus portable digital scales. All in working order. For additional details or to make an offer contact Jahn Legh-Page at (559) 389-5440 or [jlegh-page@donateblood.org](mailto:jlegh-page@donateblood.org).

**Best Offer.** PK7300 microplate blood donor typing system, Two (2) Pluggo decappers, Two (2) Immucor microplate washers for manual Capture assays, Two (2) Immucor microplate incubators for manual Capture assays. For additional details or to make an offer contact Joseph Hulina at [jhulina@cbccts.org](mailto:jhulina@cbccts.org).

**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, e-mail: [newsletter@americasblood.org](mailto:newsletter@americasblood.org)

## POSITIONS

**Executive Director. (Little Rock, Ark.)** The Arkansas Blood Institute is seeking a "community spirited" professional to lead its Little Rock team in fulfilling the mission to recruit blood donors, drive sponsors, and volunteers and to store and deliver blood units for local hospitals. This public facing, "visible" position not only requires an outgoing, bright, and energetic personality to foster relationships, but also demands detailed attention to planning, communication, regulations, finances and personnel. Significant successes in project management and organizational expansion and entrepreneurship are desirable. Connectivity with regional leaders and access to key social networks would also be positives. The successful candidate will present and maintain a credible, positive image of the Arkansas Blood Institute in the local community. He or she will act as a liaison between the Institute and the community, organizations and residents. Applicants should be goal-driven self-starters who have strong interpersonal, organizational and analytic skills. They should be able to motivate and inspire diverse constituencies including donors, sponsors, staff, and volunteers. Salary Range: Competitive salary, commission plan, and excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, and holiday pay. Apply: <http://arkbi.org/careers/>.

**Vice President, Reference & Transfusion Services.** Vitalant is currently hiring a VP of Reference & Transfusions Services to be responsible for the leadership, management, and direction of the organization's Red Cell Reference Laboratories (RCRLs) and Transfusion Services (TS) expanding and advancing the business unit's effectiveness. This role will also support the Blood Services Division product portfolio by developing and delivering value-added RCRL/TS services to client hospitals, health care providers, and patients. This vital role will oversee these functions to ensure that procedures, controls and systems are in place for accurate test results and timely provision of appropriate blood products while

maintaining compliance with all federal and state regulatory requirements and industry accreditation standards. This role will also oversee the development of organizational strategies to achieve core corporate goals aligning with the strategic initiatives of the Corporation while ensuring that all service offerings meet or exceed customer expectations. The ideal candidate will formulate the development and direct the implementation of relevant strategic plan elements to assure the ongoing success and growth of the organization, provide Executive Management with activity summaries, and fosters enterprise-wide collaboration of clinical services while promoting cost saving, standardization and economies of scale. Interested candidate can apply to the position directly at <https://bloodsystems.taleo.net/careersection/jobdetail.ftl?job=191590&lang=en>

**Reference Lab Manager.** OneBlood is currently recruiting for a Lab Manager in our AABB-Accredited Immunohematology Reference Laboratory. This position provides leadership and technical expertise, manages staff, and performs training and quality activities for the staff responsible for performing basic through advanced testing procedures on patient and/or donor samples. Applicants must have a bachelor's degree in medical technology, biological science or related scientific field from an accredited college or university. Five or more years in a clinical laboratory, preferably blood banking environment, or an equivalent combination of education, certification, training and/or experience. Applicants must have SBB certification, as well as a valid and current Florida Clinical Laboratory Supervisor license, or eligible, in Immunohematology or Blood Banking. To apply and view a complete Job Description of this position, go to [www.oneblood.org](http://www.oneblood.org) and click on the "Careers" tab. OneBlood, Inc. is an Equal Opportunity Employer/Vet/Disability.

**Manager, Plasma Operations.** Blood Centers of America (BCA) is a national cooperative comprising over 50 blood center members. BCA is seeking an individual with industry experience to serve as Manager, Plasma Operations. This position is responsible for specific aspects of the Plasma for Fractionation Program including managing day-to-day inquiries and operational tasks for this business unit. The person in this role must be successful in understanding the technical requirements of multiple agreements and assisting members with plasma optimization and contract compliance. The ideal candidate will possess outstanding communication abilities, relationship development talent and strong customer service skills. Five to 10 years of progressive experience in blood banking or similar field is required. Proven track record in managerial role is a plus. BCA is based near Providence, Rhode Island. Will consider remote location for the right candidate. Position requires up to 20 percent overnight travel. Please submit resume to [careers@bca.coop](mailto:careers@bca.coop).

**Immunohematology Reference Laboratory Manager (FT).** Miller-Keystone Blood Center (MKBC) focuses on our mission to save lives by partnering with our community to provide a continuous supply of blood products and services. The core values Integrity, Passion, Trust, and Customer Centricity have made MKBC one of the nation's best-regarded, highly experienced blood centers, and our history of compliance with FDA and AABB requirements demonstrates our commitment to quality and service excellence. We are looking for a detail-oriented and passionate professional with a BS in biologic or clinical laboratory science, ASCP certification and SBB (or eligible) to join our management team in the Immunohematology Reference Laboratory. Responsibilities include

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POSITIONS (continued from page 13)

supervising and training reference lab staff. Position oversees reference lab testing including reagent quality control, release of products and equipment maintenance. Approves patient and donor antibody work-ups and provides written and verbal consultations regarding transfusion recommendations. Writes, revised and reviews SOPs and equipment/testing validations. Duties include preparation of washed, frozen and deglycerolized components, testing, and maintenance of red blood cell phenotype database and data entry. Manages customer service and is available for on-call duties. Applicants must have a minimum five years of clinical laboratory experience in Blood Banking and three years supervisory/management experience. To apply go to our website at: [www.hcsc.org](http://www.hcsc.org). Miller-Keystone Blood Center is an EEO/AA Employer Minority/Female/Disabled/Veteran/Sexual Orientation/Gender Identity

**Medical Director.** If you have a passion to join a team that is providing cutting-edge medical expertise in the areas of blood banking, transfusion medicine, immunohematology reference laboratories, therapeutic apheresis, cellular therapy and research, consider joining OneBlood as a Medical Director. Qualified candidates should possess a minimum of three years' experience and a M.D. or D.O. degree with board certification in Clinical Pathology, Internal Medicine or Hematology and subspecialty board certified in Blood Banking/Transfusion Medicine by a Board Registry recognized by the American Board of Medical Specialties. Appropriate state licenses will be required as needed. Must meet the eligibility requirements to obtain appointments at hospitals served by OneBlood. This position includes the option of free medical coverage with a competitive benefits package, 403(b) retirement plan with company contribution PLUS a company match, company vehicle lease/allowance, paid holidays, and much more. This position will be based out of the Ft. Lauderdale, Florida area, with some of the most gorgeous beaches in the nation! If you want to join our life saving mission and team of dedicated employees, visit our "Careers" page at [www.oneblood.org](http://www.oneblood.org) to learn more. OneBlood, Inc., a proven leader in blood banking, is an Equal Opportunity Employer/Vet/Disability. ♦