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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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

2023 #44 **December 8, 2023**

INSIDE:

ABC Submits Comments to LDT Proposed Rule

America's Blood Centers (ABC) responded to the U.S. Food and Drug Administration's (FDA) laboratory developed tests (LDTs) proposed rule in comments submitted on December 4th. ABC described the potential negative impact of the proposed LDT regulation on both public health and the U.S. blood supply, in addition to its ability to be overly burdensome and, "prohibit patient access to tests necessary to ensure blood compatibility."

ABC's comments to the agency recommended that either blood centers be exempt from the regulation or that FDA revises the LDT proposed rule to maintain the flexibility of the agency to exercise enforcement discretion over all tests developed and used by blood centers. The comments outlined four specific areas of concern with the regulation including:

- "LDTs developed by blood establishments are not associated with the type of safety concerns FDA is addressing with this rule;
- many LDTs developed in a blood center's lab are 1976-Type LDTs and/or are developed with a high level of standardization across institutions;
- blood centers' LDTs are comparable to Human Leukocyte Antigen (HLA) tests. FDA should apply general enforcement discretion to all HLA tests and blood center's LDTs; [and]
- the impact [of the LDT regulation] on patient access."

The LDT comments explained that, "blood centers' LDTs are extremely safe and effective under the current framework and do not have a history of safety issues. Blood centers and hospitals are required to report adverse events to FDA. The safety record of these tests is well-documented in this reporting system, and a mechanism exists to resolve any safety issues that are potentially identified." Additionally, ABC noted that, "FDA is proposing to continue to apply the current general enforcement discretion approach to '1976-Type LDTs…[Since many] serological tests developed in a blood center's immunohematology reference laboratory (IRL) are 1976-type LDTs, [FDA] should continue to apply its current general enforcement discretion to these tests. These tests use manual techniques and are performed by highly trained laboratory personnel under the oversight of a blood center medical director and use licensed reagents." The comments also described how, "[these] tests are validated and rigorously quality-controlled, are well-established, and follow standard, published references for immunohematology. These test kits are not sold to any entity and are only utilized by the blood center. The volume of production for these tests does not make them commercially viable for mass marketing. Therefore, these important tests would be unavailable for use if not performed under the current enforcement discretion."

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ABC Submits LDT Comments (continued from page 1)

ABC listed additional examples of necessary tests used by blood centers that would be impacted by the new enforcement approach proposed in the LDT regulation including:

- ABO discrepancy resolution;
- other tests using in-house donor cells;
- tests using anti-sera created from donor plasma;
- flow cytometric analysis; and
- molecular testing.

In urging FDA to apply the same rationale and reasoning used for exempting HLA LDTs for transplantation from the proposed rule, the ABC comments stated that a similar approach should be applied to, "all LDTs in blood centers and to all HLA tests [since such] tests are generally developed, and the testing is generally performed in urgent, life-saving situations for the patient, where a physician must make a prompt decision about the transfusion based on medical judgment regarding their patient's condition and the degree of mismatch between the donor and patient when performing a blood transfusion."

ABC concluded the comments explaining that, "[u]nless blood centers' LDTs are fully excluded from FDA's enforcement approach applied to *in vitro* diagnostic products (IVDs), there will be significant patient harm due to delays in care and the lack of patient access to medically necessary tests due to the new regulatory burdens. [These] tests are generally developed, and the testing is generally performed in urgent, life-saving situations for the patient, where a physician must make a prompt decision about the transfusion based on medical judgment regarding their patient's condition and the degree of mismatch between the donor and patient when performing a blood transfusion. If these tests are unavailable, physicians must still make a prompt decision about the transfusion, and they will have less information available to them to determine the safest course of action." ABC also noted the potential of the proposed LDT regulation to, "exacerbate the impact of the existing laboratory workforce shortage without improving safety. Blood centers would need to hire additional specialized staff and provide training to staff on a new, complicated FDA regulatory scheme. This would come at a time when pathology and laboratory medicine are experiencing extreme workforce challenges. For example, the overall vacancy rate for blood bank immunohematology laboratory departments was 17.8 percent in 2022, with staff vacancy rates at 18.9 percent."

ABC will continue to provide updates regarding the proposed rule. Please contact ABC Director of Regulatory Affairs and Public Policy Justine Coffey, JD, LLM with questions. An archive of all letters and comments on America's Blood Centers' blood advocacy initiatives is available on the ABC website.

(Source: ABC LDT Comments, 12/4/23)

The *ABC Newsletter* (ISSN #1092-0412) is published by America's Blood Centers® and distributed by e-mail.

ABC advocates for and advances policies that promote the role of independent blood centers in providing life-saving blood products and recognizes the continuous need for a safe and robust blood supply. ABC exists to advocate for laws and regulations recognizing the essential role that independent blood centers play in the health care system; promote partnerships, policies, and programs that increase awareness about the need for blood donation; and serve as a thought leader in the advancement of evidence-based medical and scientific solutions related to health and safety.

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ACBTSA Publishes Additional Recommendations Ahead of January Meeting

The U.S. Department of Health and Human Services (HHS) Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) has released additional recommendations that will be considered via a vote at the next virtual meeting scheduled for January 11th, according to a HHS notice in the *Federal Register*.

The committee previously published four recommendations in September that came in the wake of ACBTSA's July meeting on surge capacity for blood and blood products. The additional recommendations are related to the committee suggesting HHS Secretary Xavier Becerra, JD "fund additional public awareness campaigns including funding for data analytics to increase the donor pool and determine effectiveness." These new recommendations include:

- "The Committee recommends that an agency within HHS be charged with safeguarding the availability of blood;
  - [t]his agency should work closely with U.S. Food and Drug Administration so that regulatory measures developed for blood safety are balanced by the need to maintain blood availability.
- The Committee recommends that companies providing critical supplies for blood manufacturing and storage shall work with HHS funding agencies to develop and enact contingency plans to stabilize the blood supply chain.
- The Committee recommends that the Office of the Assistant Secretary for Health (OASH) or other HHS funding organization receive an enabling budget to be used for projects that stabilize the blood supply such as stockpile of key supplies and components.
- The Committee recommends that an HHS funding organization offer grant or contract funding that enables the development of novel means for extending the outdate of perishable materials in the stockpile.
- The Committee recommends that the ACBTSA convene a working group dedicated to developing a risk-gap analysis with associated business costs for the mitigations and contingencies associated with these temporary regulatory measures.
  - The FDA should be engaged in this analysis to assess the risks.
  - This work should be completed by the end of calendar year 2024.
- The Committee recommends that a Memorandum of Understanding (MOU) be negotiated with Canada to allow their blood and blood products into the U.S. and utilization of their testing laboratories to relieve transient strains in the blood supply brought about by emergencies.
  - The MOU would be bi-directional.
  - The FDA would participate in this work to assure the safety of the incoming blood from Canada or other countries.
- The Committee recommends OASH contract a qualified organization to develop a risk-capability analysis with business case development informed by actuarial science.
  - This agency would be administered by the Administration for Strategic Preparedness and Response (ASPR) and OASH.
  - Representatives from blood centers, hospital transfusion services, blood system supply chain agents, and health economists would provide input."

America's Blood Centers (ABC), in consultation with the ABC Board, Policy Council, and Scientific, Medical, and Technical Committee (SMT), is preparing to submit comments to these recommendations prior to the January ACBTSA meeting. Please contact ABC Director of Regulatory Affairs and Public Policy Justine Coffey, JD, LLM, with questions. ABC previously submitted comments in June and in November to the ACBTSA. An archive of all letters and comments on America's Blood Centers' blood advocacy initiatives is available on the ABC website.

(Sources: ACBTSA Recommendations, 12/4/23; *Federal Register* Notice, 11/20/23)

CBER Creates Laboratory of Pathogen Reduction Under OBRR

The U.S. Food and Drug Administration (FDA) published a notice in the *Federal Register* on December 5th titled "Statement of Organization, Functions, and Delegations of Authority." A restructuring at FDA had previously been reported last month.

In the notice, the agency explained that the FDA's Center for Biologics Evaluation and Research (CBER), Office of Blood Research and Review (OBRR), and the Office of Vaccines Research and Review (OVRR) have been restructured due to "substantial growth in innovative, novel products, as well as a need to address an ever-changing landscape of potential public health threats [as the agency faces] scientific, medical, and regulatory challenges."

As part of the restructuring, "[i]n OBRR, the establishment of a Laboratory of Pathogen Reduction will address Center-level initiatives focusing on the optimization of new pathogen inactivation technologies. These technologies can dramatically help the American public and potentially reduce or eliminate donor deferral and/or testing requirements. Additionally, the proposed structural changes, keeping OBRR's functioning state of two divisions instead of three, will maintain operational consistency and enable the divisions to build on processes and efficiencies gained in the last two years."

(Source: *Federal Register* Notice, 12/5/23)

RESEARCH IN BRIEF

Effects of Single-Unit Transfusions on Hematology/Oncology Patients. The authors of a study published in *Leukemia Research* sought, "to demonstrate that the single red blood cell (RBC) transfusion (1-RBC) arm was non-inferior to the standard double RBC transfusion (2-RBC) arm in terms of severe complications." The study included, "[h]ospitalized patients 18 years or older, with acute leukemia requiring intensive chemotherapy or hospitalized for hematopoietic stem cell transplantation…Patients were assigned in a 1:1 ratio to the 2-RBC or to the 1-RBC transfusion arm…In [both] arm[s], patients received RBC transfusion whenever their hemoglobin level was below 8 g/dL." The authors explained that, "[t]he primary endpoint was the percentage of patients who developed grade ≥3 complications…The secondary endpoints were the number of RBC units transfused per patient per hospital stay…A total of 125 patients were randomized in the 1-RBC arm and 120 in the 2-RBC arm." The researchers noted that, "[t]he median (IQR) of RBC units transfused per patient was 7 (4- 12) in the single arm and 8 (4- 12) in the double ($p = 0.66$). The mean pre-transfusion hemoglobin level was 7.49 ± 0.83 g/dL in the 1-RBC arm and 7.46 ± 0.67 g/dL in the 2-RBC arm ($p = 0.28$). The hemoglobin level at discharge was 9.35±1.14 g/dL in the 1-RBC arm and 9.58±1.13 g/dL in the 2-RBC arm ($p = 0.12$)." The study found that, "[t]he transfusion-free time was significantly higher in the 2-RBC arm than in the 1-RBC arm (5 [days] [IQR 3–8] and 2 [1–5], $p < 0.001$, respectively)…The predefined non-inferiority criteria were achieved, with 28 patients developing a serious complication in the 1-RBC arm (22.4 percent) and 28 patients in the 2-RBC arm (23.3 percent)…The overall survival did not differ between the two groups." The authors concluded that, "the single RBC transfusion policy was non-inferior to the double RBC transfusion policy in hematological intensive care unit for patient[s] receiving a bone marrow transplant or intensive chemotherapy. Single RBC unit and double RBC transfusion can be used safely in daily clinical practice, and both may be considered as standard of care for transfusion in the hematological intensive unit. The single RBC transfusion policy did not reduce the number of RBC transfused per hospitalization."

Citation: Chantepie, S.P., Mear, J.B., Briant, A.R., *et al*. Effect of single-unit transfusion in patients treated for haematological disease including acute leukemia: A multicenter randomized controlled clinical trial. *Leuk Res.* 2023.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

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INSIDE ABC

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

FABC Grant Funding Opportunity Available

The Foundation for America's Blood Centers (FABC) has announced funding opportunities for members of America's Blood Centers (ABC) and members of ADRP, the Association for Blood Donor Professionals. A request for proposals (RFPs) for research initiatives with a focus on communications, engagement, and operational strategy to address donor deferrals has been issued. Eligible project areas include:

- effectiveness of donor communications strategies;
- effectiveness of engagement strategies with deferred donors; and
- effectiveness of alternative opportunities for deferred donors.

Proposals must originate from an ABC or ADRP member blood center and should have the potential for local implementation via customization and scalability. Requests must not exceed $20,000. Grant recipients will be required to present the program's intended goals at a meeting in addition to sharing the project's final results on a webinar for ABC and ADRP members. Completed proposals must be submitted by December 22nd. An independent grants committee will review the proposals and make recommendations to the FABC Board regarding funding. The FABC Board will make funding decisions no later than January 19th. Please contact us with any questions.

ABC SMT Journal Club Webinar Articles Announced

Register for the ABC Scientific, Medical, and Technical (SMT) Journal Club Webinar taking place on December 15th at 12 p.m. EST. The webinar will feature the articles below:

- Canadian Blood Services traceback investigation of a suspected case of transfusion-transmitted malaria (*Transfusion*);
- Early and empirical high-dose cryoprecipitate for hemorrhage after traumatic injury – The CRYOSTAT-2 randomized clinical trial (*JAMA*); and
- Therapeutic plasma exchange for mechanical red cell hemolysis (*Journal of Clinical Apheresis*).

A Continuing Medical Education (CME) credit (1.0) is now offered for this webinar and will be available for future ABC SMT Journal Club webinars. Additional details including a registration link to sign-up for the webinar are now available to ABC members in MCN 23-099. Please contact ABC Director of Scientific and Technical Operation Betzy Gonzalez, MS, BB(ASCP), with questions.

(Source: MCN 23-099, 11/20/23)

Register for 2024 ABC Annual Meeting

Registration is open for the ABC 2024 Annual Meeting. The meeting will take place March 4th-6th in Arlington, Va. at the Ritz-Carlton in Pentagon City and features several exciting changes, including expanded content offerings and a new format. With a focus on advocacy, leadership, operations, and science and medicine, the program will feature a mix of general and breakout sessions, external speakers and blood

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center-led case studies, committee and council meetings, networking events, and more. *Awards of Excellence* (AoE) winners will be recognized throughout the Annual Meeting and at a reception on Capitol Hill, where we can celebrate their achievements with fellow meeting attendees, members of Congress and their staff, our federal agency partners, Blood Advocacy Week partners, and more. Secure your room today to take advantage of the group rate. The deadline to book a room is February 16th. Sponsorship opportunities are also available. Contact us with any questions.

Registration Is Open for 2024 ADRP Annual Conference

Register today for the 2024 ADRP Annual Conference! Join more than 400 blood center professionals in St. Louis, Mo. May 14th-16th at The St. Louis Union Station Hotel. Take advantage of the member-only early bird discount rate by registering by January 31st. This year's conference will feature keynotes Jason Kotecki, an expert at helping people "Escape Adulthood" in order to beat burnout and become more innovative and creative by breaking rules that don't exist, and Candy Whirley, a recognized motivational speaker, leadership and team building expert. The 2024 ADRP Annual Conference is your opportunity to gain insights into industry trends, exchange ideas, and share information with your peers, while taking advantage of networking opportunities. Attendees will be able to participate in pre-conference workshops, educational sessions, roundtables, and have access to an expansive exhibit hall. Learn more about available exhibitor and sponsorship opportunities. Remember to book your hotel room by April 19th for the discounted rate. Please contact us with questions.

STATE ADVOCACY BRIEFS

The Illinois General Assembly recently introduced two bills in the House regarding blood donation. House Bill 4243 introduced on November 29th would amend, if passed, the Illinois Clinical Laboratory and Blood Bank Act, "[by requiring] a blood bank to test or have tested donated blood for evidence of any COVID-19 vaccine and any other messenger ribonucleic acid (mRNA) vaccine components." Additionally, the legislation would "requir[e] a blood donor to disclose during each blood donor screening process whether the blood donor has received a COVID-19 vaccine or any other mRNA vaccine during the donor's lifetime. [It would also require] blood or blood components to include on their labels a designation that the blood or blood components tested positive for evidence of a COVID-19 vaccine or any other mRNA vaccine component or was drawn from a blood donor who disclosed the donor ha[s] received a COVID-19 vaccine or any other mRNA vaccine during the donor's lifetime."

Another bill introduced in the House on December 1st would provide a tax credit for blood donors. If passed, House Bill 4250 would amend the Illinois Income Tax Act by, "[creating] an income tax credit of $250 for taxpayers who make four or more qualified donations of human whole blood or human blood components during the taxable year." The donations would need to be made to a "blood bank, as defined in the Illinois Clinical Laboratory and Blood Bank Act, that qualified as an exempt organization under Section 501(c)(3) of the Internal Revenue Code during the taxable year in which the donation was made."

(Sources: House Bill 4243, 11/29/23; House Bill 4250, 12/1/23)

WORD IN WASHINGTON

The U.S. Food and Drug Administration (FDA) announced that it has approved the first cell-based gene therapies to treat sickle cell disease (SCD) in patients 12 years of age and older. According to the agency news release, "Casgevy is the first FDA-approved therapy utilizing CRISPR/Cas9, a type of genome editing technology. Patients' hematopoietic (blood) stem cells are modified by genome editing using CRISPR/Cas9 technology. CRISPR/Cas9 can be directed to cut DNA in targeted areas, enabling the ability to accurately edit (remove, add, or replace) DNA where it was cut. The modified blood stem cells are transplanted back into the patient where they engraft (attach and multiply) within the bone marrow and increase the production of fetal hemoglobin (HbF), a type of hemoglobin that facilitates oxygen delivery…With Lyfgenia, the patient's blood stem cells are genetically modified to produce HbA^{T87Q}, a gene-therapy derived hemoglobin that functions similarly to hemoglobin A, which is the normal adult hemoglobin produced in persons not affected by sickle cell disease. Red blood cells containing HbA^{T87Q} have a lower risk of sickling and occluding blood flow. These modified stem cells are then delivered to the patient. Both products are made from the patients' own blood stem cells, which are modified, and are given back as a one-time, single-dose infusion as part of a hematopoietic (blood) stem cell transplant."

(Source: FDA News Release, 12/8/23)

FDA published a communication regarding the agency investigating the risk of t-cell malignancy with BCMA-directed or CD19-directed autologous chimeric antigen receptor (CAR) T cell immunotherapies. The agency explained in the communication that, "[we have] reports of T-cell malignancies, including chimeric antigen receptor CAR-positive lymphoma, in patients who received treatment with BCMA- or CD19-directed autologous CAR T cell immunotherapies. Reports were received from clinical trials and/or post marketing adverse event (AE) data sources. FDA has determined that the risk of T-cell malignancies is applicable to all currently approved BCMA-directed and CD19-directed genetically modified autologous CAR T cell immunotherapies. T-cell malignancies have occurred in patients treated with several products in the class…Although the overall benefits of these products continue to outweigh their potential risks for their approved uses, FDA is investigating the identified risk of T cell malignancy with serious outcomes, including hospitalization and death, and is evaluating the need for regulatory action." Recommendations from the agency included:

- [p]atients and clinical trial participants receiving treatment with these products should be monitored life-long for new malignancies;
- [i]n the event that a new malignancy occurs following treatment with these products, contact the manufacturer to report the event and obtain instructions on collection of patient samples for testing for the presence of the Chimeric Antigen Receptor (CAR) transgene; [and]
- [t]o report suspected adverse events including T cell malignancies, contact the FDA.

(Source: FDA Communication, 11/28/23)

INFECTIOUS DISEASE UPDATES

MPOX

The Centers for Disease Control and Prevention (CDC) issued a Health Alert Network (HAN) Health Advisory on December 7th regarding human to human transmission of mpox virus with geographic spread in the Democratic Republic of the Congo (DRC). According to the agency advisory, "sexually associated human-to-human transmission of Clade I mpox virus is occurring. Though no Clade I mpox virus cases have been reported in the U.S. at the time of publication, the agency felt that, "clinicians should be aware of the possibility of Clade I mpox virus in travelers who have been in DRC. Clinicians should notify their

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INFECTIOUS DISEASE UPDATES (continued from page 7)

state health department if they have a patient with mpox-like symptoms, which may include a diffuse rash and lymphadenopathy, and recent travel to DRC. Clinicians should also submit lesion specimens for clade-specific testing for these patients. Vaccines (e.g., JYNNEOS, ACAM2000) and other medical countermeasures (e.g., tecovirimat, brincidofovir, and vaccinia immune globulin intravenous) are available and expected to be effective for both Clade I and Clade II MPXV infections. However, vaccination coverage in the United States remains low…CDC recommends that clinicians encourage vaccination for patients who are eligible."

(Source: CDC Advisory, 12/7/23)

NEW on Coll*ABO*rate

COLLABORATE

SHARE STRATEGIC ADVICE | SOLVE CHALLENGES | DEVELOP NEW APPROACHES

Recent discussion topics on the ABC Coll*ABO*rate Online Member Community include:

- Quality Benchmarks (OPEN FORUM)
- Composelect Blood Bags and Hemolyzed Segments (OPEN FORUM)
- Signs and Symptoms of Reaction (COLLECTIONS & DONOR SERVICES)
- Travel Policy (HUMAN RESOURCES)
- Cryo Licensure (QUALITY BYTES)
- Transport Cooler Inspection and Cleaning (QUALITY BYTES)
- Timeframe for Responses to Internal Audit (QUALITY BYTES)
- Terumo Cobe 2991 (TECHNICAL DIRECTORS)

ABC members are encouraged to login and join the conversations today!

Upcoming ABC Webinars & Virtual Events – Don't Miss Out!

- **ABC Scientific, Medical, and Technical Journal Club Webinar** – Dec. 15. More information available to ABC Members, including a link to registration in MCN 23-099! CME credit (1.0) offered.

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

ADRP The Association for Blood Donor Professionals

CALENDAR

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

2023

Dec. 15. **ABC Scientific, Medical, Technical (SMT) Journal Club Webinar.** Registration is open. More information available to ABC members in MCN 23-099.

2024

Jan. 11. **U.S. Department of Health and Human Services (HHS) Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) (Virtual).** More information available here.

Feb.7-8. **International Plasma and Fractionation Association & EBA Symposium on Plasma Collection and Supply. Leiden, Netherlands.** Registration is open. More information available here.

Mar. 4-6. **ABC Annual Meeting, Arlington, Va.** Registration is open. More information available here.

April 12-13. **BEST Meeting, Amsterdam, Netherlands.** More information coming soon.

May 14-16. **2024 ADRP Annual Conference, St. Louis, Mo.** Registration is open. More information available here.

May 15-16. **International Plasma and Fractionation Association/Paul-Ehrlich Institut[e] 30th International Workshop on Surveillance and Screening of Blood-borne Pathogens, Aarhus, Denmark.** More information available here.

Sept. 4-6. **American Society for Clinical Pathology (ASCP), Chicago, Ill.** More information coming soon.

Sept. 30- Oct. 3. **American Association of Tissue Banks (AATB), Denver, Colo.** More information coming soon.

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

CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC members. There are charges for non-members: $139 per placement for *ABC Newsletter* subscribers and $279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, e-mail: newsletter@americasblood.org

EQUIPMENT AVAILABLE

For Sale. Two iBF125-GX, i.Series Plasma Upright Freezers. Purchased April of 2023. The freezers were validated in June and have been in use since July. Freezers are in excellent condition and have no known defects. Buyer to cover the cost of shipping. For more information, send inquiries to bbaynard@bbak.org or call (907) 222 – 5664.

POSITIONS

Manager of Donor Resources. The Blood Connection is seeking a Manager of Donor Resources for our operations based out of Piedmont, SC. This position will be responsible for monitoring progress to goal proactively, and effectively coaching and managing their team to success. The ideal candidate for this position possesses strong leadership and organizational skills with a proven ability to meet organizational goals. We offer a generous benefits package including a substantial 401k, 30 days PTO,

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POSITIONS (continued from page 9)

potential company bonuses, cell phone stipend, and tuition reimbursement. Join our team and help create a positive change in your community. *Prospective candidates may be eligible for relocation assistance.* How to apply: Manager of Donor Resources Application

Manager of Donor Services. The Blood Connection is seeking a Manager of Donor Services for our operations based out of Rock Hill, SC. This position will oversee donor collection operations within their assigned divisional territory. This position provides leadership and discipline to direct reports, interviews, and hires staff, and ensures staff are appropriately trained. We offer a generous benefits package including a substantial 401k, 30 days PTO, potential company bonuses, cell phone stipend, and tuition reimbursement. Join our team and help create a positive change in your community. *Prospective candidates may be eligible for relocation assistance.* How to apply: Manager of Donor Services Application

Director of Quality Assurance. Shepeard Community Blood Center in Augusta, Georgia, is looking for an ambitious leader to modernize its approach to product safety and compliance. Shepeard serves several communities in rapidly growing communities in Georgia and South Carolina. The ideal candidate will have at least six years of experience in blood banking, quality assurance, or compliance. Responsibilities include serving as the subject matter expert in regulatory compliance; working with operational leaders to help advance business goals; and overseeing the review and implementation of SOPs, validations, maintenance, reporting, and other related processes. The leader selected for this role must see themselves as an integral member of the leadership team and dedicated to achieving the organization's strategic plan and long-term goals. Those interested can apply at shepeardblood.org.

Vice President of Medical Services & Chief Medical Officer (VP/CMO) - *Position starting July 1, 2024.* The Vice President of Medical Services & Chief Medical Officer (VP/CMO) is responsible for the medical and technical leadership of Carter BloodCare (CBC) operations. This individual also shares administrative duties with the other vice presidents under the Chief Executive Officer. This is the administrative head of the Medical Services department, including directly overseeing five (5) Medical Directors. The Department of Clinical Apheresis, immunohematology reference lab, three transfusion services at off-site hospitals, the Cellular Therapy processing lab, Donor Notification, and Procedure Development all report up to the VP/CMO. This individual will serve as the CLIA director for the main CBC laboratories. VP/CMO will help develop new business opportunities for the abovementioned departments, as well as promote relations with local customers and participate in resident/fellow teaching with the local medical schools. **Required Education:** M.D., D.O., or equivalent degree; active Texas medical license; and Board eligible or board certified in primary field of training. **Preferred Education:** Completed pathology or internal medicine/hematology residency training. Board eligible or board-certified in Blood Banking and Transfusion Medicine by the American Board of Pathology. MBA or other business degree or certificate work. Carter BloodCare is an EEO/Affirmative Action employer. Apply at www.carterbloodcare.org/careers.

Client Relation Manager. This position will be responsible for implementing NYBCe customer strategy that will maximize customer satisfaction and revenue growth. Identify business opportunities and meeting assigned sales goals by maintaining up-to-date knowledge of the blood banking and blood products industry, how competition is doing regarding specific customers, and where business markets are changing. Develop, improve, manage, and retain relationships with customers by conducting account reviews to identify new services requirements, obtain feedback on existing services and liaison with NYBCe operational and support departments. Develop and deliver effective sales presentations to enhance customer knowledge of all NYBCe products and services available to customers. For applicants who will perform this position in New York City or Westchester County, the proposed annual salary is $94,610.00/year to $104,00.00/year. For applicants who will perform this position outside of New York City or Westchester County, salary will reflect local market rates and be commensurate with the applicant's skills, job-related knowledge, and experience. To apply, click here.

Regional Manager – Client Relations. This position will be leading a growing team responsible for designing, developing, and implementing NYBCe customer strategy that will maximize customer satisfaction and revenue growth. Oversees Client Relation Manager's business review activity with customers to identify requirements, promote services, and obtain feedback for the purpose of enhancing service and providing value-added solutions. Participates in key reviews. Provides oversight and support for Client Relations Managers, including accountability to deadlines, sales goals, and other performance metrics. Defines, refines, shapes, and implements strategic plans. Activities include primary research, industry, market, and competitive analysis; customer needs assessment and full documentation of results being achieved and /or corrective actions taken. For applicants who will perform this position in New York City or Westchester County, the proposed annual salary is $109,000/year to $118,000/year. For applicants who will perform this position outside of New York City or Westchester County, salary will reflect local market rates and be commensurate with the applicant's skills, job-related knowledge, and experience. To apply, click here.

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POSITIONS (continued from page 10)

Transfusion Lab Supervisors. Join Florida's leading blood center, **OneBlood**, as a Blood Bank Lab Supervisor in Lakeland and Tampa, FL. Bring your leadership, technical expertise, and management experience to support the transfusion testing procedures on patient and/or donor samples. Qualified candidates should possess three (3) or more years' experience in a clinical laboratory, preferably blood banking environment, including one (1) or more years' experience in supervision and management experience, as well as a valid and current Florida Clinical Laboratory Technologist license in Immunohematology or Blood Banking; Supervisor license strongly preferred. To apply and view a complete Job Description of these Lab Supervisor positions, visit: https://www.oneblood.org/careers.html. OneBlood, Inc. is an Equal Opportunity Employer/Vet/Disability.

Regional Director. The Blood Connection is expanding our operations into Virginia! We are one of the fastest growing blood centers in the country and we are seeking a Regional Director who will be responsible for our day-to-day operations and help direct our expansion of services into this new territory. The ideal candidate is a proven and results-focused self-starter with progressive leadership experience and the capacity and drive to help fulfill the needs of our community partners. We offer a generous benefits package including a substantial 401k, 30 days PTO, potential company bonuses, cell phone stipend, and tuition reimbursement. Join our team and help create a positive change in your community. This role is based in Roanoke, VA. *Prospective candidates may be eligible for relocation assistance.* How to apply: Regional Director Application

Manager of Donor Resources. The Blood Connection is expanding our operations into Virginia! We are one of the fastest growing blood centers in the country and we are seeking a Manager of Donor Resources who will provide management and oversight of the Donor Resources department as we expand into this new territory. The ideal candidate for this position possesses strong leadership and organizational skills with a proven ability to meet organizational goals. We offer a generous benefits package including a substantial 401k, 30 days PTO, potential company bonuses, cell phone stipend, and tuition reimbursement. Join our team and help create a positive change in your community. *This role is based in Roanoke, VA. Prospective candidates may be eligible for relocation assistance.* How to apply: Manager of Donor Resources Application

Immunohematology Reference Lab Manager. LifeSouth Community Blood Centers is seeking an individual who enjoys leading a team of lab professionals dedicated to providing high quality products and services for patients. Our Birmingham, AL IRL is supported by Board Certified Pathologists in Transfusion Medicine, and by LifeSouth's accredited HLA Lab, Molecular Lab, and IRLs in Gainesville, FL and Atlanta, GA. The IRL Manager is responsible for providing onsite day-to-day supervision of testing personnel, ensuring compliance with regulatory agency requirements, and reporting of test results under the direction of the laboratory director. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!

Regional Manager. LifeSouth Community Blood Centers is seeking a highly skilled leader with proven management experience and a passion for making a difference in the community. The Regional Manager in The Villages, FL, oversees daily operations of the region, is organized and decisive, and can motivate the team to reach daily and long-range blood collection goals. Join our team and help us continue our dedication to making sure the blood is there when you or your family is in need. Visit our careers page to learn more about this position, and apply here!

Chief Operating Officer. Suncoast Blood Centers is seeking a talented and passionate Chief Operating Officer to join their growing team. As a member of the senior leadership team, the Chief Operating Officer plans, organizes, directs, and evaluates all activities associated with the operations of the blood center, including recruitment and retention of donors and sponsor groups, the collection of blood from donors and further manufacturing and distribution of donations in the laboratory. In addition, this executive is accountable for the functions and staff relating to operations planning, contact center, supply chain, research, and continuous process improvement. At SunCoast Blood Center, we lead our teams while keeping our mission, vision, and values at the forefront of all we do. As a leader, you will inspire, train, coach, and collaborate within your department and within the broader organization, with a focus on strategic goal achievement. Suncoast Blood Centers is the only local blood center that has been in the community for over 75 years. Providing blood services to many local hospitals and cancer centers in SWFL. To apply: Chief Operating Officer - SunCoast Blood Centers