

URRENT EVENTS AND TRENDS IN BLOOD

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June 23, 2023

2023 #23

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Legislation Reintroduced in Senate for Improving Access to **Transfusion Care for Hospice Patients**

A bill has been reintroduced in the Senate that would require the "Center for Medicare and Medicaid Innovation (CMMI) to test allowing blood transfusions to be paid separately from the Medicare hospice all-inclusive per diem payment." Senate Bill 2186, or the "Improving Access to Transfusion Care for Hospice Patients Act of 2023," was brought forward on June 22nd by Sens. Jacky Rosen (D-Nev.), John Barrasso (R-W.Y.), and Tammy Baldwin (D-Wis.).

Ensuring patient access by expanding the availability of blood in hospice is one of the priorities of the 2023 America's Blood Centers (ABC) Advocacy Agenda and was addressed during ABC's Blood Advocacy Week 2023. ABC continues to ask CMMI to create a demonstration program to allow reimbursement for palliative blood transfusion outside of the hospice benefit.

The Senate bill states "[n]ot later than one year after the date of enactment of this subsection, the C[M]MI shall establish and implement a model under which blood transfusions furnished to an individual receiving hospice care are paid separately from the hospice all-inclusive per diem payment under section 1814(i). The separate payment amount for such blood transfusion shall be the amount that would otherwise apply under title XVIII if the transfusion was not furnished as part of hospice care." Specifically, the bill instructs the agency to "ensure it compares participants under the model with similar patients outside of the model with respect to the following metrics:

- [t]he number of chemotherapy services furnished in the last 14 days of life.
- Hospital utilization in the last 30 days of life, including emergency department visits, in-patient and observation status stays (including the length of the stays), and intensive care unit (ICU) days.
- How many days receiving hospice care before the end of life.
- The number of patients receiving hospice care who received a transfusion compared to patients with similar diagnoses not receiving hospice care.
- The average frequency of transfusion for patients receiving hospice care compared to patients not receiving hospice care.
- The number of transfusions for patients receiving hospice care compared to patients not receiving hospice care.
- Other areas determined appropriate by the CM[M]I."

(continued on page 2)







Hospice Transfusion Care Bill (continued from page 1)

Earlier this month, ABC, the Association for the Advancement of Blood & Biotherapies (AABB), and the American Red Cross also submitted joint comments to the Centers for Medicare and Medicaid Services (CMS) in response to the proposed rule titled "Medicare Program; FY 2024 Hospice Wage Index and Payment Rate Update, Hospice Conditions of Participation Updates, Hospice Quality Reporting Program Requirements, and Hospice Certifying Physician Provider Enrollment Requirements" (CMS-1787-P). ABC will continue to provide updates on both our advocacy efforts and the legislation as they become available.

(Source: Senate Bill 2186, 6/22/23) •

REGULATORY NEWS

The U.S. Food and Drug Administration (FDA) published a guidance on June 14th titled "Content of Premarket Submissions for Device Software Functions." This guidance would apply to new blood establishment computer systems (BECS) when submitted for premarket review by the manufacturer. According to the agency, the guidance "is intended to provide information regarding the recommended documentation for premarket submissions for FDA's evaluation of the safety and effectiveness of device software functions, which are software functions that meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)...This guidance describes information that would be typically generated and documented during software development, verification, and validation...The documentation recommended in this guidance is based on FDA's experience evaluating the safety and effectiveness of device software. However, sponsors may use alternative approaches and provide different documentation so long as their approach and documentation satisfy premarket submission requirements in applicable statutory provisions and regulations." The agency anticipates needing up to 60 days after publication of the guidance to operationalize the recommendations. The guidance document "replaces FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices issued on May 11, 2005, and updates FDA's thinking related to the documentation FDA recommends sponsors include for the review of device software functions in premarket submissions."

(Source: FDA Guidance, 6/14/23)



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

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RESEARCH IN BRIEF

Perioperative Red Blood Cells Affect Heart Valve Surgery Patient's Outcomes. The aim of a study in Anesthesia and Analgesia "was to evaluate the association between perioperative red blood cell (RBC) transfusion and long-term adverse cardiovascular events after heart valve surgery." The authors explained that "[t]he data of patients were retrieved from the National Health claims database of Korea." The study "identified subjects who underwent the first open-heart surgery between [2003] and 2019... The cohort was categorized into four subgroups based on the treated valve: aortic valve (AV), mitral valve (MV), tricuspid valve (TV), and complex valves (two or more simultaneous valve surgeries)." The analysis included "[a] total of 58,299 patients undergoing the first heart valve surgery...Of the participants, 51.6 percent were male, and those >60 years old were 58 percent...The median follow-up duration was 5.53 years (interquartile range [IQR], 2.09-10.19)...Of the total cohort, 86.5 percent were transfused with at least one unit of RBCs." The researchers stated that "[t]he mean number of units transfused per patient was 2.05 ± 1.75 ." The study found that "[a]mong the subgroups, the MV surgery group was likely to be less transfused than the other subgroups (P < .001)... The adjusted hazard ratios and 95 percent confidence intervals of outcomes after the transfusion of 1, 2, and ≥ 3 units compared to those with no transfusion were as follows: death, 1.53 (1.41–1.66), 1.97 (1.81–2.14), and 3.03 (2.79–3.29); ischemic stroke, 1.27 (1.16–1.39), 1.31 (1.19– 1.44), and 1.51 (1.38–1.66); hemorrhagic stroke, 1.38 (1.16–1.66), 1.71 (1.43–2.05), and 2.31 (1.94–2.76); and myocardial infarction 1.35 (1.13-1.62), 1.60 (1.33-1.91), and 1.99 (1.66-2.38), respectively (all P <.01)." The authors explained that the analysis "demonstrated that perioperative RBC transfusion was associated with an increased risk of long-term cardiovascular events, and the volume of transfusion showed a dose-dependent positive correlation with cardiovascular disease risk in patients undergoing heart valve surgery...Subgroups categorized by the valve on which surgery was performed, including AV, MV, TV, and complex, showed similar findings regarding the association of RBC transfusion with adverse cardiovascular outcomes...The mechanism underlying the association between RBC transfusions and adverse outcomes is not well understood." The authors concluded that "reduction in RBC transfusion in patients undergoing heart valve surgery may improve clinical outcomes."

Citation: Kim, H..J, Kim, J.E., Lee, J.Y., Lee, S.H., Jung, J.S., Son, H.S. <u>Perioperative Red Blood Cell Transfusion Is Associated With Adverse Cardiovascular Outcomes in Heart Valve Surgery</u>. *Anesthesia and Analgesia*. 2023.

Contributed by Richard Gammon, MD, Medical Director at OneBlood

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

- **ABC Human Resources Forum** June 27. Registration is open to ABC members. More information is available here.
- **ABC Advocacy Forum** July 11. More information coming soon.
- ABC Scientific, Medical, and Technical Committee Journal Club Webinar Aug. 11. More information coming soon.
- ADRP: The Association for Blood Donation Professionals Master Class: Change Is Good The Journey of Donor Eligibility Sept. 20-21. Registration is open. More information available here.





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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.

ABC Launches Compensation & Benefits Survey

America's Blood Centers (ABC) <u>announced</u> the launch of its annual Compensation & Benefits Survey. This benchmarking survey has become a valuable tool for identifying trends in compensation and benefits programs at ABC member blood centers. New this year, ABC has transitioned the survey to an online platform that allows for improved comparison capabilities. The survey consists of two parts – benefits questions and compensation data. Individuals can save their data and return to the survey at any time. You are also able to download the questions once you log-in to the system. Responses are due by July 14th. Individual links to complete the survey have been sent via email. All data is kept strictly confidential and managed by a third-party, Dynamic Benchmarking. Results are only reported in aggregate. Please contact ABC Chief Executive Officer <u>Kate Fry, MBA, CAE</u> with questions.

(Source: MCN 23-049, 6/13/23)

ABC Human Resources Forum Webinar Set for June 27th

The next ABC Human Resources (HR) Forum webinar will take place on June 27th at 3 p.m. EDT. The topic for this forum is: "Strategies for Blood Center Staff: Connecting with the Public Following the Implementation of an Individual Risk Based Questionnaire." The HR Forum will feature Simi Ranajee, PhD and Dina Proto, who will discuss positive approaches for blood center staff in engaging with the public including a specific focus on the U.S. Food and Drug Administration's new guidelines for blood donor screening. Following the presentations there will be an opportunity for Q&A and discussion. A registration link for the webinar is available to ABC members in MCN 23-052. Please contact ABC Director of Scientific and Technical Operations Betzy Gonzalez, MS, BB(ASCP) with questions.

(Source: MCN 23-052, 6/15/23)

Registration Is Open & Preliminary Program Available for ABC Summer Summit & MD Workshop

Join us for the ABC <u>Summer Summit and Medical Directors Workshop</u> in St. Louis, Mo. The meeting will take place August 1st-3rd. <u>Registration</u> is open and hotel <u>reservations</u> can be made at Live! by Loews (St. Louis). Topics covered will include freeze-dried blood products, cellular therapy, success and pitfalls of artificial intelligence, and an update from the U.S. Food and Drug Administration. A <u>preliminary program</u> is now available. The event will also be livestreamed. We encourage blood centers to take advantage of the group registration discount.

Save the Date: SMT Journal Club on August 11th

The next ABC Scientific, Medical, Technical Journal Club Webinar will take place on August 11th from 1-2 p.m. EDT. The webinar is free to all ABC members. An email announcement with a registration link and the articles to be reviewed on the webinar is forthcoming.

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INSIDE ABC (continued from page 4)

Registration is Open for ADRP Masterclass: Change is Good — The Journey of Donor Eligibility

Registration is open for the next <u>ADRP Masterclass</u>, "Change is Good — The Journey of Donor Eligibility," taking place September 20th-21st. This is a virtual event held over two days featuring both blood center professionals and invited speakers. Join ADRP, as the masterclass will explore all aspects of eligibility changes. This includes community outreach and education, public relations, blood donor recruitment, staff training, member resources, community partnerships, and much more. Participants will hear case studies and best practices from those who have already implemented changes. ADRP encourages teams to register together to take advantage of the discounted rate and build on the momentum of post-conference collaboration.

WORD IN WASHINGTON

President Biden formally announced his intent to appoint Mandy Cohen as the Director of the Centers for Disease Control and Prevention (CDC). "Dr. Cohen is one of the nation's top physicians and health leaders with experience leading large and complex organizations, and a proven track-record protecting Americans' health and safety," said President Biden in a June 16th statement. "Dr. Cohen has been recognized by leaders from both parties for her ability to find common ground and put complex policy into action. I look forward to working with Dr. Cohen as she leads our nation's finest scientists and public health experts with integrity and transparency." Currently serving as the executive vice president of Aledade and chief executive officer of Aledade Care Solutions, Dr. Cohen previously worked as "as chief operating officer and chief of staff of the Centers for Medicare and Medicaid Services, and served as acting-director of the Center for Consumer Information and Insurance Oversight (CCIIO). [She] was involved in many aspects of the Affordable Care Act policy development and implementation, including the expansion of coverage, insurance protections, and new provider payment models. [Dr. Cohen] is [a] graduate of Cornell University. [She] received her medical degree from Yale School of Medicine and a master's in public health from the Harvard School of Public Health. She trained in internal medicine at Massachusetts General Hospital."

(Source: White House Statement, 6/16/23)

MEMBER NEWS



The Blood Connection (TBC) recently celebrated the opening of a new donor center in Anderson, S.C. on June 14th. According to an announcement from TBC, this is the organization's 15th center in its service area. "This has been a long time coming for TBC and we are so thrilled to finally open a donation center in Anderson," said TBC President and Chief Executive Officer Delisa English in the announcement. "This community has proven again and again that it is dedicated to a stable community blood supply. We are grateful to our donors here and to the many more that will now join our family with the opening of this new center."

(Source: TBC Announcement, 6/19/23)

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MEMBER NEWS (continued from page 5)

LifeServe Blood Center held a ribbon cutting <u>ceremony</u> on June 12th for its Mitchell Donor Center in South Dakota. The location, which officially opened in December, "has allowed LifeServe to see more donors with an increased donor center footprint and provide an all-around better experience for each donor with more natural light in a clean, comfortable space. In addition to the improved donation experience at this location, increased storage benefits our mobile staging process as all the mobile blood drives for the Mitchell and surrounding areas come in and out of this facility," according to an announcement from the blood center. LifeServe Vice President and Chief Operating Officer Christine Hayes added in the announcement, "[w]e collect a little more than 160,000 units of blood a year and while new to communities LifeServe serves with mobile drives, as far as Pierre and Fort Pierre, we're certainly not new to South Dakota."

(Source: LifeServe Blood Center Announcement, 6/7/23)

GLOBAL NEWS

The European Cent[er] for Disease Prevention and Control (ECDC) issued a communication warning that Europe is at an increased risk of mosquito-borne diseases due to the spread of the Aedes albopictus and Aedes aegypti mosquitoes. The agency stated in the alert that "10 years ago, in 2013, the Aedes albopictus mosquito was established in eight European Union (EU)/ European Economic Area (EEA) countries, with 114 regions being affected. Now in 2023, the mosquito is established in 13 countries and 337 regions. In 2022, 1,133 human cases and 92 deaths of West Nile virus infection were reported in the EU/EEA, of which 1,112 were locally acquired in 11 countries, the highest number of cases since the peak epidemic year in 2018. Locally acquired cases were reported by Italy (723), Greece (286), Romania (47), Germany (16), Hungary (14), Croatia (8), Austria (6), France (6), Spain (4), Slovakia (1) and Bulgaria (1). In 2022, 71 cases of locally acquired dengue were recorded in mainland EU/EEA, which is equivalent to the total number of cases reported between 2010 and 2021. Locally acquired dengue cases were reported by France (65 cases) and Spain (six cases)." Andrea Ammon, Director of the ECDC added in the communication, "[i]n recent years we have seen a geographical spread of invasive mosquito species to previously unaffected areas in the EU/EEA. If this continues, we can expect to see more cases and possibly deaths from diseases such as dengue, chikungunya, and West Nile fever. Efforts need to focus on ways to control mosquito populations, enhancing surveillance and enforcing personal protective measures."

(Source: ECDC Communication, 6/22/23)

The World Health Organization (WHO) recently certified Belize as malaria-free. The designation follows the country going from a "peak of about 10,000 cases in 1994 to zero indigenous cases in 2019," according to a news release from the WHO. "Belize's success has hinged on strong surveillance for malaria, access to diagnosis, and effective vector control methods including insecticide-treated mosquito nets and indoor spraying of insecticides. Trained community health workers have played a vital role in timely diagnosis and treatment...a total of 42 countries and 1 territory have been certified as malaria-free by WHO, including 11 countries in the Region of the Americas."

(Source: WHO News Release, 6/21/23)

COMPANY NEWS

CSL Behring has <u>announced</u> that the first patient has received "the first and only" U.S. Food and Drug Administration (FDA) approved gene therapy to treat hemophilia B in adults "who currently use factor IX prophylaxis therapy, or have current or historical life-threatening bleeding, or have repeated, serious spontaneous bleeding episodes." In clinical trials, the gene therapy, HEMGENIX®, "demonstrated the ability to

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COMPANY NEWS (continued from page 6)

elevate and sustain factor IX levels for years, significantly reduce the rate of annual bleeds versus standard of care, and reduce or eliminate the need for prophylactic treatment in 94 percent of people who received [it]," said a company news release. The European Commission (EC) for the European Union and European Economic Area has approved the therapy as well and granted it conditional marketing authorization by the United Kingdom's Medicines and Healthcare product Regulatory Agency.

(Source: CSL Behring News Release, 6/20/23)

The FDA has accepted a biologics license application (BLA) for priority review from **bluebird bio, Inc.** for an investigational gene therapy to treat sickle cell disease in individuals ages 12 and older with a history of vaso-occlusive events (VOEs). According to a company news release, the FDA is targeting December 20th as a Prescription Drug User Fee Act (PDUFA) goal date. The BLA "is based on efficacy results from 36 patients in [in a clinical trial] with a median 32 months of follow-up and two patients in [another clinical trial] with 18 months of follow-up each. The BLA submission also includes safety data from 50 patients treated across the entire [investigational gene therapy] program, including six patients with six or more years of follow-up, which is the longest follow-up of any gene therapy program for sickle cell disease. If approved, the [investigational gene therapy] will be bluebird bio's third *ex-vivo* gene therapy approved by the FDA for a rare genetic disease and its second FDA approval for an inherited hemoglobin disorder."

(Source: bluebird bio, Inc. News Release, 6/21/23)

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

June 27. America's Blood Centers (ABC) Human Resources Forum (Virtual). More information and a registration link available to ABC members.

July 6-7. U.S. Department of Health and Human Services (HHS) Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) (Virtual). More information available here.

July 11. ABC Advocacy Forum (Virtual). More information coming soon.

July 31. **Blood Centers of America (BCA) Medical Directors Meeting, St. Lois, Mo.** The meeting will be held from 9-5 pm at the Loews. Please contact Stacy Conway for more information.

Aug. 1-3. **ABC Medical Directors Workshop and Summer Summit, St. Louis, Mo.** Registration is open. More information available here.

Aug. 11. ABC Scientific, Medical, and Technical Committee Journal Club Webinar. More information available soon.

Sept. 17-20. American Association of Tissue Banks Annual Meeting, National Harbor, Md. More information available here.

Sept. 20-21. **ADRP Masterclass: Change Is Good – The Journey of Donor Eligibility (Virtual).** Registration is open. More information available here.

Oct. 9-11. Advanced Medical Technology Association (AdvaMed) The MedTech Conference, Anaheim, Calif. Registration is open. More information available here.

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<u>CALENDAR</u> (continued from page 7)

Oct. 14-17. AABB Annual Meeting, Nashville, Tenn. Registration is open. More information available here.

Oct. 18-20. American Society for Clinical Pathology (ASCP), Long Beach, Calif. More information available here.

Nov. 18-21. ISBT Regional Congress, Cape Town, South Africa. More information available here.

2024

Mar. 4-6. ABC Annual Meeting, Arlington, Va. More information available here.

May 15-17. 2024 ADRP Annual Conference, St. Louis, Mo. More information 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 members. There are charges for non-members: \$139 per placement for ABC Newsletter subscribers and \$279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, e-mail: newsletter@americasblood.org

POSITIONS

Director of Donor Recruitment (Augusta, GA). Shepeard Community Blood Center is looking for an eager individual to lead and develop a team of donor recruiters during an exciting time of expansion. Augusta, Georgia, is a wonderful city nestled an equally short distance between bustling Atlanta and the beautiful Atlantic Ocean. The Director of Donor Recruitment will be held accountable for challenging but achievable collection goals in Georgia and South Carolina. Only high achievers with a proven record of measurable success should apply. The ability to train and develop talent within your department is a critical component of long-term success. A specific job description and information on how to apply can be found at shepeardblood.org.

Director, Donor Engagement (Austin, Texas). We Are Blood (WrB) is looking for an Engagement Director to contribute in-office to development and implementation of blood donor recruitment and retention strategies including goal setting, analysis of operations and territories, lead staff, and act as a liaison between other WrB departments. Oversee all blood donor recruitment operations, including donor center and mobile blood drive recruitment activities. Coach, develop, and lead a team of recruitment staff in a dynamic and growing market. The Director will be an integral part of WrB's management team and community engagement team as the organization sets priorities for growth in the areas of recruitment to meet blood product utilization across Central Texas. Click here for details and to apply.

Director, Marketing and Public Relations. LifeStream, based in San Bernardino, CA, providing blood services for more than 80 hospitals in Southern California, is searching for a **Director, Marketing and Public Relations**. Reporting to the Vice President, Operations, and

managing a staff of four employees, the Director of Marketing and Public Relations is responsible for developing and implementing marketing and communication strategies to ensure daily, monthly, and annual blood collection targets are achieved. The position is also responsible for account planning, staffing (marketing and creative resources), and oversight of all day-to-day marketing and public relations activities to ensure quality work is being achieved and delivered. This individual will monitor the effectiveness of marketing efforts, including: campaigns, promotions, special events, and communications with internal and external key stakeholders. This position works closely with multiple departments to ensure successful market delivery. The ideal candidate will possess a bachelor's degree (BA) in Marketing, Advertising, Business, Communications, Public Affairs, or a related field. Five years' work experience and a minimum of one year management experience in marketing and/or public relations is required. The candidate will demonstrate strategic thinking and analytical skills to help set marketing agendas. Relocation package is available for out of region candidates. Apply online: www.LStream.org. E-mail: recuitment@LStream.org. EOE.

Executive Director of Community Engagement (Shreveport, LA). LifeShare Blood Center is seeking a skilled Executive Director, Community Engagement to provide leadership, development and oversight of our marketing, public relations, communication, and branding strategies. Reporting to the Chief Operations Officer, the Executive Director will develop a clear public relations strategy and tactical plan to aggressively build brand awareness in traditional and non-traditional venues; develop and direct effective strategies and campaigns to recruit and influence blood donors; develop



POSITIONS (continued from page 8)

and maintain strong media relations in all of LifeShare's operating regions; and represent and communicate LifeShare's interests to state legislative bodies, advocacy organizations and coalitions. LifeShare offers a competitive beginning salary, commensurate with experience and a generous benefits package, including employer-paid medical, life and disability insurance; 401(k) with employer contributions; employee wellness program; and paid time off. Please visit our Careers Page to apply.

Regional Director. LifeSouth Community Blood Centers is seeking a highly skilled leader with proven management experience and a passion for making a difference. The Regional Director for Dunwoody, GA is responsible for overseeing daily operations of the region, is organized and decisive, and can motivate the team to reach daily and long-range 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 to apply. https://www.lifesouth.org/work-at-lifesouth/

Immunohematology Reference Lab Technologist.

LifeSouth Community Blood Centers is seeking individuals who want the opportunity to learn and continue to improve their skills. The Technologists working at our Immunohematology Reference Laboratory (IRL) in Atlanta, GA resolve complex immunohematology and compatibility problems to provide the safest donor blood for the patients in our community. 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 to apply. https://www.lifesouth.org/work-at-lifesouth/

Regional Manager. LifeSouth Community Blood Centers is seeking a highly skilled leader with proven management experience and a passion for making a difference. The Regional Manager for McDonough, GA is responsible for overseeing daily operations of the region, is organized and decisive, and can motivate the team to reach daily and long-range 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 to apply. https://www.lifesouth.org/work-at-lifesouth/

Purchasing Manager. LifeSouth Community Blood Centers is seeking a highly skilled leader with proven management experience and a passion for making a difference. The Purchasing Manager at our headquarters location in Gainesville, FL is responsible for vendor selection, negotiation, establishment and maintenance of all purchased materials, supplies, equipment, and services used by the company. The Purchasing Manager oversees the daily operations of the Purchasing team, is organized and decisive, and can motivate the team to reach daily and long-range 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 about this position and to apply. https://www.lifesouth.org/work-at-lifesouth/.