



ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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2021 #17

May 14, 2021

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FDA Withdraws Zika Virus Testing Guidance

On May 13th, the U.S. Food and Drug Administration (FDA) [announced](#) the withdrawal of the guidance titled “Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components.” In the notice, the agency states, “FDA has determined Zika virus (ZIKV) is no longer a relevant transfusion-transmitted infection (RTTI) under FDA’s regulations because the available evidence demonstrates that ZIKV no longer has sufficient incidence and/or prevalence to affect the potential donor population. Accordingly, FDA withdrew the guidance titled, “Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components,” dated July 2018. Because ZIKV is no longer an RTTI, blood establishments may discontinue testing for ZIKV. Licensed blood establishments that discontinue testing blood donations for ZIKV must report this change to FDA in the annual report under 21 CFR 601.12(d), noting the date testing was discontinued. Corresponding changes to the Circular of Information must also be reported in the annual report under 21 CFR 601.12(d).”

America’s Blood Centers (ABC) had long [advocated](#) for the FDA to cease ZIKV testing citing epidemiology data showing no evidence that mosquitoes in the continental U.S. had transmitted Zika virus (ZIKV) since 2017. In addition, ongoing Zika virus testing imposed significant costs to the healthcare system without materially contributing to transfusion recipient safety taking away from resources that could otherwise be used to promote a safe and available blood supply protecting against future threats.

ABC Chief Executive Officer Kate Fry, MBA, CAE added “ABC applauds this decision on a topic that has been at the forefront of our Advocacy Agenda for several years now. We sincerely thank all of the members who submitted data, lobbied your members of Congress, helped prepare comments to FDA, and more. Our collective and aligned work can achieve meaningful change. ABC will continue to advocate for evidence-based testing requirements that further the safety of the blood supply.”

(Source: FDA [Withdraws](#) Zika Virus Testing Guidance, 5/13/21) ♦

ABC Sends Welcome Letters to New Administration

America’s Blood Centers (ABC) recently issued welcome letters to [U.S. Department of Health and Human Services \(HHS\) Secretary Xavier Becerra, JD, U.S.](#)

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New Administration Letters (continued from page 1)

[Surgeon General Vice Admiral Vivek Murthy, MD](#), and [Assistant Secretary for Health Rachel Levine, MD](#). The letters provide a synopsis of who ABC is and the importance of its members blood centers and blood products to the U.S. healthcare system.

Additionally, the letters outline issues of importance to the blood community and recommendations for ways administrators and their agencies can help ensure a safe and ample blood supply for all patients in need. “For the past several years, the blood community and our government partners have examined the resilience of the blood supply and policy changes required to ensure blood centers can continue their mission of providing life-saving blood components for patients in need. Among these recommended changes is an increased focus on promoting a robust and available pool of blood donors. The current donor base has been increasingly strained by evolving societal norms and behaviors, loss of traditional venues for blood drives, including workplaces and schools, and increased donor deferrals stemming from regulatory changes. In addition, unfunded federal mandates, decreased utilization of blood, and changing hospital practices have all resulted in blood centers operating at break-even margins. The COVID-19 pandemic and 2020-2021 winter storm season have brought their own unique challenges to the blood community in the form of significant disruption to the blood supply. With tens of thousands of blood drives canceled across the country, blood centers quickly transitioned their operations to ensure a sufficient blood supply. In addition, blood centers implemented extraordinary public health measures to protect the safety of both donors and staff, including social distancing, increased infection control procedures, and the acquisition of personal protection equipment (PPE) for staff. In addition to ensuring an available blood supply, blood centers also mobilized quickly to collect COVID-19 convalescent plasma, one of the few therapeutics available for patients fighting the SARS-CoV-2 virus.”

The letters conclude by describing areas that the blood community and the administration can successfully partner and requests a meeting with each individual. Specifically, the letter to HHS Secretary Becerra specifically explains, “[o]ver the past year, support from multiple offices with the Department of Health and Human Services has been critical in raising public awareness to the need for blood donors. We hope you will continue to work with the blood community to serve as a trusted source of information to the public. In addition, the CARES Act called for a public-private public awareness campaign surrounding blood donation that has yet to be implemented. ABC and our member blood centers stand ready to serve as a resource in this initiative. We respectfully request an opportunity to meet to discuss these and other pressing issues to the blood supply.”

For questions or additional information, please [contact](#) ABC Senior Director of Federal Government Affairs Diane Calmus, JD. 💧

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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.

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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 staff only, unless otherwise specified.

2021 ADRP Award Nominations Due May 21st

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 on the ADRP website. The nomination deadline is May 21st, 2021. This year's award categories are:

- Donor Recruiter of the Year
- Donor Collections Team Member of the Year
- Rolf Kovenetsky Leader of the Year Recruitment
- Rolf Kovenetsky Leader of the Year Collections
- Ron Franzmeier Lifetime Achievement
- Ronald O. Gilcher, MD
- Media Partner Award
- Humanitarian Service Award
- Blood Drive (Most Creative and Most Productive) Awards
- School Blood Drive (High School or College)

(Source: ADRP Award [Nominations](#), 5/13/21)

Larry Frederick & Kate Fry Promote Blood Donation with Frank Zaccari

Blood donation advocate Larry Frederick and ABC Chief Executive Officer Kate Fry, MBA, CAE recently joined Frank Zaccari's "Life Altering Events" internet show to share Larry's inspirational story and spread awareness about the importance of blood donation. The episode is available [here](#). Mr. Frederick is the namesake of America's Blood Centers' Larry Frederick Award as he needed a large amount of blood when he was injured while on duty as a police officer. His tremendous gratitude for blood donors has inspired him to become a staunch supporter of blood donation and community blood centers.

ADRP's New Website Now Live

ADRP, an International Division of America's Blood Centers (ABC) is excited to announce that its new [website](#) is live. Users can experience a fresh design and have access to new tools for improved interaction with both their peers and the organization. Additional features include:

- streamlined navigation to most visited pages and easy access to tools such as webinar recordings;
- a new community platform for posting questions, sharing resources, and connecting with other ADRP subscribers; and
- expanded public awareness resources, ensuring a more unified voice for the blood community.

All users are encouraged to provide [feedback](#). 💧



RESEARCH IN BRIEF

Epitope-Based Approach of HLA Matched Platelets for Transfusion. A study in *Blood* was based upon the concept that “matching at the epitope level may be more relevant for assessing HLA compatibility between patients and donors and the effect of donor specific HLA antibodies.” The authors explained that “[e]ligible patients were >16 years with a diagnosis of aplastic anemia, myelodysplasia, or acute myeloid leukemia and refractory to random donor platelet transfusions...The HLA standard antigen-matched (HSM) approach used first-field (low-resolution) HLA type and [considered] donor-specific antibodies detected in patients’ serum...The HLA epitope-matched (HEM) approach was performed using a computer program incorporating the HLA Matchmaker-defined epitopes into a search engine to facilitate the process of HLA antigen–and/or HLA epitope–based platelet selection in platelet transfusion.” The researchers noted that “[e]ach patient received up to eight prophylactic study transfusions, each consisting of one platelet unit, comprising four each of HSM and HEM units in random order...The primary outcome measure was platelet count increment (PCI) at one-hour posttransfusion...An adequate one-hour increment was defined as $10 \times 10^9/L$.” The study indicates that “[b]etween October 2012 and November 2015, 49 participants were included as per intention to treat (ITT)...A total of 219 transfusions were evaluated for the study (HEM, $n = 107$; HSM, $n = 112$)...For ITT, there was no significant difference in PCI at one-hour posttransfusion between the two treatment arms ($P = .9686$)...The HEM method was declared noninferior to the HSM method.” The authors stated that “[s]imilar results were observed for the per-protocol (PP) analysis ($P = .7469$)...The proportion of inadequate PCIs was 16 percent in both arms...The impact of HEM mismatching and ABO matching on PCI was examined in a post hoc analysis...Adequate one-hour PCI was more frequently observed, with a mean number of 3.2 (SD, 3.6) epitope mismatches, compared with 5.5 (SD, 5.3) for inadequate one-hour increments ($P = .0485$)...For every additional one-epitope mismatch, the chance of an adequate PCI decreased by 15 percent.” The study did not “demonstrate longer transfusion-free intervals or reduced bleeding using the HEM compared with HSM method.” The authors concluded that “[i]n summary, this randomized trial supports the use of epitope-matched platelets for HLA alloimmunized patients with platelet refractoriness.”

Citation: Marsh, J.C., Stanworth, S.J., Pankhurst, L.A., *et al.* [An epitope-based approach of HLA-matched platelets for transfusion: a noninferiority crossover randomized trial.](#) *Blood.* 2021.

Contributed by Richard Gammon, MD, Medical Director at OneBlood 💧

MEMBER NEWS

LifeServe Blood Center recently shared an announcement that Iowa legislators had passed a [bill](#) that Governor Kim Reynolds had signed into law that permits state employees two hours of paid-time-off to donate blood up to four times per calendar year. “Many legislators are blood donors themselves, so we’re not surprised that this bill passed unanimously,” said LifeServe Director of Public Relations and Marketing Danielle West in the announcement. “These community members understand how important it is to have a robust blood supply at all times for our local hospital partners. Making blood donation easier by allowing employees to schedule their appointment during their workday is a huge win for donors and the blood supply in Iowa.” The legislation takes effect July 1st.

(Source: [Iowa Senate Bill 336](#), 5/10/21) 💧





GLOBAL NEWS

An independent panel established by the World Health Organization (WHO) **published** their findings and recommendations on the global preparedness and response efforts to the COVID-19 pandemic in a **report** titled “COVID-19: Make it the Last Pandemic.” In the report, the Independent Panel for Pandemic Preparedness & Response describes the “gaps and failings” that turned the COVID-19 outbreak into a pandemic. “[The findings] demonstrate[e] that the current system—at both national and international levels— was not adequate to protect people from COVID-19. The time it took from the reporting of a cluster of cases of pneumonia of unknown origin in mid-late December 2019 to a Public Health Emergency of International Concern being declared was too long. February 2020 was also a lost month when many more countries could have taken steps to contain the spread of SARS-CoV-2 and forestall the global health, social, and economic catastrophe that continues its grip. The Panel finds that the system as it stands now is clearly unfit to prevent another novel and highly infectious pathogen, which could emerge at any time, from developing into a pandemic.” Specific gaps included:

- a lack of coordinated global leadership;
- underfunded preparedness and slow response funding; and
- the WHO being “underpowered” by member states to meet the demands of response efforts.

Recommendations provided by the panel are:

- “[e]levate pandemic preparedness and response to the highest level of political leadership;
- [s]trengthen the independence, authority, and financing of WHO;
- [i]nvest in preparedness now to prevent the next crisis;
- [establish] a new agile and rapid surveillance information and alert system;
- [e]stablish a pre-negotiated platform for tools and supplies;
- [r]aise new international financing for pandemic preparedness and response; and
- [ensure] National Pandemic coordinators have a direct line to Head of State or Government.

A summary of the report and additional resources are also available [here](#).

(Source: Independent Panel for Pandemic Preparedness & Response [News Release](#), 5/12/21)

The WHO **announced** that it has formed a new global hub for pandemic and epidemic intelligence, data, surveillance, and analytics innovation with the Federal Republic of Germany. According to an agency news release, the new hub will be headquartered in Berlin and “will lead innovations in data analytics across the largest network of global data to predict, prevent, detect, prepare for, and respond to pandemic and epidemic risks worldwide.” WHO Director-General Tedros Adhanom Ghebreyesus, PhD added, “[o]ne of the lessons of COVID-19 is that the world needs a significant leap forward in data analysis to help leaders make informed public health decisions. This requires harnessing the potential of advanced technologies such as artificial intelligence, combining diverse data sources, and collaborating across multiple disciplines. Better data and better analytics will lead to better decisions.” Jens Spahn, German Minister of Health, stated, “[w]e need to identify pandemic and epidemic risks as quickly as possible, wherever they occur in the world. For that aim, we need to strengthen the global early warning surveillance system with improved collection of health-related data and inter-disciplinary risk analysis. Germany has consistently been committed to support WHO’s work in preparing for and responding to health emergencies, and the WHO Hub is a concrete initiative that will make the world safer.” According to the release, “[w]orking with partners globally, the WHO Hub will drive a scale-up in innovation for existing forecasting and early warning capacities in WHO and Member States. At the same time, the WHO Hub will accelerate global collaborations across public and private sector organizations, academia, and international partner networks.

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GLOBAL NEWS (continued from page 5)

It will help them to collaborate and co-create the necessary tools for managing and analyzing data for early warning surveillance. It will also promote greater access to data and information.”

(Source: WHO [News Release](#), 5/5/21) 💧

COMPANY NEWS

Pfizer, Inc. and **BioNTech SE** recently [announced](#) that the “initiation of a Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA) for approval of their mRNA vaccine to prevent COVID-19.” In a joint news release, the companies stated that supported data would be provided to the agency “on a rolling basis” in the coming weeks. “We are proud of the tremendous progress we’ve made since December in delivering vaccines to millions of Americans, in collaboration with the U.S. Government,” said Albert Bourla, chairman and chief executive officer (CEO) of Pfizer, Inc., in the news release. “We look forward to working with the FDA to complete this rolling submission and support their review, with the goal of securing full regulatory approval of the vaccine in the coming months.” BioNTech SE CEO and Co-founder Ugur Sahin, MD added, “[f]ollowing the successful delivery of more than 170 million doses to the U.S. population in just a few months, the BLA submission is an important cornerstone of achieving long-term herd immunity and containing COVID-19 in the future. We are pleased to work with U.S. regulators to seek approval of our COVID-19 vaccine based on our pivotal Phase 3 trial and follow-up data.”

(Source: Pfizer, Inc. & BioNTech SE Jount [News Release](#), 5/7/21) 💧

CBBS 2021 ANNUAL MEETING
 A Virtual Event | May 21-22, 2021
 Including a BBGuy Essentials Podcast with Dr Mark Yazer
 10 CE/CMEs Available!

REGISTRATION RATES

Attendee Type	Registration Rate
Physician/Member	\$264
Physician/Non-Member	\$300
Non-Physician/Member	\$180
Non-Physician/Non-Member	\$216

Registration [HERE](#)

Login information will be provided to attendees the week of the event.



Upcoming ABC Webinars – Don't Miss Out!

- **ABC Webinar (sponsored by WellSky): Blood Product Manufacturing: “Driving Efficiencies by Automating Exception Processes”** – June 2nd from 2 – 3 p.m. (EDT). [Registration](#) open to all.
- **ABC SMT Journal Club Webinar** – July 26th from 3 – 4 p.m. (EDT). More 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!

CALENDAR

***Note to subscribers:** Submissions for a free listing in this calendar (published weekly) are welcome. Send information to newsletter@americasblood.org or by fax to (202) 899-2621. (For a more detailed announcement in the weekly “Meetings” section of the newsletter, please include program information.)*

2021

May 21-22. **64th Annual California Blood Bank Society Annual Meeting (Virtual)**. More details available [here](#).

June 9-10. **South Central Association of Blood Banks (SCABB) Advanced Immunohematology and Molecular Symposium (AIMSSM), a Hybrid Event, Orlando, Fla. or Virtual**. More details available [here](#).

June 11-12. **South Central Association of Blood Banks (SCABB) Annual Meeting & Exhibit Show (ENGAGE), a Hybrid Event, Orlando, Fla. or Virtual**. More details available [here](#).

Aug. 4. **ABC Medical Directors Workshop, Cleveland, Ohio**. More details coming [soon](#).

Aug. 5-6. **ABC Summer Summit, Cleveland, Ohio**. More details coming [soon](#).

Aug. 17-19. **2021 ADRP Conference, Kansas City, Mo.** [Registration](#) is open. More details available [here](#).

Sept. 15-17. **4th European Conference on Donor Health and Management, Hamburg, Germany**. More details available [here](#).

Sept. 22. **11th Anniversary Symposium on Red Cell Genotyping 2021: The New Normal, Bethesda, MD (Hybrid)**. For more information click [here](#) or contact [Natasha Leon](#).

Oct. 16-19. **AABB Annual Meeting**. More details available [here](#). ♦

CLASSIFIED ADVERTISING

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

POSITIONS

Donor Services Performance Operations Manager (Oklahoma City, Okla.). The Donor Services Performance Manager will focus on the staff performance of key metrics for the Oklahoma City mobile operations. The manager will implement programs to ensure individuals achieve goal for key metrics. He/She will ensure staff compliance of all standard operating procedures. Qualifications: Bachelor's degree or equivalent work experience, three years supervisor or management experience sales related experience, strong spoken and written communication skills, ability to track and trend data and implement appropriate action based on analysis, diplomatic interpersonal style with excellent conflict resolution techniques, and goal achievement driven. Salary Range: Competitive salary to include excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, tuition reimbursement and holiday pay. How to apply: <http://obi.org/careers/>.

Director Cellular Life Solutions (CLS). Reporting to the Chief Medical Officer, this position is responsible for effectively developing and managing all operational, quality management and business development aspects of cellular and gene therapy activities at The Blood Center. This includes operational and quality management of Cellular Life Solutions' Medical Apheresis Center, which collects peripheral blood stem cells, as well as a variety of allogeneic and autologous cells for clinical treatment and research. Responsibilities: Develop and implement strategic goals and operations for Cellular Life Solutions' products and services. Direct supervision of CLS and staff, and ensuring staff is properly trained to perform duties adequately and maintain staffing levels. Cultivate and maintain a high-profile relationship with NMDP, accrediting agencies and institutions and related professional organizations (such as AABB, America's Blood Centers, American Society for Apheresis, Standards Coordinating Body, Blood Centers of America, Be The Match Biotherapies); including other state and regional Donor Centers, Blood Centers, academic and research hospitals, and laboratories within and outside our region. Bachelor's degree from an accredited college or university; business, medical science or related field is preferred, with a minimum of five years of previous job-related experience or training to include management experience in a regulated environment. Please click [here](#) to view the full job description and apply.

Outside Sales Representative/Event Planner (Lawton, Okla.). Outside sales representatives must develop new partnerships with targeted decision makers in community organizations, educational and religious institutions, and businesses to gain support in meeting the needs for volunteer blood donors. Responsibilities include organizing and promoting blood donation events; assessing, developing, and implementing strategic/tactical plans to achieve recruitment objective/goals. She/he is expected to develop a customer-focused culture that will result in

successful community partnerships and donation awareness. Identify opportunities for growth within current group base, and facilitate a plan to achieve growth percentage for total unit collection within territory. Book recurring blood drives for the following year. Develop and maintain relationships with key accounts. Give presentations in order to promote blood collection. Identify and provide feedback on issues regarding customer needs/requirements, customer issues/concerns and satisfaction, competitor activities/strategies, etc. Interact effectively and professionally with team members and all internal/external contacts. Qualifications: Associate/Bachelor's degree preferred, one to three years sales related experience, public speaking/presentation experience preferred, excellent communication skills, and valid driver's license with access to vehicle. 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. How to apply: <http://obi.org/careers/>.

Outside Sales Representative/Event Planner (Ardmore, Okla.). Outside sales representatives must develop new partnerships with targeted decision makers in community organizations, educational and religious institutions, and businesses to gain support in meeting the needs for volunteer blood donors. Responsibilities include organizing and promoting blood donation events; assessing, developing, and implementing strategic/tactical plans to achieve recruitment objective/goals. She/he is expected to develop a customer-focused culture that will result in successful community partnerships and donation awareness. Identify opportunities for growth within current group base, and facilitate a plan to achieve growth percentage for total unit collection within territory. Book recurring blood drives for the following year. Develop and maintain relationships with key accounts. Give presentations in order to promote blood collection. Identify and provide feedback on issues regarding customer needs/requirements, customer issues/concerns and satisfaction, competitor activities/strategies, etc. Interact effectively and professionally with team members and all internal/external contacts. Qualifications: Associate/Bachelor's degree preferred, one to three years sales related experience, public speaking/presentation experience preferred, excellent communication skills, and valid driver's license with access to vehicle. 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. How to apply: <http://obi.org/careers/>.

Sr Director Inventory Distribution (Tempe, AZ). Vitalant is a nonprofit organization that collects blood from volunteer donors and provides blood, blood products and

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POSITIONS (continued from page 8)

services across the United States. Under minimal direction, this position is responsible for managing and coordinating hospital services activities, overseeing the function to assure the team culture supports the procedures and systems which meets the Vitalant customer promise while maintaining Current Good Manufacturing Practice (cGMP) regulations are followed for the department including SOPs, training, and competency, and error management. Assists with the development and implementation of organizational strategies to achieve core corporate goals aligning with the strategic initiatives of the organization. Bachelor's degree required. Knowledge of inventory management and principles and computer inventory control systems required. Knowledge of blood center products required. Eight years of related experience required. To include: Five years supervisory experience. Click [here](#) to apply.

Executive Director of Coffee Memorial Blood Center (Amarillo, Texas). Coffee Memorial Blood Center is seeking a “community spirited” professional to LEAD its Amarillo 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 Coffee Memorial Blood Center in the local community. He/She will act as a liaison between Coffee

Memorial Blood Center 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. How to apply: <https://www.thegiftoflife.org>.

Phlebotomy Manager (Tempe, AZ). Vitalant is a non-profit organization that collects blood from volunteer donors and provides blood, blood products and services across the United States. Under limited direction, this position is responsible for managing the daily operational activities of the collections department, drawing centers and/or mobile teams. Implements assigned policies, projects, and goals towards the successful achievement of total collection goals. This position is responsible for management of other professional and administrative staff. Bachelor's degree in a directly related field (e.g., Medical Technology, relevant hard science, business) required. Three years relevant experience required. Two years supervisory experience required (healthcare-related preferred). OR: High school graduate GED required. Seven years directly related healthcare supervisory experience required. Please click [here](#) to apply. 💧