

AABB's Regulatory Updates for COVID-19

Last updated March 30, 2020

03/27/20 AABB Delays Effective Dates for BBTS, IRL Standards

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Due to the ongoing COVID-19 pandemic, AABB has elected to delay the effective dates of the 32nd edition of Standards for Blood Banks and Transfusion Services (BBTS) and 11th edition of Standards for Immunohematology Reference Laboratories (IRL) to July 1, 2020. AABB previously scheduled both sets of Standards to take effect on April 1, 2020. AABB reserves the right to extend the effective dates past July 1, 2020, if deemed appropriate.

At this time, AABB expects each set of Standards to remain in effect for 21 months, with the next editions of each set of Standards taking effect April 1, 2022. To prepare for the July 1, 2020, effective dates, individuals can access the Standards Committee's responses to comments and significant changes [online](#). Those with questions should contact AABB's Standards department at standards@aabb.org.

03/27/20 HHS Seeks Feedback on Legislation to Maintain Adequate Blood Supply

HHS Seeks Feedback on Legislation to Maintain Adequate Blood Supply

HHS is seeking public comments on Section 209 of the [Pandemic and All-Hazards Preparedness and Advancing Innovation Act \(PAHPAI\)](#), which addresses recommendations to maintain an adequate national blood supply. Specifically, HHS welcomes feedback on the following four subject areas:

- Challenges associated with the continuous recruitment of blood donors, including those newly eligible to donate.
- Ensuring the adequacy of the blood supply in the case of public health emergencies.
- Implementation of the Transfusion-Transmissible Infections Monitoring System (TTIMS).
- Other measures to promote safety and innovation, such as the development, use or implementation of new technologies, processes and procedures to improve the safety and reliability of the blood supply.

The deadline to submit comments is April 22. Instructions to submit comments electronically or in writing are available in the [Federal Register](#) notice.

03/27/20 Reminder: AABB Temporarily Suspends Assessments Due to COVID-19 Risk

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AABB has temporarily suspended all assessments in response to the ongoing COVID-19 pandemic. This action will ensure that member facilities can focus on their own internal needs and challenges during the current outbreak, and it will also help protect the health and safety of AABB employees and

volunteers. The Association's other programs and services remain fully operational, and scheduled educational programs will continue as planned.

03/27/20 [AABB, ABC, ARC Highlight Importance of Blood Supply in HHS, FDA Letters](#)

AABB, ABC, ARC Highlight Importance of Blood Supply in HHS, FDA Letters

AABB, America's Blood Centers (ABC) and the American Red Cross (ARC) reminded officials at HHS and FDA of the importance of maintaining an adequate blood supply during the ongoing COVID-19 pandemic. In a March 20 [letter](#) to HHS Secretary Alex M. Azar II and Assistant Secretary for Health Admiral Brett P. Giroir, MD, the organizations thanked the officials for their ongoing support of the blood community and requested that HHS continue to address challenges facing the nation's blood supply as a result of the COVID-19 pandemic.

In a March 20 [letter](#) to Stephen M. Hahn, MD, commissioner of Food and Drugs, the organizations asked Hahn to include challenges to the nation's blood supply in his response to the House of Representatives Committee on Energy and Commerce about the potential impact that COVID-19 could have on the supply of safe drugs and other medical products. AABB, ABC and ARC reiterated that governmental support is required to encourage all healthy individuals to donate blood and to ensure that the entire blood supply chain stays intact.

03/27/20 [Report Published in *Transfusion* Examines Response to COVID-19 in Washington State](#)

Report Published in *Transfusion* Examines Response to COVID-19 in Washington State

Adequate blood supply and public messaging, testing capacity, highly skilled laboratory personnel, transportation and alterations to hospital operations should be considered to adequately support the community during the COVID-19 outbreak, according to a brief report published this week in [Transfusion](#). The report describes the response from the hospital, the regional blood center and the hospital-based transfusion service to the events that took place in the community during the first and second weeks of the COVID-19 pandemic in Washington state. The report also details a number of transformations that were required to protect the blood supply as community activities were disrupted and hospital activities switched from routine operations to pandemic-focused and urgent care-oriented operations.

03/27/20 [AABB Releases Findings From Weekly Member Survey on COVID-19 Response](#)

AABB Releases Findings From Weekly Member Survey on COVID-19 Response

Almost half of AABB member hospitals that participated in AABB’s inaugural weekly survey of member transfusion services have implemented prospective audits for red blood cell orders and platelet orders in response to the COVID-19 pandemic. AABB intends for [these findings](#) to provide a snapshot into the impact of the blood supply on patient care during the COVID-19 pandemic. A total of 132 AABB member hospitals from 39 states responded to the survey, while total responses per question varied.

Of 131 respondents, 63 (48.1%) have implemented prospective audits for red blood cell orders, while 60 (45.8%) have not; similarly, 63 out of 132 hospitals (47.7%) implemented audits for platelets orders and 59 (44.7%) have not. A total of 75 (56.8%) and 18 (13.8%) have lowered RBC transfusion thresholds to 7 grams per deciliter of hemoglobin for most patients or any patients, respectively. In addition, among 131 respondents, 12 (9.2%) had implemented splitting of platelet and/or RBC units, while 111 (85.5%) had not; 27 of 129 (20.9%) had planned for splitting platelet and/or RBC units, while 78 (60.5%) had not. AABB will refine the questionnaire in next iterations to understand if these trends are based on whether the responding hospitals are pediatric- versus adult-serving institutions. A total of 48 of 131 respondents (36.6%) have created or revised a plan in the event that no blood is available for transfusion, while 78 (59.5%) have not.

AABB will continue to survey member transfusion services and report the results out to participating hospitals on a weekly basis in the months ahead.

03/27/20 AABB’s Spanish-Language Subsection, GCIAMT Translate COVID-19 Resources

AABB’s Spanish-Language Subsection, GCIAMT Translate COVID-19 Resources

The translation volunteer team from AABB’s Cellular Therapies (CT) Spanish-Language Subsection (SLS) partnered with the Latin American Transfusion Medicine Association (GCIAMT) to develop an [open resource](#) of COVID-19 transfusion medicine documents in the Spanish language. The web page includes translated resources from AABB’s Coronavirus Resources web page, as well as information from FDA, Vitalant, GCIAMT and the Global Advisory Panel for the Voluntary Non-Remunerated Blood Donation. AABB reminds those who utilize the Spanish-language resources that the volunteer translation may not be as precise as if performed commercially. For the official text, please refer to the English-language version.

AABB extends its gratitude to the SLS translation volunteer team and GCIAMT for making these important resources accessible to the Spanish-speaking community. Additional information about AABB’s CT Spanish-Language Subsection is available [online](#).

03/27/20 AABB Announces Town Hall eCast Series on COVID-19 Considerations

AABB Announces Town Hall eCast Series on COVID-19 Considerations

AABB is pleased to introduce an educational town hall eCast series to assist blood centers and hospital transfusion services in navigating the pressing challenges presented by the ongoing COVID-19 pandemic. Registration to the series is complimentary thanks to the generous support of the [Commonwealth Transfusion Foundation](#) (CTF).

This series comprises four 30-minute expert-led virtual town hall lectures on managing collections, operations and inventory during the pandemic, as well as highlighting the experience of professionals in Washington state in responding to COVID-19. A 30-minute Q&A period will follow each lecture, and registrants will receive supportive resources such as tools and fact sheets. Dates and descriptions of each town hall are available [online](#).

Both the live and on-demand versions of each eCast in the series will be eligible for one continuing education credit/contact hour. [Registration](#) is required and includes access to all four eCasts in the series, both live and on-demand.

03/27/20 European Health Officials Issue Guidance on Managing Clinical Trials during the COVID-19 Pandemic

European Health Officials Issue Guidance on Managing Clinical Trials during the COVID-19 Pandemic

The EMA, the EC and the Heads of Medicines Agency (HMA) [released a guidance](#) on Friday for European pharmaceutical companies whose clinical trials may be affected by the ongoing COVID-19 pandemic. The guidance outlines several considerations to protect the health and safety of participants and investigators. It also addresses the pandemic's potential effect on the completion of trial assessments and visits and the provision of investigational medicinal products. FDA issued [a guidance](#) last Wednesday for industry, investigators and institutional review boards conducting clinical trials during the COVID-19 pandemic in the United States.

03/27/20 Global Regulatory Workshop Explores Development of Novel Coronavirus Vaccine

Global Regulatory Workshop Explores Development of Novel Coronavirus Vaccine

The first [global regulatory workshop](#) on COVID-19 brought together delegates representing more than 20 regulatory authorities, including experts from the World Health Organization and European Commission (EC), to discuss the development of a vaccine for SARS-CoV-2. FDA and the European Medicines Agency (EMA) co-chaired the virtual workshop, convened under the umbrella of the International Coalition of Medicines Regulatory Authorities, on March 18. Peter Marks, MD, PhD, director of CBER, provided an overview of the meeting's discussion and outlined the next steps for FDA's and EMA's collaboration in an [FDA Voices article](#).

03/27/20 CMS Releases COVID-19 Emergency CLIA Guidance FAQ Document

CMS Releases COVID-19 Emergency CLIA Guidance FAQ Document

The Centers for Medicare & Medicaid Services (CMS) answered a series of [frequently asked questions](#) (FAQs) related to Clinical Laboratory Improvement Amendments (CLIA) guidance during the COVID-19 pandemic. The document addresses alternative specimen collection devices, COVID-19 testing and emergency use authorizations, among other topics. Additional resources from CMS are available on the agency's coronavirus [web page](#).

03/27/20 CDC Issues Interim COVID-19 Infection Control Guidance for Blood, Plasma Collection Personnel

CDC Issues Interim COVID-19 Infection Control Guidance for Blood, Plasma Collection Personnel

CDC issued [interim guidance](#) last Saturday to protect the health of staff, volunteers and donors at blood and plasma collection centers and help them set up facilities to minimize spread of COVID-19. CDC's interim guidance reinforces routine measures that are currently followed by blood centers, including considerations described in FDA's [March 11 communication](#) on the COVID-19 outbreak. The guidance complements CDC's interim infection prevention and control recommendations and AABB's [Association Bulletin #20-02](#), which outlines recommendations for providing a safe environment for blood donation.

03/27/20 CBER Pauses Some Lot Release Activities Due to Coronavirus

CBER Pauses Some Lot Release Activities Due to Coronavirus

FDA's Center for Biologics Evaluation and Research (CBER) [paused](#) certain lot release activities and stopped accepting biological product samples or protocols in physical form this week in response to the ongoing COVID-19 pandemic. CBER's Office of Compliance and Biologics Quality provided manufacturers with logistical information to assist with continuation of the lot release process during this period. In addition, the agency emphasized that the lot release process for licensed biological products will continue. CBER will notify manufacturers when the agency resumes normal operations.

03/27/20 FDA Alerts Consumers to Unauthorized Fraudulent COVID-19 Test Kits

FDA Alerts Consumers to Unauthorized Fraudulent COVID-19 Test Kits

FDA has not authorized any test that is available to purchase for at-home testing for COVID-19, the agency [reminded the public](#) last Friday. However, the agency sees the public health value in expanding the availability of COVID-19 testing through safe and accurate tests that may include home collection. FDA is actively working with test developers in this space. In addition, the agency emphasized that it continues to monitor the market for any firms selling products with fraudulent COVID-19 diagnostic, prevention and treatment claims. FDA will take appropriate action against those marketing tests that pose risks to patient health.

03/27/20 \$2 Trillion COVID-19 Stimulus Legislation Includes Blood Donor Awareness Campaign, Funding for Blood Supply Chain

\$2 Trillion COVID-19 Stimulus Legislation Includes Blood Donor Awareness Campaign, Funding for Blood Supply Chain

President Donald Trump signed the [Coronavirus Aid, Relief and Economic Security Act \(CARES Act\)](#), which includes AABB-supported provisions to promote blood donation and strengthen the blood supply chain during the COVID-19 pandemic. The Senate unanimously passed the \$2 trillion stimulus package late Wednesday evening; the House of Representatives passed the bill by a voice vote this afternoon.

The legislation requires the Secretary of Health and Human Services (HHS) to carry out a national campaign to improve awareness of the need for blood donations during the COVID-19 pandemic. Additionally, the legislation supports outreach to the public and health care providers about the importance and safety of blood donations. The legislation also mandates that the Secretary send a report to the House within two years that includes a description of the activities carried out as part of the awareness campaign, a description of trends in blood donations, and an evaluation of the impact of the public awareness campaign, including any geographic or population variations.

Additionally, the legislation allocates \$27 billion for the Public Health and Social Services Emergency Fund to prevent, prepare for and respond to coronavirus, domestically or internationally. This funding may be used to address the blood supply chain, develop several necessary countermeasures, and for other preparedness and response activities.

03/27/20 REGULATORY UPDATE: FDA Issues Considerations to Preserve Medical Gloves

REGULATORY UPDATE: FDA Issues Considerations to Preserve Medical Gloves

FDA issued a [letter to health care providers](#) last week outlining considerations to conserve surgeons' gloves and patient examination gloves should the need for personal protective equipment outpace supply during the COVID-19 pandemic.

In settings where medical glove supplies are critically low and demand is high, the agency suggests health care providers consider the following strategies:

- Refer to the CDC's [Hand Hygiene in Healthcare Settings](#).
 - Use medical gloves beyond the manufacturer-designated shelf life in a setting where there is a lower risk of transmission.
 - Extend the use of medical gloves for health care providers without changing the gloves between patients with the same infectious disease diagnosis or exposure and no other infections. FDA stated, "Gloved hands can be cleaned between patients and at other times when hand hygiene would normally be performed during routine patient care. Alcohol-based hand sanitizers may degrade vinyl gloves. If a glove becomes damaged (for example,
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discolored, deteriorated, visible tears, holes) or contaminated (for example, body fluids, chemotherapy drugs), replace it.”

- Consider using radiographic protective gloves or radiation attenuating surgeon’s gloves that are clean and offer fluid barrier protection.
- Consider using non-medical gloves, such as those used for food service, embalming, cleaning or other industrial-grade gloves.

FDA categorized the conservation strategies for a range of needs and supply levels, which are available in full [online](#).

Importantly, the agency noted that these strategies are not limited to use in the care of patients with COVID-19.

FDA also stated that it intends the conservation strategies described in the letter to augment, not replace, specific controls and procedures developed by health care organizations, the CDC or the CDC’s Healthcare Infection Control Practices Advisory Committee to aid in infection prevention and control.

FDA is collaborating with manufacturers of medical gloves to better understand the current supply chain issues related to the COVID-19 pandemic and to help mitigate any widespread shortages of these products. The agency will continue to keep health care providers, manufacturers and the public informed if new or additional information becomes available.

AABB’s [Association Bulletin #20-02](#) and AABB’s [Coronavirus Resources web page](#) provide additional information and strategies designed to promote a safe environment for blood donation.

03/27/20 REGULATORY UPDATE: New FDA Process Expedites COVID-19 Guidance Documents

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AABB encourages members to review FDA's recent communication, FDA’s [Process for Making Available Guidance Documents Related to Coronavirus Disease 2019](#), which announces procedures to allow the agency to rapidly disseminate recommendations and policies related to COVID-19 to industry, FDA staff and other stakeholders. As provided in the communication, “FDA is committed to providing timely recommendations, regulatory advice, guidance, and technical assistance ... including to clarify our expectations regarding regulatory requirements to support response efforts to this emergency.”

The new procedure allows for the following changes in FDA’s processes:

- COVID-19-related guidance documents will be released for immediate implementation without prior public participation or comment.
 - FDA will solicit and review comments received [after implementation], and revise the guidance documents as appropriate.
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COVID-19 guidance documents will be posted on FDA's [Coronavirus Disease 2019 \(COVID-19\)](#) web page and announced in a consolidated *Federal Register* notice using one docket for each center or office.

03/27/20 REGULATORY UPDATE: FDA to Expedite Emergency Access to COVID-19 Convalescent Plasma

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The Food and Drug Administration is [facilitating emergency access](#) to convalescent plasma from individuals who have recovered from coronavirus disease 2019 (COVID-19) for investigational use in patients with serious or immediately life-threatening COVID-19 infections. According to FDA, it is possible that COVID-19 convalescent plasma (CCP) containing antibodies to the 2019 novel coronavirus (SARS-CoV-2) might be effective against the infection.

FDA's emergency Investigational New Drug Application (eIND) process allows for the use of CCP for the investigational treatment of an individual patient by a licensed physician upon FDA authorization. This does not include the use of CCP for the prevention of SARS-CoV-2 infection. FDA outlines requirements for collection of CCP, patient eligibility criteria and eIND authorization instructions on its [Emergency INDs web page](#).

FDA continues to work with the National Institutes of Health and the Centers for Disease Control and Prevention to develop master protocols for use by multiple investigators in order to coordinate the collection and use of CCP.

03/20/20 AABB, Mayo Clinic Laboratories Cancel Transfuse 2020

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AABB and Mayo Clinic Laboratories announced the cancellation of Transfuse 2020 this week in response to the ongoing COVID-19 pandemic. Transfuse 2020 was scheduled for May 12-13 in Rochester, Minn. Registrants who have already paid will receive a refund. AABB thanks participants for their understanding during this challenging time.

03/20/20 REGULATORY UPDATE: AABB, ABC, ARC, ASBP Submit Joint Comments on CJD Draft Guidance

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AABB, ABC, ARC and the ASBP recently submitted [joint comments](#) to FDA on the January 2020 draft guidance, "[Recommendations to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Components](#)." The organizations applauded CBER's "new direction and the decision to restore donation opportunities for many new and returning

donors, most notably those who were deferred for time spent in Europe during military service, along with their dependents.”

The comments also included a request for clarification on the rationale behind CBER’s risk-based decision to remove receipt of human growth hormone as a reason for donor deferral without permitting reentry options and similar rationale for potential iatrogenic exposures to sporadic Creutzfeldt-Jakob Disease.

03/20/20 AABB Highlights Urgent Need for Blood in National Media

AABB Highlights Urgent Need for Blood in National Media

AABB continues to amplify the need for continuous blood donations in national, regional and local media outlets. Since the beginning of the outbreak, AABB representatives have stressed the importance of an adequate blood supply and urged the public to donate in articles from [The New York Times](#), [The Los Angeles Times](#), [USA Today](#), [Kaiser Health News](#), [Reuters](#) and more.

To assist member centers in publicizing the need for blood donations, AABB developed a [social media campaign](#) and released a [media toolkit](#) in partnership with ABC, ARC and the Armed Services Blood Program (ASBP). The toolkit includes a press release and several pre-recorded media statements. As the pandemic unfolds, AABB will continue to use every opportunity to highlight the importance of the blood supply and of the critical work of the blood community.

03/20/20 Government Officials Urge Americans to Donate Blood

Government Officials Urge Americans to Donate Blood

Surgeon General Vice Admiral Jerome Adams, MD, MPH, and Peter Marks, MD, PhD, director of the Center for Biologics Evaluation and Research (CBER), issued separate statements this week urging Americans to donate blood in response to the COVID-19 pandemic. In a Thursday news conference, Adams [reminded](#) the public that blood donation is safe and highlighted several of the extra precautions blood centers have implemented to prevent the spread of COVID-19 based on CDC recommendations.

Marks [reiterated](#) the need for blood donors and emphasized that blood centers are skilled in infection control practices and have procedures in place to prevent the spread of infections. “Blood donation centers always take steps to prevent staff and donors who are not feeling well or who have a fever from reaching the donor area,” Marks said. “And they are now taking additional social distancing precautions wherever possible.”

Last week, AABB, America’s Blood Centers (ABC) and the American Red Cross (ARC) wrote a [joint letter](#) to CDC Director Robert R. Redfield, MD, stressing that governmental support is necessary to encourage all healthy individuals to donate blood and to limit the negative impact that social distancing has on blood donation efforts.

03/20/20 CMS Recommends Delays for Elective, Non-Essential Surgeries

CMS Recommends Delays for Elective, Non-Essential Surgeries

The Centers for Medicare & Medicaid Services (CMS) [announced](#) on Wednesday that all elective surgeries, non-essential medical, surgical and dental procedures should be delayed during the COVID-19 pandemic. The recommendation is part of a [broader framework](#) for hospitals and clinicians to implement immediately during the COVID-19 response. The recommendations outline factors that should be considered for postponing elective and non-essential surgeries, including patient risk factors, availability of beds, staff, personal protective equipment and the urgency of the procedure. The recommendations will help providers to focus on addressing more urgent cases and preserve resources needed for the COVID-19 response.

03/20/20 FDA Issues Guidance for Conducting Clinical Trials During COVID-19 Outbreak

FDA Issues Guidance for Conducting Clinical Trials During COVID-19 Outbreak

FDA [issued a guidance](#) on Wednesday for industry, investigators and institutional review boards conducting clinical trials during the COVID-19 pandemic. The guidance outlines considerations to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practice and minimizing risks to trial integrity. These considerations include sponsors evaluating alternative methods for assessments, such as phone contacts or virtual visits, and offering additional safety monitoring for those trial participants who may no longer have access to the investigational product or the investigational site.

03/20/20 FDA Postpones Domestic Routine Surveillance Facility Inspections

FDA Postpones Domestic Routine Surveillance Facility Inspections

FDA has temporarily postponed all domestic routine surveillance facility inspections in response to the COVID-19 outbreak, FDA Commissioner Stephen M. Hahn, MD, [announced](#) on Wednesday. The postponement will not affect inspections that FDA considers “mission critical,” and the agency will continue to respond to natural disasters, outbreaks and other public health emergencies involving FDA-regulated products. FDA is evaluating additional ways to conduct inspectional work that would not jeopardize public safety.

03/20/20 AABB Releases New COVID-19 Cellular Therapy Resource

AABB Releases New COVID-19 Cellular Therapy Resource

AABB’s Center for Cellular Therapies released a [new resource](#) this week that compiles the latest information from FDA, AABB and partner organizations related to cellular therapy products and COVID-

19. AABB continues to monitor the COVID-19 situation closely and update the resource as new information becomes available.

03/20/20 AABB to Launch Weekly Hospital Snapshot Survey

AABB to Launch Weekly Hospital Snapshot Survey

AABB hospitals are encouraged to be on the lookout next week for a quick survey asking about new or changed blood bank practices in light of the COVID-19 pandemic. Questions include whether hospitals have changed transfusion medicine practices, such as whether indication thresholds for red blood cells and platelets have been lowered, whether prophylactic platelet transfusions have been discontinued, and similar questions. The survey, to be administered weekly, is intended to provide a weekly snapshot into the impact of the blood supply on patient care during the COVID-19 pandemic. AABB will report the results out to participating hospitals on a weekly basis during the coming months.

03/20/20 REGULATORY UPDATE: AABB Releases Updated COVID-19 Toolkit

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AABB's Regulatory Affairs posted an updated [COVID-19 toolkit](#) in response to the Food and Drug Administration's March 11 communication, [Updated Information for Blood Establishments Regarding the Novel Coronavirus Outbreak](#). AABB urges members to carefully review the information from FDA and the updated toolkit, including "Notes to Consider" which may be helpful as they determine the appropriate approach for rapidly changing events and to avoid unnecessary donor deferrals if blood availability is a concern.

In response to member questions, the toolkit clarifies the following compliance responsibilities:

1. COVID-19 is not a "transfusion-transmitted infection, nor an RTTI, under 21 CFR [630.3](#) which provides a significant part of the regulatory framework for donor screening requirements" throughout [630.10](#).
2. For example, [630.10\(a\)](#) states "To be eligible, the donor must be in good health and free from transfusion-transmitted infections..." which means the donor is eligible, according to current FDA regulations, if "feeling healthy and well" when asked on the day of donation.
3. The FDA issued "considerations, but not recommendations, to be implemented at the discretion of the Medical Director.

Because COVID-19 is not a TTI, compliance with the considerations listed in the March 11 communication is not expected, except the requirement under 630.10 to establish the donor is "feeling healthy and well" at the time of donation. The establishment may determine if additional precautionary measures should be taken.

Three key changes from FDA are highlighted in the toolkit:

1. FDA has removed the reference to optional self-deferral for travel that was in the Feb. 4 communication.
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2. FDA's considerations on post-donation information (PDI) include a "subsequent diagnosis" only and do not include close contact/lived with a person diagnosed with COVID-19. FDA has never referenced PDI for travel in the precautionary measures.
3. FDA considerations for retrieval and quarantine are also precautionary measures. As such, retrieval and quarantine for a subsequent diagnosis of COVID-19 or close contact/lived with a person diagnosed with COVID-19 (which is not listed as a PDI consideration) are not required.

AABB is actively reviewing FDA's [new guidance process](#) "to rapidly disseminate Agency recommendations and policies related to COVID-19 to industry, FDA staff and other stakeholders. The Association urges members to review the AABB's [Coronavirus Resources](#) web page for updates. Questions about the toolkit or other regulatory concerns may be sent to regulatory@aabb.org.

03/20/20 AABB Releases Association Bulletin #20-02 to Address Blood Donation During the COVID-19 Pandemic

AABB Releases Association Bulletin #20-02 to Address Blood Donation During the COVID-19 Pandemic

The AABB Board of Directors approved [Association Bulletin #20-02](#) this week, which recommends strategies for blood collection establishments to implement to protect the availability of blood nationally during the 2019 coronavirus disease (COVID-19) pandemic. The bulletin contains information and strategies designed to promote a safe environment for blood donation necessary to protect both donors and staff; address public perception, misinformation, and growing concerns regarding the risk of infection transmission during donation; and encourage blood donation during the current COVID-19 outbreak through a demonstrable commitment to safety.

These recommendations, developed by AABB's COVID-19 Working Group, are based on a review of Centers for Disease Control and Prevention recommendations to protect individuals from the spread of the virus and current practices shared by AABB members. The adoption of some or all of these strategies will help to demonstrate the commitment of blood collection organizations to the safety of their donors. As new recommendations emerge, and as warranted by the current pandemic, AABB will continue to urge adoption of these and other practices by the blood collection community.

03/13/20 AABB Temporarily Suspends Assessment Activities, Will Begin Remote Operations

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In light of the ongoing 2019 novel coronavirus epidemic, AABB will temporarily suspend all assessments and begin remote operations effective Monday. This action will ensure that member facilities can focus on their own internal needs and challenges during the current outbreak, and it will also help protect the health and safety of AABB employees and volunteers. The Association's other

programs and services remain fully operational, and scheduled educational programs will continue as planned.

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03/13/20 [AABB Releases Shareable Graphics on COVID-19 and Blood Donation](#)

AABB Releases Shareable Graphics on COVID-19 and Blood Donation

AABB developed a [shareable infographic](#) about COVID-19 and the blood supply and a series of social media images to highlight the importance of continued blood donation during the ongoing outbreak. The infographic illustrates key messages that blood centers can use to address common misconceptions about novel coronavirus transmission, while the social media graphics emphasize the critical importance of an adequate national blood supply. AABB encourages members to utilize these tools in their own COVID-19 communications. Additional resources are available on AABB's Coronavirus Resources [web page](#). AABB encourages members to check this page regularly for updates.

03/13/20 [FDA Updates Information for Blood Establishments Regarding the Novel Coronavirus Outbreak](#)

FDA Updates Information for Blood Establishments Regarding the Novel Coronavirus Outbreak

The Food and Drug Administration issued a series of updated safety and availability considerations for blood establishments in response to the ongoing outbreak of the 2019 novel coronavirus (SARS-CoV-2), which causes the illness known as coronavirus disease 2019 (COVID-19). The [updated web page](#) addresses the use of laboratory screening tests, donor education and deferral, prospective donor evaluations and post-donation instructions.

AABB is developing additional resources for the [COVID-19 Toolkit](#) based updated information from FDA and a [Centers for Disease Control and Prevention report](#) of "community spread of the disease" in the United States. The toolkit will identify all changes in the March 11 communication. AABB will post the information as soon as possible.

In addition, FDA reemphasized its support for recommendations developed by the [AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism](#), which encourage healthy individuals to make plans to donate blood to maintain the adequacy of the nation's blood supply. The agency also encouraged blood centers to prepare and evaluate their emergency plans to address possible challenges, such as the availability of donors and staff.

03/13/20 [FDA Launches COVID-19 FAQ Web Page](#)

FDA Launches COVID-19 FAQ Web Page

FDA launched a new web page on Tuesday to answer [frequently asked questions](#) (FAQs) related to COVID-19. The page includes a section on vaccines, biologics, human tissues and blood products and addresses concerns related to donor screening, transmission risk and potential treatments. The FAQ page reemphasizes information that FDA shared on the Important Information for Blood Establishments Regarding the Novel Coronavirus Outbreak [web page](#) and the Updated Information for Blood Establishments Regarding the Novel Coronavirus Outbreak web page. Additional tools and resources are available on AABB's Coronavirus Resources [web page](#).

03/13/20 FDA Postpones April 2-3 BPAC Meeting

FDA Postpones April 2-3 BPAC Meeting

FDA will [postpone](#) the April 2-3 meeting of the Blood Products Advisory Committee (BPAC). The postponement is part of a larger government decision to cancel or postpone all non-essential meetings through the month of April. FDA will reassess on an ongoing basis for future months and leverage technology to host remote meetings where possible.

03/13/20 FDA, FTC Warn Companies for Selling Fraudulent COVID-19 Products

FDA, FTC Warn Companies for Selling Fraudulent COVID-19 Products

FDA and the Federal Trade Commission (FTC) issued [warning letters](#) to seven companies for selling fraudulent products intended to treat COVID-19. The agencies noted that the products (including teas, essential oils, tinctures and colloidal silver) are unapproved drugs that pose significant risks to patient health, violate federal law and "may cause consumers to delay or stop appropriate medical treatment, leading to serious and life-threatening harm." FDA and FTC requested responses from the companies within 48 hours describing specific steps they have taken to correct the violations outlined in the respective letters. Companies selling products that fraudulently claim to prevent, treat or cure COVID-19 may be subject to legal action. The agencies reiterated that there are no vaccines or drugs approved to treat or prevent COVID-19 at this time.

03/13/20 DOJ Cautions Business Community Against Violating Antitrust Laws Regarding Health Products

DOJ Cautions Business Community Against Violating Antitrust Laws Regarding Health Products

The Department of Justice (DOJ) will hold accountable anyone who violates antitrust laws in connection with the manufacturing, distribution or sale of public health products, the agency [announced](#) Monday. The agency also warned that individuals or companies that fix prices or rig bids for health protection equipment could face criminal prosecution. The announcement is part of a broader administration effort to ensure that federal, state and local health authorities; the private

health care sector; and the public at large are in the strongest position to respond to the ongoing COVID-19 outbreak. DOJ's Procurement Collusion Strike Force will be on alert for collusive practices in the sale of such products.

03/13/20 [WHO Declares Coronavirus Outbreak a Pandemic, CDC Issues Global COVID-19 Outbreak Notice](#)

WHO Declares Coronavirus Outbreak a Pandemic, CDC Issues Global COVID-19 Outbreak Notice

The World Health Organization (WHO) now considers the outbreak of novel coronavirus disease 2019 (COVID-19) to be a pandemic, Director General Tedros Adhanom Ghebreyesus, PhD, MSc, said during a Wednesday news briefing in Geneva. "All countries can still change the course of this pandemic. If countries detect, test, treat, isolate, trace and mobilize their people in the response," he [said](#).

Following WHO's announcement, CDC issued a [Global COVID-19 Outbreak Notice](#) that classified the current situation as sustained community-level transmission. The notice encouraged travelers to practice enhanced safety precautions.

03/13/20 [AABB, ABC, ARC Urge CDC to Assist in Blood Donor Recruitment Efforts](#)

AABB, ABC, ARC Urge CDC to Assist in Blood Donor Recruitment Efforts

AABB, America's Blood Centers (ABC) and the American Red Cross (ARC) urged CDC officials to encourage healthy individuals to donate blood to help limit the negative impact that social distancing is having on blood donation.

In a March 12 [letter](#), the organizations stated that while social distancing intended to limit the spread of COVID-19 is a necessary and appropriate public health measure, it has resulted in many canceled blood drives. Efforts to reduce non-essential blood component use can reduce the strain on the blood supply, the letter states, but the impact of these blood management strategies is not big enough to make up for the loss of donors.

AABB, ABC and ARC also stressed that blood drives are not "mass gatherings," but rather they are controlled events conducted using appropriate infection control mechanisms intended to assure the safety of the products, donors and staff. They emphasized that the entire blood community is united and undertaking massive efforts to educate the public about the safety and necessity for blood donation, but noted that governmental support is required to encourage blood donation and limit the negative impact that social distancing has on blood donation efforts.

03/06/20 [Trump Signs Emergency Coronavirus Funding Package](#)

Trump Signs Emergency Coronavirus Funding Package

President Trump [signed](#) an \$8.3 billion emergency aid package on Friday in response to the novel coronavirus. The bipartisan package, negotiated and [passed by Congress](#) this week, includes more than \$3 billion for research and development of vaccines and other treatments. The bill also includes \$2.2 billion in public health funding, including grants of \$4 million or more to allow each state to prepare for and respond to the coronavirus; \$836 million for the National Institutes of Health; and \$1.25 billion for the Department of State and the United States Agency for International Development, including money for evacuations and humanitarian assistance. The bill authorizes \$500 million for telemedicine, although Congress would need to pass legislation to specifically appropriate this funding.

03/06/20 Interorganizational Disaster Task Force Encourages Continued Blood Donation to Maintain Adequate Blood Supply

Interorganizational Disaster Task Force Encourages Continued Blood Donation to Maintain Adequate Blood Supply

The AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism issued a [statement](#) on Tuesday urging healthy, eligible individuals to donate blood to help maintain an adequate blood supply for patients in need. In its statement, the Task Force reminded the public that individuals are not at risk of the novel coronavirus through the blood donation process or via a blood transfusion, since respiratory viruses are generally not known to be transmitted by donation or transfusion. The statement also emphasized that routine blood donor screening measures — which may include travel deferrals — are already in place to help prevent individuals with clinical respiratory infections from donating blood. The Task Force and the blood community will continue to work with FDA and CDC as the situation evolves to further protect the safety and maintain availability of the blood supply.

03/06/20 REGULATORY UPDATE: AABB Forms COVID-19 Working Group

REGULATORY UPDATE: AABB Forms COVID-19 Working Group

AABB formed a [COVID-19 Working Group](#) this week to help blood collection centers and transfusion services respond to the potential adverse impact on blood collections due to the ongoing outbreak of COVID-19. The COVID-19 Working Group will provide education and tools to support planning and preparation, donor and staff safety, communications, and continuity of operations necessary to promote blood safety and availability during the outbreak.

AABB will coordinate the activities of the COVID-19 Working Group, which includes representatives from AABB, America's Blood Centers, the American Red Cross (ARC) and the Association of Donor Recruitment Professionals. AABB recognizes the hard work and dedication of these volunteers.

Individuals with questions AABB's COVID-19 response or the Working Group should contact regulatory@aabb.org.

REGULATORY UPDATE: AABB Launches New Web Page for COVID-19 Resources

AABB launched a [Coronavirus Resources web page](#) to serve as a comprehensive hub for the Association's latest information and tools related to coronavirus disease (COVID-19). The new web page includes the following resources:

- [AABB's COVID-19 outbreak planning checklist](#).
- [COVID-19 resource list](#): the most current information from the Department of Health and Human Services, Centers for Disease Control and Prevention, Food and Drug Administration, the World Health Organization (WHO) and other public health authorities.
- [AABB's regulatory updates for COVID-19](#): master list of all *Weekly Report* resources for COVID-19.
- A list of [key messages](#), developed by the AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism, that health care professionals can use when discussing COVID-19 with blood donors, patients and members of the public.

Previously released information, such as the [updates](#) from the Transfusion Transmitted Diseases Committee and the [optional resources toolkit](#) for FDA's communication to blood establishments.

REGULATORY UPDATE: COVID-19 and Blood Donation

AABB Releases Member Toolkit

As announced in a [News Flash](#) last week, AABB, in collaboration with the Donor History Task Force and with support from the Transfusion Transmitted Diseases (TTD) Committee, has developed a [toolkit](#) to support the Food and Drug Administration's recently released "[Important Information for Blood Establishments Regarding the Novel Coronavirus Outbreak](#)." The toolkit is intended to assist blood collection centers considering optional precautionary measures related to COVID-19 and blood donation. The toolkit aligns with FDA's current thinking, provides examples of optional documents and reminds donor centers how to stay informed by following updates on the [CDC Travel Notices](#) page. Additional information, including the TTD's most recent [COVID-19 update](#) are posted on AABB's [Regulatory Affairs web page](#).

AABB continues to monitor the COVID-19 outbreak and will keep members informed as necessary. AABB is also working with the Interorganizational Task Force on Domestic Disasters and Acts of Terrorism to determine if the outbreak is impacting the blood supply. Additionally, the Public Relations Subgroup of the Disaster Task Force is developing communication materials for the public regarding coronavirus and the blood supply, which will be forthcoming soon.

CDC Updates COVID-19-Related Resources

The Centers for Disease Control and Prevention has developed numerous resources on COVID-19, including the [Coronavirus Disease 2019 \(COVID-19\)](#) page and a new page consolidating [Travel Notices for COVID-19](#). CDC provides [definitions](#) for the three types of travel notices and details for each location affected by a travel notice. These two pages provide links to a broad range of resources for clinical professionals. A short document offering [COVID-19 resources](#) is also available.

CDC recently updated the [Travel Health Notices web page](#) to include Japan, Iran, Italy and South Korea, underscoring the importance of reviewing its updated information frequently. Those who are interested can subscribe to receive CDC updates to the [Travelers' Health website](#) through an [RSS feed](#). In addition, CDC invites the public to “stay current with this rapidly evolving situation” by signing up for the newly launched COVID-19 “What’s New” Weekly Update via CDC’s [Sign Up for CDC.gov Email Updates](#) page. CDC also provides updates via social media on [Facebook](#), [Instagram](#), [Twitter](#) and [YouTube](#).

Asia Pacific Blood Network Releases Recommendations For Updating Optional Documents Regarding COVID-19 (also referred to as SARS-CoV-2)

The Asia Pacific Blood Network’s February 17 "[Rapid Brief White Paper 2019 Novel Coronavirus \(SARS-CoV-2\); Expected challenges and risks to blood safety](#)" provides a comprehensive update and recommends specific factors to consider when developing an effective risk reduction strategy. The briefing document suggests, for “the emerging SARS-CoV-2 epidemic it is vital that blood services consider their response to the epidemic carefully. An overly precautionary response early, given the theoretical blood safety risk, may contribute to community misinformation on the risk and make it more difficult to maintain the blood supply if sustained community transmission has occurred. A precautionary approach may be acceptable if it has the ability to be flexible and change with emerging evidence and a changing epidemiology.” The November 2010 FDA Guidance, [Recommendations for Blood Establishments: Training of Back-Up Personnel, Assessment of Blood Donor Suitability and Reporting Certain Changes to an Approved Application](#) has important information to consider when preparing for and updating strategies to respond to the COVID-19 outbreak. The November 2010 guidance states the recommendations, “are applicable regardless of the existence of a pandemic or other emergency situation.”

The decision to implement precautionary measures and flexible options for updating self-deferral and donor education as Covid-19 spreads are left to the discretion of each responsible medical director. [FDA’s Important Information for Blood Establishments Regarding the Novel Coronavirus Outbreak](#) provides a flexible model for considering precautionary measures. FDA’s communication refers to “areas of outbreak” and without specifying the type of [CDC Travel Health Notice](#) (Watch, Alert or Warning) that would prompt an update to the precautionary measures. Similarly, blood centers electing to implement donor screening questions and travel deferrals have the flexibility to determine the type of travel notice that would trigger a travel deferral.

AABB will continue to work closely with FDA, CDC and other public health authorities to monitor the evolving outbreak of COVID-19.

AABB encourages members to contact its [Department of Regulatory Affairs](#) with questions.

02/28/20 FDA Posts New Information for HCT/P Establishments Regarding the 2019 Novel Coronavirus Outbreak

FDA Posts New Information for HCT/P Establishments Regarding the 2019 Novel Coronavirus Outbreak

FDA released new [information](#) for establishments involved in the collection of human cells, tissues or cellular or tissue-based products (HCT/Ps) in response to the Covid-19 outbreak. While noting that routine screening methods are currently in place to evaluate HCT/P donors for respiratory infection, FDA suggests that establishments in the United States that are considering additional donor screening measures in response to the virus consider the following donor history in the 28 days prior to HCT/P recovery:

- Travel in areas with COVID-19 outbreaks.
 - Living with individuals diagnosed with or suspected of having COVID-19 infection.
 - Diagnosis with or suspicion of having COVID-19.
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02/20/20 AABB News Flash, Regulatory Update: Information on COVID-19 and Blood Donation

AABB News Flash, Regulatory Update: Information on COVID-19 and Blood Donation

AABB developed a [member toolkit](#) in response to the Food and Drug Administration's [Important Information for Blood Establishments Regarding the Novel Coronavirus Outbreak](#) (FDA's communication) and provided updated COVID-19 information. Both are posted on AABB's [Regulatory Affairs web page](#).

FDA has stated that "there have been no reported cases of transfusion-transmitted coronavirus" and "routine blood donor screening measures that are already in place should prevent individuals with clinical respiratory infections from donating blood." The optional resources in the [toolkit](#) can be used by blood collection centers that elect to implement additional precautionary measures. The toolkit provides examples of optional documents that align with FDA's communication. These documents were developed in collaboration with AABB's Donor History Task Force.

The Centers for Disease Control and Prevention recently updated the [Travel Health Notice web page](#). In addition to the Level 3 outbreak identified earlier in China, CDC has identified Level 1 outbreaks of COVID-19 in Hong Kong and Japan. CDC updates are also available by email through an [RSS feed](#) to those who subscribe. AABB will continue to work closely with FDA, CDC and other public health authorities to monitor the evolving outbreak of COVID-19.

AABB encourages members to contact [Regulatory Affairs](#) with questions.

02/14/20 WHO Names 2019 Novel Coronavirus ‘Covid-19’

WHO Names 2019 Novel Coronavirus ‘Covid-19’

The official name for the disease caused by the 2019 novel coronavirus is “Covid-19,” officials from the World Health Organization (WHO) announced in a [media briefing](#) on Tuesday. According to WHO Director General Tedros Adhanom Ghebreyesus, PhD, MSc, the organization had to select a name that did not refer to a geographical location, an animal, an individual or group of people, and which is also pronounceable and related to the disease. As of [Feb. 13](#), there have been more than 46,997 confirmed cases of Covid-19 reported in China, along with 1,368 deaths. Outside China, there are 447 cases in 24 countries, and 1 death.

02/07/20 FDA Shares Information for Blood Establishments on Novel Coronavirus Outbreak

FDA Shares Information for Blood Establishments on Novel Coronavirus Outbreak

The Food and Drug Administration shared [information for blood establishments regarding the novel coronavirus outbreak](#) this week. The agency stated that the potential for transfusion transmission of the 2019 novel coronavirus (2019-nCoV) is unknown at this time, but noted that respiratory viruses are not known to be transmitted by blood transfusion and that there have been no reported cases of transfusion-transmitted 2019-nCoV at this time.

AABB's Transfusion Transmitted Diseases Committee (TTD) continues to monitor the rapidly changing information for evidence suggesting risk for 2019-nCoV as a transfusion-transmitted infection (TTI). The TTD is also advising the Donor History Task Force regarding TTI risk and deferral options as the Task Force prepares potential donor screening strategies.

Individuals with questions may contact AABB’s Regulatory Affairs staff at regulatory@aabb.org.

01/31/20 REGULATORY UPDATE: AABB Issues Update on Novel Coronavirus Outbreak

REGULATORY UPDATE: AABB Issues Update on Novel Coronavirus Outbreak

AABB is closely monitoring the outbreak of 2019-nCoV, including all communications from the Centers for Disease Control and Prevention, Food and Drug Administration and other public health authorities. AABB issued an update, "[Impact of 2019 Novel Coronavirus and Blood Safety](#)," to provide new information and insight into the current issues effecting blood safety.

At this time, AABB, CDC or FDA are not recommending interventions since there are neither data nor precedents suggesting risk for transfusion transmission of the 2019-nCoV. However, AABB recognizes that some blood collections establishments may elect to take action in advance of recommendations from

FDA and CDC. This update includes important information on the range of options available.

The Transfusion Transmitted Diseases Committee (TTD) will continue to monitor the rapidly changing information for evidence suggesting risk for 2019-nCoV as a transfusion-transmitted infection (TTI). The TTD will advise the Donor History Task Force regarding TTI risk and deferral options as the Task Force prepares potential donor screening strategies in advance of such TTI risk. AABB will provide frequent communication. Members with questions may contact Regulatory Affairs at regulatory@aabb.org.

01/22/20 AABB Newsflash, AABB Update on Novel Coronavirus Outbreak, Jan. 22

AABB Newsflash, AABB Update on Novel Coronavirus Outbreak, Jan. 22

AABB's Transfusion Transmitted Diseases (TTD) Committee is continuously monitoring developments for the novel coronavirus (called 2019-nCoV), which has recently been identified in Wuhan, Hubei Province, China. The TTD Committee's [summary](#) of the expanding information describes the background and data available as of Jan 22. AABB advises readers to pay close attention to [updates from the Centers for Disease Control and Prevention](#) (CDC) and other public health resources because the increasing number of case counts and clinical and epidemiological information are extremely labile. Rapidly changing information is anticipated.

The 2019-nCoV infection is generally associated with unexplained pneumonia following an incubation period that appears to be in the range of 2 to 14 days, based on limited data. Given the potential similarities of this virus to Severe Acute Respiratory Syndrome (SARS) and the Mideast Respiratory Syndrome coronavirus (MERS-CoV), the TTD Committee has been in contact with both the Food and Drug Administration (FDA) and CDC to assess any need for interventions to ensure the safety of the blood supply.

A rapid risk assessment from the European Centers for Disease Control recommends a brief travel deferral for donors returning from Wuhan. The CDC confirmed the first U.S. case of 2019-nCoV on Tuesday; however, the CDC and FDA have not yet recommended a travel deferral.

AABB will continue to monitor the situation and issue updates as necessary, including new information from CDC and FDA as it becomes available. Individuals may contact AABB's [Regulatory Affairs staff](#) with questions.

01/10/20 Chinese Officials, WHO Monitoring Pneumonia Cases Caused by New Coronavirus

Chinese Officials, WHO Monitoring Pneumonia Cases Caused by New Coronavirus

Health authorities in China have made a [preliminary determination](#) of a novel coronavirus, identified in a hospitalized patient with pneumonia in Wuhan, Hubei Province. Investigators conducted gene

sequencing of the virus using an isolate from one positive patient sample. Officials notified the China country office of the World Health Organization (WHO) of a cluster of pneumonia cases of unknown cause last week. Of the 44 cases reported, 11 are severely ill, while the remaining 33 patients are in stable condition. WHO does not recommend any specific measures for travelers and advises against the application of any travel or trade restrictions on China based on the information currently available.

AABB's Transfusion-Transmitted Diseases Committee continues to monitor this and other emerging infectious diseases.
