AABB’s Regulatory Updates for COVID-19

Last updated March 9, 2020

03/06/20 Trump Signs Emergency Coronavirus Funding Package

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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

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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.

03/06/20 REGULATORY UPDATE: AABB Launches New Web Page for COVID-19 Resources

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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.

02/28/20 REGULATORY UPDATE: COVID-19 and Blood Donation

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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**

CDC recently updated the [Travel Health Notices web page](https://www.cdc.gov/travel/notices.htm) 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](https://www.cdc.gov/travel/) 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](https://www.cdc.gov/coronavirus/2019-ncov/news-events/what-s-new.html) page. CDC also provides updates via social media on [Facebook](https://www.facebook.com/cdc), [Instagram](https://www.instagram.com/cdcgov/), [Twitter](https://twitter.com/CDCgov) and [YouTube](https://www.youtube.com/user/CDCgov).

**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](https://www.apbb.org/sites/default/files/2020-02/apbb_rapid_brief_white_paper_2019_novel_coronavirus_sars-cov-2.pdf)" 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](https://www.fda.gov/biologicsBloodVaccines/guidancecomplianceenforcement/ucm330699.htm) 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](https://www.fda.gov/emergency-preparedness-response-communications/information-resources/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](https://www.cdc.gov/travel/health-notices.html) (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](https://www.aabb.org/about/contact) with questions.

**02/28/20** [FDA Posts New Information for HCT/P Establishments Regarding the 2019 Novel Coronavirus Outbreak](https://www.fda.gov/medical-devices/human-cell-tissue-products/human-cell-tissue-products-hctps/important-information-865.html)

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

FDA released new [information](https://www.fda.gov/medical-devices/human-cell-tissue-products/human-cell-tissue-products-hctps/important-information-865.html) 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.

**02/20/20** [AABB News Flash, Regulatory Update: Information on COVID-19 and Blood Donation](https://www.aabb.org/About/Contact/)

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

AABB developed a [member toolkit](https://www.aabb.org/About/Contact/) in response to the Food and Drug Administration’s [Important Information for Blood Establishments Regarding the Novel Coronavirus Outbreak](https://www.fda.gov/medical-devices/human-cell-tissue-products/human-cell-tissue-products-hctps/important-information-865.html) (FDA’s communication) and provided updated COVID-19 information. Both are posted on AABB’s [Regulatory Affairs web page](https://www.aabb.org/About/Contact/).

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](https://www.aabb.org/About/Contact/) 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.
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.