

Day 1 of the Special Legislative Session

The Idaho Legislature convened today for its 2020 Extraordinary Session to address two topics related to coronavirus – the November election and civil liability reforms.

The most contentious issue – civil liability – will certainly extend the special session into at least a second day. The full House has now adjourned until 8:30 Tuesday morning to give their committees time to work through four different civil liability proposals that were introduced this morning.

Late this afternoon, the Senate approved one election bill that will assist counties with in-person voting. Due to the pandemic, finding adequate polling places with sufficient space for social distancing and recruiting willing poll workers presents a serious challenge. This bill allows for an alternative to polling place voting, in the form of vote centers. Vote centers add greater flexibility for voters and clerks by allowing any voter from any part of the county to go to any voter center and vote the correct ballot. The bill now goes to the House for consideration. A second election bill dealing with how absentee ballots are distributed and tabulated was sent to the Senate's amending order.

In addition to the two issues identified in the Governor's proclamation to convene the Extraordinary Session, there was a [House Concurrent Resolution](#) (HCR) introduced to affirm there is no longer a need for a statewide emergency declaration, and "the state of disaster emergency in Idaho is declared to be terminated as of the date of passage of this concurrent resolution." There is a question as to whether the HCR is in order as that specific topic was not identified in the Governor's proclamation. There also appear to be contradictory views as to whether adjourning the legislature by forcing the end of a statewide emergency declaration, would prevent the Governor from spending any of the CARES Act funding that is available. The sponsor of the bill asserts that CARES Act funding would not be impacted but questions exist as to whether a state with no emergency declaration in place would be eligible for much of the emergency funding. The resolution is set to be heard this evening in the House State Affairs Committee.

Reimbursement & Policy

[TeleTracking changes data reporting for prior dates](#)

After providing a process for uploading corrected or missing data last week, TeleTracking released a [new process](#) over the weekend, which should be active today, that allows for retroactive data entry of up to four days.

Once logged in to TeleTracking, a new "data upload" button should be available in the upper right corner. Clicking that button will allow you to select from the four previous dates for which to submit new data. Once it is submitted, you will receive an email confirmation and the data should be visible, although you may have to refresh your browser window.

In other data news, the Wall Street Journal released an article late last week indicating that responsibility for federal hospital data reporting may be reverting back to the CDC. There is no definitive answer on if or when that might happen. We will continue to monitor the situation and update as needed.

Quality & Patient Safety

[Enclosures without negative pressure may increase risk](#)

In a [letter](#) published August 21, the FDA alerted healthcare providers (HCPs) and facilities that the use of passive protective barrier enclosures (those without negative pressure) when treating patients who are known or suspected to have COVID-19 may pose an increased health risk to patients and health care providers.

A passive protective barrier enclosure is a transparent device designed to cover a patient's head and upper body that incorporates one or more ports through which the HCP's hands are passed to perform medical procedures, and that does not include fans, air filters, or other features and is not intended to generate negative pressure. On May 1, the FDA issued an Emergency Use Authorization (EUA) for passive protective barrier enclosures used as a physical barrier to prevent HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection, when used in addition to Personal Protective Equipment (PPE), to reduce the risk of transmitting COVID-19 from a patient to HCPs treating them. However, the FDA now is aware of preliminary evidence in simulated intubation procedure models of potential adverse events that could occur or complications with protective barrier enclosures without negative pressure recently reported in the literature.

Although, the FDA has not received any medical device adverse event reports related to the use of passive protective barrier enclosures during the COVID-19 pandemic, the FDA believes HCPs should be aware of potential risks or complications associated with their use so they can take appropriate precautions. Based on this information, the FDA is also revoking the current umbrella EUA for passive protective barrier enclosures issued in May.

HCPs should not use passive protective barrier enclosures without negative pressure, as they may not be effective in decreasing HCP exposure to airborne particles, and in some circumstances, may instead increase HCP exposure to airborne particles. Their use may also contribute to complications such as increased intubation times, lower first-pass intubation success rates, increased patient hypoxia time, and damage or tearing to PPE from the enclosures. If electing to use a protective barrier enclosure for additional protection during aerosolizing procedures by HCPs, FDA recommends the use of devices that incorporate negative pressure. FDA has [authorized the use of several negative pressure barrier enclosures](#).

Protective barrier enclosures (with or without negative pressure) should never be a replacement for using PPE. Any protective barrier enclosure should be removed if it impedes the HCP's ability to perform a medical procedure on a patient.

Resources & Equipment

[Convalescent Plasma treatment receives EUA](#)

On August 23 the FDA [authorized emergency use of COVID-19 Convalescent Plasma](#) – or CCP – for treatment of patients hospitalized with COVID-19. The EUA explicitly states that the use of CCP should not constitute standard of care therapy and clinical trials are still required to demonstrate CCP efficacy and optimal therapeutic applications. The FDA encourages clinicians to continue to enroll patients in ongoing and future CCP clinical trials.

CCP authorized for use must be collected from donors meeting [eligibility requirements](#) and qualifications. Furthermore, CCP qualifying as "high-titer" units under the EUA must have been tested using the Ortho VITROS SARS-CoV-2 IgG test and found to have a signal-to-cutoff (S/C) value of ≥ 12 . To date, the largest clinical benefit from convalescent plasma has been observed when high-titer units are administered early on during the course of disease. The EUA also authorizes the use of "low-titer" units (S/C value of < 12) per an individualized assessment of a patient's risk-benefit by a health care provider.

CCP is recommended for use according to standard institutional practices and procedures, starting with the administration of one unit of CCP (about 200 mL) and administration of additional units based on provider discretion. Use of CCP in a clinical setting is to be accompanied by the provision of the [Fact Sheets for Healthcare Providers](#) and the [Fact Sheet for Patients and Caregivers](#).

Virtual Meetings & Education

[Update on COVID-19 and Thrombosis Risk](#)

Peer-reviewed reports from several different parts of the world have raised the concern that the risk of venous thromboembolism (VTE) may be unusually high in patients with SARS-CoV-2 infection. This free webinar, presented by the National Blood Clot Alliance, will tackle some of the questions surrounding the relationship between SARS-CoV-2 and VTE.

Update on COVID-19 and Thrombosis Risk
Thursday, Sept. 17 ~ 12p-1p MTN / 11a-12p PAC

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