Idaho Hospital Association

COVID-19 Report to Members ~ July 30, 2020

Reports are sent on Mondays and Thursdays, unless there's breaking news.

Reimbursement & Policy

Is a Special Legislative Session on the horizon?

A 27-member Legislative Working Group today voted to recommend the Governor call a Special Session – soon - to address issues of liability and immunity for those who make good-faith efforts during a declared disaster or emergency. Most of the impetus behind a call for the Special Session is to provide protections for teachers, schools and school districts as they prepare to reopen in the fall in the midst of the COVID-19 pandemic. The draft legislative proposal, however, would also protect hospitals and healthcare workers (and all businesses) "whose normal activities are interrupted by the disaster or emergency but who made good faith efforts to continue those activities safely during the disaster or emergency." Legislative leadership will now forward that request and the **draft legislative language** to the Governor for his consideration.

HHS changes in hospital lab reporting

HHS hopes to implement the new **COVID-19 reporting requirements for all laboratories** – including hospital-based laboratories – beginning August 1. All laboratories will be required to "report data for all testing completed, for each individual tested, within 24 hours of results being known or determined, on a daily basis to the appropriate state or local public health department based on the individual's residence."

The Idaho Bureau of Communicable Disease Prevention confirms that any in-house test results should be sent electronically to HHS and should include both positive and negative results.

CMS updates Medicare billing FAQs

In the latest update of the CMS Medicare fee-for-service billing FAQs document, CMS addresses, among other issues, hospital billing for remote services. Beginning on page 126, questions **regarding hospital billing for remote and outpatient therapy services** are addressed. There are also new sections on whether hospitals can bill for and receive separate payment for COVID-19 testing services that are provided in the outpatient department prior to an inpatient admission, as well as the application of cost-sharing modifiers to pre-survey testing services that include COVID-19 testing.

Quality & Patient Safety

SARS-CoV-2 vaccine update

As the COVID-19 pandemic continues to wreak havoc on human health and economies around the globe, a safe, effective vaccine (or vaccines) is the primary hope for a return to "old" normal or a better future. At present, about 200 vaccine candidates are actively being developed and encouraging reports of early phase trials are being published at a fast pace, both in academic journals and via press releases and media reports.

Vaccine development includes exploratory and pre-clinical stages, followed by clinical development. The pre-clinical development stages do not use human subjects. The CDC describes the three-phase process of clinical development as follows: "[d]uring Phase 1, small groups of healthy volunteers receive the trial vaccine to monitor safety and gain preliminary evidence of effectiveness. In Phase 2, the clinical study is expanded and vaccine is given to people who have characteristics (such as age and physical health) similar to those for whom the new vaccine is intended. In Phase 3, the vaccine is given to thousands of people and tested for efficacy and safety."

On July 27th, Moderna, Inc. and the National Institutes of Health **announced a multi-site Phase 3 trial of their jointly developed mRNA-1273 candidate vaccine**. "Although face coverings, physical distancing and proper isolation and quarantine of infected individuals and contacts can help us mitigate SARS-CoV-2 spread, we urgently need a safe and effective preventive vaccine to ultimately control this pandemic," said NIAID Director Anthony S. Fauci, M.D. "Results from early-stage clinical testing indicate the investigational mRNA-1273 vaccine is safe and immunogenic, supporting the initiation of a Phase 3 clinical trial. This scientifically rigorous, randomized, placebo-controlled trial is designed to determine if the vaccine can prevent COVID-19 and for how long such protection may last." The mRNA-1273 vaccine candidate will be tested at approximately 89 clinical research sites in the United States and the trial aims to enroll 30,000 participants.

Other vaccine candidates have had similar success in Phase 1/2 trials for which Phase 3 trials are also underway. These vaccine candidates use multiple techniques to prime the human immune system against SARS-CoV-2. These techniques include inactivated virus vaccines, the approach Jonas Salk used for the polio vaccine, and new techniques that use RNA and DNA sequences. On July 28, 2020, the World Health Organization released an **overview of 25 vaccines in clinical evaluation and 141 vaccines in preclinical evaluation**.

The mRNA-1273 vaccine efficacy trial is the first Phase 3 trial to be implemented under Operation Warp Speed, a multi-agency collaboration led by HHS that aims to accelerate the development, manufacturing and distribution of medical countermeasures (vaccines, therapeutics, and diagnostics) for COVID-19. Operation Warp Speed previously announced billions of dollars of support for a handful of promising vaccine candidates.

Virtual Meetings, Education & Updates

CDC webinar ~ COVID-19 & Telehealth Implementation

During this CDC call, presenters will discuss telehealth benefits and challenges during and after the COVID-19 pandemic. Presenters will share their experiences implementing telehealth across diverse healthcare settings and address considerations for its future use.

COVID-19 & Telehealth Implementation: Stories from the Field
Tuesday, August 4 – 12p MT / 11a PAC
Webinar Link / **Slides**
Dial In: 669 254 5252 or 646 828 7666 / Webinar ID: 160 872 1092

Click to get our COVID-19 Updates