

# IHA COVID-19 Legal Resources

May 4, 2020 Edition

There are substantial and complex legal questions and concerns posed by the need to respond to COVID-19 in Illinois and nationally. Below are Federal, state, local, issue-specific, and other legal resources compiled by the Illinois Health and Hospital Association. Please consult legal counsel with specific questions.

NOTE: These resources are not comprehensive and will be updated periodically.

#### **Statistics:**

- **US Count**: Current count of COVID-19 cases in US is available on CDC's website.
- Illinois Count: The count of COVID-19 cases in Illinois is available on IDPH's webpage.

# **Federal**

- Presidential Executive Orders / Declarations
  - National Public Health Emergency. 1/31/20. On January 31, 2020 HHS Secretary Azar declared a nationwide public health emergency.
  - President Trump <u>announced</u> a travel ban to Europe during a primetime news briefing to the nation.
     3/11/20
  - National Emergency Declaration. On March 13, 2020 President Trump declared a state of emergency under the National Emergencies Act and the Stafford Act. Health. 3/13/20.
  - President Trump and the White House Coronavirus Task Force issued new <u>guidelines</u> to help protect Americans during the global Coronavirus outbreak, called 15 Days to Slow the Spread. 3/16/20
  - Executive Order on Prioritizing and Allocating Health and Medical Resources to Respond to the Spread of Covid-19 delegating HHS to direct production and distribution of personal protective equipment, ventilators, and "any additional specific health and medical resources" that meet the criteria of the DPA, as determined by HHS. 3/18/20
  - President authorized Reserve, National Guard to assist in COVID-19 response. President Trump has authorized the Secretaries of Defense and Homeland Security to order up to 1 million Ready Reserve members to active duty for up to two years at a time to assist with the COVID-19 national emergency. The authorization could impact the hospital and health system workforce, as many reservists are employed in health care when not on active duty. He also authorized 100% federal cost-sharing for the governors of Connecticut, Illinois, Michigan, Florida, Louisiana, Maryland, Massachusetts, New Jersey, Guam, and Puerto Rico to use the National Guard to support COVID-19 state and local emergency assistance efforts for 30 days. 3/22/20

- Memorandum on Order Under the Defense Production Act Regarding General Motors Company 3/27/20
- Vice President Pence sent a <u>letter</u> to hospitals asking them to report data about both COVID-19 testing and hospital capacity on a daily basis. The administration intends to use the data to better understand COVID-19 disease patterns and to inform the development of policies for prevention and control. 3/29/20
- President Donald Trump <u>announced</u> that the CDC was extending its <u>social distancing</u> <u>guidelines</u> until April 30. The president also announced that Humana and Cigna would waive all cost-sharing, co-pays, and deductibles for treatment related to COVID-19. 3/29/20
- President Trump invoked the Defense Production Act to: (1) require General Electric Company; Hill-Rom Holdings, Inc.; Medtronic Public Limited Company; ResMed Inc.; Royal Philips N.V.; and Vyaire Medical, Inc. to prioritize the production of <u>ventilators</u>; and (2) require 3M to prioritize the production of <u>N-95 respirators</u>. 4/2/20
- President Trump issued a "Memorandum on Allocating Certain Scarce or Threatened Health and <u>Medical Resources to Domestic Use</u>" directing the Department of Homeland Security (DHS), FEMA, in consultation with HHS, to use the Defense Production Act to keep scarce medical resources within the United States for domestic use. 4/3/20
- During the COVID-19 task force <u>briefing</u>, the administration stated it will use a portion of the \$100 billion from the CARES Act to cover providers' costs of caring for uninsured patients with COVID 19. The administration will prohibit providers from balance billing the uninsured for the cost of their care as a condition of receiving this funding. Providers will be reimbursed at Medicare rates. 4/3/20
- President Trump unveiled "<u>Guidelines for Opening Up America Again</u>" guidance for states to reopen their economies in phases (<u>press release</u>; <u>fact sheet</u>). 4/16/20
- o White House outlined testing blueprint to spur nation's re-opening; CDC updated criteria. The Trump administration put forward a series of guidelines for testing and rapid response programs in anticipation of reopening the nation's economy. The effort is meant to be a partnership between federal, state, local and tribal governments and the private sector. The federal government will support state-based efforts by expanding the number of testing platforms, increasing testing and laboratory supplies and capacity, and enhancing sample collection. As part of the effort, the Centers for Disease Control and Prevention updated its evaluation and laboratory testing criteria, stating that "increasing testing capacity will allow clinicians to consider COVID-19 testing for a wider group of symptomatic patients and persons without symptoms in certain situations." The following remain high priorities for COVID-19 testing: hospitalized patients; health care facility workers, workers in congregate living settings and first responders with symptoms; residents in long-term care facilities or other congregate living settings, including prisons and shelters, with symptoms; and individuals identified through public health cluster and selected contact investigations. A second, priority tier was established for individuals with symptoms for potential COVID-19 infection, along with those who are without symptoms who are prioritized by health departments and clinicians based on state and local plans. 4/28/20

## American Hospital Association (AHA) Letters

o AHA Letter requesting additional waivers for or leniency for federal audits, medical review audits,

- administrative timeframes, and medical record timing requirements specific areas. 3/16/20
- AHA Letter requesting suspension of Stark and AKS. 3/19/20
- AHA <u>Letter</u> requesting direct Federal funding for hospitals. 3/19/20
- AHA Letter to Attorney General Barr requesting DOJ exercise prosecutorial discretion and will decline to pursue or prosecute alleged violations of Stark and AKS. 3/20/20
- AHA <u>Letter</u> requesting HSS to revise waiver requirements of EMTALA and HIPAA. 3/25/20
- AHA <u>Letter</u> recommends enforcement of Stark Law and Anti-Kickback Statute be temporarily suspended. 4/1/20
- AHA, AMA and ANA <u>Letter</u> to the President to Use DPA for Medical Supplies and Equipment.
   4/1/20
- AHA <u>Letter</u> urging DOL to accurately define "health care provider" in regulations implementing of the Families First Coronavirus Response Act. 4/1/20
- AHA <u>Letter</u> to CMS urging flexibility with expansion of Medicare accelerated payment program.
   4/1/20
- AHA, AAMC, CHA Letter requesting IRS grant filing extension. 4/1/20
- AHA <u>Letter</u> urging HHS and CMS to distribute funds to hospitals and health systems as designated by CARES Act. 4/1/20
- AHA <u>Letter</u> urging private insurers to help meet challenge to respond to COVID-19. 4/1/20
- AHA <u>Letter</u> requesting to immediately increase allocation of controlled substances to combat COVID-19. 4/1/20
  - AHA Letter urges SBA to ensure hospitals can participate in CARES Act loan program. 4/2/20
- AHA <u>Letter</u> seeking guidance to support hospitals' ability to access Loan Program under Section 4003(B)(4) of the CARES Act. 4/3/20
- AHA <u>Letter</u> urges additional action to expand Telehealth. 4/6/20
- AHA Letter urging CMS to extend to 20% hospital add-on payment to LTCHs. 4/6/20
- AHA <u>Letter</u> urging HHS to temporarily suspend certain requirements on health care providers.
   4/6/20
- o AHA <u>Letter</u> urging HHS to waive interest or substantially reduce interest rate on accelerated/advanced payments. 4/6/20
- o AHA Letter to SBA regarding the Paycheck Protection Program. 4/8/20
- o AHA Letter requesting assistance, guidance from HHS for behavioral health providers. 4/9/20
- o AHA Letter to CMS seeking additional Home Health Telehealth and documentation relief. 4/13/20
- AHA Letter requesting prompt guidance on Main Street new loan facility. 4/13/20
- AHA <u>Letter</u> urges HHS to distribute substantial additional emergency funds in an expedited manner.
   4/16/20
- o Hospitals, Physicians, Nurses Letter urging HHS to address COVID-19 disparities. 4/16/20
- o AHA Letter to POTUS on additional financial support for hospitals and health systems. 4/18/20
- AHA <u>Letter</u> to House Minority Leader Kevin McCarthy on next COVID-19 package. 4/19/20
- AHA <u>Letter</u> urging HHS and HRSA to provide flexibility administering 340B Program during COVID-19. 4/21/20
- AHA, Others issue <u>Letter</u> urging agencies to improve Medicare accelerated and advance payment programs. 4/23/20
- o AHA Letter urging CMS to extend CJR on voluntary basis, hold hospitals harmless in 2020. 4/24/20
- AHA <u>Letter</u> expresses concern with HHS' distribution of emergency funds. 4/27/20

- AHA, businesses and insurance providers send <u>letter</u> to Congress to keep Americans covered during the COVID-19 pandemic. 4/28/20
- AHA, others issue <u>letter</u> urging HHS to expedite revising rule on 42 CFR Part 2 provisions in CARES Act. 4/28/20
- AHA's Institute for Diversity and Health Equity (IFDHE) issued new resources to help hospitals address health disparities during COVID-19 crisis. The <u>new resource</u> highlights steps hospitals can and are taking to address disparities that arise during the fight against COVID-19. The resource includes examples of actions that can help ensure vulnerable populations receive equitable care. To learn more about hospital and health system efforts to advance equitable health and health care, visit IFDHE's webpage. 4/28/20
- AHA, others issue <u>letter</u> urging DOJ to temporarily suspended enforcement of Stark Law and Anti-Kickback. 5/1/20
- O AHA, AONL issue <u>letter</u> supporting Workforce Bill. **5/1/20**
- O AHA and ANA issue <u>letter</u> outlining priorities for next COVID-19 legislative package. 5/1/20

## • Federal Legislation

- The Senate <u>voted</u> 91-1 to pass <u>H.R. 6074</u>, the House-passed \$8.3 billion emergency supplemental appropriation to address the coronavirus (COVID-19) outbreak. The sole "no" vote was from Senator Rand Paul (R-KY). 3/5/20
- The President signed the \$8.3 billion emergency supplemental appropriation bill to address the COVID-19 outbreak into law. 3/6/20
- House Education and Labor Committee Chairman Bobby Scott (D-VA), Rep. Donna Shalala (D-FL), and Committee Democrats introduced the COVID-19 Worker Protection Act of 2020 (<u>H.R. 6139</u>). The bill was incorporated into introduced version of H.R. 6201, but was not included in the final version approved by the House. 3/10/20
- House Democrats <u>introduced</u> the Families First Coronavirus Response Act (<u>H.R. 6201</u>) a package
  of bills intended to bolster the federal government's response to the coronavirus outbreak and
  address the safety and financial impacts in communities. 3/11/20
- Sen. Tina Smith (D-MN) <u>led</u> a group of Democratic Senate colleagues in introducing the Free COVID-19 Testing Act (<u>Details</u>). 3/12/20
- The House <u>passed</u> the Families First Coronavirus Response Act (<u>H.R. 6201</u>) by a vote of 363-40 (<u>details</u>). Relating to health care, the approved version contained several changes most notably, the House approved a Medicaid Federal medical assistant percentage (FMAP) of 6.2 percent instead of the initially proposed 8 percent. 3/14/20
- The House approved by unanimous consent H.Res. 904 to make technical corrections to the Families First Coronavirus Response Act (H.R. 6201). 3/16/20
- The Senate passed the Families First Coronavirus Response Act (H.R. 6201) by a vote of 90-8.
   3/18/20
- President Trump signed the Families First Coronavirus Response Act (<u>H.R. 6201</u>) into law. 3/18/20
- Senate Majority Leader Mitch McConnell (R-KY) released the Coronavirus Aid, Relief, and Economic Security (CARES) Act – the "phase 3" coronavirus stimulus package. 3/19/20
- o On Sunday evening, March 22, 2020, the Senate <u>rejected</u> (47-47) a motion to proceed to Senate

Majority Leader McConnell's updated \$1.6 trillion COVID-19 economic stimulus package – the CARES Act. The bill text had been updated to include various Medicare, Medicaid and other key health care "extenders" and appropriations language; however, Democrats objected to its so called "no-strings attached corporate slush fund" and inadequate funding for hospitals and individuals. 3 /22/20

- Sens. Chris Murphy (D-PA) and Brian Schatz (D-HI), along with Reps. Tim Ryan (DOH) and Elisa Slotkin (D-MI), introduced the Medical Supply Chain Emergency Act of 2020 (<u>S. 3568/H.R. 6390</u>).
   3/23/20
- House Democrats <u>introduced</u> the Take Responsibility for Workers and Families Act a package of proposals intended to bolster the federal government's response to COVID-19, as well as provide economic relief to individuals and businesses (including hospitals). 3/23/20
- Senate released an updated version of the Coronavirus Aid, Relief, and Economic Security (CARES)
   Act a package of bills intended to strengthen the federal government and health care system's response to COVID-19, as well as provide economic relief to individuals and businesses. 3/25/20
- The House Appropriations Committee released a <u>fact sheet</u> on funding streams, authorized under the Coronavirus Aid, Relief, and Economic Security (CARES) Act (H.R. 748), to assist state and local governments, as well as nonprofits in responding to the COVID-19 pandemic. 3/27/20
- President Trump signed the Coronavirus Aid, Relief, and Economic Security (CARES) Act (H.R. 748) shortly after the House passed the package by a voice vote. The President also signed a <u>Presidential Memorandum</u> directing the Secretary of Health and Human (HHS) Services to invoke the Defense Production Act in order to require General Motors to prioritize the production of ventilators.
   3/27/20
- House Speaker Nancy Pelosi (D-CA) sent a "<u>Dear Colleague" letter</u> to all members on next steps on CARES Act and "CARES 2." Speaker Pelosi is calling for additional funding and resources for hospitals and community health centers, states and localities, and small businesses; more generous unemployment benefits; and additional direct payments for individuals. 4/4/20
- Democratic Reps. Joe Neguse (CO), Ben Ray Luján (NM), Andy Levin (MI), and Tom Malinowski (NJ) recently introduced the Coronavirus Community Relief Act (legislative text). The bill intends to fill a funding gap in the Coronavirus Aid, Relief and Economic Security (CARES) Act, which provides relief funds to states and localities with populations of over 500,000. The Coronavirus Comunity Relief Act would provide \$250 billion in COVID-19 relief funding to local governments with a population of 500,000 or less. 4/7/20
- Senate Democrats <u>unveiled</u> a proposal for a "<u>Heroes Fund</u>" to provide premium pay to frontline health care workers for potential inclusion in the forthcoming COVID-19 relief package. 4/7/20
- House Speaker Nancy Pelosi (D-CA) and Senate Minority Leader Chuck Schumer released a joint statement calling for: (1) \$250 billion in assistance to small businesses, with \$125 billion channeled through community-based financial institutions; (2) \$100 billion for hospital, community health centers and health systems; and (3) \$150 billion for state and local governments; and (4) a 15 percent increase to the maximum SNAP benefit. 4/8/20
- The Senate failed to pass a measure to provide additional COVID-19 relief by unanimous consent, as each party rejected the other's proposal. Senate Majority Leader Mitch McConnell (R-KY) tried to approve \$250 billion in additional funding to the Small Business Administration's Paycheck Protection Program. Senate Democrats also called for \$250 billion for PPP, with some caveats; as well as \$100 billion in health provider relief; \$150 billion for the Coronavirus Relief Fund, which

- provides funds to state, tribes and localities; a 15 percent increase to the maximum SNAP benefits; and technical fixes to election assistance funding appropriated in the CARES Act. 4/9/20
- Senate Health, Education, Labor and Pensions (HELP) Ranking Member Patty Murray (D-WA) released a <u>white paper</u> outlining Democrats' proposal to expand COVID-19 testing capacity.
   4/15/20
- Sens. Bob Menendez and Bill Cassidy <u>announced</u> they will introduce bipartisan legislation to establish the State and Municipal Aid for Recovery and Transition (SMART) Fund – a \$500 billion fund to provide COVID-19 relief to state and local governments – when the Senate reconvenes. 4/19/20
- The Senate passed by unanimous consent a \$484 billion interim package to provide additional coronavirus relief to small businesses, health care providers, and hospitals, as well as provide funding to expand COVID-19 testing. 4/21/20
- The House passed passed by a roll call vote (388-5-1) the Senate-approved Paycheck Protection Program and Health Care Enhancement Act (H.R. 266) a \$484 billion relief package to provide additional coronavirus relief to small business, health care providers, and hospitals, as well as provide funding to expand COVID-19 testing capacity. The House also passed by a roll call vote (212-182) H. Res. 935, Establishing a Select Subcommittee on the Coronavirus Crisis as a select investigative subcommittee of the Committee on Oversight and Reform. 4/23/20
- U.S. Senator Dick Durbin <u>announced</u> IHA-supported bipartisan legislation to address healthcare professional shortages by recapturing unused immigrant visas and making them available to doctors and nurses. The <u>Healthcare Workforce resilience Act</u> would recapture 25,000 unused immigrant visas for nurses and 15,000 for doctors, and allocate them to professionals able to help in the fight against COVID-19. 4/30/20
- Coronavirus Preparedness and Response Supplemental Appropriations Act (H.R. 6074) (3.6.20)
   provides \$8.3 billion in funding to support preparedness and response efforts. The bill includes:
  - \$950 million to assist states and localities in conducting activities such as virus surveillance, lab testing and infection control;
  - More than \$3 billion for research & development of vaccines, therapeutics & diagnostics;
  - Provisions allowing HHS to waive certain Medicare telehealth restrictions.
- Families First Coronavirus Response Act (<u>H.R.6201</u>) (3.18.20) is wide-ranging legislation that enacts a number of emergency measures aimed at addressing economic, public health and other impacts of the outbreak. The bill includes:
  - Requirements for public and private coverage of COVID-10 testing and testing-related services at no cost to patients;
  - 6.2% temporary increase of the Federal Medical Assistance Percentage (FMAP);
  - \$1 billion for the Public Health Social Services Emergency Fund to cover testing costs and related services for the uninsured; and
  - A new option for states to expand limited Medicaid eligibility for the uninsured to cover testing and related services.
- Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (H.R. 748), this legislation, also

known as an economic stimulus package, is the third large-scale legislative package in an effort in response to the novel coronavirus (COVID-19) outbreak. The legislation provides financial relief and resources to individuals, families and businesses particularly hard hit by the COVID-19 public health emergency. It also includes a number of important health care provisions, including:

- An emergency fund for hospitals and health systems
- A Medicaid disproportionate share hospital cut delay
- Temporary elimination of the Medicare sequester
- A Medicare diagnosis-related group add-on payment that together are estimated to make available \$117 billion in new funding for urban and rural hospitals and health systems

## Federal Agencies

## Assistant Secretary For Preparedness And Response (ASPR)

- ASPR announced collaboration with <u>Janssen</u> and <u>Sanofi</u> for the development of COVID-19 therapeutics and vaccines, respectively. **2/18/20**
- ASPR <u>announced</u> its intent to purchase 500 million N95 respirators over the next 18 months for the Strategic National Stockpile. 3/4/20
- ➤ ASPR <u>announced</u> it will provide advanced development support to a diagnostic test for COVID-19 that can be used to process up to 1,000 tests in 24 hours, which is being developed by Hologic, Inc. 3/9/20
- ➤ The Biomedical Advanced Research and Development Authority (BARDA) within ASPR <u>provided</u> advanced support to rapidly develop two diagnostic tests for COVID-19, Simplexa COVID-19 Direct Assay and QIAstat-Dx RPS2 test. 3/13/20
- ➤ BARDA <u>announced</u> it would help fund development of a fourth COVID-19 diagnostic test. 3/18/20
- ➤ ASPR <u>announced</u> a public-private partnership to create a high-speed, high-volume, emergency drug packaging solution using low-cost prefilled syringes. 3/18/20
- ➤ BARDA <u>announced</u> will provide support for a U.S. <u>Phase 2/3 clinical</u> trial to evaluate Kevzara developed under a collaboration between Regeneron and Sanofi for the treatment of rheumatoid arthritis as a potential treatment for severely ill COVID-19 patients. 3/21/20
- ASPR <u>announced</u> it will provide \$100 million in aid to the National Special Pathogen Treatment System, as directed by the Coronavirus Preparedness and Response Supplemental Appropriations Act, to assist healthcare systems with preparing for a surge in COVID-19 patients. 3/24/20
- ➤ BARDA <u>announced</u> it will support vaccines in development by Janssen (non-clinical studies and a Phase 1 clinical trial) as well as Moderna and the National Institute of Allergy and Infectious Diseases (Phase 2 and 3 clinical trials). 3/30/20
- ➤ BARDA <u>announced</u> it is providing support to the American Red Cross; Emergent BioSolutions; Grifols USA; and SAb Biotherapeutics, Inc., to facilitate development of convalescent plasma and hyperimmune globulin immunotherapies for COVID-19 patients. 4/13/20

## Center for Disease Control and Prevention (CDC)

**Note:** A complete list of CDC guidance documents is available <u>here</u>.

## **Funding Opportunities and Awards**

- CDC activated the Cooperative Agreement for Emergency Response: Public Health Crisis Response (CDC-RFA-TP18-1802) and issued <u>interim guidance</u> regarding Components A and B Supplemental Funding. 3/15/20
- CDC released <u>Frequently Asked Questions</u>: COVID-19 Crisis Response Cooperative Agreement
   Components A and B Supplemental Funding Interim Guidance. 3/31/20
- ➤ CDC issued a funding opportunity titled, "Supporting Tribal Public Health Capacity in Coronavirus Preparedness and Response" (CDC-RFA-OT20-2004). Approximately \$40 million was made available under the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (H.R. 6074) (i.e., Phase I COVID-19 bill). The application deadline is May 31, 2020. 4/1/20
- ➤ CDC issued a funding opportunity titled, "COVID-19 Response Supplement Part B: Tribal Public Health Capacity-Building and Quality Improvement Umbrella Cooperative Agreement" (CDC-RFA-OT18-18030203SUPP20). The application deadline is April 8, 2020. 4/2/20
- CDC will <u>award</u> \$186 million in supplemental funding to states and local jurisdictions to support their public health infrastructure. Specifically, \$160 million will be provided through the Public Health Crisis Response Cooperative Agreement (CoAg) and \$26.3 million will be provided through the Emerging Infections Program (EIP). In addition, \$80 million in supplemental funding is underway for tribal governments and organizations. The funding was made available through the Phase I COVID-19 package. See <a href="here">here</a> for supplemental funding data by jurisdiction. 4/6/20
- ➤ CDC issued a funding opportunity titled, "Strengthening Public Health Systems and Services through National Partnerships to Improve and Protect the Nation's Health" (CDC-RFAOT18-18020301SUPP20). Approximately \$46.7 million was made available under the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (H.R. 6074) (i.e., Phase I COVID-19 bill). The anticipated award date is August 31, 2020. The application deadline is May 14, 2020. 4/14/20
- ➤ CDC forecasted a funding opportunity titled, "ATSDR's Partnership to Promote Local Efforts To Reduce Environmental Exposure COVID-19 Supplement" (CDCRFA-TS20-20010101SUPP20). This funding opportunity is only available to organizations that received funding under Component 1 of CDC-RFA-TS20-2001 "ATSDR's Partnership to Promote Local Efforts to Reduce Environmental Exposures (APPLETREE)". The estimated post date is May 1, 2020 and the estimated application due date is May 8, 2020. 4/21/20
- CDC will <u>award</u> \$631 million in supplemental funding to 64 jurisdictions to support the COVID-19 response through the existing Epidemiology and Laboratory Capacity for Prevention and

## **Treatment**

- CDC released <u>new information</u> on therapeutic options for the treatment of patients with COVID-19. 3/23/20
- ➤ FDA reiterated the need for caution in antimalarial treatments' off-label use for treating COVID-19. FDA reminded health care providers of the need to closely monitor patients for serious and potentially life-threatening side effects of hydroxychloroquine and chloroquine when used off-label to treat COVID-19. In a <a href="Drug Safety Communication">Drug Safety Communication</a>, FDA warned "adverse events were reported from the hospital and outpatient settings for treating or preventing COVID-19, and included QT interval prolongation, ventricular tachycardia and ventricular fibrillation, and in some cases death." FDA encourages health care professionals and patients to report adverse reactions or quality problems with any human drugs to the agency's <a href="MedWatch Adverse Event Reporting program">MedWatch Adverse Event Reporting program</a>. 4/24/20

## For Providers and Public Health Professionals

- ➤ HHS <u>announced</u> that the CDC is moving forward with awarding more than \$560 million of the \$8.3 billion in supplemental spending passed by Congress. The funding will be provided to states, localities, territories, and tribes, to assist with the coronavirus response. 3/11/20
- ➤ CDC updated its <u>FAQs for healthcare professionals</u> on COVID-19 regarding whether pregnant health care personnel are at increased risk if they care for patients with COVID-19. CDC recommends pregnant healthcare personnel to follow risk assessment and infection control guidelines for personnel exposed to patients with suspected or confirmed COVID-19. 3/17/20
- CDC released a Morbidity and Mortality Weekly Report (MMWR) titled, "Severe Outcomes Among Patients with Coronavirus Disease 2019 (COVID-19) United States, February 12-March 16, 2020. 3/18/20
- CDC released <u>Prepare to Care for COVID-19</u> a new resource containing clinical tools for health care providers caring for patients with COVID-19. The resource includes steps clinicians can take to prepare their clinic to protect patients and health care workers from COVID-19 (before patients arrive, when patients arrive, and after patients are assessed); outdoor and indoor signs; and a patient handout with tips for home care. 3/18/20
- CDC issued <u>Interim Additional Guidance</u> for Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed COVID-19 in Outpatient Hemodialysis Facilities. 3/24/20
- CDC released <u>preparedness checklists</u> for hospitals and healthcare professionals preparing for patients with suspected or confirmed COVID-19. 3/25/20
- CDC updated <u>Interim Guidelines</u> for Collecting, Handling, and Testing Clinical Specimens from Persons for COVID-19. 3/25/20
- CDC released a Morbidity and Mortality Weekly Report (MMWR) titled, "Preliminary Estimates of the Prevalence of Selected Underlying Health Conditions Among Patients with Coronavirus

- Disease 2019 United States, February 12-March 28, 2020." 3/31/20
- ➤ CDC released <u>contingency and crisis capacity strategies</u> about decontamination and reuse of filtering facepiece respirators (FFRs). 4/2/20
- ➤ CDC launched <u>COVIDView</u> a weekly surveillance weekly summary of U.S. COVID-19 activity. It includes information related to COVID-19 outpatient visits, emergency department visits, hospitalizations and deaths, as well as laboratory data. The report will be updated each Friday. 4/3/20
- CDC released guidance on completing the <u>Human Infection with 2019 Novel Coronavirus</u>
  Person Under Investigation (PUI) and Case Report Form. **4/17/20**
- CMS issued Frequently Asked Questions (FAQs) clarifying requirements and considerations for hospitals and other providers related to the Emergency Medical Treatment and Labor Act (EMTALA) during the COVID-19 pandemic. The FAQs address questions around patient presentation to the emergency department, EMTALA applicability across facility types, qualified medical professionals, medical screening exams, patient transfer and stabilization, telehealth, and other topics. 4/30/20
- ➤ CDC issued COVID-19 guidance for providers who care for breastfeeding women. CDC released guidance for health care providers who care for breastfeeding women and infants who receive breast milk, based on what is currently known about the virus that causes COVID-19 and the transmission of other viral respiratory pathogens. CDC plans to update the guidance as additional information becomes available. 4/29/20

#### For the Public

- ➤ CDC issued an Order aimed at controlling the introduction, transmission, and spread of communicable diseases into the United States, such as COVID-19. 2/20/20
- > CDC Released mitigation strategies to help stop the spread of the coronavirus. 3/11/20
- ➤ CDC <u>will provide</u> \$80 million in funding to tribes, tribal organizations, and Urban Indian Organizations for resources to support the 2019 novel coronavirus (COVID-19) response. 3/20/20
- CDC released new <u>recommendations</u> for individuals to wear cloth face coverings in public settings where other social distancing measures are difficult to maintain. 4/3/20
- ➤ CDC tools track hospital bed occupancy, county-level COVID-19 cases. Launched the <a href="National Healthcare Safety Network COVID-19">National Healthcare Safety Network COVID-19</a> Module Data Dashboard, which shows the share of inpatient and intensive care unit beds occupied by state as reported by acute care facilities participating in the Patient Impact and Hospital Capacity pathway of the NHSN COVID-19 module. As states move to reopen their economies, CDC also has added county-level data on COVID-19 cases and deaths to its data tracker and webpage on U.S. cases.

## Department of Justice (DOJ)

- The DOJ and the Federal Trade Commission (FTC) issued a <u>joint statement</u> which outlines an expedited process for all COVID-19-related requests, and commits the agencies to addressing those which impact public health and safety within seven calendar days. 3/24/20
- ➤ DOJ released a <u>statement</u> noting that the department is prepared to pursue "bad actors" who

- take advantage of the COVID-19 crisis.
- ➤ DOJ established a website, hotline and email for <u>reporting</u> price gouging and fraud. They will triage complaints to the appropriate federal and/or state authorities. A listing of state laws that cover or relate to price gouging can be found <u>here</u>.
- ➤ DOJ <u>announced</u> the distribution of hoarded personal protective equipment (PPE), including 192,000 N95 masks, 598,000 medical grade gloves, and 130,000 surgical masks. This PPE will be deployed to New York and New Jersey. 4/2/20
- ➤ DOJ issued a <u>letter</u> noting it would not challenge a collaborative effort, developed and led by FEMA and HHS, for McKesson Corporation, Owens & Minor Inc., Cardinal Health Inc., Medline Industries Inc., and Henry Schein Inc., to fast-track and increase manufacturing, sourcing, and distribution of PPE and COVID-19-treatment-related medication. 4/4/20
- DOJ and FTC issues Antitrust Guidelines for Collaborations among Competitors. 4/7/20
- ➤ DOJ and the FTC issued a <u>joint statement</u> noting that the agencies will be closely monitoring anticompetitive behavior or collusion that disadvantages workers. This includes actions such as wage-fixing, no-poach agreements, anticompetitive non-compete agreements, and the unsanctioned exchange of employee information, including salary, wages, benefits, and compensation data. 4/13/20

## Center for Medicare and Medicaid Services (CMS)

#### Waivers and other Emergency Flexibilities

- CMS approved an 1135 Medicaid waiver request for the state of Washington. 3/19/20
- CMS released a <u>fact sheet</u> (<u>press release</u>) outlining provider flexibilities in response to the national emergency declaration, including Section 1135 waivers of certain Medicare, Medicaid, and CHIP requirements and how they apply to different settings of care. The transcript and audio recording from a National Stakeholder Call on these flexibilities is available <u>here</u>. 3/13/20
- CMS approved a Section 1135 waiver request for the state of Florida in response to the COVID-19 national emergency, which will allow the state to waive prior authorization requirements, streamline provider enrollment processes, allow care to be provided in alternative settings, and more. Additional Section 1135 approval letters will be posted <a href="here">here</a> as they are issued. 3/17/20
- CMS released new checklists and tools designed to support state Medicaid and CHIP programs in pursuing the various regulatory flexibilities that became available when President Trump declared COVID-19 a national emergency. 3/22/20
- CMS <u>announced</u> the approval of 1135 waiver requests from 11 states, including: <u>Alabama</u>, <u>Arizona</u>, <u>California</u>, <u>Illinois</u>, <u>Louisiana</u>, <u>Mississippi</u>, <u>New Hampshire</u>, <u>New Jersey</u>, <u>New Mexico</u>, <u>North Carolina</u>, and <u>Virginia</u>. Additional Section 1135 approval letters will be posted <u>here</u> as they are issued. 3/23/20
- CMS approved 1135 waivers for the following states: <u>Kentucky</u>; <u>Rhode Island</u>; <u>Iowa</u>; <u>Indiana</u>; <u>Kansas</u>; <u>Missouri</u>; and <u>Oregon</u>. 3/25/20
- CMS approved 1135 waivers for the following states: <u>New York</u>; <u>Colorado</u>; <u>Hawaii</u>; <u>Idaho</u>; <u>Massachusetts</u>; and <u>Maryland</u>. <u>3/26/20</u>

- ➤ CMS <u>announced</u> it approved a total of 34 state applications for 1135 waiver authority to respond to the COVID-19 outbreak. 3/27/20
- CMS approved 1135 waivers for Montana, Texas, Vermont, and West Virginia, bringing the total number approved to 38. All waivers are available here. 3/30/20
- ➤ CMS <u>announced</u> a landmark array of new waivers and flexibilities for Medicare providers to address the surge in COVID-19 cases. 3/30/20
- CMS approved an additional two state Medicaid waiver requests under Section 1135 <u>South Carolina</u> and <u>Tennessee</u> bringing the total number of approved Section 1135 waivers to forty. 3/31/20
- ➤ CMS approved Section 1135 waiver requests for <u>Georgia</u>, <u>Alaska</u>, <u>Arkansas</u>, and <u>Nebraska</u>, bringing the total number to 44. 4/2/20
- CMS approved Section 1135 waiver requests for Maine, the U.S. Virgin Islands, Nevada, Michigan, and the District of Columbia, bringing the total number to 49. 4/7/20
- CMS announced a new set of waivers for CAHs, SNFs, HHAs, and Hospices. 4/9/20
- CMS <u>announced</u> it has approved 50 emergency waivers (50th waiver was for <u>Utah</u>), 28 state amendments, 9 COVID-related Medicaid Disaster Amendments, and one CHIP COVIDrelated Disaster Amendment. 4/14/20
- ➤ CMS released <u>guidance</u> on new waivers for inpatient prospective payment system (IPPS) hospitals, long-term care hospitals (LTCHs), and inpatient rehabilitation facilities (IRFs) stemming from CARES Act changes, with specific guidance on how to code claims for receiving higher payment. CMS also included guidance on waiving the Medicare Part A requirement that patients treated in IRFs receive at least 15 hours of therapy per week. 4/15/20
- CMS released a Medicare Learning Network (MLN) <u>article</u> outlining additional guidance on new and expanded flexibilities for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs), including information on new payment for telehealth services, expansion of virtual communication services, and accelerated/advance payments, among others. 4/17/20
- CMS <u>approved</u> the state of Washington's COVID-19 Public Health Emergency (PHE) section 1115(a) demonstration, "COVID-19 PHE." This approval is the first section 1115(a) demonstration specifically intended to combat the effects of COVID-19 in a state since the President Trump declared the COVID-19 outbreak a national emergency on March 13th. 4/21/20
- ➤ CMS announced additional <u>blanket waivers</u> for Medicare providers, including RHCs, FQHCs, LTCHs, and Intermediate Care Facilities. The changes also include flexibilities around current substitute billing (locum tenens) rules. 4/22/20
- CMS <u>released</u> a virtual <u>toolkit</u> to help states respond to health care workforce shortages by leveraging new emergency flexibilities offered during the public health emergency. The toolkits also contain best practices for states and localities to reference as they implement changes in their respective areas. 4/22/20
- CMS <u>announced</u> new <u>guidance</u> that will allow independent freestanding emergency departments (IFEDs) to provide care to Medicare and Medicaid beneficiaries during the COVID-19 public health emergency. This is in effect for Colorado, Delaware, Rhode Island, and Texas. 4/23/20

CMS <u>released</u> a number of <u>new waivers</u> related to COVID-19. The waivers apply nationwide and are generally retroactive to March 1, 2020. They include waivers that expand access to COVID-19 testing, including serological and antibody tests; expand flexibility around treatment locations; expand access to telehealth; allow for additional workforce capacity; and eliminate certain administrative requirements. For more information, see a detailed <u>IHA overview memo</u>. 4/30/20

#### Infection Control and Prevention

- ➤ CMS <u>announced</u> new actions the agency is taking to limit the spread of COVID-19, and released a series of memoranda for U.S. health care facilities and **nursing homes** on how they should respond to and contain the threat of the outbreak. 3/4/20
- ➤ CMS released <u>guidance</u> on the screening, treatment and transfer procedures healthcare workers must follow when interacting with patients to prevent the spread of COVID-19 in a **hospice** setting. CMS also issued <u>guidance</u> specific to nursing homes to help control and prevent the spread of the virus. 3/9/20
- ➤ CMS published <u>guidance</u> to hospitals with <u>emergency departments</u> (EDs) on patient screening, treatment and transfer requirements to prevent the spread of infectious disease and illness, including COVID-19. 3/9/20
- ➤ CMS issued memoranda to **dialysis facilities** (<u>here</u>) and **home health** providers (<u>here</u>) on screening and containment strategies for patients, visitors, and staff. 3/10/20
- ➤ CMS released an updated <u>memorandum</u> based on recommendations from the CDC directing **nursing homes** to significantly restrict visitors and nonessential personnel, as well as restrict communal activities inside nursing homes. 3/13/20
- CMS issued COVID-19 guidance to all Programs of All-Inclusive Care for the Elderly (PACE) Organizations (POs). PACE is a Medicare and Medicaid program that helps people meet their healthcare needs in the community instead of going to a nursing home or other care facility. 3/17/20
- ➤ CMS released new <u>guidance</u> to state and local governments and long-term care facilities (i.e., nursing homes) to aid in limiting the spread of COVID-19. 4/2/20
- ➤ CMS issued <u>recommendations</u> regarding non-emergent and elective medical services. CMS provides a tiered framework to prioritize services and care to those who require urgent or emergent attention, while underlining that decisions remain the responsibility of local healthcare delivery systems. 4/7/20
- ➤ CMS released <u>supplemental information</u> to long-term care facilities on transferring or discharging residents between facilities for COVID-19 cohorting. 4/13/20
- CMS issued <u>recommendations</u> to re-open health care systems in communities that have low incidence of COVID-19 and are in Phase 1 of the Guidelines for Opening Up American Again (<u>press release</u>). This guidance updates <u>previous recommendations</u> on limiting non-essential surgeries and medical procedures during the COVID-19 pandemic 4/19/20

- CMS released a <u>memorandum</u> that outlines upcoming notification requirements of confirmed or suspected COVID-19 cases for nursing homes. While the memorandum previews these requirements, CMS states it will codify them formally in forthcoming rulemaking "very soon." 4/20/20
- ➤ CMS updated its infection control guidance for home health agencies. CMS last week updated its infection control guidance for home health agencies participating in Medicare and Medicaid and for religious non-medical health care institutions participating in Medicare. The home health updates include additional information about CMS waivers and regulations; Centers for Disease and Control guidance for optimizing personal protective equipment; CDC return-to-work criteria for health care personnel with confirmed or suspected COVID-19; and recommendations for home health personnel who care for patients in assisted and independent living facilities. 4/27/20

## <u>Personal Protective Equipment (PPE)</u>

- ➤ CMS issued guidance on the CDC's updated Personal Protective Equipment (PPE) recommendations for health care workers. 3/10/20
- CMS issued tiered <u>recommendations</u> (<u>press release</u>) for health care providers on limiting nonessential adult elective surgery and medical and surgical procedures, including all dental procedures. 3/18/20

#### Telehealth & Provider Enrollment

- CMS issued a <u>press release</u> highlighting the telehealth benefits in the agency's Medicare program for use by patients and providers. 3/9/20
- CMS released anticipated guidance on new Medicare telehealth flexibilities triggered by the national emergency declaration in response to the COVID-19 outbreak (press release; accompanying FAQs; accompanying document). Effectuated per authorities granted under the coronavirus emergency supplemental bill. 3/17/20
- ➤ CMS released two toolkits one for general practitioners (<a href="here">here</a>) and one for providers treating end-stage renal disease (<a href="here">here</a>) collating key resources in answering telehealth-related questions. 3/20/20
- CMS released <u>FAQs</u> on Medicare Provider Enrollment Relief related to COVID-19 including the toll-free hotlines available to provide expedited enrollment and answer questions related to COVID-19 enrollment requirements. 3/22/20
- CMS released another telehealth toolkit, this time for long-term care nursing homes. 3/27/20
- CMS released a <u>memo</u> to State Survey Agency Directors outlining new flexibilities that allow enrolled ambulatory surgical centers (ASCs) to temporarily enroll as hospitals and provide hospital services. 4/3/20
- > CMS released a video answering common questions about the recent Medicare telehealth

- expansions. 4/6/20
- CMS released a new toolkit for states to help accelerate adoption of broader telehealth coverage policies in the Medicaid and Children's Health Insurance Programs (CHIP) during the COVID-19 pandemic. 4/23/20

### **Quality Reporting**

- CMS announced that clinicians participating in the Merit-based Inceptive Payment System (MIPS) can now earn credit for participating in clinical trials and reporting clinical information by using the new COVID-19 Clinical Trials improvement activity. 3/20/20
- CMS recently announced two additional measures in response to the COVID-19 pandemic: one pertaining to <u>Medicare Advantage (MA) risk adjustment</u>, and the other to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) <u>Competitive Bidding Program. 4/13/20</u>
- ➤ CMS <u>announced</u> it is postponing the 2019 Benefit year Risk Adjustment Data Validation (RADV) process. 4/13/20
- CMS issued a <u>memorandum</u> to all eligible qualified health plan (QHP) issuers announcing reporting flexibilities for the Quality Rating System (QRS), the QHP Enrollee Experience Survey, and Quality Improvement Strategy Programs (QIS). 4/18/20

#### **Coding and Reimbursement**

- CMS announced it has issued a second Healthcare Common Procedure Coding System (HCPCS) code that diagnostic laboratories can use to bill for certain COVID-19 tests. 3/5/20
- CMS <u>announced</u> it is expanding advanced and accelerated payments for providers and suppliers to support response efforts to the COVID-19 outbreak (<u>fact sheet</u>). 3/28/20
- CMS released a <u>Dear Clinician Letter</u> outlining policies related to accelerated and advanced payments, testing and claims reporting for COVID-19, Medicare telehealth visits, expanded options for telehealth services, workforce flexibilities, and the CMS quality payment program. 4/7/20
- CMS <u>announced</u> it is nearly doubling Medicare payment for lab tests that use high throughput technologies for rapidly detecting COVID-19 cases. 4/15/20

## **Benefits and Coverage**

- ➤ CMS issued guidance to help Medicare Advantage and Part D plans respond to the coronavirus. 3/10/20
- ➤ CMS issued Frequently Asked Questions (<u>FAQs</u>) to ensure individuals, issuers and states have clear information on coverage benefits for COVID-19 based on the ACA's essential health

- benefits (EHBs). 3/12/20
- CMS released a <u>fact sheet</u> to assist Medicare providers with information related to the price of CDC tests and non-CDC tests for COVID-19. 3/13/20
- ➤ CMS issued <u>FAQs</u> to clarify coverage for the diagnosis and treatment of COVID-19 by catastrophic health plans. 3/18/20
- CMS <u>announced</u> qualified health plans (QHPs) would be permitted to extend payment deadlines and delay the beginning of applicable grace periods for enrollees. 3/24/20
- CMS released two sets of guidance documents (<u>here</u> and <u>here</u>) affecting individual and group market health plan issuers, Medicare Advantage (MA) sponsors, and Medicare Part D sponsors. 4/23/20

## **Medicaid & CHIP**

- CMS released a <u>fact sheet</u> outlining coverage and benefits related to COVID-19 in Medicaid CHIP. 3/6/20
- ➤ CMS released sample state plan language in a <u>document</u> intended to assist states in understanding policy options for paying Medicaid providers that use **telehealth** technology to deliver services in combating the COVID-19 pandemic. 3/17/20
- ➤ CMS released set of <u>FAQs</u> designed to give state Medicaid programs implementation guidance on the 6.2 percent increase in the Federal Medical Assistance Percentage (FMAP) for each state and territory, which was made possible under Section 6008 of the Families First Coronavirus Response Act. 3/24/20
- ➤ CMS updated its set of FAQs providing additional information on coronavirus response strategies for Medicaid and CHIP agencies. The most recently updated version of this document is available here. 4/2/20
- CMS <u>released</u> additional FAQs on enhanced federal funding for Medicaid and CHIP agencies, along with additional relevant information on recent COVID-19-related congressional action. 4/13/20

### For State Survey Agencies, Accrediting Organizations

- ➤ CMS issued a memo to State Survey Agencies and Accrediting Organizations indicating that, effective immediately, all non-emergency inspection activities are suspended so that inspectors can turn their focus to the most serious health and safety threats, including abuse and COVID-19 and other infectious disease control. 3/4/20
- CMS <u>released</u> a <u>fact sheet</u> outlining a targeted, streamlined survey process for healthcare facility inspections, further refined from guidance provided earlier this month. The agency issued the guidance based in part on findings of a recent inspection of the Life Care Center nursing home in Kirkland, Washington the epicenter of the COVID-19 outbreak in that state. 3/23/20

## Food & Drug Administration (FDA)

## **Treatments and Vaccines**

- FDA and FTC warned seven companies selling products claiming to treat or prevent COVID-19. FDA notes these products are unapproved and pose a significant risk to patient health. 3/9/20
- FDA <u>issued</u> guidance on conducting clinical trials during the COVID-19 outbreak, including considerations for protocol modifications. 3/18/20
- FDA is <u>facilitating</u> access to COVID-19 convalescent plasma for use in patients with serious of immediately-life threatening COVID-19 infections through single patient emergency Investigational New Drug Applications (eINDs). 3/24/20
- FDA <u>issued</u> Emergency Use Authorization (EUA) to allow chloroquine phosphate and hydroxychloroquine phosphate products to be distributed and used for patients with COVID-19. 3/28/20
- FDA <u>announced</u> the Coronavirus Treatment Acceleration Program (CTAP), a new program intended to expedite the development of safe and effective life-saving treatments, 3/31/20
- FDA <u>announced</u> that the FDA-ARGOS-CoV-2 Reference Grade Sequence Data is now available. This will help test developers and vaccine developers expedite the development of countermeasures, identify new or more stable targets for future tests, and support development of synthetic reference material. 4/1/20
- FDA <u>issued</u> guidance to provide recommendations to health care providers and investigators on the administration and study of investigational convalescent plasma collected from individuals who have recovered from COVID-19. 4/8/20
- FDA <u>issued</u> an Emergency Use Authorization (EUA) for a blood purification system to treat adults with confirmed COVID-19 infection. 4/10/20
- FDA <u>issued</u> product specific guidance for <u>chloroquine phosphate</u> and <u>hydroxychloroquine phosphate</u> that provide recommendations on design of bioequivalence studies to support abbreviated new drug applications (ANDAs), among other things, 4/13/20
- ➤ The FDA is <u>encouraging</u> individuals who have recovered from COVID-19 to donate their plasma through a newly launched <u>website</u> intended to guide recovered patients to local blood or plasma collection centers. 4/16/20
- FDA authorized new COVID-19 antibody test's use, accelerates approval for cancer therapy. FDA issued an <a href="mailto:emergency use authorization">emergency use authorization</a> for Abbott Laboratory's SARS-CoV-2 IgG assay for the qualitative detection of COVID-19 antibodies. FDA said that the test may be effective in diagnosing recent or prior infection with SARSCoV-2 by identifying individuals with adaptive immune responses to the virus that causes COVID-19. FDA also granted <a href="mailto:accelerated approval">accelerated approval</a> for a new dosing regimen for a cancer therapy that allows patients with certain cancers to continue treatment with fewer in-person visits. The approval was granted more

## <u>Personal Protective Equipment (PPE)</u>

- FDA and CDC took action to allow certain National Institute for Occupational Safety and Health (NIOSH) approved respirators not currently regulated by the FDA to be used in the health care setting by health care personnel. 3/2/20
- ➤ FDA <u>issued</u> a letter to health care providers on recommendations for mask and gown conservation. 3/11/20
- ➤ FDA <u>issued</u> two temporary policies to increase the production of alcohol-based hand sanitizer. Under the guidance manufacturing firms, pharmacies, and outsourcing facilities may produce or compound handrub products, 3/20/20
- FDA <u>issued</u> guidance to expand the manufacturing and availability of ventilators and other respiratory devices, such as CPAP machines. 3/22/20
- FDA <u>provided</u> instructions to manufacturers to import personal protective equipment (PPE) and other devices, 3/24/20
- ➤ FDA <u>issued</u> guidance to expand the availability of general use face masks for the general public and particulate filtering facepiece respirators, including N95 facemasks, for health care professionals. 3/26/20
- ➤ FDA <u>issued</u> two Emergency Use Authorizations (EUAs) to increase the supply of ventilators and respirators. The first <u>EUA</u> allows for the emergency use in health care settings of certain ventilators, ventilator tubing connectors, and ventilator accessories, while the second <u>EUA</u> was issued for certain imported non-National Institute for Occupational Safety and Health (NIOSH) approved respirators, 3/27/20
- FDA <u>issued</u> an EUA to decontaminate N95 or N95-equivalent respirators for reuse by health care workers in the hospital setting. The FDA estimates that this EUA has the potential to decontaminate approximately 4 million respirators per day. 4/10/20

## **Diagnostic Testing**

- FDA <u>issued</u> Emergency Use Authorizations (EUAs) to two public health labs in New York for diagnostics to test COVID-19. 2/29/20
- ➤ FDA <u>issued</u> guidance to provide a policy for COVID-19 diagnostic tests developed and used in clinical laboratories under the Clinical Laboratory Improvements Amendments (CLIA) in order to expedite testing capacity. 2/29/20
- FDA <u>issued</u> new flexibilities to the New York State Department of Health to address the COVID-19 outbreak and issued the third Emergency Use Authorization diagnostic. 3/12/20
- ➤ FDA <u>announced</u> new state flexibility to authorize diagnostic test and updated existing policy to include commercial manufacturers. 3/16/20
- > FDA warns consumers about unauthorized fraudulent COVID-19 test kits. 3/20/20

- ➤ To date, the FDA has <u>issued</u> 17 EUAs for diagnostic tests, including AvellinoCoV2, which is a real-time RT-PCR test intended for the qualitative detection of nucleic acid from SARS-CoV-2. The FDA has also kept it <u>COVID-19 Diagnostic FAQ</u> up to date. 3/26/20
- ➤ FDA <u>issued</u> an EUA for SARS-CoV-2 PCR test, a serological testing kit which can detect a positive or negative test result in two minutes. 3/31/20
- FDA <u>issued</u> the first Emergency Use Authorization (EUA) for a test that analyses blood antibodies to determine if an individual has been exposed to COVID-19. This will allow people who have recovered from the virus to be identified. 4/2/20
- ➤ To date, the FDA has <u>issued</u> 36 Emergency Use Authorization (EUA) diagnostic tests. This includes 29 in-vitro diagnostic test kits and 5 high complexity molecular-based tests. 4/6/20
- FDA announced an <u>update</u> on serological tests designed to detect antibodies and determine immunity to COVID-19. It is the hope of the agency that these tests will be used to determine when patients have recovered from COVID-19 and can return to work. To date, the FDA has <u>issued</u> one Emergency Use Authorization for a serological test. 4/7/20
- ➤ The FDA <u>announced</u> a new partnership between the Gates Foundations, UnitedHealth Group, Quantigen, and U.S. Cotton to manufacture a new type of swab for COVID-19 testing that can be produced at scale. 4/16/20
- ➤ The FDA provided an <u>update</u> on serological tests intended to detect antibodies to COVID-19, which includes the agency's approach to expand access, how the tests work, data validation, and education for frontline workers and states. 4/18/20
- The FDA <u>issued</u> an Emergency Use Authorization (EUA) for the first test for patient at-home sample collection. Under this EUA, LabCorp may test self-collected samples by patients using the LabCorp COVID-19 home collection kit. 4/21/20
- FDA issued updated EUA, FAQ on non-surgical face mask use. FDA updated and reissued its April 18 emergency use authorization on <u>face masks for the general public</u> to clarify that non-surgical face masks are not intended for use by health care personnel as personal protective equipment, meaning they are not a substitute for respirator or surgical masks. For more information, see FDA's FAQs on the EUA. <u>4/28/20</u>

#### **Medical Devices**

- FDA <u>issued</u> guidance to expand the use of devices to remotely monitor patient's vital signs, 3/20/20
- FDA <u>issued</u> a Letter to the Industry detailing steps taken by Center for Devices and Radiological Health (CDRH) to address the impact of COVID-19 on the day-to-day operations, while prioritizing efforts to respond to the national emergency. 3/24/20
- The FDA issued guidance to expand the availability and capability of imaging devices used

- to diagnose and monitor lung disease in patients during the pandemic. 4/23/20
- ➤ The FDA issued <u>guidance</u> on non-invasive fetal and maternal monitoring devices to increase the availability and capability of these devices used to monitor patients during the pandemic. 4/23/20

## Food and Drug Safety and Supply Chain

- ➤ FDA <u>issued</u> guidance on the importance of notifying the agency of any discontinuance or interruption of drug and biological product manufacturing. 3/27/20
- FDA <u>issued</u> a letter to stakeholders detailing the danger of taking chloroquine phosphate products intended to treat disease in aquarium fish. 3/27/20
- ➤ FDA <u>issued</u> guidance on a temporary policy regarding nutrition labeling of certain packaged food during COVID-19 public health emergency. 3/26/20
- The FDA <u>issued</u> a temporary policy to allow outsourcing facilities to compound certain human drugs for hospitalized individuals during the COVID-19 pandemic. 4/16/20
- ➤ FDA <u>issued</u> a temporary policy for FDA Food Safety Modernization Act (FSMA) supplier verification onsite audit requirements during the COVID-19 emergency. **4/17/20**
- ➤ The FDA has <u>expanded</u> a temporary policy to allow state-licensed pharmacies and federal facilities to compound certain human drugs for hospitalized patients during the COVID-19 pandemic. 4/20/20

### **Blood Supply**

➤ FDA <u>issued</u> guidance to address the urgent need for blood during the COVID-19 pandemic. This guidance revises previous recommendations regarding blood donor eligibility in order to expand access to critically needed bloody supply. 4/2/20

## Federal Emergency Management Agency (FEMA)

- The declaration of a national emergency allows FEMA to provide funding to state and local governments and eligible non-profit entities, including non-profit hospitals, clinics and nursing homes (among others). This article provides a summary of what we know to date.
- FEMA extended the deadline to apply for public assistance funding for individuals and organizations to make a request for public assistance funding for the duration of the public health emergency unless an earlier deadline is deemed appropriate by FEMA. FEMA also posted new fact sheets with additional information:
  - Use of Defense Production Act Authorities to Support the Pandemic Response
  - Procurement Under Grants: Under Exigent or Emergency Circumstances
  - Coronavirus (COVID-19) Pandemic: Eligible Emergency Protective Measures
- FEMA signaled its intention to fund eligible emergency protective measures to respond to COVID-19 pursuant to Category B of the standing <a href="Public Assistance">Public Assistance</a> (PA) <a href="Program">Program</a>. 3/23/20
- > FEMA simplified its public assistance program application process for eligible state, territorial,

- tribal, local government entities and certain private non-profit organizations. AHA worked with Jones Day to produce an Advisory with additional details. 3/25/20
- FEMA sent a <u>letter</u> to state and local emergency managers asking them to immediately consider and implement seven steps in response to the COVID-19 pandemic. The agency noted that state and local government emergency mangers should not wait on PPE from the federal government and are encouraged to "take aggressive action now" and source their own. 3/27/20
- FEMA <u>announced</u> opportunities for the private sector to support the COVID-19 response, including <u>selling</u> and <u>donating</u> supplies, as well as ways for medical professionals to <u>volunteer</u>. More information about how to help is available <u>here</u>. 3/27/20
- > FEMA <u>released</u> information about how to secure 100 percent federal funding for use of the National Guard under Title 32. 3/29/20
- ➤ FEMA <u>released</u> a FAQ about non-congregate sheltering during the COVID-19 public health emergency. 3/31/20
- FEMA <u>released</u> a fact sheet detailing criteria that emergency medical care activities must meet to be eligible for funding through the <u>Public Assistance (PA) Program</u>. 3/31/20
- > FEMA published a <u>fact sheet</u> outlining the requirements private non-profit (PNP) organizations must meet to be eligible to apply for funding through the <u>Public (PA) Assistance Program</u>. 4/2/20
- FEMA <u>announced</u> it has obligated more than \$44 million to the State of Iowa to purchase PPE and other supplies for its COVID-19 response. 4/4/20
- > FEMA <u>released</u> information about its "Whole-of-America COVID-19 Response." The response is a "locally executed, state managed, and federally supported strategy to meet the demand for critical supplies" and is comprised of four key components: (1) preservation of medical supplies; (2) allocation of supplies to ensure they are at the right place at the right time;
  - (3) acceleration of manufacturing and distribution; and (4) expansion of industry. 4/7/20
- > FEMA <u>issued</u> a temporary final rule to distribute certain scarce PPE for domestic use, so that these materials may not be exported from the U.S. unless exempted or with the explicit approval of FEMA. 4/7/20
- ➤ FEMA <u>announced</u> it has provided nearly \$16.7 million to the Colorado Division of Homeland Security and Emergency Management to help the state purchase PPE and other supplies for its COVID-19 response. 4/7/20
- > FEMA released information about the actions its Supply Chain Task Force is taking to

- stabilize the medical supply chain. 4/8/20
- ➤ FEMA <u>issued</u> a policy defining the framework and requirements for public assistance related to purchasing and distributing food for the COVID-19 public health emergency. 4/12/20
- FEMA released a <u>fact sheet</u> about the agency's environmental and historic preservation compliance and conditions, which includes: details about activities the Public Assistance Program will fund; requirements for projects that have the potential to adversely affect natural, historic, and/or archaeological resources; and best practices for temporary facilities, disposal of medical waste, and decontamination activities. **4/13/20**
- FEMA released a <u>fact sheet</u> about the CDC's <u>International Reagent Resource</u> which supplies resources for the surveillance and detection of respiratory pathogens to laboratories. The document lists the available resources and provides information about how to access them. 4/13/20
- ➤ The Department of Homeland Security and FEMA <u>announced</u> the funding notice for an additional \$100M in supplemental Emergency Management Performance Grant Program funds. 4/14/20
- > FEMA issued a <u>press release</u> that provides an overview of the elements of the Defense Production Act (DPA) and describes how it has been applied by the administration to date. The release also clarifies that <u>Project Airbridge</u> is not authorized under the DPA. **4/14/20**
- ➤ The FEMA Administrator sent a <u>letter</u> to emergency managers detailing lessons learned in the first 30 days of the COVID-19 response. 4/15/20
- ➤ The FEMA Healthcare Resilience Task Force has released a COVID-19 <u>Hospital Resource</u> <u>Package</u>, which offers tools to help hospitals prepare for and respond to the pandemic. 4/17/20
- FEMA and HHS <u>announced</u> a collection of best practices for the COVID-19 response. Materials available on the <u>FEMA site</u> include those most directly relevant for emergency mangers and communities, while materials available on the <u>HHS site</u> highlight information targeted to the medical community and emergency responders. 4/19/20
- > FEMA released a <u>fact sheet</u> with guidance addressing how organizations should manage PPE in non-healthcare settings. 4/22/20
- ➤ FEMA released a <u>fact sheet</u> about the temporary final rule that implements the President's Memorandum, "Allocating Certain Scarce or Threatened Health and Medical Resource to Domestic Use". 4/22/20
- > FEMA implements ventilator request process. Given the scarcity of the ventilators in the Strategic National Stockpile and the current capacity of the private sector to meet the demand, FEMA has adopted a new process to manage federal ventilator resources to ensure the ventilators are shipped to the states in the amount needed to manage the immediate crisis. For ventilators, FEMA defines "immediate" as requirements necessary to sustain life within a

72-hour window. FEMA asked states and tribes to request ventilators from the SNS through their <u>FEMA</u> and Health and Human Services regional leadership. They said the request should include detailed responses to five questions:

- How many usable ventilators, ICU beds and convertible ventilators are currently available within the state/tribe?
- What is the current hospital bed and ICU bed occupancy rate in the state/tribe?
- How many new ICU beds does the state/tribe estimate it can stand-up and the number of ventilators, or FDA-approved ventilator alternatives, it can or is standing up?
- What is the decompression ability of hospitals in the state/tribe (i.e., are there currently field hospitals or alternate care facilities established)?
- How many anesthesia machines are in the state/tribe and have they been converted?

## Health and Human Services (HHS)

- ➤ HHS <u>letter to Governors to extend capacity of health care workforce to address pandemic.</u> 3/25/20
- ➤ The HHS Assistant Secretary for Health and the U.S. Surgeon General <u>issued</u> an <u>open</u> <u>letter</u> to the health care community describing the need to carefully manage the supply of mechanical ventilators. The letter also suggests a possible "crisis standard-of-care strategy" of using one ventilator for two patients. 3/31/20
- ► HHS sets email address for hospital-specific COVID-19 questions. Hospitals and health systems are encouraged to direct COVID-19 questions to a new HHS email. The new email address serves as a one-stop resource to triage a wide range of COVID-19 inquiries from hospitals across HHS's offices and operating divisions, including the CDC, FDA, CMS and Office of Assistant Secretary for Health. HHS says hospitals can send their COVID-19 questions to HospitalCOVID19@hhs.gov. 4/1/20
- ➤ HHS <u>announced</u> that it is purchasing the ID NOW COVID-19 rapid point-of-care test, developed by Abbott Diagnostics Scarborough Inc., for use in state, territorial, and tribal public health labs. The test allows diagnostic testing at the time and place of patient care and provides results in under 13 minutes. 4/6/20
- ➤ The HHS Office of the Assistant Secretary for Health <u>issued</u> new <u>guidance</u> under the Public Readiness and Emergency Preparedness Act authorizing licensed pharmacists to order and administer COVID-19 tests that the FDA has authorized. 4/8/20
- ➤ HHS <u>announced</u> that Philips has signed a contract under the Defense Production Act (DPA) to make 2,500 ventilators by the end of May, with 43,000 expected by the end of December. 4/8/20
- ➤ HHS <u>announced</u> that effective today the Indian Health Service (IHS) is expanding telehealth services in response to the COVID-19 pandemic. Telehealth services can be provided regardless of diagnosis and are not limited to COVID-19 treatment. 4/8/20
- HHS announced HRSA has awarded more than \$1.3 billion to 1,387 health centers. The funding

- was appropriated through the CARES Act. Information about who received funding and the amount received is available here. 4/8/20
- ➤ HHS <u>announced</u> the federal government has reached a deal with DuPont to deliver 450,000 TYVEK® suits to the U.S. this week. HHS expects to receive another 2.25 million TYVEK® suits over the next five weeks and has the option to continue purchasing up to 4.5 million TYVEK suits. 4/8/20
- ➤ HHS <u>announced</u> that General Motors has signed a contract under the Defense Production Act to make 30,000 ventilators by the end of August, with more than 6,000 expected to be available by June 1. 4/8/20
- Secretary Azar sent a letter to hospital administrators detailing FAQs about the hospital, hospital laboratory, and acute care facility data reporting requested by Vice President Pence on March 29, 2020. 4/10/20
- ➤ The HHS Office for Human Research Protections (OHRP) issued (<u>press release</u>) <u>guidance</u> on COVID-19 for investigators, institutional review boards, and institutions conducting human subjects research during the COVID-19 pandemic. 4/10/20
- ➤ HHS issued a <u>press release</u> explaining how the first \$30 billion of the \$100 billion Provider Relief Fund created by the Coronavirus Aid, Relief, and Economic Security (CARES) Act has been allocated and disseminated. The Department also provided insight into how it will distribute the remaining \$70 billion. 4/10/20
- ➤ HHS <u>announced</u> five new contracts for ventilator production under the Defense Production Act (DPA), as well as two other contracts for ventilator production. In total, HHS contracts will supply 6,190 ventilators for the Strategic National Stockpile by May 8 and 29,510 by June 1. 4/13/20
- Through HRSA, HHS <u>awarded</u> \$90 million to Ryan White HIV/AIDS Program recipients for COVID-19 prevention, preparation, and response. The funding was made available via the CARES Act. More information about the award recipients is available <u>here</u>. 4/15/20
- ➤ HHS <u>announced</u> a new contract with General Electric, in partnership with Ford, for ventilator production under the DPA. GE has agreed to produce 50,000 ventilators by July 13. In total, HHS has finalized contracts to produce or acquire over 41,000 ventilators by the end of May, and more than 187,000 ventilators by the end of 2020. 4/16/20
- ➤ Through SAMHSA, HHS <u>awarded</u> FY 2020 Emergency COVID-19 grants totaling \$110 million. The grants will provide up to \$2 million for state awardees and up to \$500,000 for territory and tribal awardees for 16 months. More information about the grants is available <u>here</u>. 4/20/20
- ➤ HHS <u>announced</u> that Oracle has donated an <u>online platform</u> to collect real-time, crowd-sourced medical data related to COVID-19. 4/20/20
- > The Office of the Secretary sent a letter to administrators requesting that all hospitals report certain data by April 23, 2020. The data will be used to inform forthcoming targeted relief

- payments from the Provider Relief Fund authorized under the CARES Act. 4/21/20
- ➤ HHS <u>announced</u> that <u>OIG</u>, <u>ONC</u>, and <u>CMS</u> are working together to provide additional flexibility for the implementation and enforcement of the interoperability, information blocking, and certification final rules due to the COVID-19 pandemic. <u>4/21/20</u>
- ➤ HHS <u>announced</u> \$955 million in grants from the ACL to help communities meet the needs of older adults and people with disabilities as they work to minimize the spread of COVID-19. 4/21/20
- ➤ HHS <u>announced</u> its plan for allocating and disseminating the remaining \$70B of the \$100B appropriated to the Provider Relief Fund under the CARES Act. 4/22/20
- ➤ HHS <u>announced</u> that \$165 million was awarded HRSA to support rural hospitals and HRSA-funded Telehealth Resource Centers (TRCs). 4/22/20
- ➤ HHS <u>announced</u> the CDC will award \$631 million in CARES Act funding to state and local jurisdictions through the existing Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases cooperative agreement. More information about the awards is available <a href="https://example.4/23/20">here. 4/23/20</a>
- ➤ HHS <u>announced</u> it is extending the deadline for hospitals to submit data that will inform how \$10 billion is distributed to areas highly impacted by COVID-19. The new deadline is Saturday, April 25 by 3PM ET. 4/23/20
- Through HRSA, HHS has awarded (<u>press release</u>) nearly \$5 million to Poison Control Centers across the country to improve their capacity to respond to increased calls due to the COVID-19 pandemic. A list of award recipients is available <u>here</u>. 4/23/20
- ➤ HHS <u>announced</u> that the Administration for Children and Families (ACF) is releasing \$45 million appropriated by the CARES Act to states, territories, and tribes to support child welfare services during the COVID-19 pandemic. 4/24/20

#### Health Resources and Services Administration (HRSA)

- ➤ HRSA <u>announced</u> it is awarding 1,381 health centers across the country a collective \$100 million in funding through the Coronavirus Preparedness and Response Supplemental Appropriations Act. 3/24/20
- ➤ HRSA <u>announced</u> a coronavirus-related notice of funding opportunity (NOFO) announcement will be available soon to tribal organizations for the \$15M appropriated under the CARES Act. The funding opportunity will be posted <u>here</u>. 4/17/20
- ► HRSA issued new resources on COVID-19 Uninsured Program Portal. Hosted webinars for health care providers on the agency's COVID-19 Uninsured Program Portal. During the webinars, representatives from HRSA and United Health Group, the portal administrator, reviewed the process for submitting claims through the portal. They also announced the release of a number of new resources, including an interactive user guide, a provider checklist for claims reimbursement, and guides on Optum Pay™ direct deposit enrollment and alternative payment routing options. Additional materials will be released in the coming weeks.
  5/1/20

## National Institutes of Health (NIH)

- ➤ The NIH <u>announced</u> the first <u>treatment guidelines for COVID-19 patients</u>, intended for healthcare providers. 4/21/20
- The NIH <u>announced</u> a public-private partnership to accelerate the development of COVID-19 vaccine and treatment options. The Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership aims to develop an international strategy for a coordinated research response to COVID-19. **4/17/20**
- ➤ The NIH <u>announced</u> the launch of study to examine the number of undetected cases of COVID-19. The aims to quantify how many adults in the United States without a confirmed case of COVID-19 have antibodies to the infection. 4/10/20
- ➤ NIH <u>announced</u> the launch of a clinical trial for hydroxychloroquine as a potential therapy for COVID-19. 4/9/20
- NIH <u>announced</u> the launch of a <u>website</u> containing important educational resources for COVID-19 workers dealing with the spread of the virus. 3/23/20
- ➤ NIH, expressing concern for the health and safety of people involved in NIH research, issued guidance and information on flexibilities for NIH applicants and grantees. 3/17/20
- ➤ NIH <u>announced</u> the beginning of the first Phase I clinical trial for an investigational COVID-19 vaccine. The Seattle-based trial will enroll 45 healthy adult volunteers and will last approximately six weeks. 3/16/20
- NIH <u>announced</u> the beginning of a randomized, controlled clinical trial to evaluate the safety and efficacy of the investigational antiviral remdesivir in hospitalized adults diagnosed with COVID-19 at the University of Nebraska Medical Center (UNMC) in Omaha. 2/25/20

#### Office of Civil Rights (OCR)

- Notice of Discretion for Telehealth Remote Communications / HIPAA. OCR has published notification that it will exercise its enforcement discretion and will not impose penalties for noncompliance with the regulatory requirements under the HIPAA Rules against covered health care providers in connection with the good faith provision of telehealth during the COVID-19 nationwide public health emergency. See Issue Specific Resources section below, under Telehealth.
- ➤ OCR <u>issued</u> guidance on telehealth remote communications following its <u>Notification</u> of Enforcement Discretion during the COVID-19 nationwide public health emergency. 3/20/20
- OCR issues guidance to help ensure first responders and others receive protected health information about individuals exposed to COVID-19.
- ➤ OCR <u>issued</u> a <u>bulletin</u> reminding providers that current anti-discrimination rules and new HIPAA flexibilities apply to the COVID-19 response. 3/30/20
- ➤ OCR <u>announced</u> it will extend privileges to disclose private health information (PHI) that have been afforded to covered entities during the COVID-19 emergency to their business associates as well. This will enable both covered entities and their business associates to share PHI for health oversight activates without risk of a HIPAA penalty. 4/2/20
- > OCR announced it will not impose penalties for HIPAA violations on covered entities or

business associates participating in good faith operation of COVID-19 testing sites during the public health emergency. The <u>enforcement discretion</u> is effective immediately and is retroactive to March 13, 2020. 4/9/20

## Office of Inspector General (OIG)

- ➤ OIG released a <u>statement</u> indicating it will not subject physicians and other practitioners to administrative sanctions when a provider reduces or waives cost-sharing obligations that a beneficiary may owe for telehealth services if they are provided in a manner consistent with the applicable coverage and payment rules during the COVID-19 public health emergency. 3/17/20
- OIG posted a <u>message</u> describing its efforts to minimize the burden on providers while rooting out bad actors during the COVID-19 pandemic. 3/30/20
- ➢ OIG <u>stated</u> that it is accepting questions regarding the application of its administrative enforcement authorities, including the Federal anti-kickback statute and civil monetary penalty provision prohibiting inducements to beneficiaries. In addition to answering questions, OIG continues to offer <u>advisory opinions</u> (legally binding opinions about the application of fraud and abuse authorities on an existing or proposed business arrangement) and update its FAQs. 4/3/20
- ➤ OIG released a <u>statement</u> explaining that it will not impose administrative sanctions under the Federal anti-kickback statute for actions covered under the blanket waiver <u>issued</u> by CMS. OIG notes that this applies to conduct occurring on or after April 3, 2020 and will remain in effect as long as the blanket waiver is in place. 4/3/20
- OIG <u>released</u> the results of a "pulse survey" conducted with hospital administrators between March 23 and March 27. The survey was designed to provide decision makers with a national snapshot of hospitals' challenges and needs in responding to the COVID-19 pandemic. 4/6/20
- ➤ OIG <u>updated</u> FAQs about its administrative enforcement of arrangements connected to the COVID-19 public health emergency. 4/24/20

## Substance Abuse and Mental Health Services Administration (SAMHSA)

- Substance Abuse and Mental Health Services Administration (SAMHSA) guidance allowing states and provider to request exceptions to SAMHSA's limits on amounts of take-home medication for treatment of opioid use disorder.
- > SAMHSA issued interim COVID-19 considerations for state psychiatric hospitals. 3/18/20
- ➤ SAMHSA <u>issued</u> 42 CFR Part 2 guidance to ensure that substance use disorder treatment services are uninterrupted during this public health emergency. 3/19/20
- SAMHSA <u>issued</u> considerations for outpatient mental and substance use disorder treatment settings. 3/20/20
- ➤ SAMHSA <u>issued</u> considerations for the care and treatment of mental and substance use disorders during the COVID-19 epidemic. 3/20/20
- > SAMHSA published a set of FAQs related to COVID-19 for grant recipients. 3/22/20
- ➤ SAMHSA <u>updated</u> is FAQ document on the provision of methadone and buprenorphine for the treatment of Opioid Use Disorder in the COVID-19 emergency. 3/31/20
- ➤ SAMHSA <u>announced</u> a funding opportunity for emergency grants to address mental and substance use disorders during COVID-19. 4/1/20

- ➤ SAMHSA awarded FY 2020 Emergency COVID-19 grants totaling \$110 million today. The grants will provide up to \$2 million for state awardees and up to \$500,000 for territory and tribal awardees for 16 months. More information about the grants is available here. 4/20/20
- ➤ SAMHSA awarded grants for certified community behavioral health clinics. SAMHSA awarded \$450 million in grants, including \$250 million in emergency COVID-19 funding, to expand access to mental health and substance use disorder treatment services through certified community behavioral health clinics. Congress last year extended the AHA-supported CCBHC demonstration program through Sept. 13. 4/28/20

## **O U.S. Citizenship and Immigration Services**

- ➤ U.S. Citizenship and Immigration Services posted an <u>announcement clarifying that under Public Charge rule</u> any treatment or preventive services related to COVID-19 will not negatively affect any individual as part of a future Public Charge analysis.
- ➤ HHS launched a COVID-19 Uninsured Program Portal. Health care providers are eligible for reimbursement from the federal government for COVID-19 testing, treatment and related services provided to the uninsured. Starting today, providers, including hospitals and health systems, can register to participate with the Health Resources and Services Administration. This coverage of the uninsured was authorized and funded through the Families First Coronavirus Response Act and the Coronavirus Aid, Relief and Economic Security Act. More information regarding the program, including how to register, can be found here. 4/27/20

## Waivers for Illinois

#### Section 1115 Waivers

- 1115 Waiver Request Fact Sheet 3/27/20
- Updated Illinois Section 1115 Waiver Request and 1115 Waiver Request Fact Sheets
   3/27/20
- HFS filed an Appendix K waiver request 3/30/20

### Section 1135 Waivers

- <u>Illinois' Department of Healthcare and Family Services</u> (HFS) has submitted an 1135 waiver for Illinois's Medicaid program.
- IHA <u>submitted a Section 1135 waiver request</u> on behalf of all Illinois Hospitals on 3/20/20. IHA's request includes crucial areas that are not included in the federal blanket waivers.
- CMS granted partial approval of IHA's Section 1135 waiver request. 3/26/20
- Background Information About Section 1135 Waivers

Information about Section 1135 waivers

## State

A chart summarizing all of the state law waivers that have been granted will be posted to IHA's website this week.

#### Governor's Executive Orders

- Marriage Licenses 5/1/20 (COVID-19 Order #34)
- Suspends Various Provisions 4/30/20 (COVID-19 Order #33)
- o Cannabis Requirements 4/30/20 (COVID-19 Order #32)
- Reissues Executive Orders 4/30/20 (COVID-19 Order #31)
- New Stay At Home Order 4/30/20 (COVID-19 Order #30)
- o Amends Provisions In The Illinois School Code 4/24/20 (COVID-19 Order #29)
- Clarifies Ceasing Evictions 4/23/20 (COVID-19 Order #28)
- o Illinois Insurance Code 4/20/20 (COVID-19 Order #27)
- Radiology Certifications 4/20/20 (COVID-19 Order #26)
- o Medical Science Institutions 4/17/20 (COVID-19 Order #25)
- o Hospital Capacity 4/16/20 (COVID-19 Order #24)
- <u>Civil Procedure</u> 4/14/20 (COVID-19 Order #23)
- o Forensic Services 4/10/20 (COVID-19 Order #22)
- o Professional Regulation Law 4/9/20 (COVID-19 Order #21)
- Various Provisions 4/7/20 (COVID-19 Order #20)
- o Illinois Department of Corrections (IDOC) 4/6/20 (COVID-19 Order #19)
- Public Assistance 4/6/20 (COVID-19 Order #18)
- Liability Protections 4/1/20 (COVID-19 Order #17)
- Stay At Home Order Extension 4/1/20 (COVID-19 Order #16)
- Extends Cannabis Applications 3/28/20 (COVID-19 Order #15)
- Suspends Provisions In The Illinois Vehicle Code 3/28/20 (COVID-19 Order #14)
- Suspends Provisions In The Illinois School Code 3/27/20 (COVID-19 Order #13)
- Notary And Witness Guidelines 3/26/20 (COVID-19 Order #12)
- Suspends Admissions To IDOC From County Jails 3/26/20 (COVID-19 Order #10)
- Health Care Workers 3/24/20 (COVID-10 Order #10)
- Essential Human Services Operations 3/23/20 (COVID-19 Order #9)
- Stay-at-Home Order 3/20/20 (COVID-19 Order #8)
- o Telehealth Order 3/19/20 (COVID-19 Order #7)
- Waiving Vehicle Registration/Drivers' License Renewals etc (COVID-19 Order #6)
- Closing Restaurants and Canceling Gathering of More than 50 (COVID-19 Order #5)
- Closing Schools Through March 30th (COVID-19 Order #4)
- Canceling Large Gatherings (COVID-19 Order #3)
- Canceling Gatherings of More Than 1,000 (COVID-19 Order #2)
- Extending Cannabis Application Deadline (COVID-19 Order #1)

## Contact Information For Hospitals

#### CMS Regional Office (Region 5) Contact List

NGS has established a <u>new provider enrollment telephone hotline</u> to allow physicians and non-physician practitioners in JK and J6 to initiate provisional temporary Medicare billing privileges via telephone. Hotline staff will collect information to establish a PECOS enrollment record during the phone call. Staff will also address questions regarding these temporary provider enrollment flexibilities afforded by the COVID-19 waiver. The JK and J6 hotline number is 888

802 3898. Hours of operation are 9:00 a.m. – 5:00 p.m. ET 8:00 a.m. - 4:00 p.m. CT Monday – Friday.

#### o Governor's Office COVID-19 Email

Governor's office is attempting to be responsive to needs, concerns, and questions in a timely manner. To help facilitate this process, they have established a new e-mail address <a href="Gov.COVID19stakeholder@illinois.gov">Gov.COVID19stakeholder@illinois.gov</a>. Please, send all questions, comments, and recommendations to <a href="Gov.COVID19stakeholder@illinois.gov">Gov.COVID19stakeholder@illinois.gov</a>. We will compile your inquires and respond with answers. If you would like to sign-up for communications from the Governor's office please e-mail Dorian Manion at <a href="Dorian.Manion@Illinois.gov">Dorian.Manion@Illinois.gov</a>.

#### **Email for Retired Healthcare Workers to Volunteer**

➤ Governor J.B. Pritzker issued another plea for retired healthcare workers to return to work and assist in the response to COVID-19. Those interested in volunteering are asked to send an email to <a href="mailtoserve@illinois.gov">serve@illinois.gov</a>

## **National Guard Deployment of Tents and Personnel at Hospitals**

➤ Hospitals are being asked to respond to Anne Stilwell (<u>astilwell@team-iha.org</u>) on their interest in having the Illinois National Guard deploy tents and personnel on their facility grounds. IDPH is trying to quickly ascertain which hospitals are most in need of these resources.

## **Special IHA Portal to IDPH**

➤ IDPH has created a special portal just for IHA member to use to submit questions and issues: dph.hospitaladmin@illinois.gov

AccuWeather offers free weather warning service to hospitals with temporary structures. 3/25/20

#### SIREN

Hospitals and physicians are urged to sign up for SIREN, the State of Illinois Rapid Electronic Notification System, which IDPH uses to send COVID-19 alerts and guidance. To register for SIREN, go to <a href="https://siren.illinois.gov/agreement.php">https://siren.illinois.gov/agreement.php</a> or send an email to dph.siren@illinois.gov

#### Illinois Department of Financial and Professional Regulations (IDFPR)

- The <u>Respiratory Care Practice Act</u> allows out of state, licensed respiratory care practitioners to work in Illinois without an Illinois license in the case of a declared emergency (<u>225 ILCS</u> <u>106/15(I)(i)</u>).
- o IDFPR has <u>waived the requirement for permanent licensure of physicians, nurses, physician assistants, and respiratory care therapists who are licensed in another state.</u> Out-of-state licensees working in Illinois pursuant to this Order must hold a license from another U.S. jurisdiction and must be in good standing. Licensees are limited to working under the direction of IEMA and IDPH pursuant to a declared disaster or in a state licensed long-term care facility, state regulated hospital, or federally qualified health center (FQHC). <u>Applications for temporary licenses</u> are available on IDFPR's website.

- o IDFPR issued <u>FAQ</u> related to the intra-state reciprocal licensing waiver. **3/25/20**
- o Inactive/Nonrenewed Licenses for RNs, APRNs, Pas, and RCTs and for Physicians 3/20/20
- Proclamation Modifying Professional Licenses and Certification Statutes for Out-of-State Healthcare Professonals (Physicians, RNs, PAs, RCTs) 3/20/20
- o Information for Healthcare Providers using Telehealth Services in Illinois 3/30/20
- o <u>Amendment to Proclamation to Modify Professional License and Certification Statutes and</u> Regulations for Certain Healthcare Professions 4/3/20
- o Variance for Students pursing Speech-Language Pathology or Audiology Licenses 4/6/20
- o Variance for Clinical Professional Counselor License Applicants 4/6/20
- o Guidance for Illinois Licensed Physician Assistants Regarding COVID-19 4/6/20
- Guidance for APRNs and CRNAs regarding COVID-19 4/6/20
- Guidance for Pharmacies regarding Delivery during COVID-19 Emergency Declaration 4/6/20
- Guidance for Pharmacies regarding Remote Processing during COVID-19 Emergency Declaration
   4/6/20
- Guidance for Pharmacists regarding Dispensing during COVID-19 Emergency Declaration 4/6/20
- Use of PPE by Compounding Pharmacies during COVID-19 Emergency Declaration 4/6/20
- o Prescriber Guidelines during COVID-19 Emergency Declaration 4/6/20
- Modifying Professional License and Certification Statutes for certain Out-of-State Professions
   (Dietitian Nutritionists, Clinical Professional Counselors, Professional Counselors, Clinical Psychologists, Physical Therapists, PT Assistants, Occupational Therapists, OT Assistants and Pharmacists)
   4/6/20
- o <u>Modifying Professional License Statutes for Out-of-State Licensed Physicians and Licensed Pharmacists to Administer COVID-19 Tests</u> 4/10/20
- Guidance for PA students to assist during COVID-19 pandemic 4/17/20
- o Guidance for Nursing students to assist during COVID-19 pandemic 4/17/20
- o Guidance for Medical students and residents to assist during COVID-19 pandemic 4/17/20
- o Where Out-of-State Health Care Provides can Work 4/21/20

# • Illinois Department of Labor (IDOL)

- IDOL issued emergency rules amending the One Day in Seven Rest Act. 3/20/20
- Hospitals can obtain exemption from the 60 day notification requirement in Illinois WARN Act as set forth in 820 ILCS 54/15 and in Title 56, Chapter 1, Subchapter b, Section 230.220(c). 4/8/20

## Illinois Department of Public Health (IDPH)

- The Governor issued an Executive Order (<u>COVID-19 #24</u>) which instructs IDPH to exercise discretion regarding enforcement of all provisions of the: (i) <u>Hospital Licensing Act</u>; (ii) <u>Emergency Medical Services (EMS) Systems Act</u>; (iii) <u>Department of Public Health Powers and Duties Law</u>; (iv) <u>Illinois Adverse Health Care Events Reporting Law of 2005</u>; and (iv) corresponding regulations in order to assist hospitals and healthcare providers response to the COVID-19 pandemic and to ensure patient safety. IDPH issued emergency rules implementing the Governor's Executive Order including the <u>approval process for alternate care facilities</u>. **4/16/20**
- Guidelines on Emergency Preparedness for Hospitals during COVID-19 (Crisis Standards of Care)
   4/18/20

- Guidance on Elective Surgeries and Procedures 4/24/20
- Illinois Health Facilities and Services Review Board (IFSRB / Review Board)
  - O Hospitals may adjust their bed capacity or category of service pursuant to <u>Title 77 of the Illinois</u>

    Administrative Code: <u>Public Health Part 1130.240 Reporting and Notification Requirements, paragraph (f)(4).</u>
  - o Frequently Asked Questions for Hospitals and Health Care Facilities relating to COVID-19 4/20/20

#### State Treasurer's Office

Unclaimed Property Annual Report Filing. Treasury website indicates that a "30-day extension will be automatically granted to all annual reports due by April 30, 2020 for requests submitted via email to up report@illinoistreasurer.gov. Administrative rules require extension requests be received at least 15 business days before the due date. Thus, requests should be sent before the close of business on April 9, 2020. Additionally, interest and late-filing penalties will be waived for up to 60 days after the end of the emergency declaration in Illinois." IHA was informed by Treasury via email that hospitals can still request the extension by emailing up report@illinoistreasurer.gov but please copy the Illinois Deputy Treasurer at AMayer@illinoistreasurer.gov to ensure it is granted. 4/20/20

#### Lawsuits

#### Challenges to Governor's Executive Orders

## Bailey v. Pritzker

- Rep. Darren Bailey (R-109) filed a lawsuit arguing that the language in the Emergency Management Agency Act prohibits the Governor from extending an executive order beyond 30 days without a new disaster proclamation. 4/23/20
- IHA filed a motion in the 4<sup>th</sup> Judicial Circuit in Clay County asking the trial court to accept IHA's amicus brief in support of the Governor's position and the court accepted the motion/amicus brief, but issued a TRO in favor of Bailey. The TRO only applies to Bailey. 4/27/20
- The Fifth District Appellate Court accepted the amicus brief that was filed Wednesday by IHA, the American Nurses Association-Illinois, the Illinois Society for Advanced Practice Nursing, and the Illinois State Medical Society in the legal case challenging Governor Pritzker's stay-at-home executive order. The four organizations are speaking out against the Clay County Circuit Court's April 27 temporary restraining order, which prevents the administration from enforcing the extended stay-at-home order against the plaintiff who filed the lawsuit. See the amicus brief. 4/29/20
- The plaintiff, voluntarily asked the court to vacate the TRO and the court granted the request. However, the plaintiff has indicated that he will be amending his complaint at the trial court level. 4/30/20

#### > Cabello v. Pritzker

 A second Republican state lawmaker, John Cabello (R-68<sup>th</sup> District) filed a lawsuit challenging the Governor's stay-at-home order. This order seeks to have the order overturned for all Illinois residents. 4/29/20

## > The Beloved Church v. Pritzker

 The Beloved Church in Lena, located in northwestern Illinois, has filed a suit in the Northern District of Illinois challenging the Governor's extension as unconstitutional. 4/30/20

## > Thompson v. Pritzker

An individual pro se plaintiff has also filed suit challenging the Governor's order. This case
is currently stayed while court required that plaintiff to refile a legible copy of his request
for financial assistance to purse the case. 4/30/20

## Local

## City of Chicago

- o Mayor's Office letter to residents. 3/11/20
- Mayor's Office and CDPH letter canceling events. 3/12/20
- o Mayor's Office and CDPH order for sick to stay home. 3/19/20
- Mayor's Office and CDPH <u>order</u> requiring acute and long-term care hospitals to allow CDPH access to records. 4/30/20

#### Chicago Establishes Smart911 for Safety

The City of Chicago is encouraging residents to sign up for <u>Smart911</u> – a free, voluntary and secure service that allows individuals and families in the city to provide critical medical information when they call 9-1-1. Residents can create a safety profile for themselves and family members that will include information on current health conditions as well as information if a resident is experiencing COVID-19 symptoms or is under quarantine. This information will automatically be provided to first responders when calling 9-1-1 and will enable them to quickly and safely respond to emergencies. To learn more, view this video. 3/30/20

#### Chicago Launches COVID-19 App

CDPH and Mayor Lightfoot <u>announced</u> the launch of <u>Chi COVID Coach</u>, a mobile-friendly, web-based application to support residents during the COVID-19 pandemic and beyond. This app was built in partnership with Google and MTX. It will allow CDPH to communicate directly with Chicago residents who may be COVID-19 positive or experiencing symptoms, providing them important information and guidance. 4/27/20

#### New Chicago Isolation Housing Central Intake Form

The Chicago Dept. of Public Health (CDPH) has released a new isolation housing central intake form

and website. The housing is provided free of charge for people with COVID-19 who are unable to safely self-isolate in their own homes. More details are in a CDPH health alert. 4/23/20

# **Issue Specific Resources**

## Audit and Surveys

- Joint Commission on Accreditation for Healthcare Organizations (The Joint Commission) announced it was suspending surveying in response to the coronavirus outbreak. The suspension is expected to last through April and accreditation will be extended without disruption.
- CMS issues <u>FAQs</u> on guidance to State Survey Agencies regarding suspending non-emergency survey inspections.
- CMS granted a range of data reporting exceptions and extensions across its quality reporting and value-based payment programs for hospitals, post-acute care facilities and clinicians to relieve provider burden during the COVID-19 crisis. Specifically, the agency made it optional to submit data for the fourth quarter of 2019 (October through December) and first two quarters of 2020 (January through March, and April through June). In addition, CMS will not use data from Jan. 1 through June 30, 2020 to calculate performance in its quality reporting and value-based purchasing programs.

## Bed Capacity (See also IHFSRB Section)

IHFSRB Guidance on Expanding Bed Capacity, Suspending Service

The Illinois Health Facilities and Services Review Board (HFSRB) has released <u>emergency rules</u> and guidance on how hospitals can expand their bed capacity to respond to the COVID-19 pandemic. The guidance provides for an Emergency Preparedness Response Report to be filed with the Board within 30 days of the bed increase. *Hospitals do not need to get pre-approval for this action.* Hospitals may also temporarily suspend a facility or category of service pursuant to HFSRB rules. *This action also does not require pre-approval.* The full guidance, including information that must be included in the letter of submission to HFSRB, can be found <u>here</u>. An FAQ developed by the Planning Board can be accessed <u>here</u>. **4/1/20** 

#### Coverage and Billing for COVID-19

- CMS released <u>FAQs</u> on Catastrophic Health Coverage; the agency states that it will not take enforcement action against any health issuer that amends its catastrophic plans to provide coverage without imposing cost-sharing requirements for COVID-19 related services before an enrollee meets the catastrophic plan's deductible.
- o IRS guidance <u>released</u> last week which provides flexibility to high deductible plans to provide COVID-19 health benefits without applying a deductible or cost-sharing.
- o CMS issued guidance to help Medicare Advantage and Medicare Part D plans respond to COVID-19.
- CMS has issued <u>billing codes</u> and <u>interim guidance</u> for coding encounters related to COVID-19 Coronavirus Outbreak.
- CMS has issued guidance regarding billing services under various emergency waivers.

- Illinois HFS issued guidance on <u>Provider Enrollment</u>, <u>Billing</u>, and <u>Payment Changes Prompted by</u> COVID-19.
- CMS issued a <u>corrected announcement</u> regarding the Medicare Severity-Diagnosis Related Group Grouper to recognize the new ICD-10-CM diagnosis code, U07.1, for COVID-19. The initial MS-DRG assignment posted March 20 would have resulted in significant reimbursement reductions for hospitals.
- National Uniform Billing Committee issues COVID-19 claims guidance. 3/25/20
- CDC posts COVID-19 ICD-10-CM code. The official guidelines for the new ICD-10-CM code go into effect today through Sept. 30. These codes will help capture and report surveillance data for the virus. The AHA was in close communication with CDC to move the original October implementation earlier and collaborated on the development of the coding guidelines. 4/1/20

#### Crisis Standards of Care

- <u>AHA Advisory</u> on caring with limited resources during COVID-19 crisis. The AHA has compiled resources, tools and sample policies that hospital and clinical leaders may find helpful in developing their own organization's approach to caring for patients with limited resources or under crisis circumstances.
- o IDPH issued <u>Guidelines on Emergency Preparedness for Hospitals during COVID-19 (Crisis</u> Standards of Care) 4/18/20

## Cyber Security

- O HHS <u>identified a potential threat</u> to network security that could affect the health care and public health sector after a health care facility purchased off-the-shelf computers from a major online retailer to find that many of the devices contained malware. HHS says that providers should take standard precautions and not assume the condition of existing packaging or the reseller assures device or network safety. For more information on deploying new PCs safely click here. 3/24/20.
- CISA issued an <u>updated version of its guidance</u> on the essential critical infrastructure workforce during the COVID-19 crisis. 4/1/20

#### Day Care

## State Emergency Application License Process for Hospitals to Set Up Daycare Centers

The Governor's office, the Illinois Office of Early Childhood Development, the Illinois Department of Human Services (IDHS) and the Illinois Department of Children and Family Services (IDCFS) have established an emergency licensing process for hospitals to set up their own child care centers. Go to the OECD website and click on "An IDCFS application for providers to apply for an emergency license to provide care." Completed applications should be submitted to IDCFS at Emergency.Daycare@illinois.gov. 3/24/20.

Emergency Child Care for Essential Worker Families Outside of the City of Chicago. Essential worker families outside of Chicago who are in need of emergency child care can call 1-888-228-

**1146** and connect with Child Care Resource and Referral Agencies that will work to connect them with emergency child care. **3/24/20.** 

## Chicago Initiative on Childcare for Healthcare Workers and First Responders

Mayor Lori E. Lightfoot and Sittercity, an online resource for in-home care, announced a new initiative to help Chicago's most essential I workforce – healthcare workers, first responders and the teams who support them – continue to work on behalf of the City amid COVID-19. A new, dedicated website – <a href="sittercity.com/chicagoresponds">sittercity.com/chicagoresponds</a> – will make it easier for workers deemed an essential part of the infrastructure helping Chicago stay safe, to find reliable childcare that will allow them to continue their crucial work. The Chicago Mayor's Office asks that all Chicago Hospitals make their employees and contractual employees aware of this service.

COVID-19: Emergency Child Care Resources for Communities & Providers

## Elective Surgeries

- CMS released <u>recommendations on adult elective surgeries and nonessential procedures</u> which provides details including that decisions will be made at the local level by the clinician, patient, hospital, and state and local health departments. The CMS recommendations include suggested factors and framework for consideration.
- o IDPH has also issued guidance.
- CMS issued <u>recommendations</u> regarding non-emergent and elective medical services. CMS provides a tiered framework to prioritize services and care to those who require urgent or emergent attention, while underlining that decisions remain the responsibility of local healthcare delivery systems. 4/7/20
- American College of Surgeons issued guidance on elective surgeries. 4/7/20
- IDPH issued new Guidance on Elective Surgeries and Procedures 4/24/20

## Employment

- Department of Labor (DOL)
  - DOL released <u>guidance</u> on preparing the workplace for COVID-19.
  - DOL released FAQs regarding the FLSA
  - DOL released FAQs regarding FLMA
  - DOL <u>FAQs</u> defining health care providers for CARES Act
  - Employment and Training Administration releases guidance to states on the Federal Pandemic Unemployment Compensation program. 4/4/20
  - Employment and Training Administration releases guidance to states on the Pandemic
    - Unemployment Assistance program. 4/5/20
  - Employment and Training Administration releases guidance to states on the Pandemic
    - Emergency Unemployment Compensation program. 4/10/20

- The Employee Benefits Security Administration (EBSA) released <u>FAQs</u> regarding implementation of the Families First Coronavirus Response Act, the CARES Act and other health coverage issues related to COVID-19. The FAQs discuss requirements on health plans and health insurance issuers offering group or individual health insurance coverage (including grandfathered health plans), including what items and services must be covered, as well as telehealth and other remote care services.
  4/11/20
- DOL and the Treasury are <u>extending certain deadlines</u> affecting employee benefit plan participants' rights to health coverage, portability and continuation of coverage under COBRA, and to file claims or appeal denied claims. DOL's Employee Benefits Security Administration also is <u>extending the time for plan officials to furnish certain notices and disclosures</u> under the Employee Retirement Income Security Act if they make a good faith effort to furnish the documents as soon as administratively practicable. For more on beneficiary rights and employer responsibilities under ERISA during the emergency, see the EBSA FAQ. **4/29/20**
- o **EEOC** guidance What You Should Know About the ADA, the Rehabilitation Act, and COVID-19.

#### O OSHA

- Guidance on Preparing Workplaces for COVID-19
- OSHA issued COVID-19 respirator decontamination guidance. OSHA <u>issued interim guidance</u> on the reuse and decontamination of N95 and other filtering-facepiece respirators during the COVID-19 pandemic. The agency, via this enforcement memorandum, outlined a host of methods for decontaminating respirators, including vaporous hydrogen peroxide, ultraviolet germicidal irradiation and moist heat (e.g., using water heated in an oven). Alternately, if such methods are not available, OSHA said that microwave-generated steam and liquid hydrogen peroxide are suitable decontamination options. The guidance indicates that OSHA will, on a case-by-case basis, exercise enforcement discretion related to the reuse of decontaminated respirators consistent with the conditions outlined in this interim enforcement guidance.
- <u>Families First Coronavirus Response Act</u> requires certain employers to provide paid leave to employees impacted by the coronavirus and new refundable tax credits to employers.

#### o IDOL

- IDOL issued emergency rules amending the One Day in Seven Rest Act. 3/20/20
- Hospitals can obtain exemption from the 60 day notification requirement in Illinois WARN Act as set forth in 820 ILCS 54/15 and in Title 56, Chapter 1, Subchapter b, Section 230.220(c).
   4/8/20
- Volunteer and Employment Opportunities 3/27/20

Mayor Lori Lightfoot and Chicago Department of Public Health Commissioner Allison Arwady, M.D. have issued a call for assistance from the medical community and are seeking to hire healthcare workers immediately to help the City of Chicago in its COVID-19 response efforts.

- Medical Assistants and Nurses are encouraged to apply for temporary positions. If you have any questions about the positions or the application process, you may email shelly.johnson@sunbeltstaffing.com or call 813-261-2706.
- Chicago Medical Reserve Corps (MRC) is a network of both medical and non-medical professionals who volunteer their time to assist during public health emergencies such as the current COVID-19 outbreak. Many MRC volunteers are just like you nurses, doctors, pharmacists, therapists, public health professionals, and other community members who believe in keeping Chicago safe. Register at illinoishelps.net and be there when Chicago needs you most.

# • HIPAA (See also Telehealth)

- HHS issued a <u>limited waiver</u> of HIPAA sanctions and penalties.
- FCC issued a <u>ruling</u> confirming that the COVID-19 pandemic qualifies as an "emergency" under the Telephone Consumer Protection Act. Under this exception, hospitals, health care providers, state and local health officials, and other government officials may make automated calls and send automated text messages to wireless telephone numbers to communicate information about COVID-19, as well as mitigation measures without violating federal law.
- o <u>OCR issues guidance</u> to help ensure first responders and others receive protected health information about individuals exposed to COVID-19.

#### Homeless Patients

- CDPH Resource for Discharge of High-Risk COVID-19 Persons Under Investigation (PUI) or Confirmed Cases
  - CDPH issued an alert giving guidance to hospitals about disposition of COVID-19 PUIs and confirmed cases who are unstably housed or returning to homeless shelters and other high-risk settings. The alert describes the process and resources available to hospital discharge planners and the process for referring to CDPH Quarantine/Isolation (Q/I) facilities **starting 8:00AM on March 23, 2020.**
- O Cook County Offers COVID-19 Alternative Housing. Cook County, IEMA, Cook County Department of Public Health (CCDPH) and Cook County Department of Emergency Management and Regional Security (EMRS) announced a multi-phased, COVID-19 alternative housing plan designed to support suburban Cook County residents, health care professionals and first responders. Under this plan, in partnership with IEMA, suburban Cook County residents, who test positive for COVID-19 and are recovering well but need temporary housing as they continue to improve outside a hospital's care, will have an opportunity to stay in temporary housing identified by EMRS. Qualifying participants of the program may include homeless, those who are housing insecure or those who do not have a separate room and bathroom to safely isolate at home. 4/16/20
- Chicago Effort to Support the Homeless. Mayor Lightfoot <u>announced</u> the implementation and mobilization of a citywide system to prevent transmission and respond to cases of COVID-19

among individuals experiencing homelessness. The Chicago Dept. of Public Health (CDPH) has arranged for nurse visits at all shelters across the city to provide in-person education and screenings. Additionally, CDPH will pair community-based providers with local shelters for ongoing clinical support – building a new network of care for the homeless that will extend beyond this outbreak. Containment strategies depend on the ability to rapidly identify and address cases in congregate settings. With support from the University of Illinois Health and Rush University Medical Center, more than 700 shelter residents and staff can now be tested for COVID-19 each week. CDPH and medical student volunteers from Rush University Medical Center have distributed more than 25,000 pieces of personal protective equipment (PPE) donated by Project HOPE to shelter residents and staff, as well as Chicago Department of Family and Support Services (DFSS) outreach teams. 4/16/20

## Hospital Resource Calculator for COVID-19

Rush University Medical Center has put together a tool that allows hospitals to predict resource
utilization during the COVID-19. The tool is meant to be a rough guide to predict hospital resources
such as beds, ventilators, and PPE utilization for several weeks. The tool allows hospitals and health
systems to plug in their own numbers and generate a prediction of their potential needs. The tool
can be found <a href="here">here</a> and instruction for use can be found <a href=here</a>.

## • Intra-State Licensure (See also IDFPR Section)

- The <u>Respiratory Care Practice Act</u> allows out of state, licensed respiratory care practitioners to work in Illinois without an Illinois license in the case of a declared emergency <u>225 ILCS 106/15(I)(i)</u>).
- o IDFPR has <u>waived</u> the requirement for permanent licensure of physicians, nurses, physician <u>assistants</u>, and respiratory care therapists who are licensed in another state. Out-of-state licensees working in Illinois pursuant to this Order must hold a license from another U.S. jurisdiction and must be in good standing. Licensees are limited to working under the direction of IEMA and IDPH pursuant to a declared disaster or in a state licensed long-term care facility, state regulated hospital, or federally qualified health center (FQHC). <u>Applications for temporary licenses</u> are available on IDFPR's website.

#### Laboratory Requirements

CMS eases certain CLIA laboratory requirements during COVID-19 emergency. 3/29/20

# Nursing Homes, Long Term Care and Discharge Planning

- o CMS announced new guidance on nursing home patients and visitors.
- CMS released guidance to Program of All-Inclusive Care for the Elderly (PACE) Organizations.
- CDC updated its <u>guidance on discharging patients</u> with COVID-19, including information for patients being discharged to home and to long-term care or assisted living facilities. 3/24/20
- Long Term Care Complaint Process for when you are unable to transfer patients to LTC's in Illinois
   3/24/20
- o IDPH issued guidance to long-term care facilities on transfer of patients from hospitals. 4/7/20

## Personal Protective Equipment

- o CMS guidance for health care workers on Personal Protective Equipment (PPEs).
- FDA has provided <u>strategies</u> to assist in the conservation of for optimizing the use of eye protection, isolation gowns, facemasks, and N95 respirators.
- CDC released updated <u>guidance</u> on strategies for optimizing the use of eye protection, isolation gowns, facemasks, and N95 respirators.
- o FDA developed new guidance on the use of respirators beyond manufacturer designated shelf life.
- o The CDC also updated it infection control guidance.
- o CMS guidance regarding health care workers in home health agencies and dialysis centers.
- o The CDC's FAQs for health professionals.
- o The CDC's latest guidance on Lab Biosafety Guidelines.
- U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) <u>issues</u> tax exemption for production of hand sanitizers by distilled spirit permittees.
- PPE, other COVID-19 resources subject to hoarding restrictions under the Defense Production Act and a <u>March 23 executive order</u>. The designation includes N95 and certain other respirators, ventilators, personal protective equipment, drug products, medical device sterilization services and disinfecting devices. 3/25/20
- Personal Protective Equipment Mask Considerations When Caring for Known or Suspected
   COVID-19 Patients 3/25/20
- Emergency Management Duration for Continuing Disaster Privileges 3/25/20
- Personal Protective Equipment Conserving Facemasks and Respirators During a Critical Shortage
   3/25/20

## Pleas for Medical Supplies

- IHA's Plea. Last Thursday, <a href="IHA">IHA</a> issued a public plea to the leaders of associations for the construction industry, dentists, veterinarians, colleges and universities, and other groups that may be able to help by donating unused N95 masks and related personal protective equipment (PPE) to Illinois hospitals. In response to IHA's plea, community members across the state have emerged asking how they can donate.
- **IDPH's Plea**. IDPH released a <u>bulletin</u> encouraging donations from Outpatient Surgical and Procedural Centers, Ambulatory Surgery Centers and Veterinarians, requesting surgical gloves, gowns, goggles, face shields, surgical masks, and N95 respirator masks. All interested donors of PPE should contact IDPH at <u>PPE.donations@illinois.gov</u>.
- Homemade Mask Donations. Citizens are seeking to help their local hospitals by sewing masks at home. <u>CDC guidance</u> does discuss the use of homemade masks when there are no other options. Carle Foundation Hospital embraced their community support and created a <u>website</u> that includes specific instructions on how to make and package home-sewn masks. IHA will continue to encourage volunteers who contact us expressing interest in donating homemade masks to contact their local hospital.

- The Chicago Department of Public Health (CDPH) is coordinating multiple opportunities for individuals, organizations and businesses to donate medical supplies and personal protective equipment (PPE) and join the fight against the COVID-19. 3/27/20
   Go to the links below to:
  - Donate medical supplies and personal protective equipment (PPE)
  - Donate other products or professional services
  - Sell medical supplies and PPE

## Price Gouging

- ODJ released a <u>statement</u> noting that the department is prepared to pursue "bad actors" who take advantage of the COVID-19 crisis.
- DOJ established a website, hotline and email for <u>reporting</u> price gouging and fraud. They will triage complaints to the appropriate federal and/or state authorities. A listing of state laws that cover or relate to price gouging can be found <u>here</u>.
- Illinois Attorney General's number for reporting price-gouging at (800) 386-5438 or <u>IllinoisAttorneyGeneral.gov</u>. The office has received about 616 complaints over the past couple weeks. Under Illinois state law, violators can be fined up to \$50,000 and ordered to shut down.
- Chicago Department of Business and Consumer Affairs also is on the lookout for price-gouging and is taking reports at 311 or online at <u>311.chicago.gov</u>. This month, the department received 190 complaints of price-gouging, compared to just two in all of 2019. The city can impose fines of up to \$10,000 per offense.

#### Provider Enrollment

 CMS has released <u>frequently asked questions</u> regarding enrollment relief for Medicare providers in light of COVID-19. Among other areas, the FAQs include information on CMS's newly established Medicare provider enrollment hotlines, Medicare billing privileges and how CMS is exercising its 1135 waiver authority.

#### • Rural Healthcare

FCC extends Rural Health Care Program deadlines. 3/26/20

# • Telehealth / HIPAA (See also OCR Section)

CMS temporarily expands Medicare telehealth benefits due to COVID-19 outbreak CMS is expanding this benefit on a temporary and emergency basis under the 1135 waiver authority and Coronavirus Preparedness and Response Supplemental Appropriations Act. CMS released a fact sheet and set of telehealth FAQs. The temporary changes significantly expand the methods, locations, and circumstances under which telemedicine can be billed for Medicare enrollees, including removal of the current geographic restrictions. According Medicaid FAQs, the CMS waiver does not authorize Rural Health Clinics (RHCs) to furnish telehealth services as distant site health care providers because that is outside the scope of an 1135 waiver. States can cover telehealth without approval, and HIPAA rules will be relaxed, and penalties waived. Factsheets

## related to these changes:

- ➤ HHS 1135 HIPAA waiver factsheet
- ➤ HHS Notice of Enforcement Discretion factsheet
- ➤ HHS Office of Civil Rights <u>bulletin</u>
- ➤ HHS Office of Civil Rights <u>FAQs</u> on Telehealth and HIPAA during the COVID-19 nationwide public health emergency. OCR will be updating the FAQs based on feedback so let OCR know of other questions.
- Guidance on Business Associate Agreements.
- ➤ HIPAA Security Rule safeguards
- > AHA summary of telehealth waiver
- Illinois HFS issued guidance on the expansion of telehealth services in Medicaid.
- CMS released <u>telehealth toolkits for general practitioners</u> and providers treating patients with <u>end-stage renal disease</u>. Each toolkit links to sources of information on telehealth, such as how to initiate a telemedicine program, monitor patients remotely, develop documentation tools and other topics. They also outline temporary virtual services that could be used to treat patients during the COVID-19 pandemic.
- o FDA expands remote use of patient monitoring devices. Health care providers can now use FDA-cleared non-invasive remote devices to monitor a patient's vital signs, the agency said. The new policy, valid only for the duration of the COVID-19 emergency, includes devices capable of enabling remote interactions that measure body temperature, respiratory rate, heart rate and blood pressure. Providers can use the information as a supplement to diagnose or treat COVID-19 or co-existing conditions.

## • Testing (See also FDA Section)

- CMS announced steps to improve testing of patients in emergency departments with a memorandum for Medicare participating hospitals.
- o FDA lists test labs in diagnostic FAQs. The Food and Drug Administration has updated its <a href="COVID-19">COVID-19</a> diagnostic testing FAQs, a reference for clinical laboratories, commercial manufacturers, and Food and Drug Administration staff. The document now lists the clinical laboratories that are offering testing under FDA's Policy for Diagnostic Tests for Coronavirus Disease-2019; states that have chosen to authorize laboratories to develop and perform COVID-19 tests; commercial manufacturers that are distributing test kits and the serology tests being offered. Among other information, it also offers alternatives for certain items that are in short supply but which are needed for collecting patient samples for testing for COVID-19 infection, such as alternative swabs and transport media.
- FDA <u>announced</u> new authority for states to develop diagnostic tests for COVID-19 so that laboratories will not be required to engage with the FDA and for commercial developers once granted emergency use.
- HHS Office of the Assistant Secretary of Preparedness and Response (ASPR) <u>announced</u> that a diagnostic test for COVID-19 was nearing completion and would process up to 1,000 tests in 24 hours. Since this March 9 announcement, FDA has given four companies emergency approval for

- coronavirus diagnostic tests and assays (Roche Holding, Thermo Fisher, Hologic, and LabCorp).
- o FDA authorizes first point-of-care diagnostic test for COVID-19. The FDA issued the first emergency use authorization for a <u>point-of-care COVID-19 diagnostic</u>, which the maker plans to make available to qualified health care providers and CLIA-certified labs by March 30. Point-of-care testing means that results are delivered to patients in the patient care settings, like hospitals, urgent care centers and emergency rooms, instead of samples being sent to a laboratory thereby allowing an option for testing at the point of care, which enables patient access to more immediate results. For information, see the provider <u>factsheet</u>.
- To accommodate patient access to certain drugs, FDA also <u>said</u> it does not intend to enforce Risk Evaluation and Mitigation Strategy requirements for certain laboratory testing or imaging studies during the COVID-19 emergency.
- O Providers may request COVID-19 investigational treatment for sickest patients. The FDA is investigating whether convalescent plasma from recovered COVID-19 patients contains viable antibodies to treat SARS-CoV-2 in the sickest patients. While FDA trials continue, providers may request the plasma for investigational use in patients with the most serious and life-threatening COVID-19 infections. For more information, visit www.fda.gov. 3/25/20
- O CDC updated its COVID-19 testing priority guidance, which gives first priority to testing hospitalized patients and symptomatic health care workers. The agency also updated its interim guidelines for collecting, handling and testing COVID-19 clinical specimens to allow for self- or health care worker-collected nasal or nasal turbinate swabs if nasopharyngeal swab is not possible. In addition, CDC updated its checklists and resources for hospital and health care professionals preparing for patients with suspected or confirmed COVID-19. Check the CDC webpage frequently for the latest CDC guidance on the COVID-19 emergency. 3/25/20
- OCDC updates COVID-19 testing and preparedness guidelines. The Centers for Disease Control and Prevention has <u>updated its COVID-19 testing priority guidance</u>, which gives first priority to testing hospitalized patients and symptomatic health care workers. The agency also updated its interim <u>guidelines for collecting, handling and testing COVID-19 clinical specimens</u> to allow for self- or health care worker-collected nasal or nasal turbinate swabs if nasopharyngeal swab is not possible. In addition, CDC updated its <u>checklists and resources</u> for hospital and health care professionals preparing for patients with suspected or confirmed COVID-19. Check the <u>CDC webpage</u> frequently for the latest CDC guidance on the COVID-19 emergency. 3/24/20

## Ventilators and Respirators

- FDA released <u>updated guidance</u> to mitigate ventilator supply disruptions by providing flexibility and expanding the availability of ventilators and other respiratory devices to treat patients during the public health emergency.
- FDA released a <u>letter</u> to supplement the updated guidance that provides recommendations directed at providers.
- FDA issued an <a href="Emergency Use Authorization"><u>Emergency Use Authorization</u></a> to ease ventilator supply shortages. Effective throughout the COVID-19 emergency, the EUA authorizes use of certain alternative ventilator devices, tubing connectors and accessories in health care settings to treat patients during the pandemic. 3/25/20

- FDA Emergency Use Authorization for Respirators 3/30/20
- FAQ on the respirators included in the EUA. 3/30/20
- FDA issues guidance on producing hand-sanitizer alcohol 3/25/20

#### **Additional Links**

- CDC Coronavirus Disease 2019 website. For background and the most up-to-date information.
  - Twitter (here)
  - o Facebook (here)

## Additional federal agency links provided by White House Coronavirus Task Force:

- U.S. Department of Health and Human Services:
  - Twitter (here)
  - Facebook (<u>here</u>)

# **Situation Updates:**

- Situation Summary
- Cases in the U.S.
- Global Locations with COVID-19
- Risk Assessment
- CDC in Action: Preparing Communities

# Information for Healthcare Providers, First Responders, and Research Facilities:

- Information for Healthcare Professionals
- Resources for State, Local, Territorial and Tribal Health Departments
- Resources for Healthcare Facilities
- <u>Infection Prevention and Control Recommendations for Patients with COVID-19 or Persons Under</u> Investigation in Healthcare Settings
- Information for Laboratories
- Resources for First Responders
- <u>Guidance for Public Health Professionals Managing People with COVID-19 in Home Care and Isolation</u> Who Have Pets or Other Animals
- FAQs and Considerations for Patient Triage, Placement and Hospital Discharge
- What Law Enforcement Personnel Need to Know
- Guidance for Homeless Shelters
- Guidance for Hemodialysis Facilities
- CMS: Information on COVID-19 and Current Emergencies
- CMS: Guidance for Hospice Agencies
- CMS: Emergency Medical Treatment and Labor Act Requirements and Implications Related

- CMS: FAQs for State Survey Agency and Accrediting Organizations
- EPA: Disinfectants for Use Against COVID-19

## **Information for Families and Households:**

- Information on COVID-19 for Pregnant Women and Children
- Interim Guidance for Household Readiness
- Environmental Cleaning and Disinfection Recommendations for U.S. Households
- Guidance for Preventing the Spread of COVID-19 in Homes and Residential Communities
- FAQ: COVID-19 and Children
- EPA: Disinfectants for Use Against COVID-19

#### **Information for Schools and Childcare Providers:**

- Interim Guidance for Administrators of U.S. Childcare Programs and K-12 Schools
- Resources for Institutes of Higher Education
- Environmental Cleaning and Disinfection Recommendations Community Facilities
- USDA: USDA Makes It Easier, Safer to Feed Children in California Amid Coronavirus Outbreak
- DOE: Resources for Schools and School Personnel

# **Information for Community Events and Gatherings:**

- Interim Guidance for Mass Gatherings and Large Community Events
- Interim Guidance for Community- and Faith-Based Organizations

# **Information for Military Response:**

• DOD: Department of Defense Coronavirus Response

#### Information for Businesses:

- CDC: Interim Guidance for Businesses and Employers
- CDC: Information for Communities, Schools, and Businesses
- CDC: Environmental Cleaning and Disinfection Recommendations Community Facilities
- SBA: COVID-19 Resources
- DOL: Guidance for Preparing Workplaces for Coronavirus
- DOL: OHSA Resources for Workers and Employers on COVID-19
- WHO: Get Your Workplace Ready for COVID-19
- CISA: Risk Management for COVID-19
- EPA: Disinfectants for Use Against COVID-19
- Federal Reserve: Coronavirus Disease 2019 (COVID-19) Resources
- FDIC: Coronavirus (COVID-19) Information for Bankers and Consumers
- OCC: COVID-19 (Coronavirus)
- Conference of State Bank Supervisors: Information on COVID-19 Coronavirus
- NMLS: State Agency Communication/Guidance on Coronavirus/COVID-19

# **Information for Travel and Transportation:**

- Information for Travel
- Guidance for Ships
- Guidance for Airlines and Airline Crew
- State: <u>Travel Advisories</u>
- State: <u>Traveler's Checklist</u>
- State: Smart Traveler Enrollment Program
- DOT: FAQs from FTA Grantees Regarding COVID-19

# What you should know:

- Workplace, School, and Home Guidance
- People at Risk for Serious Illness from COVID-19
- How COVID-19 Spreads
- Symptoms
- Steps to Prevent Illness
- Testing
- Frequently Asked Questions
- What to Do If You Are Sick with COVID-19
- Stigma Related to COVID-19
- What You Need to Know
- Facts about COVID-19
- Information for People at Higher Risk and Special Populations
- <u>Communication Resources</u>