FEDERAL AGENCIES

Centers for Medicare & Medicaid Services
- CMS Announces Relief for Clinicians, Providers, Hospitals and Facilities Participating in Quality Reporting Programs in Response to COVID-19, Mar. 22, 2020 (CMS is granting exceptions from reporting requirements and extensions for clinicians and providers participating in Medicare quality reporting programs with respect to upcoming measure reporting and data submission for those programs)

Food and Drug Administration
- FDA Issues first Emergency Use Authorization for Point of Care Diagnostic, Mar. 21, 2020 (emergency use authorization for the Cepheid Xpert Xpress SARS-CoV-2 test)
- FDA Alerts Consumers About Unauthorized Fraudulent COVID-19 Test Kits, Mar. 20, 2020

Internal Revenue Service
- Notice 2020-18, Mar. 21, 2020 (restates and expands upon Notice 2020-17 that extends the IRS filing deadline to July 15)
- IR-2020-57, Mar. 20, 2020 (Treasury, IRS and Labor announce plan to implement Coronavirus-related paid leave for workers and tax credits for small and midsize businesses to swiftly recover the cost of providing Coronavirus-related leave)

US Department of Homeland Security
- Joint Statement on US-Mexico Joint Initiative to Combat the COVID-19 Pandemic, Mar. 20, 2020 (the joint initiative commenced March 21 throughout the US-Mexico land border for a period of 30 days subject to extension upon review)

STATES

- Connecticut
  - “Stay at Home” Executive Order, Mar. 20, 2020 (excludes any “essential business or entity” including “healthcare”)

- New Jersey
  - “Stay at Home” Executive Order, Mar. 21, 2020 (orders the closure of all “non-essential” retail businesses; exceptions includes pharmacies and medical supply stores)

- Texas
  - OIG extends deadlines for health care providers (OIG will not initiate new audits or inspections for 30 days effective Mar. 19, 2020)
  - OIG Chart: Deadline extensions during COVID-19

March 20, 2020
Updates today from Congress, CDC, CMS, FDA, NIH, HHS, Homeland Security and Treasury concluding with state “stay at home” executive orders from CA, IL and NY.
CONGRESS
- Senate Republicans officially introduced S 3548 - the Coronavirus Aid, Relief, and Economic Security (CARES) Act (bill text, and general summary). Summaries of the healthcare provisions are here and here.

FEDERAL AGENCIES

Center for Disease Control
- Order Suspending Introduction of Persons from a Country Where a Communicable Disease Exists, effective Mar. 20, 2020 (informs the public that CDC has issued an order suspending the introduction of persons into the US), scheduled for publication in the Mar. 24, 2020 Federal Register.

Centers for Medicare & Medicaid Services
- Guidance
  - Medicare FFS Response to the Public Health Emergency on Coronavirus (COVID-19), revised Mar. 20, 2020 (adds a note in the telehealth section to cover the use of modifiers on telehealth claims and to explain the DR condition code is not needed on telehealth claims under the waiver)
  - Section 1135 Waivers
    - Approval Letter: Section 1135 Waiver Flexibilities – Washington Coronavirus Disease 2019
    - CMS posts Section 1135 approval letters at Medicaid.gov Federal Disaster Resources
  - Tool Kits –Telehealth and Virtual Services
    - ESRD Provider Telehealth and Telemedicine Tool Kit
    - General Provider Telehealth and Telemedicine Tool Kit

Food and Drug Administration
- Expanded Use of Devices to Monitor Patients’ Vital Signs Remotely and Guidance Document, Mar. 20, 2020 (FDA does not intend to object to limited modifications to the indications, claims, functionality, or hardware or software of FDA-cleared non-invasive remote monitoring devices that are used to support patient monitoring)
- FAQs on Diagnostic Testing, recent updates as of Mar. 20, 2020
- Guidance on Production of Alcohol-based Hand Sanitizer to Help Boost Supply, Protect Public Health, Mar. 20, 2020 (FDA will continue to work with manufacturers, compounders, state boards of pharmacy, and the public to increase the supply and availability of alcohol-based hand sanitizers)

National Institutes of Health
- NIH shifts non-mission-critical laboratory operations to minimal maintenance phase, Mar. 20, 2020 ("mission-critical functions" include care of research participants in NIH clinical protocols that are non-elective, research directly on COVID-19, urgent public health research recommended by NIH scientific leadership, work involving significant research investments that could be lost if not continued, and protection of life, property and resources, including the care of research animals)
US Department of Health and Human Services
- Control of Communicable Diseases; Foreign Quarantine: Suspension of Introduction of Persons into United States from Designated Foreign Countries or Places for Public Health, effective Mar. 20, 2020 (this interim final rule provides a procedure for CDC to suspend the introduction of persons from designated countries or places, if required, in the interest of public health), scheduled for publication in the Mar. 24, 2020 Federal Register.

US Department of Homeland Security
- Essential Critical Infrastructure Workforce: Ensuring Community and National Resilience in COVID-19 Response, Mar. 19, 2020 (guidance details “essential” sectors and workers (including healthcare) for maintaining continuity of functions critical to public health and safety)
- Notification of Temporary Travel Restrictions Applicable to Land Ports of Entry and Ferries Service Between the United States and Canada, effective Mar. 20, 2020; scheduled for publication in the Mar. 24, 2020 Federal Register

US Department of the Treasury
- Secretary Steven Mnuchin announced by tweet today that “At @realDonaldTrump’s direction, we are moving Tax Day from April 15 to July 15. All taxpayers and businesses will have this additional time to file and make payments without interest or penalties”

STAY AT HOME – STATE EXECUTIVE ORDERS
- California: “Necessities” include healthcare and prescriptions
- Illinois: Exceptions include individuals who “work for or obtain services through Healthcare and Public Health Operations”
- “New York State on PAUSE”: “Essential Health Care Operations” include research and laboratory services, hospitals, doctors, walk-in-care health facilities, nursing homes, home health care workers, medical wholesale and distribution, and medical supplies and equipment manufacturers and providers

March 19, 2020
Today’s updates from Congress, CMS, HRSA, IRS and the State Department. For our Texas healthcare team: Gov. Greg Abbott has issued an Executive Order requiring Texans to avoid social gatherings with more than 10 people, and prohibiting people from visiting nursing homes, retirement centers, or long-term care facilities “unless to provide critical assistance.”

CONGRESS
- Senate Republicans released draft legislation for a third coronavirus spending package, the Coronavirus Aid, Relief, and Economic Security (CARES) Act. The legislation’s health titles would prioritize drug and device production, allow for emergency use of laboratory-developed tests, provide temporary Medicare payment increases for hospitals, authorize $1.32 billion for community health centers, and expand telehealth opportunities. Additional provisions propose to make further adjustments to paid sick leave policy. Stimulus proposals include direct cash payments to certain households, delay of estimated tax payments for corporations, delay of payment of employer payroll taxes, modifications for net operating losses, and $208 billion in loans or loan guarantees for businesses impacted by coronavirus.
FEDERAL AGENCIES

Centers for Medicare & Medicaid Services
- Adult Elective Surgery and Procedures Recommendations and Press Release, Mar. 18, 2020 (recommendations provide a framework for hospitals and clinicians to implement immediately during the COVID-19 response)
- FAQs on Catastrophic Plan Coverage and the Coronavirus Disease 2019 (COVID-19) and Press Release, Mar. 18, 2020 (CMS announces 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)

Health Resources & Services Administration
- Emergency Preparedness and Recovery Resources for Health Centers:
  - Bulletin - COVID-19 Information Collection (Mar. 18, 2020)

Internal Revenue Service
- Treasury and IRS Issue Guidance on Deferring Tax Payments Due to COVID-19 Outbreak and Notice ("...allowing all individual and other non-corporate tax filers to defer up to $1 million of federal income tax (including self-employment tax) payments due on April 15, 2020, until July 15, 2020, without penalties or interest. The guidance also allows corporate taxpayers a similar deferment of up to $10 million of federal income tax payments that would be due on April 15, 2020, until July 15, 2020, without penalties or interest. This guidance does not change the April 15 filing deadline.")
- IRS: High-deductible Health Plans Can Cover Coronavirus Costs and Notice ("...health plans that otherwise qualify as high-deductible health plans (HDHPs) will not lose that status merely because they cover the cost of testing for or treatment of COVID-19 before plan deductibles have been met. The IRS also noted that, as in the past, any vaccination costs continue to count as preventive care and can be paid for by an HDHP.")

State Department
- Global Level 4 Health Advisory – Do Not Travel (advises US citizens to avoid all international travel due to the global impact of COVID-19)

MARCH 18, 2020
Today’s updates are from the White House, Congress, CDC, CMS and FDA. A couple of informational notes: The transcripts and audio files of the CMS coronavirus stakeholder calls are now available for downloading. For updates on state legislative action on COVID-19, please refer to the National Conference of State Legislators (NCSL) website. I also wish to direct your attention to a detailed report by the Kaiser Family Foundation on State Data and Policy Actions to Address the Coronavirus, Mar. 18, 2020.

THE WHITE HOUSE
- Executive Order on Prioritizing and Allocating Health and Medical Resources to Respond to the Spread of COVID-19, Mar. 18, 2020
- The White House submitted a $45 billion supplemental appropriations request to Congress late last night. The Administration stressed that the supplemental appropriations request is separate from any stimulus packages being discussed. The supplemental appropriations request includes...
more money for the CDC, NIH, HHS (including additional funding for vaccine development), DOD, DHS, and the VA.

**CONGRESS**

- The House passed [HR 6201](https://www.congress.gov/bill/116th-congress/house-bill/6201), the Families First Coronavirus Response Act, this afternoon by a 90-8 vote. The bill now heads to the President to be signed into law. The legislation includes increased SNAP, unemployment, and **paid sick leave** benefits. The legislation also provides a temporary increase to states’ federal medical assistance percentage for the duration of the public health emergency for COVID-19. Finally, the legislation seeks to cover the cost of testing for COVID-19.

**FEDERAL AGENCIES**

**Center for Disease Control**

- [Strategies or Options to Optimize Supplies in Healthcare Settings When There is Limited Supply - Updated](https://www.cdc.gov/coronavirus/2019-ncov/hcp/strategies-optimize-supplies.html)


- [Reports](https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinicians/reports.html)
  - [COVID-19 in a Long-Term Care Facility — King County, Washington, February 27-March 9, 2020](https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinicians/reports/long-term-care-facility.html) (limitations in effective infection control and prevention and staff members working in multiple facilities contributed to intra- and interfacility spread)

**Centers for Medicare & Medicaid Services**


**Food and Drug Administration**


MARCH 17, 2020

A very busy day with updates from Congress, CDC, CMS, FDA and HHS including program instructions and policy statements on telehealth.

CONGRESS

- The House of Representatives passed the technical corrections to H.R. 6201, the Families First Coronavirus Response Act, by unanimous consent. Majority Leader Mitch McConnell (R-KY) signaled support for the House bill, following a lunch meeting with his Senate Republican colleagues and Treasury Secretary Steven Mnuchin. The House bill is expected to be taken up by the Senate tomorrow.

TELEHEALTH WAIVERS

- Centers for Medicare & Medicaid Services
  - Medicare Telemedicine Health Care Provider Fact Sheet, Mar. 17, 2020 (includes summary of Medicare telemedicine services and HCPCS/CPT codes)
  - Frequently Asked Questions, Mar. 17, 2020

- HHS Office for Civil Rights (OCR)
  - Notification of Enforcement Discretion for Telehealth Remote Communications (covered healthcare providers may use popular applications that allow for video chats, including Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, or Skype, to provide telehealth “without risk that OCR might seek to impose a penalty for noncompliance with the HIPAA Rules” related to the good faith provision of telehealth during the COVID-19 emergency)

- HHS Office of Inspector General
  - OIG Policy Statement, Mar. 17, 2020 (physicians and other practitioners that reduce or waive amounts owed by federal healthcare program beneficiaries for telehealth services during the COVID-19 outbreak)

- Medicaid.gov
  - Telemedicine webpage

FEDERAL AGENCIES

Center for Disease Control


- Criteria for Return to Work for Healthcare Personnel with Confirmed or Suspected COVID-19

- Disinfecting your home if someone is sick, Mar. 17, 2020

Centers for Medicare & Medicaid Services

- Florida Medicaid Waiver Approval Letter and Press Release (flexibilities include waiving prior authorization requirements, streamlining provider enrollment processes, allowing care to be provided in alternative settings, suspending certain nursing home screening requirements, and extending deadlines for appeals and state fair hearing requests)

- Medicaid.gov Federal Disaster Resources (CMS says additional 1135 approval letters will be posted to this link)

- Requesting an 1135 Waiver (information on how states or individual providers can ask for assistance or a waiver)
Morgan Lewis

Food and Drug Administration

- Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency, Mar. 2020
- Guidance Document, Mar. 16, 2020 (describes FDA policy regarding states and territories that authorize laboratories within their state or territory to develop their own COVID19 tests and perform specimen testing, where the notification of SARS-CoV-2 test validation is not submitted to FDA and the laboratory does not submit an EUA request to FDA)

MARCH 16, 2020

Today’s updates are from the White House, HHS, Homeland Security, the AHA and AMA. I also wish to bring your attention to the National Governor’s Association coronavirus website with its many useful links (too numerous to list here) to important state information including state emergency and public health declarations, and state-by-state actions to address the coronavirus.

WHITE HOUSE

- The President’s Coronavirus Guidelines for America (“Avoid social gatherings in groups of more than 10 people”)
- Proclamation (suspension of entry as immigrants and nonimmigrants of certain additional persons who pose a risk of transmitting coronavirus [UK and Ireland])

FEDERAL DEPARTMENTS

US Department of Health and Human Services

- 1135 Waiver or Modification of Requirements Under Section 1135 of the Social Security Act (effective at 6:00 P.M. Eastern Standard Time on March 15, 2020, but will have retroactive effect to March 1, 2020, nationwide)
- Findings Concerning Section 1812(f) of the Social Security Act in Response to the Effects of the 2019-Novel Coronavirus (COVID-19) Outbreak (SNF care without a 3-day inpatient hospital stay will be covered for beneficiaries who experience dislocations or are otherwise affected by the emergency)

US Department of Homeland Security

- Public Charge Alert (“USCIS encourages all those, including aliens, with symptoms that resemble Coronavirus Disease 2019 (COVID-19) (fever, cough, shortness of breath) to seek necessary medical treatment or preventive services. Such treatment or preventive services will not negatively affect any alien as part of a future Public Charge analysis.”)

ASSOCIATIONS

American Hospital Association

- Advisory (reports that the Joint Commission has suspended surveying effective today)
- AHA Requests Additional HHS Actions to Help Providers Respond to COVID-19 (see list of suggested waiver actions)
- AHA Letter to Surgeon General Re: Elective Surgeries and COVID-19 (“We are concerned about recent comments by government officials that could be interpreted as recommending that hospitals immediately stop performing “elective” surgeries without clear agreement on how we classify various levels of necessary care.”)
Morgan Lewis

American Medical Association

- **A Physician’s Guide to COVID-19** (“A quick-start physician guide to COVID-19, curated from comprehensive CDC, JAMA and WHO resources, that will help prepare your practice, address patient concerns and answer your most pressing questions.”)
- **COVID-19: Frequently Asked Questions**

**MARCH 15, 2020**

A quick update on what occurred late Friday and over the weekend. Today’s updates are from Congress, CDC, CMS and FDA. With the exception of Maine, every state has declared a state of emergency in response to the outbreak.

**CONGRESS**

- **HR 6201 - Families First Coronavirus Response Act** (passed 363-40 early Saturday morning by the US House of Representatives; links to the revised text and an updated summary of the bill are [here](#) and [here](#))

**FEDERAL AGENCIES**

**Center for Disease Control**

- **Updated Mar. 15 - Mass Gatherings or Large Community Events** (CDC recommends that for the next 8 weeks, organizers cancel or postpone in-person events that consist of 50 people or more throughout the US)
- **FAQs – Personal Protective Equipment (PPE)**, Mar. 14, 2020 (addresses gowns, gloves, and respirators)
- **Collecting, Handling, and Testing Clinical Specimens from PUIs**, updated Mar. 14, 2020 (revisions made to reflect recommendations to collect and test a single upper respiratory nasopharyngeal swab (NP))

**Centers for Medicare & Medicaid Services**

- **Nursing Homes - Infection Control and Prevention**, revised Mar. 13, 2020 (revised guidance for limiting transmission of COVID-19 for nursing homes effectively immediately)
- **Press Release - CMS Announces New Measures to Protect Nursing Home Residents From COVID-19**, Mar. 13, 2020

**Food and Drug Administration**

- **FAQs - Diagnostic Testing for SARS-CoV-2**, updated Mar. 13, 2020 (recent updates highlighted within the blue box)

**MARCH 13, 2020**

Today’s updates are from the White House, CMS, CDC and Homeland Security. I also wish to bring your attention to a very useful website on state quarantine and isolation statutes by the National Conference of State Legislatures. The number of states that have declared a state of emergency in response to the outbreak is now at 40. States that have not declared a state of emergency are as follows: AL, GA, ME, MS, ND, NE, OK, SD, VT and WY. For our Texas healthcare team – here’s a link to today’s [proclamation](#) by Governor Abbott.
The White House

- Proclamation on Declaring A National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak ("The Secretary of HHS may exercise the authority under section 1135 of the SSA to temporarily waive or modify certain requirements of the Medicare, Medicaid, and State Children's Health Insurance programs and of the Health Insurance Portability and Accountability Act Privacy Rule throughout the duration of the public health emergency declared in response to the COVID-19 outbreak.")

- Video (President Trump Declares National Emergency Over COVID-19)

- Memorandum for the Secretary of Health and Human Services ("...the Food and Drug Administration, in coordination with the State of New York, allowed the State flexibility in expediting State-approved COVID-19 testing. Should additional States request flexibility to authorize laboratories within the State to develop and perform tests used to detect COVID-19, the Secretary shall take appropriate action, consistent with law, to facilitate the request.")

Federal Agencies and Departments

Centers for Medicare & Medicaid Services

- CMS Takes Action Nationwide to Aggressively Respond to Coronavirus National Emergency (outlines "several key administrative actions" in response to the national emergency declaration)

- COVID-19 Emergency Declaration – Health Care Providers Fact Sheet (outlines "regulatory flexibilities" and other actions CMS is taking "to help healthcare providers and states respond to and contain COVID-19.")

- 1135 Resource Webpage (information and related downloads from CMS)

- Additional Emergency and Disaster-Related Policies and Procedures That May Be Implemented Only With a § 1135 Waiver (policies and procedures that may be available when Section 1135 waiver authority is invoked)

- Medicare Administrative Contractor (MAC) COVID-19 Test Pricing, Mar. 12, 2020 ("Local Medicare Administrative Contractors (MACs) are responsible for developing the payment amount for claims they receive for these newly created HCPCS codes in their respective jurisdictions until Medicare establishes national payment rates. The payment amounts are identified below. As with other laboratory tests, there is generally no beneficiary cost sharing under Original Medicare.")

Center for Disease Control

- Testing in the U.S. (map includes states and territories with one or more laboratories that have successfully verified and are currently using COVID-19 diagnostic tests; as of Mar. 12, 81 state and local public health laboratories in 50 states and DC have successfully verified COVID-19 diagnostic tests and are offering testing)

US Department of Homeland Security

- Notification of Arrival Restrictions Applicable to Flights Carrying Persons Who Have Recently Traveled from or Were Otherwise Present Within the Countries of the Schengen Area ("Schengen Area" comprises Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, and Switzerland); scheduled for publication in the March 17 Federal Register.

www.morganlewis.com
MARCH 12, 2020

Today’s updates are from the White House, Congress, HHS, CDC and CMS. In other news, the AHA, ANA and AMA have called on the President to declare a national emergency so the Secretary of HHS can “take critical actions, such as providing Section 1135 waivers, to ensure that health care services and sufficient health care items are available to respond to the COVID-19 outbreak.” And an updated count shows 32 states and the District of Columbia having declared a state of emergency in response to the outbreak.

THE WHITE HOUSE
- **Proclamation**, Mar. 11, 2020 (restricts travel from Europe)
- **Executive Order**, Mar. 11, 2020 (availability of general use respirators in response to COVID-19)

CONGRESS
- **HR 6201 - Families First Coronavirus Response Act** and **Title-by-Title Summary** (new legislation introduced in the US House of Representatives)

FEDERAL DEPARTMENTS AND AGENCIES

US Department of Health and Human Services
- **Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19**, Feb. 4, 2020 effective date (extends liability protection to a range of healthcare providers, suppliers, drugmakers and other entities relating to "the manufacture, distribution, administration, or use of medical countermeasures")

Center for Disease Control
- **Implementation of Mitigation Strategies for Communities with Local COVID-19 Transmission** (guiding principles and actions state and local health departments can recommend in their community to both prepare for and mitigate community transmission of COVID-19)

Centers for Medicare & Medicaid Services
- **COVID-19 FAQs for State Medicaid and CHIP Agencies** (issues addressed by this 13-page guidance document include expanding groups for which hospitals can make presumptive eligibility determinations and exceptions to timeliness standards for Medicaid and CHIP applications and renewals)

MARCH 11, 2020

Today’s updates from CMS, CDC, IRS, and the WHO follow below. I also wish to bring your attention to AHIP’s dedicated website Health Insurance Providers Respond to Coronavirus (COVID 19) that describes the actions taken by some 40+ health insurers (including Aetna, Anthem, BC/BS, Cigna, Humana, Kaiser Permanente, Oscar, Molina, United Healthcare, and others) to waive cost sharing / extend coverage for COVID-19 prevention, testing and treatment. And at last count 19 states (AZ, CA, CO, FL, HI, IL, IN, KY, MA, MD, MI, NJ, NY, NC, OH, OR, UT, WA) have declared a state of emergency in response to the outbreak.

WORLD HEALTH ORGANIZATION PANDEMIC DECLARATION
- **Media Briefing** “We have therefore made the assessment that COVID-19 can be characterized as a pandemic”

FEDERAL AGENCIES

Centers for Medicare & Medicaid Services
- Guidance Memos to State Survey Agency Directors
  - **Hospitals** (EMTALA screening)
  - **Nursing Homes** (infection control and prevention)
- **Home Health** (infection control and prevention)
- **Hospice** (infection control and prevention)
- **Dialysis Facilities** (infection control and prevention)
- **Medicare Advantage Organizations, Part D Sponsors, and Medicare-Medicaid Plans**
- **Use of Certain Industrial Respirators by Healthcare Personnel** (Face masks)

- Telehealth Benefits
  - FAQs and Press Release

**Center for Disease Control**
- FAQs on COVID-19 Testing at Laboratories (guidance for laboratories on testing for COVID-19 and access to testing kits and supplies)
- Interim Guidance for Outpatient Hemodialysis Facilities (infection prevention and control recommendations for patients with suspected or confirmed COVID-19)

**Internal Revenue Service**
- High Deductible Health Plans and Expenses Related to COVID-19 (Notice 2020-15 provides that “a health plan that otherwise satisfies the requirements to be an HDHP under section 223(c)(2)(A) will not fail to be an HDHP merely because the health plan provides medical care services and items purchased related to testing for and treatment of COVID-19 prior to the satisfaction of the applicable minimum deductible.”)