COVID-19 Daily Update

March 17, 2020

<u>**Summary**</u>

In a media briefing, WHO highlighted that the total number of COVID-19 cases and deaths reported in the rest of the world has overtaken the total number of cases within China. President Trump announced that he is preparing to ask Congress to infuse about $850 billion in additional stimulus to prop up the economy. The Trump Administration also released new coronavirus guidelines, calling for people to avoid social gatherings in groups of more than 10 people; avoid eating or drinking at restaurants; avoid discretionary travel, shopping trips, and social visits; and avoid visiting nursing homes or long-term care facilities unless to provide critical assistance. In Seattle, a Phase 1 clinical trial evaluating an investigational vaccine designed to protect against COVID-19 has begun at Kaiser Permanente Washington Health Research Institute (KPWHRI). The first participant received the investigational vaccine on Monday. New York Governor Andrew Cuomo issued an Executive Order allowing the New York State to increase hospital capacity to prepare the state's healthcare system to handle the potential influx of patients suffering from COVID-19.

<u>**General/Employer Guidance**</u>

Presidential updates

- *[White House Seeks $850 Billion Stimulus and Urges Sending Checks to Americans Within 2 Weeks](#)*, March 17
    - o President Trump announced that his administration is preparing to ask Congress to infuse about $850 billion in additional stimulus to prop up the economy. Trump further announced the expansion of Medicare patient access to include telehealth options, and added that the government would not be enforcing HIPAA penalties. As part of the broader package, the administration is supporting a request for $50 billion in economic relief for the airline industry. The industry's lobbying group publicly made the request on Monday, asking for grants, loan guarantees, and tax relief.
    - o President Trump also instructed Treasury Secretary Steven Mnuchin to allow for the deferment of tax payments, interest free and penalty free, for 90 days. People can defer up to $1 million and corporations can defer up to $10 million in payments. According to Mnuchin, this would inject $300 billion into the economy.
    - o The administration is in discussions about sending cash payments to Americans over the next two weeks to cushion the economic blow from coronavirus – rather than pushing for a payroll tax cut that would take months to reach people.

- *[Coronavirus Guidelines for America](#)*, March 16
  - The President issued new coronavirus guidelines, urging the public to follow the directions of state and local authorities. It further suggests that those who feel sick should stay home and not go to work. For older adults and those with serious underlying health conditions, it recommends staying home and away from other people.
  - The guidelines also call for people to avoid social gatherings in groups of more than 10 people; avoid eating or drinking at restaurants; avoid discretionary travel, shopping trips, and social visits; and avoid visiting nursing homes or long-term care facilities unless to provide critical assistance. It stated that those working in a critical infrastructure industry, such as healthcare services and pharmaceutical and food supply, have a special responsibility to maintain a normal work schedule.

World Health Organization (WHO)

- *[WHO Director-General's opening remarks at the media briefing on COVID-19](#)*, March 16
  - In a media briefing with WHO Director-General Tedros Adhanom Ghebreyesus, WHO highlighted that the number of cases and deaths reported in the rest of the world now exceeds those reported in China. Tedros praised the recent rapid increase in social distancing measures, like school closings and sporting event cancellations, but warned that there still needs to be a sharp increase in testing, isolation, and contact tracing.
  - Tedros noted that "we cannot stop this pandemic if we don't know who is infected" and stated that all countries should "test, test, test" every suspected case. WHO advises that all confirmed cases, even mild cases, should be isolated in health facilities, to prevent transmission and provide adequate care. Tedros recognized, however, that many countries have already exceeded their capacity to care for mild cases in dedicated health facilities. In that situation, WHO recommended prioritizing older patients and those with underlying medical conditions.
  - Although the evidence suggests that those over 60 are at highest risk, young people, including children, have died.
  - WHO urged people to express their solidarity by refraining from hoarding essential items, including medication.

- *[ICC-WHO Joint Statement: An unprecedented private sector call to action to tackle COVID-19](#)*, March 16
  - In a coordinated effort to combat the COVID-19 pandemic, the International Chamber of Commerce (ICC) and WHO have agreed to work closely to ensure that the latest and most reliable information and tailored guidance reaches the global business community. ICC will regularly send updated advice to its network of over 45 million businesses so that businesses everywhere can take informed and effective action to protect their workers, customers and local communities and contribute to the production and distribution of essential supplies.
  - ICC will also contribute to enhancing information flows on the coronavirus outbreak by surveying its global private sector network to map the global business response. The statement urges that, as an immediate priority, businesses should be developing or updating, readying or implementing business continuity plans. Business continuity plans should aim to reduce transmission, including by: promoting understanding of the disease, its symptoms, and appropriate behavior among employees; setting up a reporting system for any cases and contacts; preparing essentials; limiting travel and physical connectivity; and planning for measures such as teleworking when necessary.

- *[Coronavirus disease 2019 (COVID-19) Situation Report – 56](.)*, March 16
  - Four new territories have reported cases of COVID-19 in the past 24 hours, including two in Africa and one in Europe. The total number of cases and deaths outside China has overtaken the total number of cases in China.
  - The WHO COVID-19 Incident Management Team is working with partners across all levels. To strengthen day-to-day operations, key agencies are embedded in the global team, including UNICEF, the United Nations Office for Coordination of Humanitarian Affairs (OCHA), the International Organization for Migration (IOM), and the International Federation of Red Cross and Red Crescent Societies (IFRC). The core elements of health operations include clinical care and management, laboratory capacity strengthening, surveillance, case and contact tracing, infection prevention and control, risk communications and community engagement.

- *[Critical preparedness, readiness and response actions for COVID-19](.)*, March 16
  - New WHO technical guidance was published, calling on all countries to increase their level of preparedness to identify, manage, and care for new cases of COVID-19. The guidance recognizes that there is no one-size-fits-all approach to managing cases and outbreaks, and urges countries to prepare to respond to different public health scenarios.
  - It provides several different transmission scenarios and provides suggestions on what to do in each – depending on whether there are sporadic cases, clusters of cases, or community transmission. In the case of "community transmission" – which includes situations where an authority is unable to relate confirmed cases through chains of transmission for a large number of cases – the report suggests active community education, a continuation of contact tracing, and testing suspect cases and symptomatic contacts of probable or confirmed cases.

- *[Risk Communication and Community Engagement (RCCE) Action Plan Guidance COVID-19 Preparedness and Response](.)*, March 16
  - New WHO technical guidance was published, to support the development of Risk Communication and Community Engagement (RCCE) plan that, once completed, will constitute a basic evidence-based source for engaging and communicating effectively with identified audiences.
  - This tool is designed to support risk communication, community engagement staff and responders working with national health authorities.

U.S. Centers for Disease Control and Prevention (CDC)
- *[Coronavirus Disease 2019 (COVID-19) Update and Information for Long-term Care Facilities](.)*, March 17
  - CDC held a Clinician Outreach and Communication Activity ("COCA") webinar on the clinical key points for long-term care during the COVID-19 response. Given their congregate nature and residents served (*e.g.*, older adults often with underlying chronic medical conditions), nursing home populations are at the highest risk of being affected by COVID-19.
  - CDC recommends that nursing homes restrict all visitation except or certain compassionate care situations, restrict all volunteers and non-essential healthcare personnel, cancel all group activities and communal dining, and implement active screenings of residents for fever and respiratory symptoms.

- *[Information and Guidance about Global Travel on Cruise Ships, Including River Cruises, due to Coronavirus Disease 2019](#)*, March 15
  - CDC recommends all persons defer any travel on cruise ships, including river cruises, worldwide because of the increased risk of SARS-CoV-2 transmission onboard ships.
  - For patients who still intend to participate in leisure cruises, CDC advises them to stay in their cabins and notify the onboard medical center immediately if they get sick with fever, new or worsening cough, or trouble breathing. It further advises all cruise attendees to stay home for 14 days after returning from travel, practice social distancing, and monitor their health after they return. Social distancing is defined as staying out of crowded places, avoiding group gatherings, and maintaining distance (approximately 6 feet) from others, when possible.

New York State

- *[Governor Cuomo Issues Executive Order Allowing State to Increase Hospital Capacity](#)*, March 16
  - Governor Andrew Cuomo issued an Executive Order allowing the state to increase hospital capacity to prepare the state's healthcare system to handle the potential influx of patients suffering from COVID-19. The State will organize the National Guard and work with building unions and private developers to find existing facilities – such as dormitories and former nursing homes – that can most easily be converted to medical facilities, with the goal of creating an additional 9,000 beds. The State Department of Health is also suspending regulations to allow existing hospitals to increase space and capacity.

- *[Executive Order Delaying Village Elections Statewide Until April 28 Primary](#)*, March 16
  - Governor Andrew Cuomo issued an executive order delaying village elections statewide until the April 28 primary election. He stated that "delaying village elections will help ensure poll workers and voters are not potentially exposed to the virus and at the same time maintain integrity in our election system."

- *[Governor Cuomo Signs Executive Order Closing Schools Statewide for Two Weeks](#)*, March 16
  - Governor Andrew Cuomo signed an executive order directing all schools in New York to close by Wednesday, March 18 for two weeks ending April 1. At that time, the state will reassess whether to extend the school closures further and continue to suspend the 180-day instructional requirement. Schools that exceed the closure period without state authorization will not be exempted from the 180-day rule.

New York City

- *[Mayor de Blasio Holds Media Availability on COVID-19](#)*, March 16
  - Mayor Bill de Blasio announced new updates on the City's response to COVID-19. To avoid public gatherings to the maximum extent possible, all City Council hearings are now suspended. The regular channels for land use applications will also be suspended, and any submissions or applications going through the land use process will be halted until further notice.
  - de Blasio noted that the City is building out medical facilities, and retrofitting non-medical facilities. Four such facilities have been identified and will immediately have the capacity to hold approximately 1,200 beds. The City has also identified and plans to acquire space in five smaller hotels, totaling an additional 250 hotel rooms.
  - The Mayor urged the public to help those who are over 50 or have pre-existing major conditions by helping them to get the things they need. The grocery supply chain remains

strong, and there has been a "very intensive resupply" in recent days of food and basic household goods.

- *COVID-19 FAQ for Contracted Health and Human Service Providers*, March 15
  - The NYC Office of the Mayor released new guidance for City-contracted providers relating to business continuity questions. The guidance notes that any decisions to cancel programs or services should be made with a company's City contracting agency. City agencies will work with providers to support any modifications in programming, location and staffing as needed.
  - To the extent practicable and allowable, the City will reimburse providers for paid time off associated with NYC Department of Health protocols. The City will also reimburse the additional cost of disinfection and safety supplies that exceed the current scope of the contract if the provider is following NYC Department of Health recommendations or other rulings from the cognizant City contracting agency.

Other Related Updates

- *HHS Permits Use of FaceTime, Other Apps for Telehealth*, March 17
  - On March 17, 2020, the Office for Civil Rights at the U.S. Department of Health and Human Services ("OCR") announced that it will not penalize providers for using Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, Skype, or similar non-public facing applications, for providing telehealth during the COVID-19 nationwide public health emergency.[1] This applies to the telehealth services generally, not just diagnosis and treatment of conditions related to COVID-19. Under normal circumstances, the use of these methods of communications may not comply with HIPAA privacy and security rules, and is therefore subject to penalties by OCR, which enforces HIPAA requirements.[2]
  - OCR also named a few "public-facing" apps (Facebook Live, Twitch, TikTok) as ones that should not be used. Additionally, providers are still encouraged to notify patients that third-party applications potentially introduce privacy risks, and providers should enable all available encryption and privacy modes when using such applications.
  - Finally, OCR continues to encourage the use of HIPAA-compliant telehealth vendors, and the use of a business associate agreement, for covered health care providers "that seek additional privacy protections for telehealth." It names a few such vendors (Skype for Business, Updox, VSee, Zoom for Healthcare, Doxy.me, and Google G Suite Hangouts Meet), though OCR clarifies that it not endorsing any particular vendor (or any of the non-public facing applications it mentioned).
  - This notice was part of a larger suite of telehealth-related actions taken by HHS on March 17, 2020 to encourage telehealth during the public health emergency.[3]

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[1] OCR, Notification of Enforcement Discretion for telehealth remote communications during the COVID-19 nationwide public health emergency, dated March 17, 2020, *available at* https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html.
[2] OCR enforces regulations issued under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health (HITECH) Act, that protect the privacy and security of protected health information.
[3] Centers for Medicare & Medicaid Services, Medicare Telemedicine Health Care Provider Fact Sheet, dated March 17, 2020, *available at* https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet.

- *Updated OIG Guidance for Healthcare Practitioners*, March 17
  - The Office of Inspector General ("OIG") released a policy statement and fact sheet announcing flexibility under federal fraud and abuse laws for health care practitioners in connection with the provision of telehealth services.
  - The OIG stated that the agency would not impose administrative sanctions on physicians and other practitioners who chose to reduce or waive cost-sharing obligations of federal health care program beneficiaries arising from the provision of telehealth services under the following circumstances: (1) services must be furnished consistent with applicable coverage and payment rules; and (2) services must be furnished during the CORVID-19 public health emergency period.
  - The OIG further noted that the provision of free telehealth services during the same period would not by itself be viewed as an inducement or as likely to influence future referrals.

- *Call to Action to the Tech Community on New Machine Readable COVID-19 Dataset*, March 16
  - Researchers and leaders from the Allen Institute for AI, Chan Zuckerberg Initiative (CZI), Georgetown University's Center for Security and Emerging Technology (CSET), Microsoft, and the National Library of Medicine (NLM) at the National Institutes of Health released the *COVID-19 Open Research Dataset (CORD-19)* of scholarly literature about COVID-19. The dataset was previously requested by The White House Office of Science and Technology Policy.
  - According to the White House, the *CORD-19* resource represents the most extensive machine-readable Coronavirus literature collection available for data and text mining to date, with over 29,000 articles, more than 13,000 of which have full text. The White House issued a new call to action to artificial intelligence experts to develop new text and data mining techniques that can help the science community answer high-priority scientific questions related to COVID-19.
  - The *CORD-19* resource is available on the Allen Institute's SemanticScholar.org website and will continue to be updated as new research is published. Researchers should submit the text and data mining tools and insights they develop in response to this call to action via the Kaggle platform.

- *G7 Leaders' Statement*, March 16
  - The G7 Leaders issued a statement, acknowledging that the COVID-19 pandemic poses major risks for the world economy. The statement expressed a commitment to bringing together governments to restore confidence, growth, and protect jobs; support global trade and investment; and to encourage science, research, and technology cooperation.
  - To enhance efforts to strengthen health systems in our countries and globally, the statement stressed the value of real-time information sharing to ensure access to the best and latest intelligence, improving prevention strategies and mitigation measures. The leaders promised to support the launch of joint research projects funded by both public and private resources, and the sharing of facilities, to facilitate rapid development, manufacture and distribution of treatments and a vaccine.
  - The leaders also committed to enacting monetary and fiscal measures to support the workers, companies, and sectors most affected. They called on central banks to continue promoting economic recovery and growth, and stated that they would address disturbances to international supply chains.

- *NIH clinical trial of investigational vaccine for COVID-19 begins*, March 16
  - A Phase 1 clinical trial evaluating an investigational vaccine designed to protect against COVID-19 has begun at Kaiser Permanente Washington Health Research Institute

(KPWHRI) in Seattle. The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, is funding the trial.
- o The open-label trial will enroll 45 healthy adult volunteers ages 18 to 55 years over approximately 6 weeks. The study is evaluating different doses of the experimental vaccine for safety and its ability to induce an immune response in participants. The vaccine is called mRNA-1273 and was developed by NIAID scientists and their collaborators at the biotechnology company Moderna, Inc., based in Cambridge, Massachusetts. The first participant received the investigational vaccine on Monday.

- *[FDA Provides More Regulatory Relief During Outbreak, Continues to Help Expedite Availability of Diagnostics](link)*, March 16
  - o FDA updated a policy originally issued on Feb. 29 on diagnostic testing for COVID-19 in order to achieve more rapid testing capacity in the U.S. It particularly addresses laboratories and commercial manufacturers. Under the guidance, all states can take responsibility for tests developed and used by laboratories in their states. Laboratories developing tests in these states can engage directly with the appropriate state authorities, instead of with FDA, and are not required to pursue an Emergency Use Authorization (EUA) with FDA.
  - o Second, the applicability of the previous policy was expanded. The policy was originally applicable only to laboratories that are certified to perform high-complexity testing consistent with requirements under the Clinical Laboratory Improvement Amendments. Under the update, the agency does not intend to object to commercial manufacturers distributing and labs using new commercially developed tests prior to FDA's granting an EUA, under certain circumstances.
  - o The updated policy also provides recommendations for test developers who may wish to develop serological tests for use during this coronavirus outbreak. Serological tests measure the amount of antibodies or proteins present in the blood when the body is responding to a specific infection.

- *[FDA Issues Diagnostic Emergency Use Authorization to Hologic and LabCorp](link)*, March 16
  - o FDA issued Emergency Use Authorizations (EUAs) to: Hologic for its Panther Fusion SARS-COV-2 Assay, and Laboratory Corporation of America (LabCorp) for its COVID-19 RT-PCR test.
  - o According to FDA Commissioner Stephen Hahn, more than 90 test developers have sought FDA guidance with the development and validation of tests they plan to bring through the EUA process since the beginning of the outbreak. In addition, more than 40 laboratories have notified FDA that they are testing or intend to begin testing soon under new policies for laboratory-developed tests for this emergency.

Send questions to COVID-19-Implications@ropesgray.com