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COVID-19 Crisis: US Healthcare Provider and Payer Preparedness

Chapter 4 – Federal Actions

DOCUMENT INTENDED TO PROVIDE INSIGHT AND BEST PRACTICES RATHER THAN SPECIFIC CLIENT ADVICE

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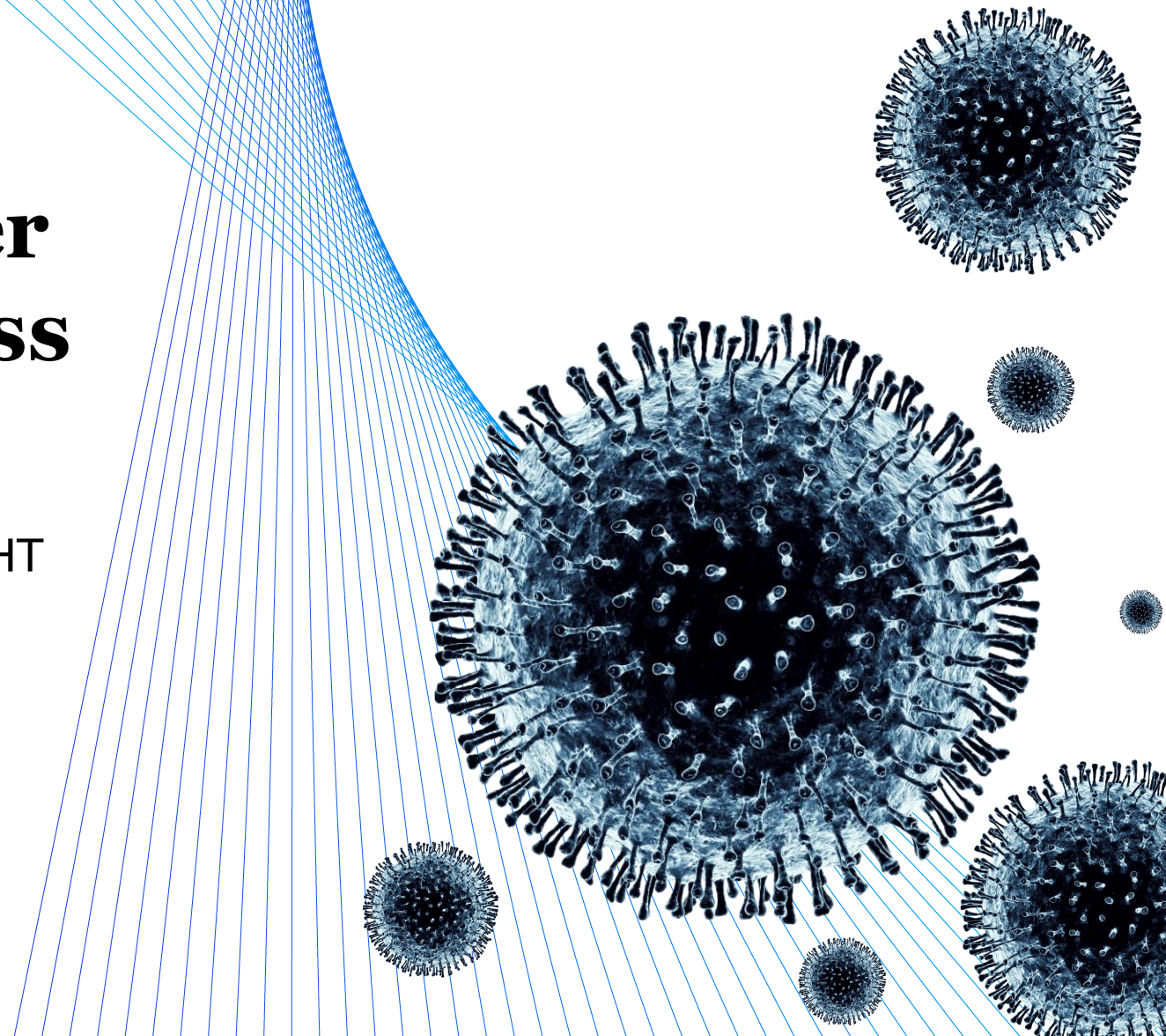

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Solving the humanitarian challenge is the top priority. Much remains to be done globally to prepare, respond, and recover, from protecting populations at risk, to supporting affected patients/ families/ communities, to developing a vaccine. To address this crisis, countries including the US will need to respond in an evidence-informed manner, leveraging public health infrastructure and proactive leadership.

This document is meant to help with a goal: provide a summarized fact base on the disease to date, insights on potential scenarios, and potential actions US healthcare providers and payers may consider.

In addition, we have developed a broader perspective on implications for businesses across sectors that can be found here: https://www.mckinsey.com/business-functions/risk/our-insights/covid-19-implications-for-business**.** This supplemental material discusses implications for the wider economy, businesses, and employment; and sets out some of those challenges and how organizations can respond in order to protect their people and navigate through an uncertain situation.

For all formal guidance, you can find **up-to-date information at CDC's COVID-19 website**, with a section specific to healthcare professionals: https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/index.html

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Federal actions

On Jan 31, Health and Human Services (HHS) Secretary Alex Azar declared the 2019 novel coronavirus a public health emergency

Vice President Mike Pence leads the Coronavirus Task Force, with Ambassador Debbie Birx serving as the White House Coronavirus Response Coordinator, and Secretary Azar as its chairman

HHS have separate collaborations with Regeneron, Sanofi and Janssen (part of J&J) to develop therapeutics and vaccines

The Trump administration asked for at least $2.5B funding for the coronavirus on Feb 26, which was followed up by Congressional authorization of $8.3B total – though additional Congressional efforts and relief are currently being considered, particularly focused on economic relief

On March 11 and 14, President Trump announced travel restrictions for foreigners traveling from Europe (now including the U.K.) into the U.S. and announced several financial relief measures to mitigate the effects of COVID-19

On Mar 13, President Trump declared a state of national emergency due to COVID-19. The declaration frees up $50B in federal disaster relief funding and grants the HHS more authority to waive certain Medicare, Medicaid, and Children's Health Insurance Program Requirements

Various government agencies have also taken action:

- **CMC waived certain** Medicare, Medicaid, and Children's Health Insurance Program **requirements** to increase testing and treatment
- **CDC has implemented its pandemic response plans** and is developing tests and issued clinical guidelines
- **FDA has issued emergency authorizations** for different diagnostic companies to **develop tests** as well granted **permission from certain laboratories to begin testing patients**
- **BARDA and ASPR have partnered with industry**, including Sanofi and Janssen (part of J&J) **to develop therapeutics and vaccines** against COVID-19

Funding level for bill, $B		**Uses**
Federal Disaster Relief Funding	50.0	Various efforts by states and U.S. territories to assist individuals affected by COVID-19
Public Health and Social Services Emergency Fund	3	Develop vaccines and countermeasures, give grants to HRSA health centers ($100M)
Center for Disease Control	2	Give states, localities, tribes etc. grants for surveillance, epidemiology, lab capacity, infection control etc.; use for detection and response
Dept of State, USAID, Bilateral Economic Assistance	1	Maintain consular operations, reimburse evacuations, and fund global health programs, international disaster assistance, and support for economic, security, and stabilization requirements
National Institutes of Health	0	Fund research, provide worker-based training to reduce exposure
Purchase of vaccines and therapeutics	0	Purchase vaccines and therapeutics
Food and Drug Administration	0	Develop vaccines and medical countermeasures, manufacture advanced medical products, monitor supply chains
Small Business Administration	0	Administer disaster loan program

Resources

Communities, schools and businesses: https://www.cdc.gov/coronavirus/2019-ncov/preparing-individuals-communities.html

Healthcare providers: https://www.cdc.gov/coronavirus/2019-ncov/hcp/index.html

Health departments: https://www.cdc.gov/coronavirus/2019-ncov/php/index.html

Source: H.R. 6074 and Congressional Budget Office estimate for H.R. 6074; Wall Street Journal ('U.S. Weighs Paying Hospitals for Treating Uninsured Coronavirus Patients', 3 March 2020), CNBC ('Trump signs $8.3 billion emergency coronavirus spending package'), Modern Healthcare "Trump declares COVID-19 emergency…", CNBC, Agencies websites

President Trump's national emergency declaration over COVID-19 provides additional funding and aims to remove several obstacles to delivering care

Current as of March 16, 2020

Context

On 3/13 President Trump declared a national emergency over COVID-19. The declaration was preceded by several travel restrictions and financial relief measures. At the time of the declaration, there were 1,701 confirmed COVID-19 cases and 40 deaths. The declaration has two components: (1) **National Emergency Act**, which formalizes the emergency powers of the president and equips the government with additional resources to deal with COVID-19, and (2) **The Stafford Act**, which coordinates the administration of disaster relief resources and assistance to states (FEMA funding), and is the same authority used by President Clinton to address West Nile Virus outbreaks in 2000

Measures announced in response to the declaration

Freeing up $50B in emergency relief funds, available to federal, state, and local governments

Asking hospitals to activate their emergency plans

Asking states and local governments to activate their Emergency Operation Centers

Allowing US Health Secretary and other health officials the permission to waive laws and license requirements to give healthcare providers more flexibility (e.g., Medicare, Medicaid, and Children's Health Insurance Program requirements)

Increasing the number of COVID-19 tests available through both private labs, vaccine developers, and healthcare providers

Engaging in several agreements with private companies to facilitate testing for COVID-19

Waiving interest in student loans

Instructing the Department of Treasury to provide relief from tax deadlines to American affected by the COVID-19 emergency

Implications of the measures

Looser regulations will speed up and increase testing, which will help officials track the spread of the virus

Reduced requirements for hospitals *(e.g., allow providers to obtain a license to work in other states, increase access to telemedicine, and lower restrictions on where patients can be treated within a hospital)* **to increase patients' access to treatment**

Additional funding provides flexibility for the government to **provide additional financial relief** to help state and localities as well as individuals affected by COVID-19

Eases financial burden for individuals across the US, increasing spending potential and minimizing economic fallout

Source: Modern Healthcare "Trump declares COVID-10 emergency, asks hospitals to activate emergency plans", BBC "Trump declares national emergency over coronavirus", Politico "Trump declares national emergency in latest bid to combat coronavirus"

Payers: Federal government actions and implications

	Federal action	Potential implications
Prevention	**All payers** • National Institute of Allergy and Infectious Diseases (NIAID) launched first US clinical trial of a COVID-19 vaccine • BARDA and ASPR have partnered with industry, including Sanofi and Janssen (part of J&J) to develop vaccines against COVID-19 **MA payers:** • CMS gave flexibility for MA/Part D plans to enable seniors to access care and treatment quickly while socially distancing (e.g., relaxation of prescription refill limits, increased access to telemedicine, removing prior authorization requirements), and has given state Medicaid/CHIP agencies ability to extend similar provisions, which would be particularly helpful for dual populations	**All payers** • Planning for to incorporate vaccine coverage as soon as widely available **MA payers** • Coordinated response across member service, provider/pharmacy relations to ensure seniors are receiving appropriate care and medication while at home • Potential need to expand access to telehealth services
Testing	**All payers** • The government expects to distribute 1.9 million tests by the end of the week, for use by 2000 commercial labs with high-speed testing capabilities as well as by pod-based "drive-through" testing sites with expected capacity of 2-4k tests a day **MA payers** • CMS issued two FFS billing codes for COVID-19 testing with implications for MA tracking • CMS gave flexibility to MA/Part D plans to waive cost-sharing for testing	• Update claims adjudication logic to incorporate new tests/sites of care • To the extent possible, track community level test results and plan for implications
Treatment	**All payers** • BARDA and ASPR have partnered with industry, including Sanofi and Janssen (part of J&J) to develop therapeutics for COVID-19 **MA Payers** • CMS announced special requirements for MA payers, including coverage and in-network cost-sharing for A, B, and C services at non-contracted facilities and waiving gatekeeping referrals • CMS gave flexibility to MA/Part D plans to waive cost-sharing for treatment of COVID-19 • CMS gave an extension of all MA and Part D appeals **Medicaid managed care payers** • CMS has allowed state Medicaid/CHIP agencies to expand presumptive eligibility **Individual payers** • HHS has released guidance that treatment of COVID-19 (including hospital-based quarantine) is considered an essential health benefit for individual exchange plans	**All payers** • Update claims adjudication logic to incorporate therapeutics as soon as widely available • Coordination with all provider systems (in-network and out-of-network) in coverage area **Medicaid managed care payers** • May see increased enrollment as a result of presumptive eligibility

Providers: Federal government actions and implications

	Federal action	Potential implications
Prevention	President Trump has asked hospitals to activate emergency response plans (e.g., minimizing elective procedures) National Institute of Allergy and Infectious Diseases (NIAID) launched first US clinical trial of a COVID-19 vaccine CMS has expanded allowed telehealth services reimbursed by Medicare/Medicaid CMS has provided targeted provider facility guidance: • Guidelines for nursing homes to restrict visitors, non essential personnel, and communal activities • Instructions for prevention of COVID-19 transmission in Outpatient Hemodialysis Facilities (e.g., policies, PPE, and patient placement techniques)	Larger clinical trials if first trial appears safe and effective- wider availability may be 12-18 months away Providers (PCPs, specialists, etc) can move some practice to video Specific provider facilities will need to adapt policies and procedures to align to guidance
Testing	The government expects to distribute 1.9 million tests by the end of the week, for use by 2000 commercial labs with high-speed testing capabilities as well as by pod-based "drive-through" testing sites with expected capacity of 2-4k tests a day	Hospitals may have increased access to tests, but may still need to limit to most vulnerable populations and healthcare staff
Treatment	Provider staffing measures • CMS has relaxed Medicare provider enrollment screening requirements and established provider enrollment hotline • CMS will allow licensed providers to practice out of state (Medicare/Medicaid) Bed capacity measures • Allows for Medicare reimbursement of SNF stays without 3-day qualifying stay when related to emergency (e.g., discharged early from a hospital to make room for COVID-19 patients) and extends benefits for patients who have exhausted SNF benefits • CMS has waived requirements that Critical Access Hospitals limit stays to 96 hours and total beds to 25 • CMS has enabled greater flexibility in bed allocation by allowing acute care inpatients to be housed in non-acute care beds, and for psychiatric patients and rehabilitation inpatients to be housed in acute care beds where appropriate • CMS allows long-term care hospitals to exclude emergency admits/discharges from the 25 day average length of stay requirement CMS declared masks which protect from splashes and sprays can act as an acceptable and temporary alternative to respirators for most medical services until demand for respirators lessens, while eliminating requirement for state surveyors to validate last test of N-95 masks CMS has suspended non-emergency facility survey inspections Administration and billing • CMS established new billing codes for services related to treatment/diagnosis of COVID-19 • CMS has allowed state Medicaid/CHIP agencies to expand presumptive eligibility	Provider staffing measures create flexibility for provider systems to increase staffing as needed using out-of-state providers or providers not currently enrolled with Medicare Bed capacity measures allow more flexibility for provider systems to reallocate patients between units and facilities (including to SNFs/other non-acute care settings) as is clinically appropriate Personal protection equipment (PPE) regulatory changes enable provider systems to ease supply burden by substituting masks for respirators where necessary and minimizing discarded masks Suspension of non-emergency facility inspections allow providers to focus on serious health and safety threats including infectious disease and abuse Administration and billing changes enable better tracking and ease financial burden of COVID-19 treatment on providers

Deep dive: COVID-19 testing

Background

- When the first cases of COVID-19 were reported in the US, only **two labs at the CDC were permitted to conduct COVID-19 testing** using a **test developed by the agency's own researchers**
- When CDC tried to expand testing by providing its test kits to state and local public health labs, there were **issues with the initial versions of the** kits, requiring rework and delaying the supply
- The delay, along with growing number of cases, prompted the **FDA to expand its approval criteria on 2/29** to allow any **qualified lab to develop its own test**
- Two of the largest diagnostic commercial labs, **Quest Diagnostics** and **LabCorp**, **quickly began developing their own tests** and had to take time to build up capacity, but are now carrying out an expansive number of tests
- As of March 11, CDC state and public health labs had conducted **more than 11,000 tests since mid-January**. By comparison, **South Korea** has tested **more than 200,000 people** since January (and only has a population of 51M)

Current and future supply

- According to the March 17th CDC update, **31,878 tests have now been carried out in the US** and **supply is increasing**
- HHS announced March 13th it is funding two companies, DiaSorin Molecular and QIAGEN, for the development of **rapid diagnostic tests** which would provide results within an hour. Development is targeting completion within 6-12 weeks
- The FDA has **given states such as NY the authority to approve labs for coronavirus testing without waiting for federal approval** – NY is contracting with 28 private labs to increase testing capacity
- As of March 17th, the government is working to distribute **1.9 million more tests by the end of this week** for use by **2,000 commercial labs with high-speed testing capabilities**
- The federal government, using **FEMA and the Public Health Service Corps**, is **supporting state efforts** to develop and run pod-based "drive-through" testing sites with **expected capacity of 2-4k tests a day.** As of March 17th, more than 10 states have implemented their own "drive-through" testing sites
- Looking ahead, **2 million tests are expected to be available next week** and at least **5 million the week thereafter**

SOURCE: https://www.whitehouse.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-briefing-2/; https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/testing-in-us.html; https://www.propublica.org/article/how-south-korea-scaled-coronavirus-testing-while-the-us-fell-dangerously-behind; https://time.com/5801790/coronavirus-testing-us/; https://www.modernhealthcare.com/politics-policy/covid-19-testing-delays-shine-light-lab-developed-test-regulation-debate; https://www.whitehouse.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-briefing-2/