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Congress Responds to Coronavirus:

Health and Health Care Policy Digest: Public Health and Healthcare Provisions of the CARES Act

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Well-being and Equity (WE) in the World

The Coronavirus Aid, Relief and Economic Security (CARES) Act includes numerous provisions for health care providers intended to provide financial assistance, regulatory relief, technology development encouragement, and extensions of existing programs. **We have highlighted the health equity relevant portions below** in the context of this broader summary. The CARES Act expands access to diagnostic testing and telehealth; bolsters the stockpile of personal protective equipment and other needed supplies; mitigates drug and device shortages; and provides financial support and flexibilities for providers to respond to the outbreak. The package contains \$140.4B in additional appropriations for the Department of Health and Human Services (HHS), including \$100 B to reimburse hospitals and other providers for expenditures and lost revenues related to COVID-19, among billions of dollars in other supplemental funding for HHS agencies.

The CARES Act extended multiple health care programs that were set to expire in May of this year. These “extenders” are part of Congress’ annual appropriations process, and do not relate directly to the pandemic. Specifically, it provides funding through November 30, 2020, for community health centers, the National Health Service Corps, the Teaching Health Center Graduate Medical Education program, the Special Diabetes Program and the Special Diabetes Program for Indians. It also extends several expiring Medicaid programs through November 30, including the Money Follows the Person demonstration and Medicaid spousal impoverishment protections.

The CARES ACT also includes reauthorizations of a number of health programs many of which had not been formally reauthorized in years. These include telehealth network and telehealth resource centers grants, several rural health grant programs, modernization of the Public Health Service, and several health workforce development programs. Notably, the CARES Act made substantive changes in how the Food and Drug Administration regulates over-the-counter medication (i.e., medications not requiring a prescription).

CDC

- Appropriates \$4.3B for the Centers for Disease Control and Prevention (CDC). This money is available through September 2024 and is not exclusively dedicated to immediate response. It includes:
 - \$1.5B for grants and cooperative agreements with states, localities, territories, and tribal governments for “surveillance, epidemiology, laboratory capacity, infection control, mitigation, communications, and other preparedness and response activities.”
 - \$300M for the Infectious Diseases Rapid Response Reserve Fund.
 - \$500M for global disease detection and response.
 - \$500M to improve state and local public health data infrastructure through surveillance and analytics modernization.

Strategic National Stockpile

- Appropriates \$16B to the Strategic National Stockpile to increase availability of protective equipment for providers, including ventilators and masks or any other medical supplies necessary for treatment and prevention of COVID-19.
- Clarifies that the Strategic National Stockpile can stockpile medical supplies and equipment that are of use with respect to COVID-19.

Hospitals (including Marshall Plan provisions)

- Appropriates \$100B for hospital response, in the form of a Public Health and Social Services Emergency Fund which should be dispersed as quickly as possible through grants or other mechanisms to providers for coronavirus-related expenses or lost revenues attributable to the outbreak. For more detailed discussion, see <https://www.kff.org/coronavirus-policy-watch/a-look-at-the-100-billion-for-hospitals-in-the-cares-act/>.
 - Eligible providers include public entities, Medicare or Medicaid enrolled providers and suppliers, and other for-profit and not-for-profit entities that provide diagnoses, testing or care for individuals with possible or actual COVID-19.
 - Funding can support building or construction of temporary structures, leasing of properties, medical supplies and equipment, increased workforce and training costs, emergency operation centers, repurposing facilities and surge capacity. Hospitals cannot use this funding for expenses for which they will receive or are seeking other reimbursement.
 - HHS will review applications for payments on a rolling basis and will make pre-payments, prospective payments or retrospective payments.

- The secretary will have to report to Congress every 60 days on the use of funds, and an audit of the spending is required within 3 years.
- Appropriates an additional \$27B for further medical response efforts under the Assistant Secretary for Preparedness and Response (ASPR), including \$250 million for grants through the Hospital Preparedness Fund to respond to medical events broadly.
- Delays scheduled reductions in Medicaid disproportionate share hospital payments through November 30, 2020 (see also Medicaid section below).

Food and Drug Administration (FDA)

- Appropriates \$80M for FDA to expedite approval of new drugs.
- Speeds the development of a vaccine, treatments and faster diagnostics by prioritizing FDA review of certain drugs.
- Requires FDA to prioritize and expedite the review of drug applications and inspections to prevent a drug shortage (see also section below on shortages).

Medicaid

- Delays scheduled reductions in Medicaid disproportionate share hospital payments through November 30, 2020.
- Extends and expands to 2 additional states the Medicaid Community Mental Health Services demonstration that provides coordinated care to patients with mental health and substance use disorders, through November 30, 2020.
- Extends the Money Follows the Person demonstration program through November 30, 2020 to help patients transition from nursing homes to a home setting.
- Allows State Medicaid Programs to pay for direct support professionals and caregivers trained to help with activities of daily living, to assist hospitalized and disabled individuals transitioning to home care and community-based care, thereby reducing length of stay and freeing up hospital beds.
- Clarifies that that states can access the enhanced Medicaid Federal Medical Assistance Percentage (FMAP) under the recently passed Families First Coronavirus Response Act.
- Gives states the option to offer coverage for COVID-19 testing and related services with no cost-sharing to uninsured individuals through the Medicaid program regardless of eligibility.

Medicare

- Temporarily suspends sequestration-mandated reductions to Medicare payments from May 1 through the end of 2020 and extends the sequester an additional year to provide an

immediate bump in funds to providers during the pandemic. The sequester reduced most Medicare payments by two percent starting in 2013.

- Increases by 20% the amount Medicare pays to a hospital for inpatient hospital care for a patient with COVID-19.
- Allows for accelerated Medicare payments (as enumerated in subsequent guidance). Providers and suppliers can receive advance payments of up to 100% of the Medicare payment amount during a 3-month period. Inpatient acute care hospitals, Puerto Rico hospitals with demonstrated cash flow problems, children's hospitals, and PPS-exempt cancer hospitals are eligible for advance payments up to 100% of the Medicare payment amount during a 6-month period. Critical access hospitals are eligible for up to 125% of their payment amount during a 6-month period.
- Increases payments for the work component of physician fees in areas where labor cost is determined to be lower than the national average through December 1, 2020.
- Allows Physician Assistants and Nurse Practitioners to provide the certification for Medicare home health services during the 6 months following enactment.
- To increase access to post-acute care by: waiving the "3-Hour Rule" for inpatient rehabilitation facilities during the emergency period, which requires that patients receive at least 3 hours per day (15 hours per week) of intensive rehab therapy services to increase the ability of acute care hospitals to transfer patients into such settings; allowing long-term care hospitals to maintain their designation even if more than 50% of cases are less intensive; and temporarily pausing the current long-term care hospital site-neutral payment methodology.
- Eliminates Medicare Part B's cost-sharing requirements for COVID-19 testing and any future COVID-19 vaccine.
- Requires Part D prescription drug plans to provide 90-day supplies of medication upon request during the public health emergency
- Provides different blended payment rates to increase Medicare reimbursement for durable medical equipment (DME) suppliers in both rural and non-rural non-competitive bidding areas for the duration of 2020 and the end of the public health emergency, respectively.
- Delays scheduled payment reductions to clinical laboratories.
- Extends funding for funds for outreach and counseling for Medicare low-income programs through November 30, 2020.
- Extends and increases funding for HHS to contract with a consensus-based entity, e.g., the National Quality Forum, for quality measurement input and selection through November 30, 2020 and increases funding to \$20 million for each of the years 2020 and 2021.

Private Health Insurance

- Requires all private insurance plans to cover COVID-19 treatments, preventive services and vaccines and coronavirus tests 15 days after the date it is recommended with no cost-sharing. The contemplated measures include an item, service or immunization that receives a rating of A or B in the current U.S. Preventive Services Task Force or receives a recommendation from the Advisory Committee on Immunization Practices.
- Requires price transparency from providers of COVID-19 diagnostic testing and limits prices paid by health insurers to those in the pre-emergency period.

Safety Net/Access to Care for Vulnerable Populations

- Appropriates \$1.32B for community health center prevention, diagnosis and treatment of COVID-19.
- Appropriates \$19.57B to ensure the Department of Veterans Affairs (VA) has the equipment, tests, telehealth capabilities and support services necessary to support veterans and the health care workforce, including \$14.4B to expand telehealth services at VA facilities and \$2.15B to expand Coronavirus-related services (see telehealth detail below).
- Appropriates \$1.032B to the Indian Health Service to boost healthcare services, including mobile health units and increased capacity for telehealth.
- Appropriates \$275M to the Health Resources and Services Administration (HRSA) to support the Ryan White HIV/AIDS programs and rural critical access hospital and telehealth programs.
- Reauthorizes rural health care services programs including HRSA's Rural Health Care Services Outreach, Rural Health Network Development and Small Health Care Provider Quality Improvement grant programs, as well as the Telehealth Network and Telehealth Resource Center grant programs.
- Appropriates \$955 Million for the Administration for Community Living to support nutrition programs, home and community based services, family caregivers and other programs for seniors and individuals with disabilities.
- Appropriates \$425M to SAMHSA to increase mental health services through Community Behavioral Health Clinics, suicide prevention programs, emergency response systems, and outreach for people experiencing homelessness.
- Reauthorizes the Healthy Start Program to improve birth outcomes for infants and their mothers and appropriates \$125.5M for each fiscal year 2021 through 2025.

Workforce

- Supports the healthcare workforce, including reauthorization of health professions workforce programs, education and training related to practitioners in family medicine, general internal medicine, pediatrics and other specialties such as geriatrics (\$40M) and nursing workforce development. Requires the secretary to develop a coordinated plan for assessing and enhancing programs designed to meet the needs of older individuals who are at the highest risk during the outbreak.
- Limits liability for volunteer health professionals for any harm caused to patients related to COVID-19 volunteer services during the public health emergency. This limitation is written to preempt state law and will be effective at the time of enactment.
- Creates a Ready Reserve Corps to ensure that there are enough doctors and nurses ready to respond to public health emergencies like COVID-19 and gives the secretary authority to assign members of the National Health Services Corps, with the individual member's agreement, to provide COVID-19-related care as needed.

Telehealth

- Authorizes new telehealth program, including expansion of Medicare services not related to COVID-19. It is unclear whether the Act allows for other licensed health professionals, such as respiratory, physical, and occupational therapists, to provide and get paid for telehealth services to Medicare beneficiaries during the emergency.
- Provides \$25M to Distance Learning and Telemedicine program in rural areas and funds \$100M to the ReConnect program to ensure broadband access for rural Americans.
- During the Emergency Period this section eliminates the requirement that Medicare telehealth benefits require the patient to be seen by the professional performing the telehealth services within the past 3 years. This allows for patients to access telehealth services from a broader range of providers.
- Allows FQHCs and Rural Health Clinics to serve as a “distant site” for Medicare telehealth services and receive reimbursement for the service provided.
- During the official COVID-19 emergency declaration, allows for substantial expansion of telehealth services in Medicare to things normally required to be conducted in person, such as hospice recertification and periodic evaluations of dialysis patients
- Directs the Secretary to issue guidance encouraging the use of remote patient monitoring and other telehealth services in home health.
- Includes \$14.4B to expand telehealth services at VA facilities and \$2.15B to expand Coronavirus-related services, including the purchase of mHealth devices and broadband expansion. Authorizes the VA to expand telemental health services, enter into short-term agreements with telecommunications companies to provide temporary broadband services to veterans, temporarily waives the in-person home visit requirement and allows telehealth

and phone calls as an alternative, and ensures that telehealth is available for homeless veterans and case managers in the HUD-VASH program.

- Appropriates to the Federal Communications Commission \$200M to support telecommunications and other services aimed at boosting telehealth use.
- Allows high deductible health plans paired with a health savings account to fully cover telehealth services even if a patient has not met their annual deductible.

Privacy/Confidentiality

- Permanently amends confidentiality regulations related to substance use disorder records, allowing certain disclosures with patient consent. Among these changes is a loosening of restrictions on sharing 42 C.F.R. Part 2-protected information for treatment, payment and health care operations.
- Requires new HIPAA guidance on the sharing of protected health information related to COVID-19 and allows HHS to lift additional restrictions as it sees fit.

Research and Innovation

- Appropriates \$945.5M for National Institutes of Health research into vaccines, treatments, and diagnostics related to COVID-19.
- Appropriates \$3.5B to the Biomedical Advanced Research and Development Authority (BARDA) for the manufacturing, production, and purchase of vaccines, diagnostics, and treatments. Removes barriers to allow BARDA to partner with private sector on research and development and to allow BARDA to expedite diagnostics and vaccines.
- Amends the Federal Food, Drug and Cosmetic Act (FDCA) to permit expediting the review of a new animal drug if there is preliminary clinical evidence that the drug may have an impact on treating a zoonotic disease in animals that could have a serious impact on human health.

Drug and Device and Other Supply Shortages

- Funds NASEM report on security of the U.S. medical supply product chain, including potential public health or national security risks posed by the country's reliance on foreign suppliers. With input from various federal departments, the report will also include the National Academies' recommendations with regard to "improv[ing] the resiliency of the supply chain for critical drugs and devices."
- Mandates that the secretary prioritize and expedite reviews and inspections for drug applications that have the potential to prevent or lessen an existing drug shortage. Improves the flow of knowledge between the Secretary of HHS and Congress. For example, no later than 180 days after the enactment of this Act, and every 90 days thereafter, the Secretary must submit a report regarding drugs on the current drug shortage list to the Centers for Medicare and Medicaid Services (CMS).

- Requires drug manufacturers to provide an annual report to the Secretary detailing total production of a particular drug for commercial distribution. Requires drug and device manufacturers to submit more information when there is an interruption in supply and to maintain contingency plans to ensure a backup supply of products. Drug manufacturers must also notify the Secretary if there is an interruption or discontinuance of an active pharmaceutical ingredient used to manufacture a critical drug. This notification must include the reason for the cited discontinuation or interruption, whether there are alternative sources, if there is a problem with an associated device and the expected duration of the interruption. The Secretary is empowered to request additional information as required. While FDA is authorized to make certain device shortage information public via a newly established device shortage list, the agency will have discretion to determine whether providing such information would be detrimental to the public health, namely by leading to over-purchasing of a certain product.
- Provides permanent liability protection for manufacturers of respirators.

Other

- Requires a national awareness campaign to the public and health care providers to encourage blood donation. The secretary may partner with public or private nonprofit organizations to carry out the campaign and must report to Congress on the activities undertaken, the impact of those efforts and overall trends in blood supply donations.
- Appropriates \$200M for CMS to assist nursing homes with infection control programs and support States in preventing the spread of COVID-19 in nursing homes.
- Reforms the regulatory framework for over-the-counter drugs by updating the FDCA and provides a new 18-month marketing exclusivity period under certain circumstances, for some novel OTC drugs or new drug conditions of use. Authorizes the secretary to assess and use OTC drug user fees beginning in fiscal year 2021.