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Updated March 27, 2020

Summary of Healthcare Provisions of COVID-19 Stimulus Package #3 (CARES Act)

The Big Picture

On March 27, Congress passed a third stimulus package in response to COVID-19—H.R. 748, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). This summary reviews healthcare provisions in the sweeping, $2 trillion legislation, which also includes provisions related to, for example, unemployment benefits, loans and aid to industries (e.g., airlines), tax credits for businesses that keep idled employees on their payroll during the pandemic, emergency assistance for schools, and stimulus checks (or direct deposits) to most Americans.

Many of the healthcare provisions in the CARES Act are consistent with provisions in the stimulus package that Senate Republicans offered late last week, but bipartisan negotiations this week led to some changes. For example, Senate Minority Leader Chuck Schumer (D-NY) highlighted a $55 billion increase (for a total of $100 billion) in a new program to provide direct aid to healthcare providers—hospitals, public entities, not-for-profit entities, and Medicare- and Medicaid-enrolled suppliers and institutional providers—to cover costs related to the current public health crisis. The bill also includes a new $150 billion Coronavirus Relief Fund for state, tribal and local governments.

House Democrats have also developed additional legislation (H.R. 6379) to address COVID-19, which includes significant healthcare provisions. While most of these provisions were not included in the CARES Act, they likely represent the House Democrats' priorities for a fourth stimulus bill.

This analysis of the CARES Act is organized in the following sections:

- **Additional Appropriations for Federal Agencies**—the bill allocates funding to HHS agencies and the Department of Defense for responding to COVID-19. *(See page 4)*
- **Addressing Supply Shortages**—these sections include provisions aimed at increasing medical supplies, such as respirators, and establishes new reporting requirements for manufacturers of "life-saving drugs." *(See page 6)*
- **Access to Testing and Treatment for COVID-19 Patients**—these sections include provisions related to coverage and cost-sharing for COVID-19 testing, treatment and vaccines for Medicare, Medicaid, and individual and employer insurance programs. It also includes corrections to provisions enacted in the previous COVID-19 stimulus packages, including clarification regarding populations eligible for the new, optional Medicaid coverage category for uninsured individuals. *(See page 7)*
- **Significant Additional Funding/Payment Increases for Providers**—in addition to the appropriations outlined above, these sections include funding such as temporarily lifting the Medicare sequester, a Medicare hospital Inpatient Prospective Payment System (IPPS) add-on payment, and several provisions impacting funding for health centers and other providers. *(See page 9)*
- **Telehealth Provisions**—most notably, these sections include provisions to expand HHS authority to use Section 1135 waivers in a way that extends the waivers to providers of telehealth services; to permit Medicare payment for telehealth services delivered by Federally Qualified Health Centers and Rural Health Clinics during emergency periods; and to relax criteria for eligibility for telehealth network and resource center grant programs. *(See page 11)*
- **Home Health and Post-Acute Care Provisions**—these sections include provisions to improve the care planning process for Medicare and Medicaid home health services, increase access to post-acute care during this emergency period, and provide home and community-based care services in acute care hospitals. *(See page 12)*
- **Other COVID-19 Provisions**—these include a range of targeted provisions impacting healthcare programs and services during the state of emergency. *(See page 13)*

The package also includes provisions that are not directly related to responding to COVID-19, including those outlined below. Notably, the delay of Medicaid Disproportionate Share Hospital (DSH) allotment reductions and continuation of healthcare extenders through November 30, 2020, sets the next "must-pass" target for Congress to potentially tack on provisions related to healthcare priorities—such as drug pricing and surprise billing—that have fallen to the wayside as COVID-19 dominates lawmakers' near-term focus.

- **Delay in Medicaid Disproportionate Share Hospital Allotment Reductions**—the bill delays the effective date of Medicaid DSH allotment reductions through November 30, 2020. *(See page 15)*
- **Healthcare Extenders**—the bill extends several healthcare programs through November 30, 2020 (which were otherwise set to expire on May 22); this includes community health

center funding and an extension and expansion of the community mental health services demonstration program. *(See page 16)*

- **Privacy Provisions**—these sections include changes to confidentiality and disclosure of records for patients with substance use disorder (42 CFR Part 2); while these disclosures could impact coordination of care during this state of emergency, the statutory changes would endure. *(See page 14)*
- **Other Provisions** *(See page 17)*

Appropriations for the Public Health and Social Service Emergency Fund

The bill provides substantial funding for the Public Health and Social Service Emergency Fund under the Office of the HHS Secretary.

$100 Billion in Direct Funding for Healthcare Providers. The bill allocates $100 billion for a grant program (or another mechanism) to reimburse eligible healthcare providers[1] for expenses or lost revenues attributable to COVID-19 and not reimbursable by other sources. The funding may be used for building or construction of temporary structures, leasing of properties, medical supplies and equipment (including personal protective equipment and testing supplies), increased workforce and trainings, emergency operation centers, retrofitting facilities, and surge capacity. The bill stipulates that these payments should be made via the "most efficient payment systems practical" to provide emergency payment. The funding is available until expended.

Vaccine, Therapeutics, Diagnostics and Other Preparedness Needs. The bill appropriates $27 billion in funding for the development of necessary countermeasures and vaccines, prioritizing platform-based technologies with U.S.-based manufacturing capabilities, and the purchase of vaccines, therapeutics, diagnostics and necessary medical supplies in quantities determined by the HHS Secretary to meet the public health need. This funding also provides support for medical surge capacity, addressing the blood supply chain, workforce modernization, telehealth access and infrastructure, initial advanced manufacturing, novel dispensing, enhancements to the U.S. Commissioned Corps, and other preparedness and response activities. Specifically, this includes:

- No more than $16 billion for supplies for the Strategic National Stockpile
- No more than $250 million for grants and cooperative agreements for the Hospital Preparedness Program
- No less than $3.5 billion available to the Biomedical Advanced Research and Development Authority for necessary manufacturing, production, and purchase of vaccines, therapeutics, diagnostics and small molecule active pharmaceutical ingredients, including

[1] Eligible healthcare providers are public entities, Medicare- or Medicaid-enrolled suppliers and providers, and for-profit and not-for-profit entities within the United States that provide diagnosis, treatment and care for possible or expected cases of COVID-19.

the development, translation and demonstration of innovations in manufacturing platforms
- No more than $289 million transferrable to other federal agencies for expenses incurred for COVID-19-related medical care
- $1.5 million to the National Academies of Sciences, Engineering and Medicine for a report on the security of the United States medical product supply chain

Notably, the products purchased under this bill must be purchased in accordance with Federal Acquisition Regulation guidance on fair and reasonable pricing. The Secretary may take measures, as authorized under current law, to ensure that vaccines, therapeutics and diagnostics developed with these funds will be affordable in the commercial market without taking actions that delay the development of such products.

The funding under this section will remain available through September 2024.

Health System Capacity. The bill allocates $275 million to the Public Health and Social Service Emergency Fund to increase health system capacity through specific programs and rural health initiatives. In the appropriations, $90 million is earmarked for the Ryan White HIV/AIDS Program, $5 million is allocated to poison control centers, and $180 million would be transferred to the Health Resources and Services Administration (HRSA) to carry out telehealth and rural health initiatives outlined in the bill (see page 11). This funding is available until September 30, 2022.

Laboratory Reporting. The bill also requires any laboratory that performs or analyzes tests to detect COVID-19 to report the results to the HHS Secretary.

Additional Appropriations for Federal Agencies[2]

Department of Health and Human Services

***Centers for Disease Control and Prevention*.** The bill allocates an additional $4.3 billion for Centers for Disease Control and Prevention (CDC)-wide COVID-19 response activities, program support and grants through September 2022. Specifically, no less than $1.5 billion is allocated to grants or cooperative agreements with states, localities, territories and tribal entities,[3] including to carry out surveillance, epidemiology, infection control, increased laboratory capacity, mitigation, communications, and other preparedness and response activities.

[2] Given the haste with which this bill was drafted and the large volumes of money at stake, Section 3841 prevents appropriations included in this bill from duplicating other appropriations made in the Continuing Appropriations Act, 2020; the Health Extenders Act of 2019; the Further Continuing Appropriations Act, 2020; the Further Health Extenders Act of 2019 (Public Law 116-69); and the Further Consolidated Appropriations Act, 2020.

[3] Including tribes, tribal organizations, urban Indian health organizations or health service providers to tribes. These entities must receive at least $125 million in grants under this allotment.

Further allocations include:

- $500 million for global disease detection and emergency response
- $500 million for public health data surveillance and analytics infrastructure modernization
- $300 million for the Infectious Diseases Rapid Response Reserve Fund

As part of this funding, the CDC shall report to Congress on the development of a public health surveillance and data collection system for COVID-19 within 30 days of enactment.

Centers for Medicare & Medicaid Services. This bill allocates $200 million through September 2023 for program management specific to COVID-19 response. Within the allocation, $100 million is dedicated to expenses related to a survey and certification program prioritizing nursing home facilities in localities with community transmission of COVID-19.

Substance Abuse and Mental Health Services Administration. The bill allocates an additional $425 million to the agency through September 2021, which includes no less than $250 million for certified Community Behavioral Health Clinics, $100 million for emergency response grants, $50 million for suicide prevention services and $15 million to the Indian Health Service.

Indian Health Service. An additional $1 billion is allocated for surveillance, testing capacity, community health representatives, public health support, telehealth, Purchased/Referred Care and other health service activities necessary to meet the increase in need for services and to protect the safety of patients and staff. These amounts include up to $65 million for emergency health record (EHR) stabilization and support, no less than $450 million for contracts and grants under the Indian Health Care Improvement Act, and $125 million may be transferred and merged with Indian Health facilities. The funding will be available until September 30, 2021.

National Institutes of Health. The bill includes allocations for research institutes, including additional funding to the National Heart, Lung, and Blood Institute ($103 million), the National Institute of Allergy and Infectious Disease ($706 million), the National Institute of Biomedical Imaging and Bioengineering ($60 million), the National Library of Medicine ($10 million), and the National Center for Advancing Translational Science ($36 million) through September 2024. These allocations include funding for vaccine research facilities.

Food and Drug Administration. The bill appropriates $80 million for additional salaries and expenses for the development of necessary medical countermeasures and vaccines, advanced manufacturing for medical products, the monitoring of medical product supply chains, and related administrative activities.

Department of Defense

The bill includes $1 billion for additional procurement under the Defense Production Act for a two-year period beginning from bill enactment. (For more information on the use of the Defense Production Act, see the Manatt Insights summary of the executive order.)

Coronavirus Relief Fund

Section 5001. *Coronavirus Relief Fund.* This section establishes a $150 billion Coronavirus Relief Fund for the Secretary of the Treasury to make payments for COVID-19 response efforts to states, tribal governments, and local governments with populations of 500,000 or more. It requires that the District of Columbia and U.S. territories collectively receive $3 billion of that funding, that $8 billion in payments be made to tribal governments, and that no state receives less than $1.25 billion. State allocations are determined based on the state's population, relative to the population of all 50 states. Any funding provided to local governments is subtracted from the amount otherwise available to their state government. Local government funding is also apportioned by population, but local governments may receive only 45% of the amount associated with their population.

To initiate payments—which are to be made within 30 days of enactment of the legislation—governments must submit to the Treasury a certification that their proposed uses of the funding are within certain guardrails. All funds must be used for *new* government spending in response to COVID-19—defined as spending that was not approved by the government recipient as of the bill's enactment (and the spending must be incurred between March 1, 2020, and December 30, 2020). This provision may penalize states that have pre-empted federal action and—prior to this bill's enactment—already appropriated funding in response to COVID-19. But, if states easily deplete the fund, this point may be moot. The provision also allocates funding for the Inspector General of the Department of the Treasury to conduct oversight activities and authorizes the recoupment of funding used in ways that do not comply with this provision. The bill applies Hyde amendment prohibitions on using funds for abortion to the relief fund.

Addressing Supply Shortages

Section 3101: *National Academies Report on America's Medical Product Supply Chain Security.* This section requires that a report be commissioned from the National Academies of Sciences, Engineering and Medicine on the security of the U.S. medical supply chain.

Section 3102: *Requiring the Strategic National Stockpile to Include Certain Types of Medical Supplies*. This clause requires the Strategic National Stockpile, a national supply of medical equipment for emergencies, to stock personal protective equipment and other ancillary medical supplies.

Section 3103: *Treatment of Respiratory Protective Devices as Covered Counter-Measures*. This provision would amend the Public Readiness and Emergency Preparedness (PREP) Act to declare

respirators can be "covered countermeasures," when approved by the National Institute for Occupational Safety and Health and the Secretary of HHS determines them to be a priority for use. The PREP Act, which HHS activated in a March 12 declaration, immunizes manufacturers, distributors, program planners and other qualified persons from liability in the development, distribution, administration and use of covered countermeasures, and provides for injury compensation through a federally administered fund. This provision modifies an earlier, similar amendment to the PREP Act in the House-authored Families First Coronavirus Response Act that had the same end, but required that the respirators be used under a specific emergency use authorization.

Section 3111: *Prioritize Reviews of Drug Applications; Incentives*. Requires mandatory prioritized and expedited reviews of applications, and expedited inspections of facilities, in cases of shortages of lifesaving drugs. Current law says that the Food and Drug Administration (FDA) *may* expedite these processes.

Section 3112: *Additional Manufacturer Reporting Requirements in Response to Drug Shortages*. In this section, Congress has proposed changes to the scope of and reporting requirements under provisions of the Food, Drug, and Cosmetic Act (FDCA) intended to protect the supply of "life-saving drugs." It adds those drugs critical to public health during pandemics, and "active pharmaceutical ingredients" of drugs to the listing of items subject to federal requirements relating to interruptions in supply of lifesaving drugs. It requires additional reporting of information in cases of disruptions of supply of lifesaving drugs or active ingredients, while allowing Freedom of Information Act protection for reports. And it requires manufacturers of lifesaving drugs to develop contingency and redundancy plans for disruptions.

Section 3121*: Discontinuance or Interruption in the Production of Medical Devices*. The bill adds a new section to the FDCA intended to prevent and respond to shortages of critical medical devices in a public health emergency. It applies to manufacturers of devices that are either "critical to the public health during an emergency," or for which the Secretary of HHS determines information on a potential disruption is needed during or before such an emergency. Those manufacturers must notify the Secretary in advance of any permanent discontinuance of manufacture, or interruption that would lead to a meaningful disruption in supply, at least six months in advance. The Secretary, who is required to maintain a "shortage list," would then distribute this information publicly, unless found to be against the public interest (such as by inducing panic buying), and without disclosing trade secrets. The provision also calls for expedited inspections and reviews of manufacturers and devices in order to ameliorate any shortage.

Section 3226: *Importance of the Blood Supply*. This provision authorizes a national public awareness campaign to increase blood donations.

Access to Testing and Treatment for COVID-19 Patients

Provisions Affecting Individual and Employer Plan Coverage

Sections 3201–02. ***Coverage of Diagnostic Testing for COVID-10. Pricing of Diagnostic Testing.*** The recently passed Families First Coronavirus Response Act required individual and group insurers and group health plans to cover COVID-19 tests, the administration of tests, and certain items and services relating to the testing or evaluation for testing, during the same office visit, without cost sharing. These sections expand the types of COVID-19 tests that these plans must cover, and establish provisions for their pricing so as to prevent surprise billing.

The originally enacted language called for coverage of tests when approved, cleared or authorized under Sections 510(k), 513, 515 or 564. This bill, in Section 3201, expands the types of tests that must be covered without cost sharing to include those for which the developer has submitted or intends to submit an emergency use authorization request (until that request is denied); those offered in a state that is reviewing tests for COVID-19 independently; and any other tests the Secretary of HHS determines appropriate.

In a separate section, the bill addresses the costs of the tests and services themselves. Plans are required to pay providers' cash price (or negotiate a lower price), thereby relieving some risk of surprise bills, unless the provider is in network and has a negotiated rate in place. Negotiated rates established prior to the current emergency declaration must remain in place throughout the duration of the emergency. Providers must publicize their cash price on an internet website. This provision extends only to items and services that the plan is required to cover without cost sharing.

Provisions Affecting Medicare

Section 3713: ***Coverage of the COVID-19 Vaccine Under Part B of the Medicare Program Without Any Cost-Sharing.*** The bill extends Medicare Part B coverage in original Medicare and Medicare Advantage, without cost sharing or application of a deductible, to COVID-19 vaccines (similar to coverage of influenza vaccines). Absent this change, approved vaccines would become covered under Part D, but might be subject to cost sharing and formulary limitations.

Section 3714: ***Requiring Medicare Prescription Drug Plans and MA-PD Plans to Allow During the COVID-19 Emergency Period for Fills and Refills of Covered Part D Drugs for Up to a 3-Month Supply.*** This provision requires Part D plan sponsors (including MA-PD sponsors) to allow enrollees to obtain a single fill or refill, without utilization management, of an up to 90-day supply of any covered Part D drug on a one-time basis during the COVID-19 public health emergency. This change is presumably meant to allow beneficiaries to stock up on needed medications without running afoul of refill-too-soon edits. But as currently drafted, it would allow any Part D enrollee one fill of any drug without any utilization management restrictions, for any purpose.

Section 3718: ***Amendments Relating to Reporting Requirements With Respect to Clinical Diagnostic Laboratory Tests.*** Under the Protecting Access to Medicare Act of 2014, the Medicare payment amount for most clinical diagnostic laboratory tests is determined by the rates paid for those tests by private payors. This bill delays reporting and implementation of these reductions, so that laboratories can reduce prices for tests in 2020 without fear of impacting Medicare reimbursement.

Provision Affecting Most Health Plans and Certain Medicaid Populations

3203: ***Rapid Coverage of Preventive Services and Vaccines for Coronavirus.*** This section requires coverage of COVID-19 preventive services and vaccines on an accelerated schedule, within 15 business days after they receive an A or B rating from the United States Preventive Services Task Force or the CDC Advisory Committee on Immunization Practices. Current law would have coverage take effect only in the next plan year beginning one year after the decision. This applies to all plan types that must currently cover preventive services without cost sharing.

Provisions Affecting Medicaid

Section 3716: ***Clarification Regarding Uninsured Individuals.*** Section 6004 of P.L. 116-127 created a new optional eligibility group to make coverage of COVID-19 testing and testing-related services available to otherwise uninsured individuals. Section 3716 corrects a presumed drafting error that excluded low-income adults in states that have not yet adopted the Affordable Care Act (ACA) Medicaid expansion from such coverage. The section also amends the definition of "uninsured individual" to clarify that individuals with certain categories of Medicaid that do not provide "minimum essential coverage" (e.g., individuals enrolled for treatment of tuberculosis or breast and cervical cancer, the medically needy, and pregnant women in the few states that do not provide full-scope Medicaid benefits to these women) also may be considered as uninsured for purposes of eligibility for the new optional COVID-19 testing group.

Section 3717: ***Clarification Regarding Coverage of COVID-19 Testing Products.*** Section 6004 of P.L. 116-117 amended the Medicaid statute to provide that COVID-19 diagnostic products administered during the emergency period are covered Medicaid services (and must be provided with no cost sharing). Section 3717 amends the language enacted last week to provide that such diagnostic products are covered services even if they have not been approved, cleared or authorized under specified sections of the FDCA.

Clarification About Medicaid Matching Rate Increase

Section 3720: ***Delaying Requirements for Enhanced FMAP to Enable State Legislation Necessary for Compliance.*** Section 6008 of P.L. 116-127 established a 6.2 percentage point

increase in the Medicaid matching rate, available retroactive to January 1, 2020, through the end of the quarter during which the public health emergency period ends. The federal medical assistance percentage (FMAP) increase is available for all states that satisfy four coverage and eligibility-related conditions established by the new legislation, including not imposing higher premiums than were in effect on January 1, 2020. Section 3720 amends Section 6008 of P.L. 116-127 to specify that a state that increased premiums between January 1 and March 18, 2020, is not ineligible for the increased FMAP during the 30-day period after passage of P.L. 116-127, giving the state time to secure a legislative change to restore premiums to the level in effect as of January 1, 2020.

Additional Funding/Payment Increases for Providers

Section 3709: *Adjustment of Sequestration*. The bill temporarily lifts the Medicare sequester (which went into effect in 2013) that reduces Medicare fee-for-service claims payments to providers by 2%. The temporary duration extends from May 1 to December 31, 2020. To offset this lift, the bill also extends the Medicare sequestration payment reduction through fiscal year 2030, instead of its currently legislated end in fiscal year 2029. The suspension was a key priority for hospital and physician groups because it enables them to access additional Medicare funding for hospital, physician, nursing home, home health and other care.

Section 3710: *Medicare Hospital Inpatient Prospective Payment System (IPPS) Add-On Payment.* For discharges that occur during the public health emergency for which the diagnosis is COVID-19, Section 3710 increases the weighting factor that would otherwise apply to the diagnosis-related group (DRG) by 20%. It directs the Secretary to identify relevant discharges via "diagnosis codes, condition codes, or other such means as may be necessary." This adjustment is not considered in applying budget neutrality.

Further, in the case of a state for which HHS has waived all or part of this section under the authority of Section 1115A, nothing would preclude the state from implementing a similar adjustment.

Section 3211: *Supplemental Awards for Health Centers*. The bill appropriates $1.32 billion for fiscal year 2020 in supplemental funding to community health centers for the detection of SARS-CoV-2 or the prevention, diagnosis and treatment of COVID-19.

Section 3712: *Revising Payment Rates for Durable Medical Equipment (DME) Under Medicare*. In rural and noncontiguous areas, this section prevents scheduled DME payment adjustments from going into effect until December 31, 2020, or until after the COVID-19 emergency period ends. For areas other than rural and noncontiguous, the fee schedule amount for the area becomes 75% of the adjusted payment amount and 25% of the unadjusted fee schedule amount, for the period of March 6, 2020, through the end of the emergency period.

Section 3213: *Rural Health Care Services Outreach, Rural Health Network Development and Small Health Care Provider Quality Improvement Grant Programs*. The bill authorizes $79.5 million for each fiscal year 2021 through 2025 ($397.5 million over five years) for grant programs to be administered by HRSA to support improved quality, access and outcomes for rural underserved populations, including through evidence-based or innovative evidence-informed models and the development of integrated collaborative healthcare networks. Grant award periods under this provision may not be longer than five years. In addition, the bill directs the Secretary of HHS to report to Congress on the impact of the projects funded under this provision no later than four years after enactment and every five years thereafter.

Section 3719: *Expansion of the Medicare Hospital Accelerated Payment Program During the COVID-19 Public Health Emergency*. The bill expands, for the duration of the COVID-19 emergency period, an existing Medicare accelerated payment program. Hospitals, especially safety net and rural facilities, need reliable and stable cash flow to help them maintain an adequate workforce, buy essential supplies, create additional infrastructure and keep their doors open to care for patients. Qualified facilities may request up to a six-month advanced lump sum or periodic payment. Most hospital types could elect to receive up to 100% of the prior period payments, with Critical Access Hospitals able to receive up to 125%. Finally, a qualifying hospital is not required to start paying down the loan for 120 days (four months) and also has at least 12 months to complete repayment.

Telehealth Provisions

Section 3212: *Telehealth Network and Telehealth Resource Centers Grant Programs*. Section 3212 modifies the telehealth network and telehealth resource center grant programs under PHSA 330I in ways that encourage new types of potential grantees to apply, particularly if they already possess the types of equipment that can quickly improve patient access to healthcare services. Specifically, Section 3212:

- Extends the maximum duration of grants from four to five years
- Removes caps on maximum grant amounts
- Decreases from 40% to 20% the total allowable proportion of grant funds that can be spent on equipment
- Permits for-profit entities to apply for grants
- Permits narrowly tailored telehealth initiatives to be eligible for grants
- Relaxes various other former telehealth grant requirements
- Authorizes an appropriation of $29 million for each fiscal year 2021 through 2025 to fund telehealth network and telehealth resource center grants

Section 3701: *Exemption for Telehealth Services*. Section 3701 permits high-deductible health plans to offer telehealth and remote care services benefits without applicable deductibles for the current plan year.

Section 3703: *Increasing Medicare Telehealth Flexibilities During Emergency*. Section 3703 appears[4] intended to expand HHS authority to use Section 1135 waivers in a way that extends the waivers to providers of telehealth services as defined under SSA Section 1834 (m). Section 1135 waivers permit HHS to waive or modify certain Medicare, Medicaid and Children's Health Insurance Program requirements to ensure that sufficient healthcare items and services are available to meet the needs of individuals enrolled in SSA programs in the emergency areas and time periods. These waivers had not expressly applied to telehealth providers in the past.

Section 3704: *Enhancing Medicare Telehealth Services for Federally Qualified Health Centers and Rural Health Clinics During Emergency Periods*. Section 3704 revises the rules regarding Medicare payments for telehealth services to permit payment for those telehealth services delivered by Federally Qualified Health Centers and Rural Health Clinics to beneficiaries outside their clinics during emergency periods.

Section 3705: *Temporary Waiver of Requirement for Face-to-Face Visits Between Home Dialysis Patients and Physicians*. Section 3705 permits Medicare beneficiaries with end-stage renal disease who are receiving home dialysis to choose to receive monthly clinical assessments via telehealth, even without first receiving the face-to-face clinical assessment and without continuing to receive the ongoing face-to-face assessments that would typically be required outside of emergency situations.

Section 3706: *Use of Telehealth to Conduct Face-to-Face Encounter Prior to Recertification of Eligibility for Hospice Care During Emergency Period*. Section 3706 permits a Medicare hospice beneficiary to satisfy the face-to-face encounter requirements via telehealth visits with a hospice physician or nurse practitioner during emergency periods.

Section 3707: *Encouraging Use of Telecommunications Systems for Home Health Services Furnished During Emergency Period*. Section 3707 requires HHS to consider ways to encourage use of telehealth systems in home health settings, including for remote patient monitoring.

Home Health and Post-Acute Care Provisions

Section 3708: *Improving Care Planning for Medicare Home Health Services.* As a condition of payment for Medicare Part A, Medicare Part B and Medicaid home health services, this section improves the care planning process for covered home health services by authorizing, in addition to a physician, a nurse practitioner or clinical nurse specialist working in accordance with state law or a physician assistant under the supervision of a physician to certify eligibility for home health services and establish and periodically review a plan for furnishing such services to an individual. Prior to certification, the physician, nurse practitioner, clinical nurse specialist or physician assistant must document that a physician, nurse practitioner, clinical nurse specialist, certified nurse-midwife (as authorized by state law) or physician assistant has

[4] Section 3703 refers to nonexistent sections of SSA Section 1135.

had a face-to-face encounter with the patient (including through the use of telehealth as is currently allowed). The section also includes nurse practitioners, clinical nurse specialists, certified nurse-midwives and physician assistants, in addition to physicians, in the home health agency's group of professional personnel who can establish policies that govern the services it provides, and provide supervision for home health services. The Secretary shall prescribe regulations to apply these changes, which shall become effective no later than six months after the date of enactment of the CARES Act.

Section 3711*: Increasing Access to Post-Acute Care During Emergency Period.*

- ***Waiver of IRF 3-Hour Rule.*** The section temporarily, during the national emergency, waives the federal requirement under 42 CFR 412.622(a)(3)(ii) that patients of an inpatient rehabilitation facility (IRF) must receive at least 15 hours of therapy per week for the facility to be eligible for payment under Medicare's prospective payments for inpatient rehabilitation hospitals.
- ***Waiver of LTCH Site Neutral Payment Rate Provisions.*** This section also temporarily waives certain site-neutral payment rate provisions related to inpatient hospital services furnished by long-term care hospitals (LTCHs), which are hospitals that meet Medicare's acute care hospital conditions of participation and have an average inpatient length of stay of greater than 25 days. These include a waiver of the payment limitations for LTCHs that do not have a discharge payment percentage for the period that is at least 50% (the "50-percent rule"), and to the application of the site-neutral payment rate for a discharge if the admission occurs during the emergency period and is in response to the COVID-19 public health emergency. With respect to the site-neutral payment rate, the section states that a payment shall be made to an LTCH without regard to the site-neutral payment rule.

Section 3715*: Providing Home and Community-Based Services in Acute Care Hospitals.* This section authorizes the provision of home and community-based services provided under 1915(c), (d) or (i) of Section 1915 of the Social Security Act or 1115 waivers or demonstrations, self-directed personal assistance services provided under 1915(j), and home and community-based attendant services and supports provided under 1915(k), in acute care hospitals, as long as the services are identified in an individual's person-centered care plan, are provided to meet needs not met through the provision of hospital services, don't substitute for services that hospitals are obligated to provide under federal or state laws or requirements, are designed to ensure a smooth transition between acute care settings and home and community-based settings, and will preserve the individual's functional abilities.

Other COVID-19 Provisions

Section 3608: *Expansion of DOL Authority to Postpone Certain Deadlines*. Allows the Department of Labor (DOL) to use its emergency authority under Section 518 for public health emergencies. This allows DOL to exempt enrollees, employer health plans and sponsors from

legal requirements for a period of up to one year. This provision grants DOL broad authority so its impact depends on subsequent guidance, but presumably could be used for relaxing a variety of healthcare insurance-related deadlines and requirements.

Section 3214: *United States Public Health Service Modernization*. This section reproduces the text of the United States Public Health Service Modernization Act, which passed the Senate in January. The ACA created legal authority for a cohort of reserve officers to supplement the U.S. Public Health Service Corps. But that reserve was never formally launched, as the ACA failed to include the statutory authority for pay and benefits. The Modernization Act (and now this section) corrects that error and makes other technical changes to enable the formation of a USPHS Ready Reserve Corps.

Section 3215: *Limitation on Liability for Volunteer Healthcare Professionals During COVID-19 Emergency Response.* This section precludes volunteer healthcare professionals from being liable—under federal and state law—for any harm unintentionally caused by providing healthcare services during the COVID-19 public health emergency, within certain guardrails.

Section 3216: *Flexibility for Members of National Health Service Corps During Emergency Period*. This section grants the Secretary of HHS additional flexibility to assign members of the National Health Service Corps (NHSC) to new service locations. Under current law, these health professionals are assigned to approved sites in Health Professional Shortage Areas, or to Federally Qualified Health Centers and Indian Health Service Sites. As amended in this bill, NHSC members could be reassigned during the COVID-19 public health emergency to another location, with their consent, so long as the new location is a reasonable distance from their current posting.

Section 3222: *Nutrition Services.* This section gives the HHS Secretary the authority, for the duration of the public health emergency, to allow states and area agencies on aging to reallocate certain Nutrition Services Program funding (made available through the Older Americans Act)[5] to meet the needs in the state/area. It also makes certain services, such as home-delivered nutrition services, available to individuals who are homebound due to social distancing.

Section 3301: *Removing the Cap on Other Transaction Agreement (OTA) During Public Health Emergencies*. This section gives additional procurement authority to the Biomedical Advanced Research and Development Authority (BARDA). BARDA is responsible for procurement and development of medical countermeasures, such as vaccines, against pandemic influenza and emerging infectious diseases.

[5] More information about the Nutrition Services Program and Older Americans Act is available here: https://fas.org/sgp/crs/misc/IF10633.pdf.

Privacy Provisions

Section 3221: *Confidentiality and Disclosure of Records Relating to Substance Use Disorder*. This section substantially revises the federal substance use disorder (SUD) statute at 42 U.S.C. § 290dd-2, which underpins the federal SUD confidentiality regulations known as 42 CFR Part 2 (Part 2). The SUD confidentiality statute generally requires written patient consent in order to disclose records subject to the law (Part 2 records), even in cases where the disclosure relates to treating a patient or obtaining reimbursement from a health plan. This differs from the Health Insurance Portability and Accountability Act (HIPAA) privacy rule, which allows disclosure without patient consent for treatment, payment or healthcare operations, among other purposes. Section 3221 changes the federal SUD confidentiality statute in several important ways:

- ***Consent.*** The law still requires written patient consent, but it broadly allows redisclosures of Part 2 information once the patient had given consent. That is, once a patient signed a consent form allowing the SUD provider to disclose the patient's information, that information could be used or disclosed by any organization subject to HIPAA so long as the use or disclosure was for purposes of treatment, payment or healthcare operations and the patient had not revoked the consent form. That means, for example, if a hospital received information from a methadone clinic subject to the federal SUD confidentiality statute, the hospital could use or disclose that information so long as the hospital complied with HIPAA in doing so and the patient had not revoked consent.
- ***Use in proceedings*.** The prohibition on the disclosure of Part 2 information for criminal proceedings extends to civil, administrative and legislative proceedings. However, the statute permits the patient to consent to disclosures for these proceedings.
- ***Penalties*.** Penalties for violating the statute are no longer imposed under the federal criminal code, but instead are imposed by HHS, the same department that enforces HIPAA. This could lead to more active federal enforcement of the SUD confidentiality statute, since the DOJ rarely enforces the law.
- ***Antidiscrimination*.** Anyone who receives Part 2 information could not use that information to discriminate against the patient regarding treatment, employment, housing, access to courts or the provision of government benefits.
- ***Breach notification and notice of privacy practices*.** Providers subject to the SUD confidentiality law are required to comply with HIPAA breach notification and notice of privacy practice requirements. The statute extends these privacy protections to the small minority of Part 2 programs that are not already subject to HIPAA.

The provision also clarifies that, if SUD information is de-identified, it may be disclosed to public health authorities without patient consent; such disclosures arguably are already permitted since Part 2 does not apply to de-identified data.

Section 3224: *Guidance on Protected Health Information.* This section requires HHS to issue guidance on the sharing of protected health information under HIPAA during the COVID-19 public health emergency. HHS must do so within 180 days of enactment. The legislation does not provide any details on what such guidance should say. HHS has already waived certain HIPAA requirements for hospitals operating under disaster protocols and for providers engaging in telehealth.

Delay in Medicaid Disproportionate Share Hospital Allotment Reductions

Section 3813: *Delay of DSH Reductions.* This provision eliminates FY 2020 Medicaid DSH allotment reductions; delays FY 2021 allotment reductions from taking effect until December 1, 2020, and lowers them to $4 billion (from the prior $8 billion); and maintains DSH allotment reductions of $8 billion for FY 2022 through FY 2025. The prior schedule of reductions compared to the new schedule of reductions is shown in the table below.

Change in DSH Allotment Reductions

	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025
Previous Reduction Amounts	$4 billion[6]	$8 billion	$8 billion	$8 billion	$8 billion	$8 billion
Reduction Amounts Under Section 3813	-	$4 billion[7]	$8 billion	$8 billion	$8 billion	$8 billion

Healthcare Extenders

Medicare Extenders

Section 3801: *Extension of the Work Geographic Index Floor (GPCI) Under the Medicare Program.* Section 3801 extends until December 1, 2020, an adjustment to the Work GPCI to 1.000 for all localities that have a Work GPCI of less than 1.000—which increases payments for the work component of the Physician Fee Schedule in areas where labor costs are lower than the national average.

Section 3803: *Extension of Funding Outreach and Assistance for Low-Income Programs.* Section 3803 extends funding until December 1, 2020, for grants to states to provide information, counseling and assistance to individuals eligible for Medicare low-income

[6] Congress previously delayed these cuts from taking effect until May 22, 2020.
[7] Beginning December 1, 2020.

programs. It also extends additional funding for aging and disability resource centers through December 1.

Medicaid Extenders

Section 3811: ***Extension of Money Follows the Person Rebalancing Demonstration Program.*** This provision extends the Money Follows the Person program through November 30, 2020; the revised appropriation for FY 2020 totals $337.5 million, an increase from 2019 funding—but less funding than the $450 million appropriated for FYs 2011 through 2016 (funding expired in 2016 and was not restored until 2019). The bill maintains, on a pro rata basis, the FY 2020 funding level from October 1 (when FY 2020 ends) through November 30 (when program funding will again expire).

Section 3812: ***Extension of Spousal Impoverishment Protections.*** This provision extends, through November 30, 2020, spousal impoverishment protections that allow states to disregard individuals' spousal income and assets when determining eligibility for Medicaid home and community-based services and supports.

Section 3814: ***Extension and Expansion of Community Mental Health Services Demonstration Program.*** This provision extends the community mental health services demonstration program (underway in eight states) through November 30, 2020, and directs the HHS Secretary to expand the program to two additional states. Section 3814 stipulates that the Secretary choose the two additional states from those that were awarded planning grants *and* applied to participate in the demonstration but were not one of the eight states selected (19 states would meet this criteria per HHS's 2016 announcement regarding selected state participants). HHS may not require states to submit any additional application to participate and must make the awards within six months of the bill's enactment. The bill authorizes the eight currently participating states to receive two years of an enhanced matching rate for program expenditures, beginning January 1, 2020; the two newly selected states' two-year enhanced matching rate will begin in their first quarter of participation. The bill also requires the Government Accountability Office (GAO) to submit to Congress, no later than 18 months following the bill's enactment, a report on states' experiences with the program, its effects on patient health and cost of care, and federal efforts to evaluate the program.

Other Extenders

Section 3831. ***Extension for Community Health Centers, The National Health Service Corps, and Teaching Health Centers that Operate GME Programs.*** This section:

- Extends community health center funding through November 30, 2020, providing $4 billion for FY 2020 (the same as FY 2019) and approximately $668 million for October 1 through November 30, 2020.

- Extends National Health Service Corps funding through November 30, 2020, providing $310 million for FY 2020 (the same as FY 2019) and approximately $52 million for October 1 through November 30, 2020.
- Extends funding for teaching health centers that operate Graduate Medical Education (GME) programs through November 30, 2020, providing $126.5 million for FY 2020 (the same as FY 2019) and approximately $21 million for October 1 through November 30, 2020.

Section 3832. *Diabetes Programs.* This section extends funding for both the Special Diabetes Program for Type I Diabetes and the Special Diabetes Programs for Indians at current levels through November 30, 2020 (for each program, $150 million for FY 2020 and approximately $25 million for October 1 through November 30, 2020.)

Other Provisions

Healthcare Workforce. These sections describe workforce development programs in primary care and geriatrics. The programs are intended to be implemented or maintained over a period of years and are unlikely to have a direct effect on COVID-19 workforce availability.

- **Section 3401: *Reauthorization of Health Professions Workforce Programs*.** This section reauthorizes and updates the terms of a number of workforce programs, including training programs for primary care physicians.
- **Section 3402: *Health Workforce Coordination*.** This section authorizes the development of a comprehensive, coordinated plan with respect to HHS healthcare workforce development programs.
- **Section 3403: *Education and Training Relating to Geriatrics*.** This section authorizes and updates the terms of geriatric training programs, including for academic physicians.
- **Section 3404: *Use of Supplemental Educational Opportunity Grants for Emergency Aid*.** This section authorizes the development of Nurse Managed Health Clinics as well as other enhancements to nursing training.

Section 3225: *Reauthorization of Healthy Start Program.* This section provides $125.5 million for FYs 2021 through 2025 to the Healthy Start Program—an HRSA program that provides funding to selected communities with high infant mortality rates to reduce negative birth outcomes (including maternal mortality). The reauthorization also revises elements of the program, such as making state substance abuse agencies eligible for program funding; allowing grants to be made not only on the basis of communities' rates of infant mortality and poor perinatal outcomes, but also on the basis of outcomes among subpopulations within the community (acknowledging the stark disparities in maternal and infant health outcomes); and establishes new cross-program coordination, data collection and reporting requirements. The bill also requires a GAO report regarding program effectiveness.

Section 3302: *Priority Zoonotic Animal Drugs*. This section requires the FDA to prioritize review of a drug for use in animals if the drug treats a zoonotic disease that has the potential to spread to humans and cause serious adverse health consequences for humans.

Section 3702: *Inclusion of Certain Over-the-Counter Medical Products as Qualified Medical Expenses.* This section provides that amounts paid for menstrual care products are considered medical expenses for purposes of health savings accounts, Archer medical savings account, flexible spending arrangements and health reimbursement arrangements. The provision allows taxpayers who have such accounts/arrangements to purchase these products using pretax dollars.

Sections 3851-3856: *OTC Drug Review*. These sections substantially revise FDA regulation of over-the-counter (OTC) drugs. The provisions mirror the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2019, which passed the Senate in December. Currently, the FDA regulates most OTC products through a monograph process. Under that process, the FDA establishes conditions under which active ingredients, indications, labels and other aspects of OTC drugs are "generally recognized as safe and effective" for use. These sections modify the monograph process in several respects, such as by changing the rulemaking process to establish monographs and allowing for marketing exclusivity for certain innovations.

Sections 3861-3862: *User Fees*. These sections impose user fees on those who submit a monograph order request; the fees would be either $100,000 or $500,000 based on the complexity of review. The fees would be used to fund FDA oversight activities related to the new OTC drug review processes.

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