



On March 27, 2020, President Trump signed the Coronavirus Aid, Relief and Economic Security (CARES) Act, a \$2 trillion stimulus bill and the third major piece of legislation addressing the COVID-19 public health emergency. This alert provides an overview of several significant provisions of the Act that impact healthcare businesses, including hospitals, physicians, long-term care providers, laboratories and others. Businesses should expect to see additional legislation addressing the COVID-19 emergency, as well as guidance from applicable federal and state agencies.

## **ALL PROVIDER TYPES**

### **Funding for Healthcare Providers**

The Act provides \$100 billion in funding for “eligible healthcare providers”, through grants or other mechanisms, for healthcare-related expenses or lost revenues that are attributable to COVID-19. (This funding is in addition to the advances that are available under the Medicare Accelerated Payment Program, discussed below).

- “Eligible healthcare providers” means Medicare or Medicaid-enrolled suppliers and providers, public entities, and other for-profit and nonprofit entities as the Secretary of Health and Human Services (HHS) may specify, that provide testing or care for individuals with possible or actual cases of COVID-19.
- Funds are available for construction of temporary structures, leasing of properties, medical supplies and equipment, including personal protective equipment and testing supplies, increased workforce and training, emergency operation centers, retrofitting facilities and surge capacity.
- The funds may not be used to reimburse expenses or losses that have been reimbursed from other sources or that other sources are obligated to reimburse.
- To be eligible for payment, an eligible healthcare provider must submit to the Secretary an application that includes a statement justifying the provider’s need for funds.
- Recipients are required to submit reports and maintain documentation to demonstrate compliance with the conditions for payment, and all payments are subject to audit by the Inspector General and the Comptroller General.

### **Business Loans**

The commercial lending provisions of the Act provide funding to eligible businesses in the form of loans to fund payroll and other operating costs during the COVID-19 public health emergency.

- The \$349 billion Paycheck Protection Program (PPP) provides loans of up to \$10 million per borrower, with certain portions subject to complete forgiveness if specific conditions are satisfied.
- Economic Injury Disaster Loans (EIDLs) provide low interest, long-term working capital loans of up to \$2 million to borrowers in declared disaster areas. Applicants can also obtain emergency advances for up to \$10,000 on EIDLs, which are payable within three days of submitting a completed loan application. These advances are not required to be repaid, even if the loan application is not accepted.
- Borrowers are eligible to apply for both a PPP loan and an EIDL, so long as the funds are not used for duplicative purposes and all other requirements are met.

For additional information regarding the CARES Act business loan programs, please see Gray Reed’s alert [Business Loan Programs in the CARES Act: What Businesses Need to Know](#).

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### **Suspension of Medicare Sequestration**

The Act temporarily suspends, from May 1 through December 31, 2020, automatic 2 percent Medicare payment reductions. It also extends the automatic Medicare payment reductions for an additional year, through 2030 instead of 2029.

### **Medicare Telehealth Rules**

The Act eliminates the requirement that the patient has been treated by the practitioner or a member of his/her group within the past three years in order for the practitioner to be reimbursed for telehealth services rendered to the patient. The Act does not eliminate the “originating site” requirements that restricts the patient’s location while receiving telehealth services. However, CMS previously issued broad guidance that temporarily eliminated both the three-year and the originating site requirement during the emergency period. CMS issued [interim final rules](#) on March 30 allowing for additional flexibilities for telehealth.

For additional information regarding recent changes in telehealth rules and regulations, please see Gray Reed’s alert [Keeping a Pulse on Telemedicine Changes in Light of COVID-19](#).

### **Coverage of Diagnostic Testing and Related Services**

The Act amends and supplements a provision in the Families First Coronavirus Response Act (FFCRA) requiring group health plans and health insurance issuers to cover diagnostic testing for COVID-19 and other items and services furnished during office visits (including in-person and telehealth visits), urgent care center visits, and emergency room visits that relate to the furnishing or administration of a COVID-19 diagnostic test or to the evaluation of a patient for purposes of determining the need for a COVID-19 diagnostic test. (The FFCRA eliminated cost-sharing requirements for coverage of COVID-19 testing-related visits under Medicare Part B and for coverage of COVID-19 diagnostic tests under the Medicare Advantage, Medicaid and CHIP programs).

- “Health insurance issuer” means an insurance company, insurance service or insurance organization (including an HMO) which is licensed to engage in the business of insurance in a state and which is subject to state law regulating insurance. “Group health plan” means an employee welfare benefit plan as defined under ERISA.
- Each provider of a diagnostic test for COVID-19 is required during the emergency period to publicize on a public website its cash price for the test. HHS may impose civil monetary penalties to providers who fail to comply with this requirement in amounts up to \$300 per day.
- The services will be reimbursed at the cash price listed by the provider on a public website, unless the provider has a previously negotiated rate or negotiates a new rate that is lower than the cash price.

### **Coverage of Vaccines and Other Preventive Services**

The Act requires Medicare Part B, group health plans and health insurance issuers to cover, without cost-sharing, “qualifying coronavirus preventive services”, defined as an item, service or immunization intended to prevent or mitigate COVID-19.

### **Expansion of Medicare Accelerated Payment Program**

The Act expands the existing Medicare accelerated payment program (APP) for hospitals for the duration of the emergency period. Additionally, CMS has issued guidance expanding the APP for both hospitals and other Medicare providers and suppliers (including physicians, ambulatory surgery centers, home health agencies, etc.) during the emergency period. The APP generally allows providers and suppliers to receive Medicare payments as advances that are to be repaid on an interest-free basis (which is in addition to the \$100 billion funding discussed above). Under the expanded APP:

- Qualifying hospitals may request accelerated payments on a periodic basis or in up to a six-month advanced lump sum. Other providers and suppliers may request advanced payments based on a three-month period.
- Providers and suppliers may request up to 100 percent of the Medicare payment amount (or up to 125 percent for critical access hospitals).
- Providers and suppliers must repay the accelerated amounts beginning 120 days following receipt of payment. Qualifying hospitals will have up to 12 months to repay the balance. Other providers and suppliers will have 210 days to repay the balance.
- “Qualifying hospitals” has been expanded to include acute care hospitals, critical access hospitals, children’s hospitals, and certain cancer research or treatment hospitals. Hospitals that are not eligible for accelerated payments include psychiatric hospitals, rehabilitation hospitals and hospitals with an average length of stay greater than 25 days.

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- To qualify for accelerated payments, the provider or supplier must: (1) have billed Medicare for claims within 180 days immediately prior to the date of the request; (2) not be in bankruptcy; (3) not be under active medical review or program integrity investigation; and (4) not have any outstanding delinquent Medicare overpayments.
- The provider or supplier must request the accelerated payment by submitting a request form to the applicable Medicare Administrative Contractor. There is no need-based threshold for receipt of payments (only that there is a delay in billing).
- If the request is approved, the payment will be issued within seven days from the request.

### **HIPAA Guidance**

Within 180 days following enactment of the Act, the Secretary shall issue guidance related to the use and disclosure of patients' protected health information (PHI) during the emergency period. Notably, HHS recently issued HIPAA guidance specifically applicable to hospitals, and separate guidance addressing HIPAA and telehealth during the emergency period.

- HHS exercised the authority to waive sanctions and penalties against a covered hospital that does not comply with certain provisions of the HIPAA Privacy Rule, including requirements related to speaking with a patient's family members or friends, opting out of the hospital directory, distribution of notice of privacy practices, and a patient's request for privacy restrictions and confidential communications. The waiver only applies (1) in the emergency area identified in the public health emergency declaration; (2) to hospitals that have instituted a disaster protocol; and (3) for up to 72 hours from the time the hospital implements its disaster protocol.
- HHS stated that the Office for Civil Rights (OCR) will exercise enforcement discretion and waive penalties for HIPAA violations against healthcare providers that serve patients in good faith through everyday communications technologies, such as FaceTime or Skype, during the emergency period.

### **HOSPITALS**

#### **Medicare Payment Increase**

During the emergency period, hospitals receive a 20 percent increase in Medicare payments for services related to the treatment of COVID-19 patients.

#### **Delay in DSH Reductions**

The Act delays until December 1, 2020 a \$4 billion reduction in Medicaid funding for fiscal year 2020 for disproportionate share hospitals serving a large number of low-income or uninsured patients.

#### **Access to Post-Acute Care**

The Act includes several measures intended to provide acute care hospitals with additional capacity by permitting patients to be transferred to post-acute care settings during the emergency period:

- Waiver of the requirement that a patient receive at least 15 hours of therapy a week in an inpatient rehabilitation facility.
- Waiver of payment adjustments for long-term care hospitals that do not have at least a 50 percent discharge payment percentage rate.
- Waiver of the site neutral payment rate for long-term care hospitals.

#### **Home and Community-Based Services**

The Act allows state Medicaid programs to cover home and community-based services, self-directed personal assistance services, and home and community-based attendant services that are provided in an acute care hospital. The measure is intended to reduce length of stay by assisting hospitalized patients in transitioning to home and community-based care, freeing up beds and permitting hospitals to devote their resources to addressing COVID-19.

### **PHYSICIANS AND OTHER PRACTITIONERS**

#### **Volunteer Liability Immunity**

The Act shields volunteer healthcare professionals from liability for negligent acts and omissions in providing volunteer healthcare

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services within the scope of the professional's license during the emergency period. Professionals are not protected against errors or omissions arising from willful or criminal misconduct, gross negligence or reckless misconduct. This immunity is in addition to the protections afforded by the federal Volunteer Protection Act.

#### **Extension of Physician Work Geographic Index Floor**

The Act extends the increased payment floor through December 1, 2020 for the work component of physician fees in areas where labor cost is determined to be lower than the national average.

#### **ESRD Telehealth Visits**

The Secretary is permitted to waive the requirement that individuals with end stage renal disease receiving home dialysis receive certain periodic face-to-face clinical assessments, which would allow these assessments to be provided via telehealth.

### **LONG-TERM CARE**

#### **Funding of Aging and Disability Services Programs**

The Act provides \$955 million in funding for aging and disability services programs, to remain available until September 30, 2021, to prevent, prepare for and respond to COVID-19.

#### **Telehealth**

Hospice physicians and nurse practitioners are permitted, during the emergency period, to conduct a face-to-face encounter via telehealth to determine recertification for continued eligibility for hospice care. Additionally, the Act directs the Secretary to consider ways to encourage the use of telecommunications systems for home health services during the emergency period.

#### **Expansion of Home Health Providers**

The Act expands certain Medicare provisions to allow (in addition to physicians) nurse practitioners, clinical nurse specialists, certified nurse-midwives and physician assistants to certify home health services.

### **COMMUNITY AND RURAL HEALTH**

#### **Distant Sites for Telehealth**

During the emergency period, a federally qualified health center (FQHC) or a rural health clinic (RHC) can serve as the "distant site" for telehealth services, meaning the practitioner is located at the FQHC or the RHC but the patient is not. (FQHCs and RHCs are also eligible to serve as the "originating site" where the patient is located). Reimbursement is based on payment rates similar to the national average payment rates for comparable telehealth services under the Medicare Physician Fee Schedule, and excludes the costs associated with the services from both the FQHC prospective payment system and the RHC all-inclusive rate calculation.

### **MEDICAL DEVICE AND DRUG MANUFACTURERS**

#### **Liability Immunity**

The Act makes permanent a provision in the second coronavirus response package extending liability immunity under state and federal law to manufacturers of respiratory protective devices, such as masks and ventilators that HHS designates for use during a declared public health emergency.

#### **Device and Drug Shortages**

Manufacturers of critical medical devices and drugs are required to notify the U.S. Food and Drug Administration (FDA) of discontinuations and shortages.

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- Manufacturers of critical medical devices are required to notify the FDA of a discontinuance in or the interruption of the manufacture of the device at least six months prior to the discontinuance or interruption (or as soon as practicable). If the FDA determines there is a shortage, it may prioritize and expedite the review of submissions and notifications in order to assist in mitigating the shortage. These manufacturers are also required to develop, maintain and implement risk management plans related to shortages and are subject to shortage-related inspections by HHS.
- In addition to other reporting requirements, drug manufacturers are required to report any discontinuation and disruption of the sourcing of active pharmaceutical ingredients and to report on an annual basis the amount of each drug created for commercial distribution. Finally, drug applications to mitigate emergency drug shortages will receive prioritized review by the FDA.
- The FDA is required to publish a list of device and drug shortages (but the FDA can withhold the device information to prevent hoarding).

## OTHER PROVIDERS

### Laboratories

The Act requires all laboratories that analyze COVID-19 diagnostic tests to report to the Secretary the results of each such test during the emergency period. Further, the Act delays through December 31, 2021 certain market data reporting requirements for Medicare laboratories (involving the reporting of private payor reimbursement data). The Act also delays the reduction in Medicare payment rates (up to 15 percent) for an additional year so that the reduction begins in 2022 and ends in 2024.

### Substance Use Disorder Treatment

The Act provides \$425 million in funding for Substance Abuse and Mental Health Services Administration programs. Further, the Act amends 42 CFR Part 2, which governs the confidentiality of substance use disorder patient records to align the regulations more closely with HIPAA. Under the amended regulations, instead of requiring a patient's consent each time the record is shared, once a patient gives prior written consent, the contents of a record may be used or disclosed for purposes of treatment, payment and healthcare operations as permitted by HIPAA, and re-disclosures may then be made in accordance with HIPAA until the patient revokes the consent. In addition, the Act incorporates certain HIPAA provisions related to breach notification, accounting of disclosures, notice of privacy practices, and civil and criminal penalties. It also adds an anti-discrimination provision prohibiting discriminating against an individual on the basis of certain information received from substance use disorder patient records.

### Durable Medical Equipment

The Act prevents during the emergency period a reduction in Medicare payment rates for durable medical equipment by suspending revisions to the Medicare durable medical equipment payment methodology for areas other than those that are rural and noncontiguous.

Healthcare businesses should keep in mind that the laws, regulations and guidance addressing the COVID-19 public health emergency are evolving quickly. If you have questions about the legal issues associated with the CARES Act or other responses to COVID-19, please [contact us](#).

## ABOUT THE AUTHOR



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