WINSTON & STRAWN LLP

CLIENT ALERT

Congress Passes the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act") with Significant Implications for Providers, Suppliers, and Manufacturers in the Health Care and Life Sciences Industry

MARCH 30, 2020

On March 27, 2020, the President signed the CARES Act into law. Among the approximately 350 pages of legislation designed to address the economic and public health impact of the novel coronavirus (COVID-19) pandemic, the CARES Act includes significant measures targeted at assisting the U.S. health care system across its various sectors. The assistance is targeted to: (i) address immediate clinical and operational needs of providers of health care services and suppliers of health care items and products, including manufacturers and distributors of diagnostic tests, drugs, biologics, and devices; (ii) address economic stability in the health care system by, among other things, injecting both new and accelerated financial assistance to providers responding to the public health emergency; and (iii) bolster future readiness for similar events and provide for accountability for official actions taken in response to the public health emergency.

This alert includes summaries of many of the major provisions of the bill that address the three targeted areas mentioned above. We have organized the summaries in alphabetical order by provider or supplier type in most instances. The following areas are summarized below: (1) Clinical Laboratories; (2) Drug, Biologics and Device Manufacturers and Distributors; (3) Durable Medical Equipment; (4) ESRD; (5) Home Health Agencies; (6) Hospice; (7) Hospitals; (8) Innovation; (9) LTACHs and Inpatient-Rehabilitation; (10) Physicians; (11) Public Health; (12) Skilled Nursing Facilities; (13) Telehealth; (14) Volunteer Health Care Professionals – Liability Protections; (15) Diagnostic Testing and Treatment Coverage; (16) Health Care Workforce; and (17) Medicare Sequestration. There are additional sections that cross disciplines and a section toward the end focused on public health readiness-related matters. Additionally, we will be completing separate and more comprehensive summaries on certain specific issues in the CARES Act in the future as more information about implementation becomes available.

1. Clinical Laboratories

Sec. 3718. Amendments Relating to Reporting Requirements with Respect to Clinical Diagnostic Laboratory Tests. Planned reductions during 2021 in Medicare payments for clinical diagnostic laboratory tests are halted. Laboratories offering clinical diagnostic tests are given a one-year deadline extension for the reporting of private payer data.

See also:

Sec. 3709. *Discussed in All Providers and Suppliers – Medicare Sequestration below.*

Sec. 3713. **Sec. 3201**. **Sec 3202**. and **Sec. 3203**. *Discussed in All Providers and Suppliers – Diagnostic Testing and Treatment Coverage below.*

2. Drug, Biologics and Device Manufacturers and Distributors

Sec. 3112. Additional Drug Shortages Reporting Requirements. A drug manufacturer is required to notify the Secretary of Health and Human Services ("the Secretary") of the discontinuance or interruption of a life-saving drug. The categories of drugs that require notification of a discontinuance or interruption are expanded to include drugs that are critical to the public health during a public health emergency declared by the Secretary. Notification is also now required if there is a permanent discontinuance or interruption in the manufacture of the active pharmaceutical ingredient of such drug that is likely to lead to a meaningful disruption in the supply of such drug.

Sec. 3121. Establishes Reporting Requirements for Critical Devices. Manufacturers of devices critical during a public health emergency must notify the Secretary of a discontinuance or meaningful supply disruption. Notice is required to be made at least six months prior to the discontinuance or interruption, or if that's not possible, as soon as practicable.

Sec. 3226. Importance of the Blood Supply. In order to promote public awareness of the importance of donating blood during the public health emergency, the CARES Act authorizes the Department of Health and Human Services ("HHS") to enter into contracts with vendors to develop and present a media campaign on the subject. HHS is tasked with coordinating this activity across its sub-agencies, such as the Center for Disease Control, National Institutes of Health, and the Food & Drug Administration. An accountability provision is included that requires HHS to provide a report to Congress within two years of the end of the public health emergency regarding actions taken under this provision.

3. Durable Medical Equipment

Sec. 3712. Revising Payment Rates for Durable Medical Equipment under the Medicare Program through Duration of Emergency Period. In rural areas and noncontiguous areas, payment adjustments for durable medical equipment items/services will be limited to 50% of the adjusted payment amount and 50% of the unadjusted fee schedule amount. In all areas other than rural and noncontiguous areas, beginning in 30 days, durable medical equipment items/service payments that are dated March 6, 2020, through the end of the COVID-19 emergency period will be 75% of the adjusted payment amount established under 42 C.F.R. 414.210 and 25% of the unadjusted fee schedule amount (as opposed to 100% of the adjusted payment amount).

See also **Sec. 3709**. *Discussed in All Providers and Suppliers – Medicare Sequestration below.*

4. ESRD

Sec. 3705. ESRD Face to Face. HHS can waive the requirement that an individual with end-stage renal disease receiving home dialysis must first receive a face-to-face clinical assessment before they can have assessments conducted through telehealth.

See also **Sec. 3709**. *Discussed in All Providers and Suppliers – Medicare Sequestration below.*

5. Home Health Agencies

Sec. 3707. Home Health Face-to-Face. HHS is to provide guidance to encourage the use of telecommunication systems for the provision of home health services, including for remote patient monitoring.

Sec. 3708. Orders for HHA Services. Expands who can order home health services for Medicare beneficiaries to include nurse practitioners, clinical nurse specialists, and physician assistants.

Sec. 3715. Providing Home and Community-Based Services in Acute Care Hospitals. State Medicaid programs may permit/reimburse services provided by caregivers and direct support providers to patients during their hospital stays if such services are identified in the patient's plan of care, are services that the hospital does not provide, are not in substitution of the services that the hospital is obligated to provide, and are designed to support/facilitate the patient's transition out of the hospital into home and community-based settings.

See also:

Sec. 3709. *Discussed in All Providers and Suppliers – Medicare Sequestration below.*

Sec. 3713. **Sec. 3201**. **Sec 3202**. and **Sec. 3203**. *Discussed in All Providers and Suppliers – Diagnostic Testing and Treatment Coverage below.*

Sec. 3401. **Sec. 3402**. **Sec. 3403**. and **Sec. 3404**. *Discussed in All Providers and Suppliers – Health Care Workforce regarding measures to address the health care workforce shortage and training.*

6. Hospice

Sec. 3706. Hospice Face-to-Face. A hospice physician or nurse practitioner can conduct hospice recertification through telehealth during the emergency period, rather than through a face-to-face visit.

See also:

Sec. 3709. *Discussed in All Providers and Suppliers – Medicare Sequestration below.*

Sec. 3401. **Sec. 3402**. **Sec. 3403**. and **Sec. 3404**. *Discussed in All Providers and Suppliers – Health Care Workforce regarding measures to address the health care workforce shortage and training.*

7. Hospitals

Sec. 3710. Medicare Hospital Inpatient Prospective Payment System Add-On Payment for COVID-19 Patients during Emergency Period. When calculating payments to hospitals for inpatient treatment of an individual covered by Medicare who has been diagnosed with COVID-19, the weighting factor that would otherwise apply to the COVID-19 patient's diagnosis-related group at discharge will be increased by 20%. These adjustments will not be taken into account in applying budget neutrality.

Sec. 3719. Expansion of the Medicare Hospital Accelerated Payment Program During the COVID-19 Public Health Emergency. During the COVID-19 emergency, a qualifying hospital may request up to six months of advance Medicare payments (in lump sum or periodic payments), up to the full amount (100%) of the payment it is expected to be due during the period – in the case of a critical access hospital, up to 125% of what it is expected to be due. The advance payment will be collected by offsetting actual claims subsequently filed with Medicare, but such offsets can be held off for up to four months before applicability. Full payment on the outstanding balance of the accelerated payment will only be required 12 months after the advance payment was made.

See also,

Sec. 3709. *Discussed in All Providers and Suppliers – Medicare Sequestration below.*

Sec. 3713. **Sec. 3201**. **Sec 3202**. and **Sec. 3203**. *Discussed in All Providers and Suppliers – Diagnostic Testing and Treatment Coverage below.*

Sec. 3401. **Sec. 3402**. **Sec. 3403**. and **Sec. 3404**. *Discussed in All Providers and Suppliers – Health Care Workforce regarding measures to address the health care workforce shortage and training.*

8. Innovation

Sec. 3301. Removing the Cap on OTA during Public Health Emergencies. This provision amends Section 319L(c)(5)(A) of the Public Health Service Act (42 U.S.C. § 247d-7e(5)(A)) to eliminate caps on Other Transaction Authority ("OTA") for the purpose of directing HHS to use competitive procedures for entering into transactions, including presumably contracts, during the public health emergency that promote innovation in response to the COVID-19 crisis. Transactions entered into are not limited in duration to the life of the current public health emergency. Also, the provision comes with an obligation for the agency to report to Congress on actions taken under this provision.

9. LTACHs and Inpatient-Rehabilitation

Sec. 3711. Increasing Access to Post-Acute Care during Emergency Period. Rehabilitation facilities are temporarily exempt from the requirement that patients of an inpatient rehabilitation facility must receive at least 15 hours of therapy per week. Long-term care hospitals are temporarily exempt from the "50-percent rule," which adjusts payments to long-term care hospitals that fail to meet a discharge threshold of 50%. The current site-neutral payment methodology for long-term care hospitals is also temporarily suspended.

10. Physicians

See:

Sec. 3709. *Discussed in All Providers and Suppliers – Medicare Sequestration below.*

Sec. 3705. *Regarding a discussion of Face-to-Face Requirements for ESRD above.*

Sec. 3707. *Regarding a discussion of Face-to-Face Requirements for Home Health above*.

Sec. 3706. *Regarding a discussion of Hospice Face-to-Face Requirements above.*

Sec. 3703. *Regarding the definition of "qualified provider" for telehealth services under Telehealth below.*

Sec. 3704. *Regarding FQHC telehealth services under Telehealth below.*

Sec. 3713. **Sec. 3201**. **Sec 3202**. and **Sec. 3203**. *Discussed in All Providers and Suppliers – Diagnostic Testing and Treatment Coverage below.*

11. Public Health

Sec. 3102. Certain PPE Added to the Strategic National Stockpile. Personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines, and other biological products, medical devices, and diagnostic tests are added into the definition of items required to be kept in the strategic national stockpile pursuant to the Public Health Service Act.

Sec 3103. PPE as Countermeasures in the PREP Act. The PREP Act generally exempts from certain liability defined individuals and entities who use "countermeasures" in response to a declared national public health emergency. The list of countermeasures is defined by both statute and the Secretary of HHS. This section adds "a respiratory protective device that is approved by the National Institute for Occupational Safety and Health under part 84 of title 42, C.F.R. (or any successor regulations), and that the Secretary determines to be a priority for use during a public health emergency" as a covered countermeasure.

12. Skilled Nursing Facilities

See:

Sec. 3709. *Discussed in All Providers and Suppliers – Medicare Sequestration below.*

Sec. 3713. **Sec. 3201**. **Sec 3202**. and **Sec. 3203**. *Discussed in All Providers and Suppliers – Diagnostic Testing and Treatment Coverage below.*

Sec. 3401. **Sec. 3402**. **Sec. 3403**. and **Sec. 3404**. *Discussed in All Providers and Suppliers – Health Care Workforce regarding measures to address the health care workforce shortage and training.*

13. Telehealth

Sec. 3701. High Deductible Health Plans. HDHPs will be allowed to cover telehealth services even if the HDHP did not have deductibles for telehealth and other remote services. COVID-19 patients will be provided with increased access to telehealth services by covering such services prior to a patient reaching particular deductible requirements.

Sec. 3703. Removal of Limitation Relating to Qualified Provider. Under the previously passed Coronavirus Preparedness and Response Supplemental Appropriations Act, the Secretary was given the authority to waive or modify requirements for the provision of telehealth services furnished within any emergency area by a "qualified provider." The definition of "qualified provider" included a limitation that the provider has treated the patient within the last three years. Sec. 3703 removes that limitation.

Sec. 3704. FQHC Telehealth Services. Medicare will reimburse for telehealth services furnished by a Federally Qualified Health Center ("FQHC") or a Rural Health Clinic ("RHC") to an eligible telehealth individual even if the center or clinic is not at the same location as the beneficiary (allowing them to serve as a distant site for telehealth consultations). The Secretary is required to develop and implement payment methods for these telehealth services, based on payment rates similar to the national average payment rates for comparable telehealth services under the Medicare Physician Fee Schedule. The costs of these services are excluded from the FQHC prospective payment system and the RHC all-inclusive rate calculation.

See also:

Sec. 3705. *Regarding a discussion of Face-to-Face Requirements for ESRD above.*

Sec. 3706. *Regarding a discussion of Hospice Face-to-Face Requirements above.*

Sec. 3707. *Regarding a discussion of Home Health Face-to-Face Requirements above.*

14. Volunteer Health Care Professionals – Liability Protections

Sec. 3215. Limitation on Liability for Volunteer Health Care Professionals. Provides greater protections from liability for these volunteers. According to the Act, a health care professional shall not be liable under Federal or State law for any harm caused by an act or omission that occurs in the provision of health care services during the COVID-19 public health emergency. In order to benefit from the Act's protection, the volunteer professional must have been providing health care services within the scope of their license, registration, or certification, in response to the emergency.

15. All Providers and Suppliers – Diagnostic Testing and Treatment Coverage

Sec. 3713. Coverage of the COVID-19 Vaccine under Part B of the Medicare Program without any Cost-Sharing. The deductible requirement for Medicare Part B will not apply to a COVID-19 vaccine.

Sec. 3201. Coverage of Diagnostic Testing for COVID-19. Requires all group health plans and health insurance issuers offering group or individual coverage to cover FDA-approved testing needed to detect or diagnose COVID-19 and the administration of that testing without cost-sharing or prior authorization requirements. The coverage includes any services or items provided during a medical visit—including telehealth services, in-person doctor visits, urgent care center and emergency room visits—that relate to COVID-19 testing or screening.

Sec 3202. Pricing of Diagnostic Testing. Requires all group health plans and health insurance issuers offering group or individual coverage to reimburse a test provider based on the rate negotiated between the plan and the provider that was put in place prior to the emergency. If no rate was negotiated, the plan is required to fully reimburse the provider based on the provider's own "cash price." The cash price for such service, COVID-19 testing or screening, must be listed by the provider on a public Internet website. Providers that fail to make their price publicly available could face a civil monetary penalty of up to $300 per day.

Sec. 3203. Rapid Coverage of Preventive Services and Vaccines for Coronavirus. Requires all group health plans and health insurance issuers offering group or individual coverage to cover, in addition to COVID-19 diagnostic testing, any qualifying COVID-19 preventive services. Qualifying preventive services include any items, services, or vaccines that are intended to prevent or mitigate COVID-19. Plans will be required to cover such vaccines, items, or services without cost-sharing within 15 days after a recommendation. Medicare Part B and Medicare Advantage plans are also required to cover the COVID-19 vaccine without cost-sharing.

16. All Providers and Suppliers – Health Care Workforce

Sec. 3401. Reauthorization of Health Professions Workforce Programs. Amends Title VII of the Public Health Service Act to authorize just over $23.7 million for each of fiscal year 2021 through 2025 to be provided to schools and other public and nonprofit health or educational entities that train future health care employees (*e.g.*, doctors, nurses, etc.) so they may offer programs in health professions education for under-represented minority individuals. Appropriates funds to be provided to various initiatives, including: $51.47 million in scholarship funds (16% or more of which must be distributed to nursing schools), $1.19 million per year for education loan repayment for individuals who are faculty at these schools, and $15 million in educational assistance to students from disadvantaged backgrounds. Schools are also eligible for grants to plan, develop, and operate a program that identifies or develops innovative models of providing care, and trains primary care physicians on such models.

Sec. 3402. Health Workforce Coordination. Requires development of a comprehensive and coordinated plan for health care workforce development programs of HHS, including education and training programs. The Secretary develops these programs in consultation with the Advisory Committee on Training in Primary Care Medicine and Dentistry and the Advisory Council on Graduate Medical Education, and they must include performance measures, identify gaps between program outcomes and health care workforce needs, identify actions to address the gaps, and identify barriers to implementing these actions.

Sec. 3403. Education and Training Relating to Geriatrics. Authorizes HHS grants, contracts or cooperative agreements for health professions schools and programs for the establishment or operation of programs that support the training of health professionals in geriatrics, including through: clinical training; interprofessional training; training-related community-based programs for older adults and caregivers; and Alzheimer's and dementia education for families and caregivers, direct care workers, health professions students, faculty, and providers.

Sec. 3404. Nursing Workforce Development. Authorizes funding for programs that are focused on developing and improving the nursing workforce to address national nursing needs (such as geographic shortages and increasing access and quality).

17. All Providers and Suppliers – Medicare Sequestration

Sec. 3709. Adjustment of sequestration. Temporarily lifts the Medicare sequester from May 1 to December 31, 2020. The impact of this provision is providing economic assistance to health care providers during the COVID-19 emergency period by boosting payments for health care services provided to Medicare beneficiaries.

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If you have additional questions or need further assistance, please feel free to reach out to our Health Care & Life Sciences Industry Group or your Winston relationship attorney.

We will be updating our COVID-19 perspectives here. Contact a member of our COVID-19 Legal Task Force here.

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