Katten

Health Care Advisory

The CARES Act From a Health CARE Perspective

March 30, 2020

On March 27, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act or the Act). This $2.2 trillion package is designed to provide relief to those impacted by the COVID-19 crisis. This Advisory provides a high-level summary of key sections of the Act that impact the health care industry. The Act does the following:

Coverage of Diagnostic Testing for COVID-19

- Requires health insurers and group health plans to cover diagnostic tests that can either detect SARS-CoV-2 or diagnose COVID-19 in a manner that does not impose cost-sharing or medical management requirements on individuals, as long as the tests meet certain criteria, such as the test being authorized under the U.S. Food and Drug Administration (FDA).

Cost of Diagnostic Testing

- Requires each provider of a COVID-19 diagnostic test to publicize the cash price of its diagnostic test on a public interest website provided by the respective provider. The Secretary of Health and Human Services (the Secretary of HHS) can impose a civil monetary penalty of up to $300 per day on a provider who fails to meet this obligation.

Clarification Regarding Coverage of COVID-19 Testing Products

- Removes the requirement that in vitro testing products for SARS-CoV-2 or COVID-19 be "approved, cleared or authorized" by the Federal Food, Drug, and Cosmetic Act in order to be considered reimbursable "medical assistance."

Reporting Requirement for Clinical Diagnostic Laboratory Tests

- Extends to December 31 the period for which no reporting to the Secretary of HHS is required with respect to clinical diagnostic laboratory tests that are not advanced diagnostic laboratory tests and provides that reporting of such tests are required between January 1–March 31, 2022.
- Extends the phase-in of Medicare payment rates for clinical diagnostic laboratory tests through 2024 by reducing the percentages by which payments may be reduced to 0 percent for 2021 and extending the 15 percent reduction from 2022–2024.

Rapid Coverage of Preventative Services and Vaccines for Coronavirus

- Directs the Secretary of HHS, the Secretary of Labor and the Secretary of the Treasury to require health insurers and group health plans to cover any "qualifying coronavirus preventative service." A qualifying coronavirus preventative service is an item, service or immunization that is intended to prevent or mitigate COVID-19 that is either: (1) evidence-based and has a rating of "A" or "B" in the current recommendations

of the U.S. Preventive Services Task Force; or (2) an immunization that is recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved.

Supplemental Awards for Health Centers

- Appropriates $1.32 billion, for the purposes of detecting SARS-Cov-2 or preventing, diagnosing and treating COVID-19, to eligible health centers that serve populations that are medically underserved or comprised of migratory and seasonal agricultural workers, the homeless or residents of public housing.

Grant Programs for Rural Health Care Services Outreach, Rural Health Network Development, and Small Health Care Provider Quality Improvement

- Provides that rural health care providers with demonstrated experience serving rural underserved populations can receive grants for up to five years to improve or provide access to basic services rather than solely essential services.
- Grants a funding increase to $79.5 million for fiscal years 2021-2025 rather than the previous $45 million per fiscal year.

United States Public Health Service Modernization

- Amended federal law so that Regular Corps and Ready Reserve Corps can be commissioned for public health and national emergencies.

Limited Liability for Volunteer Health Care Professionals During COVID-19 Emergency Response

- Provides that health care professionals who volunteer to provide health care services relating to the diagnosis, prevention or treatment of COVID-19 will not be liable for the provision of such services, so long as:
  1. The services fall within the scope of the health care professional's licensure;
  2. The services are performed in good faith and the individual being treated requires the services; and
  3. The services are provided in a manner that is not grossly negligent, reckless or while the health care professional is under the influence.
- Provides that volunteers cannot receive payment, or anything of value in lieu of payment, with the exception of items used to provide health care services or reimbursement for travel, food and board if the volunteer travels over 75 miles.

Nutrition Services

- Provides that individuals who are homebound as a result of social distancing during the COVID-19 public health emergency shall be treated the same (i.e., eligible for home delivered meals) as individuals homebound by reason of illness.
- Provides that federal nutritional requirements for home delivered meals may be waived during the COVID-19 public health emergency.

Continuity of Services and Opportunities for Participants in Community Service Activities

- Provides that the Secretary of Labor may allow participation in the community service employment program to extend beyond the program's maximum period of 48 months for participants in the program as of March 1.
- Provides that the Secretary of Labor may increase the average participation cap in the community service employment program beyond 72 months due to the effects of the COVID-19 public health emergency.

Reauthorization of Healthy Start Program

- Authorized $125.5 million for each of fiscal years 2021-2025 to be appropriated for the Healthy Start Initiative.
- Broadened the scope of considerations considered by the Secretary of HHS in making grants to applicants to include "poor birth outcomes (such as low birthweight and preterm birth) and social determinants of health" and communities with "high rates of infant mortality or poor perinatal outcomes in specific subpopulations within the community."

Importance of the Blood Supply

- Provides that the Secretary of HHS shall carry out a national campaign to support public awareness for the need of blood donations during the COVID-19 public health emergency, including announcements on television, radio, internet and newspapers. The Secretary of HHS may contract with public or private non-profit entities to facilitate this campaign.

Inclusion of Certain Over-the-Counter Medical Products as Qualified Medical Expenses

- Revises the Internal Revenue Code to (1) include menstrual care products as qualified medical expenses for purposes of account-based medical plans, including Health Savings Accounts (HSAs), Archer Medical Savings Accounts (Archer MSAs), Health Flexible Spending Accounts (Health FSAs) and Health Reimbursement Arrangements (HRAs); and (2) removes the limitation (added by the Affordable Care Act in 2010) requiring that Over-the-Counter drugs could only be reimbursed by such account-based plans with a prescription.

Improving Care Planning for Medicare Home Health Services

- Expands federal government payments to cover home health services that nurse practitioners, clinical nurse specialists or physician assistants may establish, certify and periodically review.

Adjustment of Sequestration

- Adjusts Medicare payments from May 1–December 31, so they are temporarily exempt from reduction under Medicare sequestration.

Add-on Payment for COVID-19 Patients Receiving Care at Inpatient Prospective Payment System Hospitals

- During the emergency period, the ACT will provide a 20 percent add-on to the diagnosis-related group rate for COVID-19 patients, who received care at inpatient prospective payment system hospitals.

Increasing Access to Post-Acute Care

- Provides that the Secretary of HHS waive the following:
  1. Requirement that inpatient rehabilitation facility patients receive at least 15 hours of therapy each week;
  2. Site-neutral payment rate provisions for long-term care hospitals, if the services are provided during the COVID-19 emergency period; and
  3. Payment adjustments for long-term care hospitals that do not have discharge payments of at least 50 percent.

Expansion of the Medicare Hospital Accelerated Payment Program

- Extends the accelerated payment program eligibility set forth in Section 1815(e)(3) of the Social Security Act to include, during a public health emergency, inpatient acute care hospitals, children's hospitals, hospitals involved in the extensive treatment or research of cancer and critical access hospitals.

- Provides that, upon the request of the hospitals, the Secretary of HHS may (1) make accelerated payments to the hospitals; (2) increase the amount of the payment to the hospitals by up to 100-125 percent, as applicable; and (3) extend accelerated payment periods to cover up to 6 months.
- Provides that, upon the request of the hospitals, the Secretary of HHS is required to (1) provide up to 120 days before claims are offset to recoup any accelerated payments; and (2) allow at least 12 months from the date of the first accelerated payment before requiring any outstanding balance be paid in full.

Health and Human Services Extenders

- Includes a variety of "Health and Human Services Extenders" to delay the start of previously-scheduled reductions in disproportionate share hospital (DSH) allotments to states, as well as aggregate reductions, to December 1. This provision is, by definition, especially important for those hospitals that treat a disproportionate share of needy individuals and receive much-needed Medicaid DSH payments.

Revising Payment Rates for Durable Medical Equipment under Medicare

- Payment rates for durable medical equipment and the maintenance and servicing related to such equipment has been extended from December 2020 through the duration of the COVID-19 emergency.

Coverage of the COVID-19 Vaccine Under Medicare Part B Without Cost-Sharing

- Amends Medicare Part B and Medicare Advantage plans to cover the COVID-19 vaccine without cost-sharing, once the vaccine is licensed and approved by the FDA.

Requiring Medicare Part D Prescription Drug Plans and Medicare Advantage Plans to Provide Three-Month Supplies of Prescription Drugs

- Requires Medicare Part D prescription drug plans and Medicare Advantage plans to provide three-month supplies of prescription drugs upon an enrollee's request, excluding prescription drugs with more stringent prescription and safety requirements (e.g., opioids).

Providing Home and Community-Based Services in Acute Care Hospitals

- Provides that 1902(h) of the Social Security Act shall not be construed to limit payment for certain (1) home and community based services; (2) self-directed personal assistance services; and (3) home and community based attendant services.
- Provides that 1902(h) of the Social Security Act shall not be construed to prohibit the services noted above from being provided in an acute care hospital, so long as the services received are (1) included in the individual's "person-centered plan of care"; (2) not otherwise met through the provision of hospital services; (3) not a substitute for other services the hospital is obligated to provide; and (4) designed to facilitate the transition to a community-based setting.

Clarification Regarding Uninsured Individuals

- Excludes from the Social Security Act's definition of "uninsured individual" any person under 65 years of age who is not pregnant and not entitled to, or enrolled for, benefits under part A or B of title XVIII of the Social Security Act and whose income does not exceed 133 percent of the poverty line, if the state that such person lives in does not otherwise provide medical assistance to such person.
- Exempts from the Social Security Act's general definition of "enrolled individual" (1) individuals who receive medical assistance under certain subsections of Section 1902 of the Social Security Act to the extent that such individuals are not deemed to have minimum essential coverage; and (2) certain pregnant women receiving medical assistance under limited subsections of Section 1902 of the Social Security Act.

Delaying Requirements for Enhanced Federal Medical Assistance Percentage

- Provides that, during the first 30 days after the enactment of the Families First Coronavirus Response Act (FFCRA), a state will not be disqualified from receiving an increase in Federal medical assistance funding on the basis that such state imposes a premium that violates the FFCRA, and such premium was in effect on the date the FFCRA was enacted.

Confidentiality and Disclosure of Records Relating to Substance Use Disorder

- Significantly amends the federal law governing the confidentiality of substance use disorder (SUD) records (42 U.S.C. 290dd-2 (Part 2 Law)) effective for uses and disclosures occurring 12 months after enactment of the Act. Key changes include:
  1. **Disclosures for treatment, payment and health care operations purposes with written consent; re-disclosure**. Once prior written consent is obtained, SUD records may be used or disclosed by a covered entity, business associate or Part 2 program for treatment, payment and health care operations purposes, as permitted by HIPAA regulations, and may be re-disclosed in accordance with HIPAA. An individual's written consent will apply to all future uses or disclosures until revoked in writing.
  2. **Restrictions on Disclosures**. An individual has a right to request restrictions on the disclosure of SUD records to health plans for payment and health care operations purposes, if the information pertains solely to a health care item or service for which the program has been paid in full.
  3. **Disclosure of De-Identified Information to Public Health Authorities**. SUD record information may be disclosed without consent to a public health authority if de-identified in accordance with HIPAA's de-identification standard.
  4. **Alignment to HIPAA Definitions**. The Part 2 Law is amended to incorporate HIPAA definitions of "breach," "business associate," "covered entity," "health care operations," "HIPAA regulations," "payment," "public health authority," "treatment," and "unsecured protected health information."
  5. **Prohibiting Use of Records in Proceedings Against Patients Absent Court Order or Patient Consent**. SUD records (or testimony of contents therein) may not be used in civil, criminal, administrative or legislative proceedings against a patient by any governmental authority, unless authorized by court order or patient consent, and specifically cannot: (a) be entered into evidence in criminal prosecutions or civil actions; (b) form part of the record for a decision or otherwise be taken into account in government agency proceedings; (c) be used by a governmental agency for law enforcement purposes or investigations; or (d) be used in a warrant application.
  6. **Violations Subject to HIPAA Civil and Criminal Penalties**. Violations of the Part 2 Law are made subject to the same civil monetary penalties as HIPAA violations and may be enforced by state attorneys general, in addition to the Secretary of HHS. Certain knowing and willful violations of the Part 2 Law are subject to criminal penalties under the HIPAA criminal statute.
  7. **Anti-Discrimination Provisions**. Entities are prohibited from discriminating against an individual based on information in SUD records in matters of health care, employment, worker's compensation, housing and government-funded or provided social services and benefits. Recipients of federal funds are prohibited from discriminating against an individual based on information in SUD records in affording access to federally-funded services.
  8. **HIPAA Breach Notification Duties**. HIPAA breach notification obligations apply to breaches of SUD information to the same extent, and in the same manner, as such provisions apply to a covered entity in the case of a breach of unsecured protected health information.
  9. **User-Friendly Notice of Privacy Practices**. The Secretary of HHS is required to update HIPAA's notice of privacy practice regulations to require covered entities and entities creating or maintaining SUD records to provide an easily understandable notice of privacy practices with regard to SUD records.

10. **No Limit on Patient's Right to Request Restrictions**. The amendments do not limit (a) a patient's right to request restrictions on uses or disclosures of the patient's SUD records for purposes of treatment, payment or health care operations; or (b) a covered entity's choice to obtain consent to use or disclose a SUD record to carry out treatment, payment or health care operations.
11. **"Sense of Congress" Statement**. Congress notes that: (a) providers treating patients in Part 2 programs are encouraged to access the state prescription drug monitoring database where clinically appropriate; (b) SUD patients have a right to request restrictions on disclosures of SUD records for treatment, payment and health care operations, and covered entities should attempt to accommodate such restrictions where feasible; (c) in applying the definition of health care operations [presumably to SUD programs], the definition should exclude the creation of de-identified information or limited data sets and fundraising; and (d) Part 2 programs should be incentivized to discuss with patients the benefits of consenting to the sharing of SUD records.

Guidance on Protected Health Information

- Requires the Secretary of HHS to issue guidance concerning the sharing of protected health information during the COVID-19 public health emergency within 180 days of enactment of the Act, including guidance on complying with HIPAA regulations and related policies.

Temporary Waiver of Requirement for Face-to-Face Visits Between Home Dialysis Patients and Physicians

- Revises the Social Security Act to permit the Secretary of HHS to, during a national emergency or public health emergency, waive the rule which requires a Medicare beneficiary to first undergo a face-to-face clinical assessment with a provider before obtaining monthly end stage renal disease related clinical assessments via telehealth.

Encouraging Use of Telecommunications Systems

- Instructs the Secretary of HHS to consider ways to encourage the use of telecommunications systems, including remote patient monitoring and other monitoring services, in the context of home health services that are furnished during a national emergency or public health emergency.

Telehealth Network and Telehealth Resource Center Grant Provisions

- The Act provides that eligible entities that render services through a "telehealth network" can receive grants for evidence-based projects that utilize telehealth technologies in rural areas, frontier communities and medically underserved areas, and for medically underserved populations, to expand and improve access to, and the quality of, health care services and health information available to health care providers, patients and their families. The composition of a "telehealth network" now includes providers of outpatient substance use disorder services and entities operating outpatient substance use disorder services facilities.
- Telehealth resource center grants may be awarded to eligible entities for products to support initiatives that utilize telehealth in such areas and communities.
- Grant recipients do not need to be nonprofit entities.
- Grant funding decreased from $60 million ($40 million for telehealth network and $20 million for telehealth resource center projects) to $29 million for each of fiscal years 2021-2025.

Exemption for Telehealth Services

- Provides a safe harbor for plan years beginning on or before December 31, 2021, permitting High Deductible Health Plans (HDHPs) to waive or reduce the plan deductible for telehealth and other remote care services. Normally, to be compatible with an HSA, any services for diagnosis or treatment covered by a HDHP would need to be subject to a minimum deductible of $1,400 for self-only coverage or $2,800 for family coverage.

Increasing Medicare Telehealth Flexibilities

- Authorizes the Secretary of HHS to waive or modify Medicare requirements for the payment of telehealth services in the case of a telehealth service furnished in an emergency area during an emergency and removes language limiting waivers to a telehealth service provided by a "qualified provider." Under the Coronavirus Preparedness and Response Supplemental Appropriations Act (H.R. 6074), the Secretary of HHS was authorized to waive only certain Medicare payment requirements relating to the definition of originating site and restrictions on the use of telephone, if the telephone has audio and video capabilities that are used for two-way, real-time communication. Further, those requirements could be waived only in the case of telehealth services furnished by a qualified provider, generally defined as a physician/practitioner who treated the individual during the prior three-year period. Thus, the "qualified provider" requirement had effectively limited waivers to telehealth services furnished by providers who had (or whose group had) an established relationship with the patient. The Act removes this limitation and significantly broadens the authority of the Secretary of HHS to waive or modify Medicare requirements for the payment of telehealth.

Enhancing Medicare Telehealth Services for Federally Qualified Health Centers and Rural Health Clinics

- Provides that, during the emergency period, the Secretary of HHS shall pay for telehealth services provided by a federally qualified health center (FQHC) or a rural health clinic (RHC) to an eligible telehealth individual enrolled in Medicare, notwithstanding that the FQHC or RHC providing the telehealth service is not at the same location as the beneficiary. The Act permits FQHCs and RHCs to serve as "distant sites" to provide telehealth services to eligible telehealth individuals and provides for the development of special payment rules relating to the same. The Act excludes costs associated with telehealth services from the calculation of prospective payment to the FQHC or all-inclusive rate payment to the RHC.

Use of Telehealth for Face-to-Face Encounters Prior to Recertification of Eligibility for Hospice Care

- Permits the use of telehealth to conduct face-to-face encounters prior to recertification of eligibility for hospice care during the emergency period.

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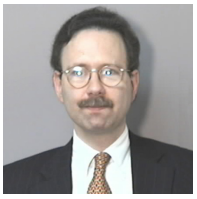

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