COVID-19: CARES ACT OVERVIEW: RELEVANT HEALTH CARE PROVISIONS

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U.S. Health Care Alert

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On March 27, 2020, the United States Congress passed the Coronavirus Aid, Relief, and Economic Security ("CARES") Act, which President Donald J. Trump signed into law on the same day (Public Law No: 116-136). [1] The CARES Act is the third in a series of recent government stimulus packages aimed at buoying the nation's economy during an economic downturn primarily triggered by the worldwide spread of COVID-19. In particular, the CARES Act includes an extensive $2 trillion federal aid package, which is comprised of a combination of funding for public health programs, tax benefits for businesses and individuals, appropriations for government programs supporting COVID-19 relief efforts, and other items to help stabilize the economy.

While the CARES Act includes broad financial aid nationally in response to the COVID-19 crisis, some of the CARES Act's most impactful provisions are those related to the expansion, relaxation, and/or clarification of certain rules/regulations/guidance in the health care industry. Indeed, the CARES Act includes provisions related to, inter alia, telehealth expansion, changes to confidentiality and disclosure requirements tied to substance use disorder records, and expansion of the Medicare hospital accelerated payment program during the COVID-19 crisis. What follows is an overview of the relevant health care-related provisions of the CARES Act, which are organized by various topical categories and subcategories.

I. APPROPRIATIONS

Title VIII, Public Health and Social Services Emergency Fund ("PHSSEF") - $100 Billion for Hospitals/Health Systems/Physician Practices. Allocating $100 billion to "health care related expenses or lost revenues that are attributable to coronavirus" for "eligible health care providers," and providing that funds are available until they are expended. "Eligible health care providers" is defined in the CARES Act as, "public entities, Medicare or Medicaid enrolled suppliers and providers, and such for-profit entities and not-for-profit entities … as the Secretary may specify … that provide diagnoses, testing, or care for individuals with possible or actual cases of COVID-19." This definition would, therefore, appear to cover a range of health care providers, such as hospitals, physician practices, long-term care providers, amongst others.

Several requirements must be met to receive funds under this allocation:

- Applicants "shall submit to the Secretary of Health and Human Services an application that includes a statement justifying the need of the provider for the payment and the eligible health care provider shall have a valid tax identification number." The CARES Act does not provide any further direction on the application process.

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- Rolling review of applications by the Secretary of Health and Human Services (the "Secretary").
- Payments can be prepaid, prospective, or retrospective payment, as determined appropriate by the Secretary. Further, payments "shall be made in consideration of the most efficient payment systems practicable to provide emergency payment."
- Funds must 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."
- "Recipients of payments under this paragraph shall submit reports and maintain documentation as the Secretary determines are needed to ensure compliance with conditions that are imposed by this paragraph for such payments, and such reports and documentation shall be in such form, with such content, and in such time as the Secretary may prescribe for such purpose." [2]

II. FEDERAL HEALTH CARE PROGRAM COVERAGE

A. Financial Assistance for Hospitals/Health Workforce/Patients

Secs. 3401 through 3404. Reauthorization of Health Professions Workforce Development and Training Programs. Amending sections of the Public Health Service Act ("PHSA") to reauthorize and fund a number of health professions workforce training support programs through 2025. These programs provide financial support to applicants offering clinical training and workforce development in a number of common specialty areas, including family medicine, general internal medicine, geriatrics, nursing, and others. The language of the reauthorization requires HHS to prioritize applicants who provide such training to residents in rural areas, including for Tribes and Tribal Organization in rural areas.

Secs. 3501 through 3519. COVID-19 Pandemic Education Relief Act of 2020. Establishing a number of loan forgiveness and financial support measures related to institutions of higher education and patients thereof that receive federal funding through loans or otherwise. These sections cover the following key measures:

- Public and nonprofit institutions of higher education are not required to provide a nonfederal share to match federal funds provided pursuant to Federal Supplemental Educational Opportunity Grants and Federal Work-Study Programs during award years 2019–2020 and 2020–2021.
- Institutions of higher education may reallocate certain federal funds for use as emergency financial aid grants for certain students.
- Students currently enrolled in institutions of higher education are excused from a number of federal loan repayment conditions and obligations associated with withdrawals or leaves of absence caused by a qualifying public health emergency.
- The Department of Education may grant waivers of certain federal assessment and accountability requirements to State education agencies and Indian Tribes.
- All payments due and interest accrual on federally held student loans are suspended through September 30, 2020.

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Sec. 3709. Adjustment of Sequestration. Providing that the Medicare programs are exempt from any budget sequestration order, regardless of the date of issue, for the period running from May 1, 2020 until December 31, 2020.

Sec. 3710. Medicare Hospital Inpatient Prospective Payment System Add-On Payment for COVID-19 Patients During Emergency Period. Amending Section 1886(d)(4)(C) of the Social Security Act to provide that, for hospital inpatients discharged during the COVID-19 emergency period, if the discharged patient was diagnosed with COVID-19, HHS shall increase the weighting factor that would otherwise apply to the IPPS DRG to which the discharge is assigned by twenty percent (20%).

Sec. 3711. Increasing Access to Postacute Care During Emergency Period. Providing for the following waivers of CMS requirements for postacute care during the COVID-19 emergency period:

- *Waiver of IRF 3-Hour Rule.* HHS is required to waive the requirement that IRF patients receive at least fifteen (15) hours of therapy per week.
- *Waiver of Site Neutral Rule for Payments to LTCHs.* HHS is required to (a) waive the payment adjustment for LTCHs that do not have a discharge payment percentage that is at least fifty percent (50%), and (b) waive the application of the site neutral payment rate for a discharge if the admission occurs during the COVID-19 emergency period and is in response to the COVID-19 public health emergency.

Sec. 3715. Providing Home and Community Based Services in Acute Care Hospitals. Amending Section 1902(h) of the Social Security Act to prohibit HHS from limiting the amount that may be paid under a State Medicaid plan for home and community-based services provided in an acute care setting.

Sec. 3719. Expansion of the Medicare Hospital Accelerated Payment Program During the COVID-19 Public Health Emergency. Amending Section 1815 of the Social Security Act to expand access to the Medicare Hospital Accelerated Payment Program during the COVID-19 emergency period to (a) children's hospitals, (b) cancer hospitals, and (c) critical access hospitals. This section also expands the recoupment period for advance payments offered under this program to one hundred twenty (120) rather than ninety (90) days until claims are offset to recoup the funds, and at least twelve (12) months before providers are required to repay the funds in full.

B. Telehealth Expansion

Sec. 3703. Increasing Medicare Telehealth Flexibilities During Emergency Period. Expanding the waiver of telehealth requirements under Medicare to eliminate the requirement that such services be provided by a provider that has furnished services to the patient in the past three years. Under the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (Public Law 116-123), the Secretary was empowered to waive certain telehealth restrictions during the COVID-19 public health emergency; however, such waiver required telehealth services to be provided by a "qualified provider," defined as a provider who has furnished services to the patient in the past three (3) years, among other requirements. Section 3703 amends this provision by eliminating the definition and references to qualified provider and, therefore, the three (3)-year restriction.

Sec. 3704. Enhancing Medicare Telehealth Services for Federally Qualified Health Centers and Rural Health Centers and Rural Health Clinics During Emergency Period. Enabling HHS to reimburse FQHCs and RHCs during a public health emergency for the provision of telehealth services to eligible individuals enrolled in a federal health care program, notwithstanding that the FQHC or RHC is not at the same location of the beneficiary.

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This is significant, as telehealth services provided by an FQHC or RHC are generally only reimbursable if the patient is located at the FQHC or RHC while receiving telehealth services. HHS is required to develop special payment rules for telehealth services provided by FQHCs and RHCs at a distant site.

Sec. 3705. Temporary Waiver of Requirement for Face-to-Face Visits Between Home Dialysis Patients and Physicians. Enabling HHS to allow health care providers to provide a monthly end stage renal disease-related clinical assessment by a physician to patients determined to have ESRD that are receiving home dialysis during a public health emergency, regardless of whether they have first received a face-to-face assessment from the physician.

Sec. 3706. Use of Telehealth to Conduct Face-to-Face Encounter Prior to Recertification of Eligibility for Hospice Care During Emergency Period. Enabling HHS to allow hospice physicians and hospice nurses to conduct a face-to-face encounter for purposes of recertifying eligibility for hospice care via telemedicine during a public health emergency.

C. Coverage of COVID-19-Related Testing/Vaccination

Sec. 3201. Coverage of Diagnostic Testing for COVID-19. Expanding the types of in vitro diagnostic products required to be covered without cost-sharing by group health plans and health insurers in the Families First Coronavirus Response Act ("FFCRA") (Public Law 116-127) to include those (1) for which a "developer has requested or intends to request emergency use authorization" from the FDA, unless and until the emergency use authorization request is denied or if the request is not submitted within a reasonable time; (2) "developed in or authorized by a State;" or (3) any other test determined appropriate by the Secretary. The FFCRA only required coverage of FDA-approved diagnostic tests. While mandatory coverage of FDA-approved diagnostics is still required, this section expands those types of COVID-19 tests that must be covered.

Sec. 3202. Pricing of Diagnostic Testing. Requiring group health plans and health insurers to reimburse providers for COVID-19 diagnostic testing at the negotiated rate with such provider that was in effect before the public health emergency. If the health plan or insurer does not have a negotiated rate, such plan or insurer must reimburse the provider at the cash price as listed on the provider's website or at a lower rate, if negotiated. Providers of COVID-19 diagnostic testing must publish their cash price for such testing on their public website and those who fail to comply with this publishing provision may be subject to a fine of up to $300 per day.

Sec. 3203. Rapid Coverage of Preventative Services and Vaccines for Coronavirus. Requiring coverage without cost-sharing by group health plan and health insurers of "qualifying coronavirus preventive service[s]." A qualifying coronavirus preventive service includes "an item, service, or immunization that is intended to prevent or mitigate coronavirus disease 2019" and that is either (1) "an evidence-based item or service that has in effect a rating of 'A' or 'B' in the current recommendations of the United States Preventive Services Task Force," or (2) "an immunization that has in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved." This section takes effect fifteen (15) days after the date on which a recommendation is made regarding a qualifying coronavirus preventive service.

Sec. 3713. Coverage of the COVID-19 Vaccine Under Part B of the Medicare Program Without Any Cost-Sharing. Amending Sections 1861(s)(10)(A), 1833(b), and 1852(a)(1)(B) of the Social Security Act to require full

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coverage of the COVID-19 vaccine, once developed, with no required cost sharing under Medicare Part B and Medicare Advantage.

Sec. 3716. Clarification Regarding Uninsured Individuals. Amending Section 1902 of the Social Security Act (enacted by the recently passed FFCRA), to clarify that, for purposes of the provision allowing states to offer free COVID-19 testing to uninsured individuals, the term "uninsured individuals" includes individuals who either (a) would be eligible for Medicaid if they lived in an expansion state, but do not live in an expansions state, or (b) have only limited Medicaid coverage due to a particular condition or situation.

Sec. 3717. Clarification Regarding Coverage of COVID-19 Testing Products. Amending Section 1905(a)(3) of the Social Security Act to clarify that the COVID-19 tests that states may cover under their Medicaid programs need not be limited to tests that are cleared or approved by FDA.

D. Reporting Requirements for Clinical Diagnostic Laboratory Tests

Sec. 3718. Amendments Relating to Reporting Requirements with Respect to Clinical Diagnostic Laboratory Tests. Amending Section 1834A(a)(1)(B) of the Social Security Act to delay for one (1) year both the reporting of private payment rates for clinical laboratory tests and the associated implementation of adjusted Medicare payment rates for such tests based on the private payor data.

E. Durable Medical Equipment Payment Rates

Sec. 3712. Revising Payment Rates for Durable Medical Equipment Under the Medicare Program Through Duration of Emergency. Compelling HHS to apply the transition rules set forth at 42 C.F.R. § 414.210 (g) (9) (iii) for the duration of the COVID-19 emergency period, except that, for areas other than rural or noncontiguous areas, calculation of the transition reimbursement amount should be based on seventy-five percent (75%) of the adjusted payment amount established by CMS, and twenty-five percent (25%) of the unadjusted fee schedule amount. In essence, this will provide for a gentler transition curve to adjusted fee schedule amounts for certain items of DME that will stay in place for the duration of the COVID-19 emergency period.

F. Home Health Services

Sec. 3707. Encouraging the Use of Telecommunications Systems for Home Health Services Furnished During Emergency Period. Requiring HHS to consider ways in which to encourage the use of telecommunications technology for the remote provision of home health care, in a manner consistent with the plan of care for each individual. This section specifically mentions the use of remote patient monitoring, as described at 42 C.F.R. § 409.46 (e).

Sec. 3708. Improving Care Planning for Medicare Home Health Services. Amending Section 1814(a) of the Social Security Act to allow nurse practitioners, clinical nurse specialists, and physician assistants to certify and recertify home health plans, so long as they do so in accordance with applicable state scope of practice limitations, including that the face-to-face encounter required for the certification or recertification may be performed by the nurse practitioner, clinical nurse specialist, or physician assistant. This modification will become effective on a date determined by HHS, but in no event later than six (6) months following enactment of the CARES Act.

III. COVERAGE AND REPORTING REQUIREMENTS FOR DEVICES, MANUFACTURERS, AND DRUGS

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Sec. 3103. Treatment of Respiratory Protective Devices as Covered Countermeasures. Adding respiratory protective devices approved by the National Institute for Occupational Safety and Health ("NIOSH") and that the Secretary determines to be a priority for use to the definition of "Covered Countermeasure" under the Public Readiness and Emergency Preparedness Act ("PREP Act"). [3] The Secretary issued a PREP Act Declaration with an effective date of February 4, 2020, which provides immunity from tort liability claims to those that manufacturer, distribute, administer, prescribe, or use Covered Countermeasures. [4] This section expands the type and number of respiratory protective devices provided with PREP Act Immunity, as previously only those with FDA approval were included in the definition of Covered Countermeasure and numerous NIOSH-approved devices are not regulated by the FDA.

Sec. 3112. Additional Manufacturer Reporting Requirements in Response to Drug Shortages. Adding (1) any drug that is critical to the public health during a public health emergency and (2) active pharmaceutical ingredients ("API") of any such drug to the list of disclosures that manufacturers must report to the FDA if production is interrupted or discontinued. See Sec. 3121 for similar provision for medical devices. Additionally, manufacturers must develop, maintain, and implement a "redundancy risk management plan" that identifies and evaluates risks to the supply of a drug or API. Certain biological products or categories of biological products may be exempted from such reporting requirements, if such product is not necessary to protect public health.

Sec. 3121. Discontinuance or Interruption in the Production of Medical Devices. Requiring manufacturers of medical devices that are (1) "critical to public health during a public health emergency" or (2) identified by the Secretary as devices "for which information on potential meaningful supply disruptions of such device[s] is needed during, or in advance of, a public health emergency" to report permanent discontinuances or meaningful interruptions in the manufacturing of such devices. Devices that are critical to public health include "those that are life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery." Such notice must be provided six (6) months prior to the date of the discontinuation or interruption, or as soon as practicable, and the Secretary will issue a letter to those who fail to provide the notice. Manufacturers will have thirty (30) days to respond to the letter and it will be published on the FDA website forty-five (45) days after its issuance. The Secretary may notify industry stakeholders of the shortage as appropriate and practicable, but may choose not to inform stakeholders, if disclosure would affect the public health.

Sec. 3302. Priority Zoonotic Animal Drugs. Adding a new Section 512A to the FDCA that provides for expedited FDA review of applications for new animal drugs intended to prevent or treat a zoonotic disease in animals, including a vector borne disease that has the potential to cause serious adverse or life threatening diseases or health consequences in humans. Sponsors of new animal drug applications wishing to take advantage of priority designation under Section 512A must request such designation at the time the application is submitted to the FDA. If approved, the FDA may take a number of actions (summarized at Section 512A (c)(2) of the FDCA) to facilitate the rapid review and approval of the application.

IV. CONFIDENTIALITY & PROTECTED HEALTH INFORMATION

Sec. 3221. Confidentiality and Disclosure of Records Relating to Substance Use Disorder. Revising the federal substance use disorder statute, at 42 U.S.C. § 290dd-2, to allow for the use and disclosure of substance use disorder records from federally assisted programs ("Part 2 Records") for treatment, payment, and operations, consistent with HIPAA and its attendant regulations once written patient consent is obtained. Such records also

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may be redisclosed, consistent with HIPAA. A patient's prior written consent, given once, is permissible for the disclosure of Part 2 Records for all future uses and disclosures by the Part 2 program, a Covered Entity, or Business Associate for its treatment, payment, and health care operations purposes. Exceptions where patient consent is not needed are expanded to include the disclosure of de-identified Part 2 Records to a public health authority (as defined by HIPAA). Prohibitions on the use of Part 2 Records in criminal matters is expanded to include administrative and legislative proceedings, and additional provisions reiterate prohibited uses in any criminal, civil, or agency actions and for law enforcement purposes. A new provision prohibits discrimination based on intentional or unintentional Part 2 disclosures in housing, employment, the provision of health care, access to legal services, and access to social services. The breach notification standard of the HITECH Act now applies to Part 2 Records, and violations are no longer subject to criminal penalties but are subject to HITECH/HIPAA penalties.

Sec. 3224. Guidance on Protected Health Information. Requiring that, no later than September 23, 2020, pursuant to 45 C.F.R. § 160.103, the Secretary must issue guidance on the sharing of patient's protected health information during the COVID-19 public health emergency, including compliance with HIPAA and its attendant regulations.

V. FILLS AND REFILLS FOR COVERED PART D DRUGS

Sec. 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. Amending Section 1860D-4 of the Social Security Act to require Medicare Part D and Medicare Advantage prescription drug plans to allow Part D eligible enrollees to obtain a single fill of the total day supply prescribed for the individual, not to exceed a ninety (90) day supply.

VI. HEALTH SAVINGS ACCOUNTS

Sec. 3701. Exemption for Telehealth Services. Adding a safe harbor to the Internal Revenue Code for high deductible health plans that fail to have a deductible for telehealth and other remote care services. For health plan years beginning on or before December 31, 2021, a health care plan may be treated as a high deductible plan even if there is no deductible for telehealth and remote care services.

Sec. 3702. Inclusion of Certain Over-the-Counter Medical Products as Qualified Medical Expenses. Expanding the definition of “qualified medical expenses” to include “menstrual care products.” For menstrual care product expenses incurred after December 31, 2019, such expenses may be purchased using funds from health savings accounts, health flexible spending arrangements, and health reimbursement arrangements. Menstrual care products “means a tampon, pad, liner, cup, sponge, or similar product used by individuals with respect to menstruation or other genital tract secretions."

VII. HEALTH CARE PROFESSIONALS

Sec. 3215. Limitation on Liability for Volunteer Health Care Professionals During COVID-19 Emergency Response. Limiting tort liability under both state and federal law for any harm caused by an act or omission of a volunteer health care professional who is providing health care services in his or her capacity as a volunteer in response to the COVID-19 public health emergency. The section does not apply if “the harm was caused by an

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act or omission constituting willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious flagrant indifference to the rights or safety of the individual harmed by the health care professional," or if "the health care professional rendered the health care services under the influence (as determined pursuant to applicable State law) of alcohol or an intoxicating drug."

Volunteer is defined as "health care professional who, with respect to the health care services rendered, does not receive compensation or any other thing of value in lieu of compensation."

Compensation "includes a payment under any insurance policy or health plan, or under any Federal or State health benefits program," but excludes (1) "receipt of items to be used exclusively for rendering health care services in the health care professional's capacity as a volunteer," and (2) "any reimbursement for travel to the site where the volunteer services are rendered and any payments in cash or kind to cover room and board, if services are being rendered more than 75 miles from the volunteer's principal place of residence."

Health care professional is defined as "an individual who is licensed, registered, or certified under Federal or State law to provide health care services."

Health care services is defined as "any services provided by a health care professional, or by any individual working under the supervision of a health care professional that relate to (A) the diagnosis, prevention, or treatment of COVID-19; or (B) the assessment or care of the health of a human being related to an actual or suspected case of COVID-19."

Harm "includes physical, nonphysical, economic, and noneconomic losses."

VIII. HEALTH AND HUMAN SERVICES EXTENDERS

Sec. 3813. Delay of DSH Reductions. Postponing Disproportionate Share Hospital ("DSH") reductions through November 30, 2020, unless United States Congress intervenes.

Sec. 3831. Extension for Community Health Centers, the National Health Service Corps, and Teaching Health Centers that Operate GME Programs. Extending applicable date through November 30, 2020.

NOTES:

[1] *See* Coronavirus Aid, Relief, and Economic Security Act (Public Law No: 116-136) [hereinafter, CARES Act].
[2] Title VIII of the CARES Act also provides that "not less than $250,000,000 shall be available for grants to or cooperative agreements with entities that are either grantees or sub-grantees of the Hospital Preparedness Program authorized in section 319C–2 of the PHSA or that meet such other criteria as the Secretary may prescribe, with such awards issued under such section or section 311 of such Act."
[3] 42 U.S.C. § 247d–6d.
[4] Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 FR 15198 (March 17, 2020).

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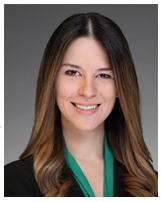

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