THE CARES ACT: CHANGES SPECIFICALLY IMPACTING HEALTH CARE PROVIDERS AND SUPPLIERS

On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act (the "Act"). The purpose of the Act is to address the numerous areas impacted by the COVID-19 pandemic, including public health, business, economic, and others. This article sets forth major impacts of the Act on health care providers and suppliers.

Health Insurer Reimbursement of COVID-19 Services

The Act modified the Families First Coronavirus Response Act ("FFCRA") to increase access to care during the COVID-19 pandemic. Health insurance plans covering diagnostic tests are required under the Act to reimburse a provider either at a rate negotiated with the provider or an amount equal to the cash price for the test listed on the provider's public website. It is important to note that the Act requires providers of COVID-19 diagnostic tests to make their cash price for their tests available on their public websites. Providers who do not publicize the cash price for their diagnostic test(s) could face a civil monetary penalty of $300 per each day that they are out of compliance.

Additionally, health insurance plans are required to cover the costs of any "qualifying coronavirus preventive services" without cost-sharing being imposed on the patients. "Qualifying coronavirus preventive services" are items, services, or immunizations that are intended to prevent or mitigate COVID-19 and are either an evidence-based item or service with an "A" or "B" rating, or an immunization that recommended by the Centers for Disease Control and Prevention.

Limitations on Liability

Congress has stepped into an area of traditional state law by limiting the liability of a health care professional for any harm caused by any act or omission while providing services under certain circumstances during the public health emergency. The limitation of liability applies if the professional is:

1. Providing care or services as a volunteer;

2. The act or omission occurs in the course of providing services in the capacity of a volunteer;

3. The services are within and do not exceed the scope of his/her license under state law;

4. The services were related to the diagnosis, prevention, or treatment of COVID-19 or the assessment or care of an actual or suspected case of COVID-19; and

5. The professional was acting in good faith.

This limitation on liability does not apply if the professional acted with willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious flagrant indifference to the rights or safety of the individual harmed or if he/she provided services while under the influence of alcohol or an intoxicating drug.

Confidentiality of Substance Use Disorder Records

The Act makes several important changes to the confidentiality of substance use disorder records. While consent of the patient is still required to make a disclosure, once prior written consent is obtained, the contents "may be used or disclosed by a covered entity, business associate, or a program subject to this section for purposes of treatment, payment, and health care operations as permitted by the HIPAA regulations. Any information so disclosed may then be redisclosed in accordance with the HIPAA regulations." 42 U.S.C. 290dd-2(b)(1)(B). The patient's consent only needs to be obtained once, unless the patient revokes the consent in writing. Additionally, the Act permits substance use disorder records to be de-identified in accordance with HIPAA and to be disclosed to a public health authority. Please see "SUD Program Privacy Rules Modified by CARES ACT" available at: https://www.dickinson-wright.com/news-alerts/sud-program-privacy-rules-modified-by-cares-act for more information on these changes.

Congress has directed the Secretary to issue guidance within 180 days after the enactment of the Act on sharing a patient's information in response to public health emergencies.

Additional Telehealth Modifications

The Act modifies a number of provisions related to telehealth services to increase access during this emergency period. Most of these changes have been made to increase access for Medicare and Medicaid beneficiaries. One interesting change not directly related to reimbursement is the modification to the Internal Revenue Code's (the "IRC") deductions for Health Savings Accounts ("HSAs"). 26 U.S.C. 223. Under the IRC, individual taxpayers are eligible for an itemized deduction for payments to HSAs. For eligibility, an individual must be covered by a high-deductible health plan, which is a plan with an annual minimum deductible of $1,000 for an individual or $2,000 for a family, and the sum of the annual deductible and other out-of-pocket expenses of not more than $5,000 for an individual and $10,000 for a family. The modification creates a safe harbor so that plans charging no deductible for telehealth and other remote care services can still qualify as a high-deductible health plan and individuals can remain eligible for the deduction for contributions to HSAs.

The Act also modifies the waiver authority under Section 1135 of the Social Security Act (the "SSA"), 42 U.S.C. 1320b-5, to give the Secretary greater flexibility to grant waivers from requirements related to telehealth during an emergency period. The limitation requiring a "qualified provider" to provide the service was removed. A "qualified provider" was a physician

or practitioner who furnished services to a beneficiary or is in a practice with another physician who furnished an item or services to a beneficiary in the three years prior to the telehealth service. Additionally, the limitations that the facility fee can only be paid to an "originating site" and that a telephone used for telehealth must have audio and video capabilities were removed. These provisions were limitations on the Secretary's Section 1135 waiver authority; they do not change the general telehealth requirements.

Prior telehealth coverage requirements specified that the "physician or practitioner located at a distant site that furnishes a telehealth service to an eligible telehealth individual" would receive payment. A "distant site" was previously limited to "the site where the physician or practitioner delivering the service is located at the time the service is provided via a telecommunications system." 42 C.F.R. 410.78(a)(2). However, during an emergency period, Federally Qualified Health Centers and Rural Health Clinics now can also act as distant site providers and be reimbursed by Medicare for the telehealth services. Additionally, Congress has advised that these payments made to Federally Qualified Health Centers and Rural Health Clinics are not to be used to calculate payments under the prospective payment system.

The Act also makes important changes to the use of telehealth for certain home care services. Prior requirements for patients receiving home dialysis treatment required a physician to complete an in-person clinical assessment monthly during the initial three month period and then once during each subsequent three month period. These restrictions have been temporarily suspended to permit the monthly assessments to be done through a telehealth service. Additionally, the face-to-face encounter prior to the 180th-day recertification for home health services can be completed through telehealth. Congress has directed the Secretary to consider how telehealth, remote patient monitoring, and other technology-based services can be used by home health agencies to provide services in a manner consistent with the patient's plan of care. It is important to remember, these changes are for the emergency period only, and do not permanently modify restrictions on these services.

Congress granted the Secretary additional authority to authorize grants related to telehealth networks and services, for the purpose of expanding access to these services and supporting initiatives that utilize telehealth technologies.

Modifications to Home Health Services

The Act also makes important changes to the normal provision of home health services. One important change is the expansion of the scope of nurse practitioners, clinical nurse specialists, and physician's assistants in the provision of home health services, from the date of enactment of the Act to a period set by the Secretary no more than six months from enactment. Nurse practitioners, clinical nurse specialists, and physician assistants will be permitted, during this period, to certify and recertify patients for home health services and review the patient's plan of care. Additionally, while prior law required patients to be under the care of a physician, during

the emergency period, beneficiaries can be under the care of nurse practitioners, clinical nurse specialists, and physician's assistants and still qualify for services. Finally, during this period, nurse practitioners, clinical nurse specialists, and physician's assistants may also prescribe covered osteoporosis drugs to be furnished by a home health agency. In order to qualify, nurse practitioners, clinical nurse specialists, and physician's assistants must be licensed and acting within the scope of State law and must be enrolled as Medicare providers. This expansion also applies to Medicaid covered home health services.

Modifications to Payments

The Act includes multiple modifications to the payment rates. The weighting factor for the diagnosis related group for a discharge of a beneficiary diagnosed with COVID-19 under the inpatient prospective payment system ("IPPS") is to be increased by 20%. Notably, this increase is not to be used in applying budget neutrality requirements of the IPPS.

Payments for durable medical equipment ("DME") are transitioning based on a list of factors enumerated in 42 C.F.R. 414.210. Medicare had originally established a transition period that went through December 31, 2020. However, Congress has extended these transition periods through the emergency period, if the emergency period extends past that date. For rural and noncontiguous areas (Alaska, Hawaii, and U.S. territories), the payment amount will be equal to 50% of the adjusted amount and 50% of the unadjusted fee schedule amount. For other areas, the DME fee schedule is equal to 75% of the adjusted payment amount and 25% of the unadjusted amounts for items furnished.

Finally, Congress has expanded which hospitals with significant cash flow problems may request accelerated payments. This expansion now includes hospitals with inpatient populations predominantly under the age of 18, hospitals operating a demonstration project, hospitals recognized as comprehensive cancer centers, cancer research centers, or clinical centers, and critical access hospitals. These hospitals may request accelerated payments on a periodic or lump sum basis. Additionally, at the request of the hospital, the Act provides a 120-day grace period before claims are offset to recoup the accelerated payments and grants the hospital 12 months before the full amount of the accelerated payment is due.

Increased Access to Acute Care and Post-Acute Care Services

The Act permits acute care hospitals serving a disproportionate number of low-income patients to provide home and community-based services approved by the Secretary under a waiver or demonstration project, so long as the services are identified in an individual's person-centered care plan, provided to meet the needs of the patient that are not met through hospital services, do not substitute for hospital services the hospital is required to provide, and are designed to ensure smooth transitions between acute care and home and community-based services.

The Act also waives several requirements related to post-acute care for patients in an inpatient rehabilitation facility ("IRF") and long-term care hospitals ("LTCH"). The requirements that beneficiaries be capable of three hours of therapy, five days per week ("15-hour therapy requirement") in order for an IRF claim to be considered medically necessary have been waived for the emergency period. For LTCHs, the requirements that they must achieve a 50% discharge payment percentage and the site-neutral IPPS payment rate for admissions have been waived during the emergency period.

Medication Changes

The Act has included the "COVID-19 vaccine and its administration" in the definition of "Medical and other health services" under Medicare Part B. Additionally, the COVID-19 vaccine and its administration have been excluded from the deductible beneficiaries are required to pay, so that beneficiaries would not be required to pay for these services.

Congress has also directed that Medicare Part D prescription drug plans or Medicare Advantage Prescription Drug Plan ("MA-PD") permit enrollees to receive a three-month supply of their Part D covered medication unless there is an applicable safety edit assigned to that drug.

Increased Funding for Certain Programs

The Act has expanded both the time period numerous programs may receive funding and the amount of funding they may receive. Funding for Qualified Teaching Health Centers for direct and indirect expenses related to maintaining, expanding, and establishing new graduate medical residency training programs has been increased for 2018 and 2019 to $126,500,000 for the fiscal year 2020, and an additional $21,141,096 has been approved for the period of October 1, 2020, through November 30, 2020.

There is additional funding for diabetes programs. For programs researching type I diabetes, there is an increase for the fiscal year 2020 to $150,000,000 and an additional $25,068,493 for the period of October 1, 2020, through November 30, 2020. For programs for the prevention and treatment of diabetes through Indian health facilities, there is an increase to $150,000,000 through the fiscal year 2020 and an additional $25,068,493 for the period of October 1, 2020, through November 30, 2020.

Congress has also appropriated $1,320,000,000 for the fiscal year 2020 for supplemental grants awarded by the Secretary of the U.S. Department of Health and Human Services (the "Secretary") for "the detection of SARS-CoV-2 or the prevention, diagnosis, and treatment of COVID-19."

The Act modifies grants for rural health care services. The current Public Health Act grants apply to programs "to expand access to, coordinate, and improve the quality of *essential* health care services." 42 U.S.C. 254c(d)(2)(A) (emphasis added). The Act modifies this to apply to "basic

health care services," rather than "essential health care services. Additionally, an entity no longer needs to be a rural public or rural nonprofit private entity to qualify for these grants. The Act expands the qualifications to any "entity with demonstrated experience serving, *or the capacity to serve*, rural underserved populations." These modifications, while small in words, could have significant benefits to providers looking to serve rural areas and the services they can provide.

Congress has appropriated $40,737,000 for eligible entities or health professional schools/programs to establish Geriatrics Workforce Enhancement Programs. Grant recipients shall support the training of health professionals in geriatrics. Additionally, the Secretary may provide geriatric academic career awards to eligible entities to promote career development of academic geriatricians or geriatrics health professionals. Awards are limited to five years and shall be at least $75,000 for the fiscal year 2021, and will be adjusted in subsequent years in accordance with the consumer price index.

Congress also expands grants to nursing programs and creates a new Authorized Clinical Nurse Specialist Program to provide training to clinical nurse specialists and qualified nurses to effectively provide care through the wellness and illness continuum to patients with acute and chronic illnesses.

Medical Supplies and Shortages

Under the Act, Congress directed the Secretary to review and assess the medical product supply chain within 60 days, focusing on critical drugs and devices sourced or manufactured outside the United States, gaps in the supply chain, and the economic impact of increased domestic manufacturing, and to report on recommendations to improve the supply chain. Such recommendations could have significant impacts on supply chains for practitioners, affecting where and how they get their medical supplies in the future.

Manufacturers of life-supporting drugs, life-sustaining drugs, drugs for a debilitating disease and condition, or drugs critical to public health emergencies must now disclose the reason for a discontinuance or interruption of such drugs. Congress directed the Secretary to prioritize and expedite the review of new drug applications for drugs to help mitigate the harm of discontinuation or interruption. The Secretary is also directed to prioritize and expedite inspections of facilities that could help mitigate or prevent drug shortages. Manufacturers of such drugs must also develop Risk Management Plans to identify and evaluate the risk to drug supplies, and such plans may be inspected and copied by the Secretary.

Congress has also placed a new obligation on medical device manufacturers. A manufacturer of a device that is critical during a public health emergency or which the Secretary determines information is needed in the event of potential disruptions must notify the Secretary of a permanent discontinuance or an interruption that would likely lead to a meaningful disruption in the supply of that device. Manufacturers will be required to submit this notification either during

or in advance of a public health emergency; or at least six months (or as soon as practicable) prior to an expected discontinuance or interruption.

Additionally, the Secretary must establish and make an up-to-date list of devices the Secretary determines to be in shortage in the United States which shall be disclosed to appropriate organizations, including physicians, health providers, patient organizations, and supply chain partners. However, the Secretary is not permitted to violate any rights to trade secrets and confidential information in these public filings or disclose information that would adversely affect public health.

Conclusion

Above are key highlights of the changes implemented by the CARES Act. Do not hesitate to reach out to your Dickinson Wright Health Care Attorneys with any questions you may have regarding the changes. We are here to help you navigate through these changes.

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