The CARES Act, while viewed as an economic stimulus bill, contained many impactful health care policies that will alter federal programs on a long-term basis.

In passing the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (P.L. 116-136) on March 27, 2020, Congress prioritized patient access to care and patient safety over the competing interests of payers and even privacy during the public health emergency brought on by the novel coronavirus (COVID-19). The law allows for increased usage of telehealth, boosts Medicare payments for hospitals, and allows providers certain additional flexibility. This Strategic Perspective explores the most impactful health care provisions of the CARES Act, which attorney experts Michael Clark and Laura Collins from Baker, Donelson, Bearman, Caldwell & Berkowitz, PC described in an interview with Wolters Kluwer as "breathtaking in scope," but, along with other government actions, "reactive."

**Medicare payment provisions and new operational flexibility benefit providers**

In a sweeping relief measure for many providers, the Medicare sequester, an annual 2 percent cut in payments, is suspended from May 1, 2020 through the rest of the calendar year under section 3709 of the CARES Act. However, to offset the cost of suspending the cuts for this year, the sequester is extended by one year and will last through 2030. Additionally, the entirety of $4 billion in scheduled payment cuts to disproportionate share hospitals (DSHs) have been eliminated for fiscal year (FY) 2020, and the cuts for FY 2021 have been halved from $8 billion to $4 billion under section 3813. Price reductions to the durable medical equipment (DME) payment methodology were suspended for areas other than rural and noncontiguous, as were scheduled reductions in payments for clinical diagnostic laboratory tests for 2021, under sections 3712 and 3718, respectively.

**Hospital payments.** The CARES Act also provided some financial aid to hospitals through increased and advanced payments. Under section 3710, hospitals will receive a 20 percent increase to the diagnosis-related group weighting factor when a patient diagnosed with COVID-19 is discharged. In addition, section 3719 expanded the hospital accelerated payment program. Upon request, HHS may provide accelerated payments on a periodic or lump-sum basis, increase the amount of payment up to 100 percent (125 percent for critical access hospitals), and extend accelerated payment periods to cover up to six months. HHS is required to provide, if requested, up to 120 days before claims are offset to recoup the accelerated payment and allow at least 12 months from the first accelerated payment to require the outstanding balance to be paid in full. This payment relief comes as hospitals are forced to cancel elective procedures in favor of patient safety.

**Post-acute care.** Section 3711 provides care provision and payment flexibility for post-acute care providers. During the public health emergency, inpatient rehabilitation facilities (IRFs) are released from the requirement under 42 C.F.R. §412.622 that patients receive at least 15 hours of therapy each week (known as the three-hour rule). Long-term care hospitals (LTCHs) received a waiver of certain payment rate provisions. During the public health emergency, an LTCH can maintain its long-term care status even if fewer than 50 percent of its Medicare cases are paid under the LTCH prospective payment system (PPS). Additionally, the current LTCH site-neutral payment policy that uses an inpatient prospective payment system (IPPS) payment rate for patients with less severe cases has been suspended.
Telehealth. Typically, *Soc. Sec. Act §1834(m)* severely limits Medicare payment for telehealth services, generally requiring the patient to be in a designated rural area and receive the telehealth services at a medical facility. The Coronavirus Preparedness and Response Supplemental Appropriations Act (P.L. 116-123) amended HHS’ emergency response powers under *Soc. Sec. Act §1135* to allow HHS to waive the “originating site” requirements that typically prevent a patient from receiving telehealth services at home and restriction on use of telephones under *42 C.F.R §410.78(a)(3)*, as long as the phone has audio and video features that are used for interactive communication. However, this statute required that the provider have furnished, or be part of the same practice in which another provider has furnished, face-to-face services to that patient within the last three years in order to receive payment for telehealth services. The CARES Act officially removed this three-year requirement in section 3703, although CMS stated in a fact sheet pre-dating the CARES Act that if a section 1135 waiver required an established relationship for telehealth services, HHS would not conduct audits to ensure that such a relationship existed for telehealth claims submitted during the COVID-19 public health emergency.

CARES Act section 3704 provided that federally qualified health centers (FQHCs) and rural health clinics (RHCs) are able to serve as “distant sites” to provide telehealth services. These providers will be reimbursed at similar rates under the physician fee schedule for telehealth services. Sections 3705 through 3707, respectively, waive the requirement of face-to-face visits between home dialysis patients and physicians, allow for the use of telehealth to conduct face-to-face encounters for hospice care eligibility recertifications, and require HHS to consider ways to encourage the use of telehealth for home health services.

The Baker Donelson experts highlighted the various telemedicine provisions in recent legislation, regulations, guidance, and licensure requirements as particularly innovative and beneficial to the health care industry long term. Clark noted that even "provincial protectionist state medical boards have reluctantly begun to realize that telemedicine regulation should be liberalized." Most states have modified their in-state licensure requirements for telehealth to allow providers from out-of-state to provide health care services via telemedicine—while also providing emergency licensure to out-of-state providers who are able to travel in person to the various "hotspots" to provide care. Clark calls for even more expansive access to practice, and feels that the current circumstances are a "good time to remove unnecessary barriers to access by implementing national licensure of health care professionals."

**Home health certifications and care planning.** In addition to requiring HHS to clarify guidance and conduct outreach on using telehealth as appropriate for providing home health services, the CARES Act significantly improves access to home health services by allowing certifications to be made by non-physician practitioners. Under section 3708, nurse practitioners, clinical nurse specialists, and physicians assistants may certify and recertify patient need for home health care under Medicare Parts A and B and Medicaid. These non-physician practitioners can also establish and review the plan of care. Clark applauded the move, noting that these practitioners “are fully capable of assessing when patients require home health care services.” The HHS Secretary is required to promulgate regulations to this effect no later than six months after the enactment of the CARES Act.

**Loosened privacy rules reduce fear of OCR**

CARES Act section 3224 required HHS to release guidance on sharing protected health information (PHI) during the public health emergency within 180 days of enactment. The guidance must include information on regulatory compliance with the Health Insurance Portability and Accountability Act (HIPAA). Prior to the passage of the CARES Act, the HHS Office for Civil Rights (OCR) issued a notification on March 17, 2020, stating that during the public health emergency, OCR would not impose penalties on providers for failing to comply with HIPAA requirements when using telehealth in good faith.

By using enforcement discretion, OCR allows providers to use technology like direct video chat applications with patients’ phones or computers, even if that technology would typically not comply with HIPAA requirements. Providers are freely able to use telehealth for any reason, even if treatment is not related to COVID-19, in order to reduce risk of exposure. OCR encouraged providers to let patients know that common applications, such as...
FaceTime, Skype, Zoom, or Facebook Messenger video chat may present privacy risks. Any public facing video communications, like Facebook Live and Twitch, are not permitted under OCR’s notice.

For providers seeking additional privacy protections, OCR also provided a list of video applications that hold themselves out to be HIPAA-compliant and will enter into business associate agreements (BAAs) under HIPAA to provide services. These options include Zoom for Healthcare, GoToMeeting, and Microsoft Teams. However, OCR cautioned that it does not endorse the listed products and has not reviewed their BAAs. The agency will not impose penalties for using products from video technology vendors without a BAA.

**Substance use disorder patient records.** Medical records related to substance use disorder (SUD) have received heightened privacy protections under [42 C.F.R. Part 2](#) for many years, in order to encourage patients to seek necessary treatment. Congress used the CARES Act to legislate permanent reform that has been under discussion for several years and aligned "Part 2" protections with HIPAA requirements—requiring HHS to revise Part 2 regulations within 12 months to comply with the law. Under section 3221, instead of requiring specific authorization of disclosures as before, an initial patient consent allows SUD-related records to be shared with covered entities, business associates, or programs for purposes of treatment, payment, and health care operations (TPO) just like other medical records under HIPAA. Additionally, once information has been released for TPO reasons, the receiving entity can now use or re-disclose that information for TPO purposes without seeking another authorization. This initial consent stands until revoked.

Although disclosure restrictions are loosened, the CARES Act implemented some extra protections for SUD information beyond HIPAA’s normal requirements. An anti-discrimination provision prevents SUD records from being used to discriminate against patients for health care, employment, access to courts and social services, and housing. Additionally, SUD information cannot be used in any civil, criminal, administrative, or legislative proceeding without either patient consent or a court order.

Despite these protections, the Baker Donelson attorneys believe that the loosened rules, combined with providers being under significant stress and operating with fewer resources, present a risk as "bad actors will try harder to obtain PHI." Clark noted that increased [phishing](#) and [ransomware](#) attacks on providers have been reported during the global health crisis.

**Medical supply availability**

The news is full of tales of lack of personal protective equipment (PPE) for health care workers and lack of COVID-19 testing availability. The CARES Act attempted to address this issue in several ways. Section 3101 directed HHS to form an agreement with the National Academies of Sciences, Engineering, and Medicine (National Academies) to examine and report on the security of the medical product supply chain. This report is to examine the U.S.’s dependence on critical drugs and devices sourced or manufactured outside of the country and provide recommendations to improve the supply chain’s resiliency and address supply vulnerabilities or potential disruptions. Sections 3102 and 3103 require the strategic national stockpile to include PPE, diagnostic tests, and supplies required for administering drugs and vaccines, and added respiratory protective devices to the list of "covered countermeasures" for which manufacturers and distributors receive broad tort immunity.

**Drug and device shortage reporting.** Under section 3111, the FDA is required to prioritize and expedite drug application review and inspections that might mitigate or prevent a drug shortage. In addition, section 2113 requires drug manufacturers to report shortages of pharmaceutical ingredients that are critical to public health during emergencies. The reporting must include the reasons for discontinuing or interrupting the manufacture of the ingredient, any alternative sources for the ingredient, how long the disruption is expected to last, and other relevant information. Manufacturers are also required to maintain redundancy risk management plans for drug supplies. Similarly, device manufacturers are required under section 3121 to provide information about device or component shortages if the FDA requests it during a public health emergency.

The Baker Donelson attorneys believe that current events highlight the supply chain issues that prevented a rapid, thorough response to the pandemic. Noting that the supply chain involving drugs and medical devices is a national security issue, they believe that the matter will require "careful reassessment," particularly in weighing...
the benefit of obtaining cheaper products through foreign sources against the "fragility" of the supply chains exposed by a global event.

Policy changes looking forward

The CARES Act provides payment and operational relief to providers during a public health emergency that has caused fear and uncertainty to sweep the nation. While certain measures implemented through this legislation and other government efforts will have long-lasting benefits to the provision of health care, much will be learned from the government’s response. Clark noted that the novelty of the virus and questions about effective treatments understandably made it difficult for the government to provide a "more targeted response," represented in the shifting approach in using ventilators for COVID-19 patients and the Centers for Disease Control and Prevention’s (CDC) changing position on the use of facemasks in public. Still, he says it was a "huge mistake" for the government to wait on the CDC to develop and deliver COVID-19 tests rather than allowing other sources to address the need and that relaxing this "traditional approach" allowed for more people to be tested—albeit after the virus had already spread uncontrollably.

Clark left Wolters Kluwer with three prevalent questions that he believes will be helpful in analyzing the problems that contributed to the U.S.’s difficulty in responding to the pandemic:

- To what extent did federal interagency turf battles impact the delays?
- To what extent have the complex program reimbursement rules for federal and state health care benefit programs limited the ability of hospitals to have on hand adequate supplies of necessary medical devices and pharmaceutical supplies to deploy in a health emergency?
- What processes must be streamlined to be more efficient for addressing public health emergencies?

After the urgent nature of the virus passes and operations return to normal, it will become increasingly evident which of the provisions in the CARES Act will most benefit patients and providers and remain in place long term. The COVID-19 pandemic will provide many lessons for the health care field and government oversight.

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