

Key Takeaways:
The CARES Act and CMS Response to the COVID-19 Public Health Emergency
Interim Final Rule with Comment Period

Comments on the Interim Final Rule are due June 1, 2020.

On March 27, 2020, Congress enacted the Coronavirus Aid, Relief, and Economic Security (CARES) Act, which makes a number of changes to support the ability of the health care system to respond to the COVID-19 crisis. The CARES Act also includes additional appropriations for the U.S. Department of Health and Human Services (HHS), much of which will be distributed to providers.¹

On March 30, 2020, the Centers for Medicare and Medicaid Services (CMS) released an [Interim Final Rule](#) with comment period providing additional flexibility to entities that care for Medicare beneficiaries in light of the current crisis.² The regulations set forth in the Interim Final Rule took effect immediately and apply retroactively beginning March 1, 2020. The CMS fact sheet on the Interim Final Rule is available [here](#). Although the Interim Final Rule has already taken effect, CMS may make changes to it in response to comments.

Many of the provisions of the Interim Final Rule apply only for the duration of the public health emergency (PHE) determined to exist nationwide by the Secretary of HHS on January 31, 2020, including any subsequent renewals. By statute, the PHE will expire after 90 days, unless renewed by the Secretary.³ It is anticipated that the Secretary will renew the PHE before it expires at the end of April, and he may ultimately renew it several more times. The renewal will extend the PHE for another 90 days, unless terminated earlier by the Secretary.

Key takeaways from the CARES Act and the Interim Final Rule are summarized below. A full list of CMS waivers related to the COVID-19 PHE is available [here](#).

Executive Summary		
TOPIC	OVERVIEW	EFFECTIVE DATES
Sequestration	The suspension of sequestration will increase most Medicare payments, including payment for Part B drugs	May 1, 2020 – December 31, 2020
\$100 Billion for Providers	The CARES Act appropriates \$100 billion to reimburse health care providers for lost revenue and expenses related to COVID-19	Funds are being distributed on a rolling basis until they are exhausted
Accelerated/Advance Payment Programs	The CARES Act and CMS have expanded programs that provide short-term, interest-free loans to providers	The programs are expanded for the duration of the PHE

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Payment for Telehealth Services	Medicare will pay for telehealth services as if they had been provided in person, which will increase payment for providers furnishing telehealth services in the office setting	Duration of the PHE
Expansion of Telehealth Services	Telehealth is available for an expanded set of Medicare services, for both new and established patients	Duration of the PHE
	CMS eliminated frequency limitations for certain telehealth services	Duration of the PHE
Other Telemedicine Services	Remote patient monitoring, e-visits, virtual check-ins, and telephone E/M services are available to more patients	Duration of the PHE
Requirements for “Direct Supervision”	Physicians and other practitioners can provide “direct supervision” via a video call	Duration of the PHE
	Direct physician supervision is no longer required for the initiation of non-surgical extended duration therapeutic services provided in a hospital outpatient department or critical access hospital	Duration of the PHE
Services Furnished in the Home	“Confined to the home” may include patients with suspected or diagnosed COVID-19 or patients who are particularly susceptible to contracting COVID-19	Permanent – CMS clarifies how unchanged statutory language applies to COVID-19
	All rural health centers and federally qualified health centers may furnish nursing care to homebound individuals	Duration of PHE
Quality Payment Programs	CMS has extended or waived data submission deadlines for a number of quality payment programs	Details are available here
	CMS added a new Merit-based Incentive Payment System improvement activity for participation in a COVID-19 clinical trial	2020 Performance Year
Mental Health Services	The CARES Act loosens restrictions on the sharing of patient records related to substance use disorders protected by 42 C.F.R. Part 2	HHS is directed to update Part 2 regulations so they take effect March 2021
	The legislation extends the Certified Community Behavioral Health Clinic demonstration	Extended through November 30, 2020

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Stark Law	CMS will permit certain referrals and related claims that would otherwise violate the Stark Law	March 1, 2020 through the duration of the PHE
Medical Reviews and Surveys	CMS has suspended most Medicare fee-for-service (FFS) medical reviews and certain non-emergency state survey inspections	Duration of the PHE
Drug Coverage	Part D and Medicare Advantage prescription drug plans must permit beneficiaries to obtain up to a 90-day supply of covered Part D drugs	Duration of the PHE
	Medicare Part B will provide coverage for a COVID-19 vaccine, once developed, with no beneficiary cost-sharing	Permanent
	Health insurance plans must cover certain COVID-19 preventive services without cost-sharing	Permanent

Provider Payments

- **The CARES Act temporarily suspends the Medicare sequester from May 1, 2020 through December 31, 2020.**⁴ The sequester reduced most Medicare payments by 2% beginning in 2013. The suspension of these reductions will increase Medicare payments to providers for all Part B services.
 - During this period, payment for Part B drugs and biologics will be restored to Average Sales Price (ASP) + 6%. Sequestration had effectively reduced payment for Part B drugs and biologics to ASP + 4.3%.
- **The CARES Act directs \$100 billion to HHS to reimburse certain health care providers for expenditures and lost revenues related to COVID-19.**⁵
 - Medicare or Medicaid enrolled suppliers and providers that provide diagnoses, testing, or care for individuals with possible or actual COVID-19 are eligible for grants.
 - By statute, this funding may be available for building temporary structures, leasing property, medical supplies and equipment, increasing workforce and training, emergency operation centers, retrofitting facilities, and surge capacity. Compensation for lost revenues is also contemplated.
 - Beginning April 10, 2020, HHS is disbursing \$30 billion from this fund to Medicare enrolled providers based on their share of 2019 Medicare FFS reimbursements.⁶ Additional funding will be used to compensate providers for treating uninsured patients with COVID-19. It is not yet clear how the remainder of the fund will be distributed.

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- **The CARES Act expands the existing Medicare Hospital Accelerated Payment Program during the PHE to make it available to more providers and extend the timeline in which providers are required to repay advance payments.**⁷ CMS has expanded the preexisting Advanced Payment Program for Medicare Part B providers and suppliers in conjunction with the CARES Act provision.⁸ The CMS fact sheet on the expanded programs is available [here](#).
 - Under the expanded programs, most qualified providers and suppliers can receive advance payments of up to 100% of the Medicare payment amount for a three-month period.
 - Inpatient acute care hospitals, children’s hospitals, PPS-exempt cancer hospitals, and Puerto Rico hospitals are eligible for advance payments up to 100% of the Medicare payment amount for a six-month period. Critical access hospitals are eligible for payments up to 125% of the payment amount for a six-month period.
 - Providers are required to begin repaying the advance payments after 120 days.⁹
- **The Interim Final Rule changed payment for telehealth services such that physicians and other furnishing practitioners will be paid as if the service had been furnished in person.**¹⁰
 - Usually, under the Physician Fee Schedule (PFS), practitioners who provide telehealth services to a patient at an “originating site” are paid the PFS facility rate—even if the practitioner was in an office setting and would have otherwise received the higher PFS non-facility rate.
 - The “originating site” is the location of the beneficiary during the telehealth service, such as a physician office, hospital, or rural health clinic.
 - CMS reasons that the facility costs (clinical staff, supplies, etc.) associated with furnishing the telehealth service are generally incurred by the originating site. So, in addition to payment to the practitioner, Medicare pays an originating site facility fee to the site that hosts the patient.¹¹
 - Due to the waivers that allow telehealth services to be furnished to Medicare beneficiaries at home during the PHE, under the Interim Final Rule, physicians and other practitioners will be paid the rate that would have been paid had the services been furnished in person.¹²
 - Practitioners in an office setting will be paid the higher non-facility rate for telehealth services, as opposed to the lower facility rate usually provided, because they would receive the non-facility rate if the service was performed in person. This will increase payment to these providers for telehealth services.

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- Practitioners providing telehealth services in a hospital will continue to receive the facility rate because that is the rate the practitioner would receive if the service was performed in person.
- When the patient obtains telehealth services from home, Medicare will not make a separate originating site payment.

Change in Medicare Payment for Telehealth Services Under the Interim Final Rule						
Practitioner Setting	Normal PFS Payment			Interim Final Rule Payment		
	Payment to Practitioner	Payment to Originating Site	Place of Service Code	Payment to Practitioner	Payment to Originating Site	Place of Service Code
Physician Office	Facility Rate	Facility Fee	02	Non-Facility Rate	N/A	Same as in person, CPT modifier 95
Hospital or Other Setting of Care	Facility Rate	Facility Fee	02	Facility Rate	N/A	Same as in person, CPT modifier 95

Telehealth Services

- **The CARES Act, Interim Final Rule, and other CMS guidance allow providers to furnish an expanded set of telehealth services to new and established Medicare patients at home.**
 - On March 17, 2020, CMS issued a waiver that allows telehealth services to be furnished to Medicare beneficiaries across the country in their homes, effective March 6, 2020.¹³
 - Prior to this waiver, Medicare only paid for a telehealth service when the patient was in a designated rural area and traveled to a clinic, hospital, or certain other types of medical facilities to receive the service.
 - The CARES Act eliminates a provision from the “Phase 1” COVID-19 stimulus package that required providers to have treated a patient without the last three years to furnish telehealth services to that patient during the PHE.¹⁴
 - In the Interim Final Rule, CMS added a number of services to the list of services that may be provided to Medicare beneficiaries via telehealth, including emergency department visits and critical care services.¹⁵ A complete list of services that may be provided via telehealth during the PHE is available [here](#).

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- **The Interim Final Rule eliminated frequency limitations on certain telehealth services.** For example, a subsequent inpatient visit can be furnished via Medicare telehealth without the limitation that the telehealth visit is only once every three days.¹⁶

Other Telemedicine Services

- **In the Interim Final Rule, CMS clarifies that remote patient monitoring services may be provided to patients with an acute or chronic condition.** Additionally, for the duration of the PHE, clinicians can provide remote patient monitoring services to both new and established patients.¹⁷
- **The Interim Final Rule provides payment for prolonged, audio-only evaluation and management (E/M) services.** CMS explains that these codes could be used for new and established patients when the video technology required to furnish a telehealth service is not available.¹⁸
- **Through the Interim Final Rule, CMS waives any National Coverage Determination (NCD) or Local Coverage Determination (LCD) requirement that clinicians provide services face-to-face for the duration of the PHE.**¹⁹
- **SEPARATE PRESCRIBING FLEXIBILITY:** Separate from the provisions of the CARES Act and CMS Interim Final Rule, the HHS Secretary, with the concurrence of the Acting Drug Enforcement Administration (DEA) Administrator, designated that effective March 16, 2020, for the duration of the PHE, practitioners registered with the DEA may prescribe controlled substances via telemedicine to patients for whom they have not conducted an in-person evaluation. The telemedicine visit must be conducted using audio-visual, real-time, two-way interactive communication. Additionally, the prescription must be issued for a legitimate medical purpose, in the usual course of the practitioner’s professional practice, and in accordance with other applicable state and federal law.²⁰

Medicare Telemedicine Services Available During the PHE ²¹			
SERVICE	DESCRIPTION	HCPCS/CPT CODES	PATIENT TYPE
Telehealth	A provider-patient visit that uses an interactive telecommunication system.	For a complete list, see here .	New or established
Virtual Check-In	5–10 minute check-in with a patient via phone or other device to decide whether an office visit is needed, or remote evaluation of recorded video or images submitted by a patient.	G2012 G2010	New or established
E-Visits	Communication between a patient and their provider through an online patient portal.	99421–99423 G2061–G2063	New or established

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<p>Remote Patient Monitoring</p>	<p>Collection and analysis of digitally collected physiologic data, development of a treatment plan, and management of the treatment plan for patients with one or more chronic or acute conditions.</p>	<p>99453 99454 99457 99458</p>	<p>New or established</p>
<p>Telephone E/M</p>	<p>Telephone E/M services provided by a physician or other practitioner.</p>	<p>98966–98968 99441–99443</p>	<p>New or established</p>

Practitioner Supervision

- **The Interim Final Rule amends the definition of “direct supervision” to allow physicians and other practitioners to provide such supervision virtually using real-time audio and video technology.²²**
 - If a procedure is required to be performed under the “direct supervision” of a physician or other practitioner, the practitioner must be immediately available to furnish assistance and direction as needed.²³ This standard does not require the practitioner to be present in the room when the procedure is performed, but—prior to the Interim Final Rule—it generally required the practitioner to be in the office suite.²⁴
 - Under the Interim Final Rule, direct supervision may be provided via real-time interactive audio and video technology, as needed, during a procedure.²⁵
 - CMS provides that physicians may contract with a home health agency or a qualified infusion therapy supplier to use their nurses or other clinical staff to provide services to patients in their homes, with the physician providing “direct supervision” remotely.²⁶
 - In these instances, the services performed by the home health agency, qualified infusion therapy provider, or other contracted personnel would be performed “incident to” the physician (or other practitioner) service. So, the supervising practitioner would submit claims to Medicare, and the contracted personnel would seek payment from the billing practitioner.
 - CMS is seeking comment on whether it should place any guardrails around this interim policy and what kind of risk this policy might introduce for beneficiaries.²⁷
 - Importantly, this provision does not allow practitioners to provide services under the home health benefit or home infusion therapy benefit if the patient is not otherwise eligible for services under those benefits.²⁸ Rather, for services provided “incident to” professional services, it gives supervising practitioners the flexibility to supervise from a remote location. Additionally, it provides flexibility for practitioners to supervise services taking place in health care settings from a different location, such as their own home.

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- **Direct physician supervision is no longer required for the initiation of non-surgical extended duration therapeutic services provided in a hospital outpatient department or critical access hospital.** Instead, a physician can provide a general level of supervision throughout the duration of the service—i.e., the physician is not required to be immediately available in the office suite during the initiation of the service. Effective 2020, CMS had already changed the required level of supervision for most hospital outpatient therapeutic services from direct supervision to general supervision. In the Interim Final Rule, CMS extends this change to non-surgical extended duration therapeutic services.²⁹

Services Furnished in the Home

- **The Interim Final Rule clarifies that “confined to the home” or “homebound,” for purposes of the Medicare home health benefit, may include patients with a confirmed or suspected diagnosis of COVID-19 or a condition that makes the patient particularly susceptible to contracting COVID-19.**³⁰
 - Medicare home health services, such as skilled nursing visits, physical therapy, or speech-language pathology, are only available to patients who are “confined to the home” and meet other requirements. In general, a patient is considered confined to the home if the patient has a condition that restricts his or her ability to leave home without assistance or a condition such that leaving home is medically contraindicated.³¹
 - As applied to the COVID-19 pandemic, CMS explains that a patient would qualify as “confined to the home” if a physician has determined that it is medically contraindicated for a patient to leave home because of (1) a confirmed or suspected case of COVID-19, or (2) a condition that may make the patient particularly susceptible to contracting COVID-19.³²
 - However, a patient who is self-quarantining for general safety purposes would not be considered “confined to the home” unless a physician certifies that it is medically contraindicated for the patient to leave home.³³
 - CMS solicits comments on this clarification.³⁴
- **For the duration of the PHE, any area typically served by a rural health center (RHC) or included in a federally qualified health center (FQHC) service plan is deemed to have a shortage of home health agencies, thus allowing RHCs and FQHCs to furnish nursing care to homebound individuals.**³⁵

Quality Payment Programs

- **Through guidance, CMS has extended the deadlines for data submission, or waived submission requirements, for a number of quality payment programs, including the Merit-based Incentive**

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Payment System (MIPS) and the Hospital Inpatient Quality Reporting Program.³⁶ The full list of waivers related to quality payment programs is available [here](#).

- **The Interim Final Rule adds a new MIPS improvement activity for the Calendar Year 2020 performance period.** The new improvement activity gives credit to MIPS-eligible clinicians for participating in a COVID-19 clinical trial utilizing a drug or biologic to treat a patient with a COVID-19 infection and reporting their findings through a clinical data repository or clinical data registry.³⁷
- **In the Interim Final Rule, CMS also extends the deadline for MIPS-eligible clinicians to submit an application for reweighting some or all MIPS performance categories for 2019 based on extreme and uncontrollable circumstances to April 30, 2020.** The original deadline was December 31, 2019.³⁸ The effect of this would be for those clinicians to receive no MIPS payment adjustment, positive or negative, in 2021.

Mental Health Services

- **The CARES Act loosens the restrictions on sharing patient records protected by 42 C.F.R. Part 2, which governs the confidentiality of substance-use disorder records held by certain programs.** Among other changes, the legislation makes it easier for covered programs to share information regarding a patient's substance use disorder for treatment, payment, and health care operations purposes with the patient's authorization. The CARES Act directs HHS to revise the Part 2 regulations to implement these changes such that they will apply beginning March 27, 2021.³⁹
- **The CARES Act extends the Certified Community Behavioral Health Clinic (CCBHC) demonstration program through November 30, 2020 and provides for the expansion of the program to two additional states within 6 months.** Before the CARES Act, the demonstration was set to end on May 22, 2020. Eight states are currently participating. The legislation directs HHS to choose two additional states to participate in the demonstration.⁴⁰

Stark Law

- **Through guidance, CMS has announced that during the PHE it will permit certain referrals and the submission of related claims that would otherwise violate the Stark Law, effective March 1, 2020.**⁴¹ For example, hospitals and other health care providers can pay above or below fair market value to rent equipment from physicians (or vice versa). Additionally, CMS has loosened Stark Law restrictions on when a group practice can furnish medically necessary designated health services in a patient's home. The full list of Stark Law waivers is available [here](#).

Medical Reviews and Surveys

- **CMS has suspended most Medicare FFS medical reviews and certain non-emergency state survey inspections during the PHE.** Medicare reviews that have been suspended include pre-payment medical reviews conducted by Medicare Administrative Contractors (MACs) under the Targeted

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Probe and Educate program.⁴² CMS has limited state survey activity to certain urgent circumstances, such as surveys in response to immediate jeopardy complaints and statutorily required recertification surveys.⁴³

Drug Coverage

- **The CARES Act requires Medicare standalone prescription drug plans (PDPs) and Medicare Advantage prescription drug plans (MA-PDs) to allow beneficiaries to receive up to a 90-day supply of covered Part D drugs during the PHE.** Notwithstanding any utilization management or medication therapy management programs, PDPs and MA-PDs must permit beneficiaries, at their option, to obtain the total day supply of a covered Part D drug that has been prescribed in a single fill or refill, up to a 90-day supply.⁴⁴
- **The CARES Act provides coverage for a COVID-19 vaccine, once it is developed, under Medicare Part B, without any beneficiary cost-sharing.** The vaccine and its administration will be covered at no cost to Medicare beneficiaries.⁴⁵
- **Under the CARES Act, group health plans and health insurance issuers are required to cover “any qualifying coronavirus preventive service” without cost-sharing 15 days after the date it is recommended.** The contemplated measures include an item, service, or vaccine that receives a rating of A or B in the current U.S. Preventative Services Task Force or receives a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (CDC) with respect to the individual involved.⁴⁶

Interim Final Rule Comment Period

Commenters must refer to file code CMS-1744-IFC when commenting on the Interim Final Rule. Interested stakeholders can submit comments electronically by visiting [regulations.gov](https://www.regulations.gov). Alternatively, comments can be submitted by mail to the following addresses:

Regular Mail

Centers for Medicare & Medicaid Services
 Department of Health and Human Services
 Attention: CMS-1744-IFC
 P.O. Box 8016
 Baltimore, MD 21244-8016

Express or Overnight Mail

Centers for Medicare & Medicaid Services
 Department of Health and Human Services
 Attention: CMS-1744-IFC
 Mail Stop C4-26-05
 7500 Security Boulevard
 Baltimore, MD 21244-1850

The deadline for submitting comments is 5:00 p.m. ET on June 1, 2020.

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¹ The Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. No. 116-136 [hereinafter “The CARES Act”].

² Centers for Medicare and Medicaid Services (CMS), Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 85 Fed. Reg. 19,230 (April 6, 2020), *available at* <https://www.govinfo.gov/content/pkg/FR-2020-04-06/pdf/2020-06990.pdf> [hereinafter “Interim Final Rule”].

³ 42 U.S.C. § 247d(a)(2).

⁴ The CARES Act, § 3709.

⁵ *Id.* Division B.

⁶ CMS, HHS to Begin Immediate Delivery of Initial \$30 Billion of CARES Act Provider Relief Funding (April 10, 2020), <https://www.hhs.gov/about/news/2020/04/10/hhs-to-begin-immediate-delivery-of-initial-30-billion-of-cares-act-provider-relief-funding.html> (last accessed April 15, 2020).

⁷ *Id.* § 3719.

⁸ Interim Final Rule at 19,280.

⁹ CMS, Fact Sheet: Expansion of the Accelerated and Advance Payments Program for Providers and Suppliers During COVID-19 Emergency at 1, *available at* <https://www.cms.gov/files/document/accelerated-and-advanced-payments-fact-sheet.pdf>.

¹⁰ Interim Final Rule at 19,233.

¹¹ *Id.*

¹² *Id.*

¹³ CMS, Medicare Telemedicine Health Care Provider Fact Sheet (March 17, 2020), <https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet> (last accessed April 5, 2020).

¹⁴ The CARES Act, § 3703.

¹⁵ Interim Final Rule at 19,233–43.

¹⁶ *Id.* at 19,241.

¹⁷ *Id.* at 19,264.

¹⁸ *Id.* at 19,264–66.

¹⁹ *Id.* at 19,266.

²⁰ U.S. Department of Justice Drug Enforcement Administration, COVID-19 Information Page, Telemedicine, <https://www.deadiversion.usdoj.gov/coronavirus.html#TELE> (last accessed April 13, 2020).

²¹ CMS, Medicare Telemedicine Health Care Provider Fact Sheet (March 17, 2020); Interim Final Rule at 19,264–66; CMS, List of Telehealth Services, Covered Telehealth Services for PHE for the COVID-19 pandemic, effective March 1, 2020, <https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes> (last accessed April 10, 2020).

²² Interim Final Rule at 19,245–46.

²³ 42 C.F.R. § 410.32(b)(3)(ii).

²⁴ Interim Final Rule at 19,245.

²⁵ *Id.*

²⁶ *Id.* at 19,245–46.

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²⁷ *Id.* at 19,245.

²⁸ CMS, COVID-19 Interim Final Rule FAQs at 31–32, <https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf> (last updated April 9, 2020).

²⁹ Interim Final Rule at 19,266.

³⁰ *Id.* at 19,246–47.

³¹ *Id.*

³² *Id.* at 19,247.

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.* at 19,254–55.

³⁶ CMS, CMS Announces Relief for Clinicians, Providers, Hospitals and Facilities Participating in Quality Reporting Programs in Response to COVID-19 (March 22, 2020), <https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting> (last accessed April 8, 2020).

³⁷ Interim Final Rule at 19,276–77.

³⁸ *Id.* at 19,277–78.

³⁹ The CARES Act, § 3221.

⁴⁰ *Id.* § 3814.

⁴¹ CMS, Blanket Waivers of Section 1877(g) of the Social Security Act Due to Declaration of COVID-19 Outbreak in the United States as a National Emergency, *available at* <https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf>; *see also* CMS, Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19 at 4–5, *available at* <https://www.cms.gov/files/document/covid-19-physicians-and-practitioners.pdf>.

⁴² CMS, 2019–Novel Coronavirus (COVID-19) Provider Burden Relief Frequently Asked Questions (FAQs) (March 2020), *available at* <https://www.cms.gov/files/document/provider-burden-relief-faqs.pdf>.

⁴³ CMS, Center for Clinical Standards and Quality/Quality, Safety & Oversight Group, Suspension of Survey Activities (QSO-20-12-All) (March 4, 2020), *available at* <https://www.cms.gov/files/document/qso-20-12-all.pdf>.

⁴⁴ The CARES Act, § 3714.

⁴⁵ *Id.* § 3713.

⁴⁶ *Id.* § 3203.

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