haynesboone

UPDATED May 14, 2020

COVID-19 Quick Reference
Regulatory Guide for Healthcare Providers

Authored by Phil Kim, Jennifer Kreick, Kayla Cristales, Bill Morrison, Neil Issar, and Chris Rogers

As healthcare providers respond to increased demands on supplies and resources due to the COVID-19 pandemic, regulators have issued certain flexibilities and guidance in responding to the public health emergency. The following guide and frequently asked questions are designed to address some of the more common issues and questions that providers face. As always, legal advice is fact-sensitive. Particularly given the rapidly evolving medical and legal landscape, legal conclusions can evolve on these matters and likely will. If in doubt, seek current, up-to-date legal advice based on your company's facts and circumstances.

TABLE OF CONTENTS

1. CMS WAIVERS AND RULE CHANGES

What regulatory flexibilities have been granted to healthcare providers by CMS?

Answer: The President's declaration of the COVID-19 pandemic as a national emergency and the Secretary of Health and Human Services' (the "Secretary") declaration of a public health emergency ("PHE") gave regulators authority to waive or modify certain requirements. In response, the Centers for Medicare & Medicaid Services ("CMS") granted unprecedented regulatory flexibilities to healthcare providers through the issuance of certain waivers of various administrative requirements. These waivers can take several forms, including (i) Medicare blanket waivers, (ii) Medicare provider/supplier individual requested waivers, and (iii) state-granted Medicaid waivers. Certain special waivers have also been issued, as discussed more in the Stark Law, EMTALA, and telehealth sections below. For more information about the CMS waivers and other rule changes, see the CMS Waiver Site, CMS Waiver Summary, our prior Client Alerts here and here.

Do the waivers apply to state requirements as well?

Answer: No. The waivers apply to federal requirements only and do not apply to state requirements for licensure or conditions of participation. For example, while CMS has waived requirements that out-of-state practitioners be licensed in the state in which they are providing services so long as they meet certain requirements, state or local licensure requirements would still apply. Therefore, in order for a practitioner to use the waiver, the state also would have to waive its licensure requirements.

How long will the waivers last?

Answer: Many of the waivers and flexibilities are effective beginning March 1, 2020 and end no later than the termination of the emergency period, or 60 days from the date the waiver or modification is first published. The Secretary can extend the waiver by notice for additional periods of up to 60 days, up to the end of the emergency period. Given the limited timeframe, providers should plan to unwind arrangements at the end of the PHE and ensure appropriate mechanisms are in place to do so.

What are the Section 1135 blanket waivers and to whom do they apply?

Answer: CMS has issued and continues to issue various blanket waivers that apply to healthcare practitioners, hospitals, psychiatric hospitals, critical access hospitals, rural health clinics, federally qualified health centers, inpatient rehabilitation facilities, long-term care acute hospitals, skilled nursing facilities and other nursing facilities, home health agencies, hospice, end-stage renal dialysis facilities, and durable medical equipment, and others. Waivers have also been issued for requirements related to provider licensing and enrollment, suspension of enforcement activities, telehealth, and signature requirements. The blanket waivers apply automatically to all applicable providers and suppliers without the need to make any request. The blanket waivers can be found here. A graphic summary available from CMS can be found here.

Are there special billing requirements for the waivers?

Answer: When submitting claims covered by the blanket waivers, the "DR" (disaster-related) condition code should be used for institutional billing (i.e., claims submitted using the ASC X12 837 institutional claims format or paper Form CMS-1450). The "CR" (catastrophe/disaster-related) modifier should be used for Part B billing, both institutional and non-institutional (i.e., claims submitted using the ASC X12 837 professional claim format or paper

Form CMS-1500 or, for pharmacies, in the NCPDP format). This requirement does not apply to the Stark Law waivers (blanket or individual).

Are there other waivers available to individual providers and suppliers and how do they apply?

Answer: States and individual providers and suppliers can submit requests for individual waivers that will be evaluated on a case-by-case basis. The request should include a justification for the waiver and expected duration of the modification requested. The waiver request process is managed by the Survey Operations Group and CMS locations (previously known as CMS Regional Offices). Additional information to include in the waiver request and contact information for each CMS location is available here. General information regarding the process is available here.

What waivers are available to states and how do I find out what waivers were issued in my state?

Answer: States and territories can request approval for the waiver of certain Medicaid and CHIP requirements. CMS has approved at least 54 waivers from states and territories. The list of states and their approved waivers is available here.

2. STARK LAW

What are the Stark Law waivers?

Answer: CMS has issued blanket waivers of sanctions under the physician self-referral law, also known as the Stark Law, for certain COVID-19 purposes. In addition, CMS may grant individual waiver requests. Unlike other 1135 waiver requests, questions and requests for individual Stark Law waivers should be sent to 1877CallCenter@cms.hhs.gov. More information regarding the Stark Law waivers can be found on the CMS Stark Law Waiver Site, in the Stark Law Blanket Waivers, in the CMS Explanatory Guidance, and in our Client Alert.

What are the limitations of the waivers?

Answer: The Stark Law blanket waivers only protect certain enumerated financial arrangements and referrals that are solely related to "COVID-19 Purposes," as defined by CMS. While the definition of COVID-19 Purposes is broad, parties using the blanket waivers must make records relating their use available to the Secretary upon request. The blanket waivers only apply to certain arrangements directly between an entity and (1) the physician or the physician organization in whose shoes the physician stands under 42 CFR § 411.354(c), or (2) the immediate family member of the physician. There is no blanket waiver for indirect compensation arrangements. The blanket waivers are limited in duration (note that CMS has issued guidance related to repayment of loans after termination of the waivers when the repayment terms were previously agreed to).

When do the Stark Law waivers apply?

Answer: The blanket waivers are effective March 1, 2020 and may be used without notifying CMS, although records relating to the use of the blanket waivers must be made available to the Secretary upon request. The Stark Law waivers will terminate upon the expiration of the emergency period. CMS has issued guidance addressing specific issues related to the waivers and remuneration after the termination of the waivers (e.g., loan repayments), as well as amendments to existing compensation arrangements. Because of the limited timeframe, parties desiring to use the waivers should consider how the arrangement will be wound-down prior to entering into the arrangement.

3. ANTI-KICKBACK STATUTE

Is there an Anti-Kickback Statute waiver?

Answer: There is no 1135 waiver for the Anti-Kickback Statute ("AKS"), but the U.S. Department of Health & Human Services ("HHS") Office of Inspector General ("OIG") has announced that it will exercise its enforcement discretion and will not impose administrative sanctions under the federal AKS for certain arrangements covered by the Stark Law blanket waivers. For more information, please see the OIG's Policy Statement and FAQs. In addition, instead of following the typical OIG advisory opinion process, providers can submit questions regarding how the OIG would view an arrangement connected to the COVID-19 public health emergency to OIGComplianceSuggestions@oig.hhs.gov.

What are the limitations of the AKS policy of enforcement discretion?

Answer: The OIG's policy statement does not apply to arrangements that do not meet every element of a Stark Law blanket waiver. This means that arrangements that fall outside of the Stark Law blanket waivers (such as an arrangement between a pharmaceutical or medical device manufacturer and a physician or between providers when there is no physician involved) are not covered by the OIG's policy statement. Further, only certain of the Stark Law blanket waivers are covered (specifically, those covered by section II.B.(1)-(11) of the blanket waivers). In addition, the OIG's policy statement applies to conduct occurring on or after April 3, 2020 (the Stark Law blanket waivers are retroactive to March 1, 2020) and terminates on the same date as the date that the Stark Law blanket waivers terminate. The policy applies to enforcement of the federal AKS only, and states may have anti-kickback statutes that could still apply.

4. TELEHEALTH

What Medicare telehealth requirements have been waived?

Answer: CMS has waived numerous telehealth requirements on a temporary basis beginning March 6, 2020 and continuing during the PHE. For example, CMS has temporarily waived the requirement that the originating site must be a physician's office or other authorized healthcare facility, allowing Medicare to pay for telehealth services when beneficiaries are in their homes or any other setting of care. In addition, during the PHE, CMS waived the requirement for an established relationship between the provider and the patient, thus telehealth services can be provided to new or established patients. For more information regarding the waiver of specific telehealth requirements, please see our Client Alert.

What telehealth services can be provided and who can provide them?

Answer: CMS has expanded the list of Medicare telehealth services. The list of eligible codes is available here. In addition, CMS has expanded the types of healthcare professionals that can furnish telehealth services to include all those that are eligible to bill Medicare for their professional services. This means that healthcare professionals, including physical therapists, occupational therapists, speech language pathologists, and others, that were previously ineligible may now furnish and receive payment for covered telehealth services.

Are there special billing requirements for telehealth services rendered by physicians and practitioners during the PHE?

Answer: Typically, claims for Medicare telehealth services submitted by physicians or practitioners must include the Place of Service ("POS") code 02-Telehealth to indicate the billed service was furnished as a professional telehealth service from a distant site (and thus will be paid at the Physician Fee Schedule facility rate). During the PHE, CMS is instructing physicians and practitioners who bill for Medicare telehealth services to report the POS code that would have been reported had the service been furnished in person. This will allow Medicare systems to pay for services furnished via Medicare telehealth which, if not for the PHE, would have been furnished in person, at the same rate they would have been paid if the services were furnished in person. Further, because CMS currently uses the POS code on the claim to identify Medicare telehealth services, it is instructing providers to use the CPT telehealth modifier (modifier 65) for claim lines that describe services furnished via telehealth. For more information, please see the CMS Interim Final Rule here.

Can I waive copays for telehealth services?

Answer: Maybe. The OIG issued a policy statement on March 17, 2020, permitting (but not requiring) healthcare providers to reduce or waive beneficiary cost-sharing for telehealth visits furnished during the PHE paid for by federal healthcare programs, provided that all applicable CMS payment and coverage rules are met. Ordinarily, if healthcare providers routinely reduce or waive costs owed by federal healthcare program beneficiaries, including cost-sharing amounts such as coinsurance and deductibles, they would potentially implicate the federal AKS, the civil monetary penalty and exclusion laws related to kickbacks, and the civil monetary penalty law prohibition on inducements to beneficiaries. The OIG will not bring an enforcement action if providers reduce or waive cost-sharing for telehealth visits during the PHE, but there are other considerations that may apply (see below). For more information, see the OIG's Policy Statement and Fact Sheet.

What are the limitations to the OIG's policy statement regarding reducing or waiving copays for telehealth services?

Answer: The policy statement is limited to enforcement of the federal AKS and civil monetary penalty laws by the OIG. The policy statement does not affect CMS's rules and regulations, nor any applicable state laws. The policy statement applies to reductions or waivers of cost-sharing obligations for federal health care program beneficiaries only. Commercial and other third-party payors may prohibit or limit this practice. Providers should consult with their attorney regarding any decision to waive copays.

What HIPAA requirements and flexibilities apply to telehealth services during the PHE?

Answer: Generally, covered entities (including healthcare providers) must comply with the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations ("HIPAA"). For example, covered entities must typically enter into a business associate agreement ("BAA") with a vendor that provides services that involve the use or disclosure of protected health information ("PHI"). However, effective March 17, 2020, the HHS Office for Civil Rights ("OCR") issued a Notification of Enforcement Discretion ("Notice") stating that it will not impose penalties against healthcare providers for noncompliance with HIPAA in connection with the good faith provision of telehealth during the PHE. For more information, please see the OCR's Notice and FAQ, and our Client Alert.

What kind of communication technology can I use to provide telehealth services?

Answer: The OCR's Notice permits any non-public facing remote communication product that is available, so long as the use is related to the good faith provision of telehealth during the PHE. Under the Notice, healthcare providers may use popular applications that allow for video chats (e.g., Zoom). OCR encouraged providers to notify patients that these third-party applications potentially introduce privacy risks, and to enable all available encryption and privacy modes when using these applications. Public facing video communications applications (e.g., Facebook Live, Twitch, and TikTok) should not be used for the provision of telehealth services.

Do I need a BAA with the vendor before I can use the telehealth application?

Answer: No, as long as the application is used for the good faith provision of telehealth during the PHE. Specifically, the OCR stated in the Notice that it will not impose penalties against healthcare providers for the lack of a BAA with video communication vendors or any other noncompliance with HIPAA rules that relates to the good faith provision of telehealth services during the PHE. However, the Notice only applies during the PHE, so to the extent that the healthcare provider will continue to provide telehealth services using the application after the termination of the PHE, the provider should ensure a BAA is put in place if needed.

5. HIPAA

May I disclose the name or other identifying information of an individual who has been infected with or exposed to COVID-19 to law enforcement, paramedics, other first responders, and public health authorities without an individual's authorization?

Answer: Yes, in certain circumstances. OCR issued guidance addressing when disclosures of PHI to law enforcement, first responders, and public health authorities are permitted under existing HIPAA regulations, such as when disclosure is needed to provide treatment to an individual, when notification is required by law, to notify a public health authority in order to prevent or control spread of a disease, when first responders may be at risk of infection if authorized by law, or when the disclosure to first responders is necessary to prevent or lessen a serious or imminent threat to the health and safety of a person or the public. The OCR reminded covered entities that except when the disclosure is required by law or for treatment purposes, covered entities must make reasonable efforts to limit the information used or disclosed to the minimum necessary to accomplish the purpose for the disclosure. For more information and specific examples of permitted disclosures, please see the OCR's Guidance and our Client Alert.

What flexibilities under HIPAA are available for participation in the operation of a COVID-19 specimen collection and testing site?

Answer: Effective March 13, 2020, OCR issued a Notification of Enforcement Discretion (the "CBTS Notice") stating that it will not impose penalties for noncompliance with regulatory requirements under HIPAA against covered health care providers and their business associates in connection with the good faith participation in the operation of a COVID-19 specimen collection and testing site ("Community-Based Testing Site" or "CBTS") during the COVID-19 nationwide public health emergency. The operation of a CBTS includes all activities that support the collection of specimens from individuals for COVID-19 testing. The CBTS Notice does not apply to health plans or health care clearinghouses when they are performing health plan and clearinghouse functions, or to covered health care providers or their business associates when they are performing non-CBTS related activities. For more information, please see OCR's CBTS Notice and our Client Alert.

What flexibilities under HIPAA are available for covered entities and their business associates for public health or health oversight activities?

Answer: HIPAA permits a business associate to use and disclose PHI to conduct certain functions or activities on behalf of the covered entity, or provide certain services to the covered entity, but only pursuant to the explicit terms of a BAA, or as required by law. According to the OCR, some business associates were not able to provide federal public health authorities and health oversight agencies, state and local health departments, and state emergency operations centers with PHI or perform public health data analytics on such PHI because their BAAs did not expressly permit these uses and disclosures. Effective April 2, 2020, OCR issued a Notification of Enforcement Discretion (the "BAA Notice") stating that it will not impose penalties for violations of certain HIPAA Privacy Rule provisions against health care providers or their business associates during the COVID-19 nationwide public health emergency if:

- the business associate makes a good faith use or disclosure of the covered entity's PHI for public health activities consistent with 45 CFR § 164.512(b), or health oversight activities consistent with 45 CFR § 164.512(d); and

- the business associate informs the covered entity within 10 calendar days after the use or disclosure occurs (or commences, with respect to uses or disclosures that will repeat over time).

For more information, please see OCR's BAA Notice and our Client Alert.

What flexibilities under HIPAA are available for healthcare providers providing telehealth services?

Answer: Please see Section 4 (*Telehealth*) above.

Are there any other waivers of HIPAA sanctions and penalties?

Answer: Effective March 15, 2020, the Secretary exercised its authority to waive sanctions and penalties against a covered hospital that does not comply with the following provisions of the HIPAA Privacy Rule:

- the requirement to obtain a patient's agreement to speak with family members or friends involved in the patient's care. *See* 45 C.F.R. § 164.510(b).

- the requirement to honor a request to opt out of the facility directory. *See* 45 C.F.R. § 164.510(a).

- the requirement to distribute a notice of privacy practices. *See* 45 C.F.R. § 164.520.

- the patient's right to request privacy restrictions. *See* 45 C.F.R. § 164.522(a).

- the patient's right to request confidential communications. *See* 45 C.F.R. § 164.522(b).

This limited waiver only applies (1) in the emergency area identified in the public health emergency declaration; (2) to hospitals that have instituted a disaster protocol; and (3) for up to 72 hours from the time the hospital implements its disaster protocol. For more information, please see OCR's Waiver.

6. EMTALA

Are there any EMTALA waivers for hospitals related to COVID-19?

Answer: Effective March 1, 2020, CMS issued a blanket waiver of sanctions under the Emergency Medical Treatment and Active Labor Act ("EMTALA") to allow hospitals, psychiatric hospitals, and critical access hospitals (CAHs) to screen patients at a location offsite from the hospital's campus to prevent the spread of COVID-19, so long as it is not inconsistent with a state's emergency preparedness or pandemic plan. The waiver is effective only if actions under the waiver do not discriminate as to source of payment or ability to pay. The waiver does not apply to transfer of an individual who has not been stabilized if the transfer arises out of an emergency. The EMTALA waiver is effective until the termination of the PHE. For more information, please see the CMS EMTALA Guidance, the Blanket Waivers, and our Client Alert.

7. CIVIL RIGHTS

How do civil rights laws impact providers during COVID-19 and are these requirements being enforced?

Answer: Civil rights laws and requirements still apply to healthcare providers during COVID-19 and can impact pandemic-related triaging policies (particularly regarding age and disability). Healthcare providers should ensure that their triaging policies do not contain criteria that automatically deprioritize persons on the basis of particular disabilities and do not contain strict age cutoffs, but instead, require individualized assessments based on the best available, relevant, and objective medical evidence to support triaging decisions. Relevant guidance and enforcement activity is described below:

- OCR Bulletin: On March 28, 2020, OCR issued a bulletin reminding healthcare providers of their obligations under laws and regulations that prohibit discrimination on the basis of race, color, national origin, disability, age, sex, and exercise of conscience and religion in HHS-funded programs.

- OCR Investigations: In April 2020, OCR resolved two complaints related to violations of civil rights laws, although both complaints were resolved by implementing changes to policies and without a finding of liability.

The first investigation involved the State of Alabama's ventilator rationing guidelines that allegedly discriminated on the basis of disability (including "profound mental retardation and "moderate to severe dementia") and age. OCR was concerned that the triaging policies could result in discrimination against person with disabilities by denying or stopping ventilator services simply because an individual has an intellectual disability and that they could be used to impose blunt age categorizations, such that older persons might automatically be deemed ineligible for life-saving care without any individualized assessment or examination.

The second investigation involved a complaint against the Pennsylvania Department of Health ("PDH") after it revised its Interim Pennsylvania Crisis Standards of Care for Pandemic Guidelines ("CSC Guidelines") in a manner that allegedly denied treatment to individuals with disabilities when prioritizing access to critical care and ventilators. PDH was required to revise its CSC Guidelines to (1) remove criteria that automatically deprioritized persons on the basis of particular disabilities; (2) require individualized assessments based on the best available, relevant, and objective medical evidence to support triaging decisions; and (3) ensure that no one is denied care based on stereotypes, assessments of quality of life, or judgments about a person's "worth" based on the presence or absence of disabilities.

For more information, see the OCR Bulletin, Alabama Press Release, and PDH Press Release.

8. LIABILITY PROTECTIONS

What type of liability protections do healthcare providers have under the PREP Act in relation to COVID-19?

Answer: On February 4, 2020, HHS issued a declaration under the Public Readiness and Emergency Preparedness Act ("PREP Act") to provide liability immunity to certain individuals and entities ("Covered Persons") against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures against COVID-19 ("Covered Countermeasures"), except for claims involving "willful misconduct" as defined in the PREP Act.

Covered Persons include, among others, a licensed health professional or other individual authorized to prescribe, administer, or dispense Covered Countermeasures under the law of the state in which the Covered Countermeasure was prescribed, administered, or dispensed. Covered Countermeasures include any drug, device, or biological product that is approved, cleared, or licensed by the FDA and is used to diagnose, mitigate, prevent, treat, cure, or limit the harm of COVID-19 is a covered countermeasure. This includes any drug, device, or biological product authorized for emergency use with respect to COVID-19 under an Emergency Use Authorization ("EUA"), described in Emergency Use Instructions issued by the CDC, or being researched under certain investigational provisions (i.e., IND, IDE) to treat COVID-19 is a covered countermeasure.

In addition, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") amended the PREP Act to include respirators, that may not be medical devices, to the list of Covered Countermeasures so long as they are NIOSH approved and subject to an EUA. For more information, please see the Declaration, the HHS Advisory Opinion, and our Client Alert.

What type of liability protections do healthcare providers have under the CARES Act in relation to COVID-19?

Answer: The CARES Act includes a provision that limits liability for "volunteer" healthcare providers during the PHE. Under this section, providers shall not be liable under federal or state law for any harm caused by an act or omission of the professional in the provision of health care services during the PHE if certain requirements are met and subject to applicable exceptions. Importantly, the liability protections only apply if the professional is providing healthcare services in response to the public health emergency as a volunteer and the services are within the scope of the provider's license (as defined by the state of licensure). There are exceptions for willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious flagrant indifference to the rights or safety of the individual that was harmed, or if the healthcare provider rendered the services under the influence of alcohol or drugs. Please see the CARES Act for more information.

9. THE CARES ACT AND OTHER LEGISLATIVE SOURCES OF FUNDING

What funding does the CARES Act provide for healthcare providers?

Answer: The CARES Act, as supplemented by the Paycheck Protection Program and Health Care Enhancement Act (the "PPP/HCE Act"), provides $175 billion in relief funds to hospitals and other healthcare providers on the front lines of the COVID-19 response (the "Provider Relief Fund"). The funds are allocated as follows:

- $50 billion for general distribution to Medicare facilities and providers impacted by COVID-19, based on eligible providers' net patient revenue:
    - $30 billion of automatic payments were distributed via direct deposit between April 10, 2020, and April 17, 2020, proportionate to providers' share (around 6.2%) of Medicare fee-for-service reimbursements in 2019 as part of the initial rapid distribution phase;
    - The remaining $20 billion was distributed beginning April 24, 2020, proportionate to providers' share of 2018 net patient revenue (not just Medicare revenue). Payments go out weekly, on a rolling basis, as information is validated;
- $12 billion to 395 hospitals who provided inpatient care for 100 or more COVID-19 patients through April 10, 2020 (i.e., hospitals in areas particularly impacted by COVID-19);
- $10 billion for rural distribution, including rural acute care general hospitals and critical access hospitals ("CAHs"), rural health clinics ("RHCs"), and community health centers located in rural areas;
    - Rural acute care general hospitals and RHCs will each receive a minimum base payment plus a percent of their annual expenses.
    - RHCs with no reported Medicare claims, such as pediatric RHCs, and CHCs lacking expense data will receive a minimum level of support no less than $100,000, with additional payment based on operating expenses.
    - Rural acute care general hospitals and CAHs will receive a minimum level of support of no less than $1,000,000, with additional payment based on operating expenses.
- $400 million to Indian Health Service facilities, distributed on the basis of operating expenses;
- Unspecified amount to reimburse providers, at Medicare rates, for COVID-related treatment of uninsured patients; and
- Unspecified amount to skilled nursing facilities, dentists, and providers that solely take Medicaid.

HHS's methodology for determining payments of the targeted allocations can be found here. The state and county breakdowns of funds for high-impact areas and rural distribution can be found here. HHS has also issued FAQs regarding the general distribution available here.

Who is eligible to receive payments from the Provider Relief Fund's general distribution?

Answer: To be eligible for payment under the general distribution of $50 billion, a provider must have billed Medicare in 2019 and provide or provided after January 31, 2020 diagnoses, testing, or care for individuals with possible or actual cases of COVID-19. These payments do not need to be repaid.

If a provider ceased operation as a result of the COVID-19 pandemic, it is still eligible to receive funds so long as it provided diagnoses, testing, or care for individuals with possible or actual cases of COVID-19. Care does not have to be specific to treating COVID-19. HHS broadly views every patient as a possible case of COVID-19.

How are funds from the Provider Relief Fund distributed?

Answer: HHS partnered with UnitedHealth Group to provide rapid payment to providers eligible for the distribution of the initial $30 billion in funds. Providers are paid via Automated Clearing House account information on file with UnitedHealth or CMS. The automatic payments will come to providers via Optum Bank with "HHSPAYMENT" as the payment description. Providers who normally receive a paper check for reimbursement from CMS will receive a paper check in the mail for this payment.

What are requirements for providers who receive payments from the Provider Relief Fund?

Answer: Providers who receive funds from the general distribution must sign an attestation confirming receipt of funds, agree to the terms and conditions of payment, and confirm the CMS cost report within 45 days. This can be done via the CARES Act Provider Relief Fund Payment Attestation Portal. Providers should review the attestation and terms and conditions carefully to ensure they are willing and able to agree to the terms.

Providers should also review the specific Terms and Conditions for different allocations of the Provider Relief Fund as well as CMS's FAQs for the general distribution.

Is there funding for testing and treatment of the uninsured?

Answer: Yes. The Families First Coronavirus Response Act ("FFCRA"), enacted on March 18, 2020, and the PPP/HCE Act each appropriated $1 billion to reimburse providers for conducting COVID-19 testing for the uninsured. In addition, part of the CARES Act's Provider Relief Fund will be used to reimburse hospitals and other health care providers for expenses related to the treatment of uninsured individuals with COVID-19.

How do healthcare providers receive funds for testing and treatment of the uninsured?

Answer: Healthcare providers who have conducted COVID-19 testing or provided treatment for uninsured COVID-19 individuals on or after February 4, 2020 can request claims reimbursement through the COVID-19 Uninsured Program Portal, administered by the Health Resources and Services Administration ("HRSA"). The portal opened for registration on April 27, 2020, and has been accepting claims for reimbursement since May 6, 2020.

Providers will be reimbursed generally at Medicare rates, subject to available funding. Steps will involve: enrolling as a provider participant, checking patient eligibility, submitting patient information, submitting claims, and receiving payment via direct deposit. HRSA has issued guidance on the claims reimbursement process.

Is there funding for telehealth?

Answer: Yes. The CARES Act appropriated $200 million to help healthcare providers seeking to purchase telecommunications, broadband connectivity, and devices necessary for providing telehealth services. On April 2, 2020, the Federal Communications Commission ("FCC") announced that it was using the $200 million to set up the COVID-19 Telehealth Program and accepting funding applications from providers on a rolling basis.

HHS also provided an additional $20 million through HRSA to increase telehealth infrastructure and access to help prevent and respond to COVID-19. Specifically, HRSA's Maternal and Child Health Bureau awarded $15 million to four organizations developing telehealth services for pregnant women, families, children, and adolescents, while HRSA's Federal Office of Rural Health Policy awarded $5 million to two recipients through the

Licensure Portability Grant Program to aid licensing boards and national compacts in developing a streamlined process for telehealth providers to obtain multi-state licensure and credentialing.

Who is eligible to receive funding through the COVID-19 Telehealth Program?

Answer: The COVID-19 Telehealth Program is open to nonprofit and public eligible health care providers, whether located in rural or non-rural areas, that fall within the categories of healthcare providers in Section 254(h)(7)(B) of the Telecommunications Act of 1996:

- Post-secondary educational institutions offering health care instruction, teaching hospitals, and medical schools;
- Community health centers or health centers providing health care to migrants;
- Local health departments or agencies;
- Community mental health centers;
- Not-for-profit hospitals;
- Rural health clinics;
- Skilled nursing facilities; or
- Consortia of health care providers consisting of one or more entities falling into any of the above seven categories.

Private and for-profit entities are not eligible to receive funding through the COVID-19 Telehealth Program. The FCC's COVID-19 Telehealth Program website and FAQs provide additional information about eligibility and the application process.

Is the CARES Act funding different from the CMS Accelerated and Advance Payment Program?

Answer: Yes. The CMS Accelerated and Advance Payment Program provides expedited funds to providers when there is a disruption in claims submission or processing or in cases of national emergencies or disasters. Unlike payments made via direct deposit under the CARES Act, accelerated/advance payments are effectively loans that must be requested and subsequently paid back.

On March 28, 2020, CMS expanded the program to a broader group of Medicare Part A providers and Part B suppliers to increase cash flow to providers of services and suppliers impacted by the COVID-19 pandemic. To qualify for accelerated/advance payments, a provider/supplier must (1) have billed Medicare for claims within 180 days immediately prior to the date of signature on the provider's/supplier's request form; (2) not be in bankruptcy; (3) not be under active medical review or program integrity investigation; and (4) not have any outstanding delinquent Medicare overpayments. CMS also delayed the recoupment of accelerated payments to 120 days after the date of issuance of the payment; after 120 days, every claim submitted by the provider/supplier will go toward repaying the accelerated/advance payment amount.

After the PPP/HCE Act was enacted and allocated additional direct funding for healthcare providers, however, CMS announced that it would not be accepting any new applications for accelerated/advance payment after April 26, 2020, and would be reevaluating all pending applications. By that date, CMS had approved over 21,000 applications advancing $59.6 billion in payments to Part A providers, including hospitals, as well as nearly 24,000 applications advancing $40.4 billion in payments to Part B suppliers, including doctors, non-physician practitioners, and durable medical equipment suppliers. CMS has issued a Fact Sheet with additional information.

10. FALSE CLAIMS ACT

What does fraud enforcement look like during the COVID-19 pandemic?

Answer: The federal government has emphasized that it will be cracking down on fraud during the COVID-19 pandemic. For example, on March 16, 2020, U.S. Attorney General William Barr issued a memorandum directing all U.S. Attorneys to "prioritize the detection, investigation, and prosecution of all criminal conduct related to the current pandemic." In a follow-up memorandum, Deputy Attorney General Jeffrey Rosen further directed each U.S. Attorney to appoint a Coronavirus Fraud Coordinator to serve as the legal counsel for the federal judicial district on matters relating to COVID-19, direct the prosecution of COVID-19-related crimes, and conduct outreach and awareness. And on March 20, 2020, Attorney General Barr issued a press release urging the public to report suspected fraud schemes related to COVID-19, including providers "fraudulently bill[ing]" for tests and procedures.

One anti-fraud statute that may be implicated by the government's increased enforcement efforts is the False Claims Act, 31 U.S.C. §§ 3729 *et seq*. ("FCA"). The FCA imposes liability for knowingly presenting a false or fraudulent claim or making a false record or statement material to a false or fraudulent claim. The U.S. Department of Justice ("DOJ") affirmed that it remains "committed to pursuing" violations of the FCA, "especially during this critical time as our nation responds to the outbreak of COVID-19." For more information, please see our Client Alert.

What theories of liability may result in FCA liability?

Answer: In the wake of the COVID-19 pandemic, we may see an increase in cases dealing with common FCA issues such as false or misleading statements made in connection with marketing drugs or devices, improper coding or billing for testing or treatments of different types or amounts than those actually provided, and billing for testing or treatments that are not medically necessary.

A defendant can also be liable under the FCA for falsely certifying compliance with a federal statute or regulation or a prescribed contractual term. A false certification can be express or implied. This "false certification" theory of FCA liability may be particularly relevant to entities accepting federal funds under the CARES Act and PPP/HCE Act, which, as discussed above, contains several relief programs conditioned on certifying compliance with specific eligibility requirements.

The federal government will be carefully scrutinizing applications for funds during the COVID-19 pandemic. Importantly, the Second Circuit Court of Appeals recently confirmed that loan applications submitted to federal

reserve banks during the 2008 financial crisis constituted "claims" for FCA purposes and that false certifications in those applications could lead to FCA liability. False certifications in applications for funding under the CARES Act or other statutes enacted to provide COVID-19 funding relief could likewise lead to FCA liability. For more information, please see our Client Alert.

11. ANTITRUST

What does antitrust enforcement look like during the COVID-19 pandemic?

Answer: Federal antitrust laws are enforced by both the Antitrust Division of the DOJ and the Federal Trade Commission ("FTC"). The DOJ offers a business review procedure by which businesses can request DOJ review of a proposed joint venture or other business conduct. Similarly, the FTC provides guidance regarding proposed conduct in the form of advisory opinions. Review through these processes typically takes several months.

In response to COVID-19, however, the agencies issued a joint statement announcing an expedited seven-day review process to evaluate proposed joint ventures. The agencies acknowledged that the pandemic "will require unprecedented cooperation" between governments and businesses, with many "trying to address a rapidly evolving crisis as quickly as possible." The DOJ has since issued two business review letters under the expedited review process, approving proposals for collaboration with federal agencies to expedite and increase manufacturing, sourcing, and distribution of equipment and medication needed to address the COVID-19 pandemic.

The agencies' joint statement also provided a list of collaborative activities designed to improve the health and safety response to the pandemic that would be presumed to be consistent with antitrust laws, including firms collaborating on research and development, sharing technical know-how, or developing standards for patient management to assist providers, as well as most joint purchasing arrangements among healthcare providers.

On April 13, 2020, the agencies issued another joint statement announcing that although there may be many procompetitive collaborations to address COVID-19 concerns, the agencies would remain "on alert for employers, staffing companies (including medical travel and locum agencies), and recruiters, among others, who engage in collusion or other anticompetitive conduct in labor markets, such as agreements to lower wages or to reduce salaries or hours worked." The agencies indicated concern that some individuals and business may use COVID-19 as "an opportunity to prey on American workers by subverting competition in labor markets." Towards that end, they may criminally prosecute companies and individuals who enter into naked wage-fixing and no-poach agreements.

The DOJ also announced that its Procurement Collusion Strike Force, an interagency partnership created to combat antitrust crimes and related schemes affecting procurement, grant, and program funding, remains on "high alert" for collusive practices in the sale of COVID-19-related products to federal, state, and local agencies.

12. ELECTIVE PROCEDURES

What guidance or directives were issued regarding limiting elective procedures during the COVID-19 pandemic?

Answer: On March 1, 2020, the Centers for Disease Control and Prevention ("CDC") issued guidance recommending that inpatient healthcare facilities reschedule elective surgeries as necessary and shift elective urgent inpatient diagnostic and surgical procedures to outpatient settings, when feasible, in response to COVID-19.

On March 18, 2020, CMS released guidance to limit "non-essential adult elective surgery and medical and surgical procedures, including all dental procedures." The guidance additionally noted that while "decisions remain the responsibility of local healthcare delivery systems . . . and those surgeons who have direct responsibility to their patients," when determining the risks and benefits of any planned procedures " . . . not only must the clinical situation be evaluated, but resource conservation must also be considered." The guidance outlined tiers of procedures to facilitate providers' decisions to postpone procedures, which was updated on April 7, 2020.

Industry groups and several state officials issued their own directives and guidance regarding elective procedures, ranging from recommendations that providers scale back elective procedures to mandates that elective procedures be canceled or postponed. For example, Texas Governor Greg Abbott issued an executive order on March 22, 2020, which directed "all licensed health care professionals and all licensed health care facilities" to "postpone all surgeries and procedures that are not immediately medically necessary to correct a serious medical condition of, or to preserve the life of, a patient who without immediate performance of the surgery or procedure would be at risk for serious adverse medical consequences or death, as determined by the patient's physician." The order's prohibition did not apply, however, to "any procedure that, if performed in accordance with the commonly accepted standard of clinical practice, would not deplete the hospital capacity or the personal protective equipment needed to cope with the COVID- 19 disaster."

What guidance has since been issued about resuming elective procedures?

Answer: On April 19, 2020, CMS issued guidance on providing essential non-COVID-19 care to patients without symptoms of COVID-19 in regions with low and stable incidence of COVID-19. The guidance is intended specifically for states or regions that have passed the Gating Criteria of the federal government's Guidelines for Opening Up American Again. It recommends a gradual transition and encourages healthcare providers to coordinate with local and state public health officials, and to review the availability of personal protective equipment and other supplies, workforce availability, facility readiness, and testing capacity when making the decision to re-start or increase in-person care.

In Texas, Governor Abbott issued an executive order on April 17, 2020, which revised the exception to the prohibition on elective procedures. Now, licensed health care professionals and health care facilities can perform:

(a) any procedure that, if performed in accordance with the commonly accepted standard of clinical practice, would not deplete the hospital capacity or the personal protective equipment needed to cope with the COVID-19 disaster, or

(b) any surgery or procedure performed in a licensed health care facility that has certified in writing to the Texas Health and Human Services Commission both:

(1) that it will reserve at least 25% of its hospital capacity for treatment of COVID-19 patients, accounting for the range of clinical severity of COVID-l9 patients; and

(2) that it will not request any personal protective equipment from any public source, whether federal, state, or local, for the duration of the COVID-19 disaster.

Several healthcare associations also issued a joint statement providing a list of principles and considerations to guide physicians, nurses, and local facilities in resuming elective surgeries, including considerations about timing, testing, personal protective equipment, and case prioritization and scheduling. Further, the ACS issued a checklist of issues that should be addressed locally before elective surgeries may be safely reinstituted as well as a set of guidelines for triage and management of elective cancer surgeries specifically.

13. OTHER RESOURCES

- CMS (COVID-19) Partner Toolkit
- CDC Guidance for Healthcare Professionals
- Haynes and Boone COVID-19 Resource Center