COVID-19 Spurs Government Action Through Multiple Temporary Regulatory Waivers for Health Care Providers

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On March 30, 2020 the Centers for Medicare and Medicaid Services ("CMS") issued multiple temporary regulatory waivers and new rules in an effort to provide the American healthcare system with maximum flexibility as it reacts and responds to the 2019 Novel Coronavirus (COVID-19) pandemic. These are obviously unprecedented times, and CMS has made great use of President Trump's recent emergency declaration and emergency rule making authorization, as well as Secretary Azar's public health emergency declaration.

According to CMS, its temporary regulatory waivers meet five goals, which are summarized below.

(1) "to ensure that local hospitals and health systems have the capacity to handle a potential surge of COVID-19 patients through temporary expansion sites (also known as CMS Hospitals Without Walls)." [1] To accomplish this goal, CMS has authorized, among other waivers, hospitals to provide inpatient care in temporary expansion sites through the use of surge capacities at remote locations, including hotels or community facilities where patients may be screened and furnished inpatient and outpatient services; the conversion of ambulatory surgical centers to be enrolled as hospitals; the expansion of physician owned hospitals by increasing the number of licensed beds, operating and procedure rooms; and the use of non-hospital buildings/space to be used for patient care and quarantine sites; waiving the length of stay and bed number limitations for Critical Access Hospitals ("CAH"); and waiving the enforcement of EMTALA requirements to allow screening at offsite locations.

(2) to "remove barriers for physicians, nurses and other clinicians to be readily hired from the community or from other states so the healthcare systems can rapidly expand its workforce."[2] To accomplish this goal, CMS waived physician supervision requirements by allowing direct supervision to occur using real-time audio/video technology; suspending the direct supervision requirements for non-surgical extended duration therapeutic services provided in hospital outpatient departments and CAH; allowing hospitals to place patients under the care of physician assistants and nurse practitioners, where possible, and suspending the supervision requirements for CRNAs; waiving requirements that practitioners be licensed in the state in which services are provided; expediting provider enrollment and waiving certain screening requirements; and allowing the extension of medical staff privileges without governing body/medical staff review and approval.

In addition, CMS is waiving sterile compounding requirements to allow used face masks to be retained in compounding areas and re-donned and reused during the same work shift in the compounding area:

(3) to "increase access to telehealth in Medicare to ensure patients have access to physicians and other clinicians while keeping patients safe at home."[3] To accomplish this goal, CMS has

1 Hospitals: CMS Flexibilities to Fight COVID-19 at https://www.cms.gov/files/document/covid-hospitals.pdf and Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19 at https://www.cms.gov/files/document/covid-19-physicians-and-practitioners.pdf

2 *See id.*

3 *See id.*

authorized, among other waivers, the waiver of telehealth requirements so that clinicians can care for their patients while mitigating the risk of spreading the coronavirus. CMS' waivers authorize all beneficiaries to receive Medicare telehealth and other communications technology-based services regardless of location or frequency, and by a broad range of clinicians to include physicians, nurse practitioners and physician assistants, therapists, psychologists and social workers, among others. The services include virtual check-ins and e-visits for both new and established patients, as well as remote patient monitoring for both acute and chronic conditions.[4]

Clinicians are authorized to provide these services to new or established patients to include emergency department visits; initial and subsequent observations and observation discharge day management visits; initial hospital care and hospital discharge day management; initial nursing facility visits; critical care services; home visits – both new and established patients; inpatient neonatal and pediatric critical care – both initial and subsequent; initial and continuing intensive care services; care planning for patients with cognitive impairment; psychological and neuropsychological testing; physical and occupational therapy visits; radiation treatment management services; and behavioral health services:

(4) to "expand in-place testing to allow for more testing at home or in community based settings."[5] To accomplish this goal, CMS is allowing healthcare systems, hospitals, and communities to set up testing and screening sites exclusively for the purpose of identifying COVID-19 positive patients in a safe environment. CMS guidance describes circumstances in which hospital emergency departments can test and screen patients for COVID-19 at drive-through and off-campus test sites. For Medicare beneficiaries, Medicare will pay laboratory technicians to travel to a beneficiary's home to collect a specimen for COVID-19 testing. Under certain circumstances, hospitals and other entities will also temporarily be able to perform tests for COVID-19 on people at home and in other community-based settings.[6]

(5) to "put Patients Over Paperwork to give temporary relief from many paperwork, reporting and audit requirements so providers, health care facilities, Medicare Advantage and Part D plans and States can focus on providing needed care to Medicare and Medicaid beneficiaries affected by COVID-19."[7] To accomplish this goal, among other waivers, CMS is permitting certain referrals and the submission of related claims that would otherwise violate the Stark Law.[8] These waivers include paying above or below fair market value to rent equipment or receive services from physicians; authorizing the financial support amongst health care providers to ensure continuity of health care operations; providing incidental medical staff benefits without regard to financial limitations; allowing the provision of certain items and services related solely to COVID-19 Purposes even if it would exceed the annual non-monetary compensation cap, such as training on testing protocols for home bound patients, or isolation shelter and meals to family members of a physician exposed to coronavirus; and group practices can furnish medically necessary MRIs, CT scans or clinical laboratory services from locations like mobile vans in parking lots. It is important to note that CMS expects that some documentation will be maintained demonstrating that the providers are utilizing the Stark waiver for the purposes set forth in the blanket waiver.

Other paperwork waivers include lengthening the time period for the authentication of verbal orders; waiving reporting requirements relating to the use of wrist restraints in the ICUs; limiting discharge planning requirements to focusing on appropriate placement; waiving nursing care plan requirements; waiving the necessity of written policies and procedures when evaluating emergencies at surge facilities; delaying cost report due dates; and authorizing Medicare Administrative Contractors and Qualified Independent Contractors to extend deadlines to file appeals and waive timing requirements in responding to requests for additional information to adjudicate appeals.

Finally, CMS has expanded the Accelerated and Advance Payment Program to provide necessary funds caused by a

4 Providers should consult state requirements when using telehealth services for Medicaid patients as state requirements may not mirror CMS' temporary regulatory requirements.

5 Hospitals: CMS Flexibilities to Fight COVID-19 at https://www.cms.gov/files/document/covid-hospitals.pdf and Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19 at https://www.cms.gov/files/document/covid-19-physicians-and-practitioners.pdf.

6 https://www.cms.gov/newsroom/fact-sheets/additional-backgroundsweeping-regulatory-changes-help-us-healthcare-system-address-covid-19-patient

7 *See id.*

8 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 at https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf.

disruption in claims submission and/or claims processing.[9] Most providers and suppliers may request 100% of Medicare payments. Inpatient acute care hospitals, children's hospitals and certain cancer centers may request 100% of Medicare payment for six months. Critical Access Hospitals can request up to 125% for a six month period. Payments will be issued within 7 calendar days from the MAC's receipt of a request, provided the provider/supplier meets the qualifications, which are set forth below.

The repayment of these accelerated/advance payments has been extended until 120 days after issuance of the repayment, during which time providers/suppliers can continue to submit claims. Repayments are not required in full at the end of 120 days. Rather, CMS will begin a recoupment of the payments against claims the provider/supplier submits. Hospitals have up to one (1) year from the date the payment is issued to repay the balance. All other recipients have 210 days from the date of payment to repay the balance.

This Program is available to any Medicare provider/supplier who submits a request to the appropriate MAC and meets the following specific qualifications:

- Has billed Medicare for claims within 180 days prior to the provider's/supplier's signature on the request form;
- Is not in bankruptcy;
- Is not under active medical review or a program integrity investigation; and
- Does not have any outstanding delinquent Medicare overpayments.

Although the waivers are temporary and will terminate upon termination of the COVID-19 Public Health Emergency, the waivers are retroactive to March 1, 2020.

9 Hospitals: CMS Flexibilities to Fight COVID-19 at https://www.cms.gov/files/document/covid-hospitals.pdf and Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19 at https://www.cms.gov/files/document/covid-19-physicians-and-practitioners.pdf.

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