

[Latham & Watkins Healthcare & Life Sciences Practice](#)

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CMS Expands Healthcare Delivery Options During COVID-19 Pandemic

CMS takes unprecedented action to streamline regulatory requirements, expand the availability and reach of healthcare resources, and encourage new delivery models.

In response to the COVID-19 public health emergency (PHE), the Centers for Medicare and Medicaid Services (CMS) continues to take historic and unprecedented action to expand the methods providers may use to furnish healthcare services to COVID-19 and non-COVID-19 patients alike. As a follow-on to the initial emergency waiver notification provided on March 13 by Health and Human Services (HHS) Secretary Alex Azar, CMS issued new regulations and waivers on March 30 in the form of an interim final rule (the Rule) and additional guidance.

These waivers greatly expand the initial waivers from HHS and CMS, marking one of the most significant regulatory actions to date in response to the COVID-19 PHE. These regulations took effect on March 31, 2020, and apply retroactively as of March 1, 2020. This *Client Alert* outlines CMS' new waivers and considers the implications for providers and suppliers.

Overview

CMS' most recent set of waivers achieve three overarching objectives:

- Provide new flexibility for physicians and hospitals to care for patients through remote means or to meet surge demands by coordinating with other facilities
- Increase provider ability to directly perform telehealth services or monitor care remotely
- Broaden patient eligibility and/or coverage criteria for certain items and services

These waivers will remain in effect for the duration of the public health emergency declaration. As discussed in a separate *Client Alert*,¹ the Rule also includes provisions expanding access to accelerated payments for Medicare suppliers.

For healthcare providers seeking to furnish care subject to these waivers, there is no need to apply to CMS or otherwise take further action. Although the waivers took effect on March 31, 2020, the Rule has a 60-day comment period ending on June 1, 2020, and CMS is seeking input on specific policies.

Companies should evaluate the extent to which this initial Rule resolves current regulatory and operational challenges they face in furnishing care during the PHE, and consider submitting comments requesting additional flexibility.

Expanding How and Where Care Is Delivered

Given the growing workforce constraints and the pressing need to minimize potential viral exposure, CMS expanded the healthcare services that may be delivered to patients in the home and reimbursed by Medicare.

- **Physicians may provide “direct supervision” through telehealth:** In the Rule, CMS adopts a novel definition of “supervision” to allow a physician to provide “direct supervision” of a service by virtual means. Importantly, this expansion is distinct from Medicare’s expanded telehealth benefit, described below, which allows practitioners to deliver a specific set of services remotely through telehealth technology. This new expansion, available only during the public health emergency, enables physicians to provide virtual supervision to auxiliary personnel (*e.g.*, nurses) who are present with the patient. This authority may enable the delivery of services outside the defined list of telehealth services and may also enable the delivery of “incident-to” services, such as drug injection or infusion by the healthcare practitioner, if both of the following criteria are satisfied:
 - The physician maintains a “virtual presence through audio/visual real-time communications technology.”
 - Use of such technology is “indicated to reduce exposure risks for the beneficiary or health care provider.”²

CMS also adopted a similar policy with respect to supervision of diagnostic services furnished in hospitals, allowing these services to be performed by non-physician personnel that are virtually supervised via telehealth by a physician in a remote location. These policies only pertain to the difficulty in providing direct supervision — they do not affect the payment rate, which will continue to be the same.

- **“Routine inpatient services” provided outside the hospital:** Ordinarily, hospitals are limited in their ability to bill for routine services (*e.g.*, bed, board, and nursing services) that are provided at sites outside the hospital. Given mounting concerns about hospital and ICU bed capacity and ventilator access, CMS will allow these routine inpatient services to be provided and reimbursed as inpatient care if they are performed under arrangements with other locations outside the hospital’s walls, including ambulatory surgical centers (ASCs), hotels, and dormitories, subject to state law and their State’s Emergency Preparedness or Pandemic Plan.³
- **Payment for travel and collection of specimens for COVID-19 tests:** In a continuing effort to make COVID-19 testing broadly available to Medicare beneficiaries, including patients who may be unable to access testing outside the home, CMS will provide separate payment to clinical laboratories to collect a patient specimen for a COVID-19 test if the collection required travel to a beneficiary’s home or temporary residence, such as a skilled nursing facility.⁴

Leveraging Telehealth and Remote Monitoring Services

In conjunction with the policy of allowing providers to remotely supervise other healthcare personnel providing services in the home or at other locations, during the public health emergency, CMS is separately expanding the types of procedures that physicians may perform directly using telehealth technologies. CMS expects this approach will help patients and providers minimize exposure to and transmission of the coronavirus while also allowing for more flexible staffing arrangements during the emergency.

- **Designated telehealth services to include additional evaluation and management (E/M) services:** Ordinarily, CMS maintains a tightly curated list of services eligible to be furnished via telehealth. Through the Rule, however, CMS added a number of additional E/M procedure codes, including emergency department visits, initial and subsequent inpatient visits, home visits, and monthly end-stage renal disease services.⁵ CMS also removed the limits on the frequency with which many of these codes may be furnished via telehealth,⁶ and stated it will exercise enforcement discretion to allow certain services to be performed without a face-to-face consultation with the patient or caregiver.
- **CMS-authorized technologies to provide care via telehealth:** The Rule clarifies the definition of “interactive telecommunications system” to remove prior language that suggested all telephones were excluded from being used to perform services through telehealth. CMS clarifies that smartphones can qualify as interactive, audio/visual telecommunications systems for the purposes of furnishing telehealth services.⁷ CMS also established coverage and payment for a specified set of E/M procedures conducted between providers and patients through a voice-only telephone call.⁸
- **Expanded patient eligibility for remote physiologic monitoring services:** Taking account of the new set of remote physiologic monitoring (RPM) services, the Rule allows RPM services to be provided to both new and established patients, and reduces the frequency with which providers must obtain patient consent to provide these monitoring services. CMS also clarifies that RPM services may be used to monitor both acute and chronic conditions — allowing, for example, COVID-19 patients to have their pulse and oxygen saturation levels monitored remotely.

Extending Patient Eligibility and Coverage Criteria for Certain Services

Finally, CMS' new waivers include modifications to certain Medicare coverage criteria, enabling beneficiaries to obtain medically necessary items and services while remaining in their homes to reduce potential exposure to the coronavirus.

- **Home health eligibility for patients who must remain in the home to prevent COVID-19 exposure:** Under existing law, patients are only eligible for Medicare home health services if they meet the statutory requirement of being “confined to the home.”⁹ During the emergency, CMS has announced that patients will be considered to have satisfied the confined-to-the-home requirement if one of the following criteria is met:
 - A physician determines it is medically contraindicated for the beneficiary to leave the home because they have a confirmed or suspected diagnosis of COVID-19.
 - A physician determines it is medically contraindicated for the beneficiary to leave the home because they have a condition that may make them more susceptible to contracting COVID-19.¹⁰

- CMS is waiving certain National Coverage Determination (NCD) and Local Coverage Determination (LCD) criteria to reduce potential viral exposure for susceptible patients: CMS recognizes that certain NCDs and LCDs, particularly those related to supply of durable medical equipment (DME), may require patients to engage in a face-to-face or in-person visit with the treating practitioner to qualify for coverage. To reduce the need for patients to leave their homes and visit a healthcare facility, CMS decided to waive coverage requirements associated with “face-to-face or in-person encounter[s] for evaluations, assessments, certifications or other implied face-to-face services.”¹¹
 - For NCDs and LCDs related to respiratory, home anticoagulation management, and infusion pump NCDs and LCDs, CMS goes even further, stating that the agency will not enforce any clinical requirement for coverage, recognizing that patients may need to receive care in unexpected settings during the emergency.¹² For example, CMS has clarified that it will exercise enforcement discretion to cover medically necessary home use of oxygen for patients for indications beyond those listed in the LCD, including patients diagnosed with COVID-19 during the PHE.¹³

These emergency waivers and regulatory changes from CMS are expected to dramatically alter the methods of clinical care delivery in the US during the COVID-19 PHE. The rapid expansion of technology-enabled services and the waiver of in-person requirements for practitioners will enable patients and providers to continue social-distancing actions while ensuring Medicare will provide reimbursement for critical services and items.

To the extent further flexibility is necessary to deliver care for patients, facilities and practitioners should review the Rule and consider submitting a comment to CMS within the 60-day comment window. Congressional leaders are beginning to discuss another legislative package, which may provide further relief in response to the unique challenges COVID-19 has presented.

Latham will continue to monitor these developments closely and provide updates on a regular basis.

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Endnotes

¹ See Latham & Watkins *Client Alert* 2683, "Expanded Medicare Payment Policy and CARES Act Provide Financial Relief for Healthcare Providers and Suppliers (Mar. 31, 2020), available at <https://www.lw.com/admin/upload/SiteAttachments/Alert%202683v6.pdf>.

² CMS, No. CMS-1744-IFC, Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, at 59 (Mar. 30, 2020) (hereinafter the "Rule").

³ *Id.* at 173 (citing CMS, Pub. 100-01, Medicare General Information, Eligibility, and Entitlement Manual, Ch. 5, § 10.3).

⁴ *Id.* at 92.

⁵ *Id.* at 19.

⁶ *Id.* at 42.

⁷ *Id.* at 48. The Rule also reiterates that the HHS Office of Civil Rights (OCR) and Office of the Inspector General (OIG) have issued separate guidance indicating they will apply enforcement discretion to cases in which everyday communications are used for telehealth or cost-sharing obligations are waived for telehealth services. See HHS OIG, OIG Policy Statement Regarding Physicians and Other Practitioners That Reduce or Waive Amounts Owed by Federal Health Care Program Beneficiaries for Telehealth Services During the 2019 Novel Coronavirus (COVID-19) Outbreak (Mar. 17, 2020); HHS OCR, Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency, <https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html>.

⁸ Rule, at 122.

⁹ CMS, Medicare Benefit Policy Manual, Ch. 7, § 30.1.1.

¹⁰ Rule, at 61.

¹¹ *Id.* at 128.

¹² *Id.* at 128-29.

¹³ See CMS, COVID-19 FAQs (March 23, 2020) available at <https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf>.