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CMS Finalizes Permanent Changes for Certain Telehealth Services Modified During COVID-19 Public Health Emergency

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On December 1, 2020, the Centers for Medicare & Medicaid Services ("CMS") released the annual Physician Fee Schedule Final Rule ("Final Rule").[1] Among other things, the Final Rule:

- Makes permanent certain changes that CMS had put in place since the declaration of the public health emergency for the COVID-19 global pandemic ("PHE") that modified coverage of telehealth services in the Medicare program;[2]
- Adds certain services permanently to the list of telehealth services covered by Medicare ("Medicare Telehealth Services List");[3]
- Reduces, on a permanent basis, frequency limitations on nursing facility services delivered through telehealth;[4]
- Removes an outdated and, due to the existence of smartphones, confusing reference to "telephones" in the definition of interactive telecommunications system;[5]
- Makes permanent certain flexibilities that CMS had granted during the PHE related to remote monitoring care management services and virtual Communication Technology-Based Services ("CTBS") based on CMS' determination that these are not considered telehealth services; and
- Clarifies several payment policies related to remote physiologic monitoring ("RPM") services.

The Final Rule's regulations became effective on January 1, 2021, though select policies will be applicable retroactive to January 1, 2020,[6] or from the start of the PHE on January 27, 2020.[7] For a discussion of the proposed rule and prior modifications to telehealth services during the PHE, please see Ropes & Gray's prior Alert.

This Alert summarizes key telehealth changes made by the Final Rule, and includes a table for quick reference.

Background: PHE Relaxation of Certain Limitations on the Secretary's Authority

Historic statutory limitations. The Medicare statute limits the Secretary of the U.S. Department of Health and Human Services' ("Secretary") authority to expand Medicare coverage of telehealth services in several respects.[8] The statute restricts Medicare coverage for telehealth services to those services furnished in certain geographic areas and provided at certain originating sites, such as hospitals or physician offices. It limits Medicare coverage of telehealth services to those furnished by certain practitioners and identified on the Medicare Telehealth Services List maintained by CMS as updated through agency notice-and-comment rulemaking. It also restricts the modality of telehealth coverage, limiting it to services furnished through a synchronous, two-way, audio and video communication.

PHE waivers. A series of legislation[9] passed in response to the PHE gave the Secretary the authority to waive or to modify Medicare telehealth coverage requirements during the PHE. The Secretary used this waiver authority to: (i) remove geographic and site-of-service originating site restrictions; (ii) remove the restriction on the types of practitioners who could furnish telehealth services; (iii) allow certain telehealth services to be furnished through audio-only communications technology; and (iv) remove the requirement to undertake rulemaking to add or delete services on the Medicare Telehealth Services List. Through emergency rulemaking, CMS has given health care providers considerable flexibility in providing telehealth services, vastly expanding the scope of services that could be provided by telehealth, allowing services to be furnished to patients in their homes without regard to geographic location or originating site restrictions, and broadening the types of practitioners who could provide telehealth services to include emergency department physicians, physical therapists ("PTs"), occupational therapists ("OTs"), speech language pathologists

("SLPs"), and others. CMS also relaxed policies to allow teaching hospitals to provide resident supervision by telehealth, and to allow required in-person visits for nursing home residents to be conducted by telehealth where appropriate.

At the same time, CMS enlarged the types of practitioners able to furnish CTBS services to include licensed clinical social workers, clinical psychologists, PTs, OTs and SLPs. It also clarified payment policies related to RPM services that allowed for increased care management services during the PHE.

Limitations on post-PHE changes. The increased use of telehealth services during the PHE has spurred questions regarding the state of telehealth after the PHE, with many lauding its value and utility within the health care system. Notwithstanding the growing recognition of telehealth's value, several Medicare coverage and reimbursement changes that have been implemented during the PHE, which many might expect to become permanent once the PHE ends, cannot be made permanent without legislative action. At the conclusion of the PHE or the end of the calendar year in which the PHE terminates, as applicable, the waivers and interim final rules will expire, and Medicare coverage and reimbursement for telehealth services will once again be limited by the statutory restrictions.

For example, following the expiration of the PHE, legislative action will be necessary to allow for audio-only communications for telehealth services and to allow most patients to receive reimbursable telehealth services in their home rather than at, for example, a hospital or physician office. CMS will again be bound by the notice-and-comment rulemaking process before expanding or reducing the services included on its Medicare Telehealth Services List. Significantly, because CTBS and RPM services are not considered telehealth services, CMS will not be statutorily limited in developing coverage and payment policies for CTBS and care management services delivered virtually and remotely.

Changes Implemented by the Final Rule

Permanent and certain continued temporary expansions. Notwithstanding the limitations on post-PHE changes, CMS, in the Final Rule, has made several permanent and temporary modifications to its Medicare coverage of telehealth services, CTBS and RPM services. As detailed more fully in the table below, it has permanently added to the list of telehealth services covered by Medicare, including evaluation and management ("E/M") services provided to established patients in their homes. It has added many other services on a temporary basis, including those that normally require a face-to-face visit, such as higher-level services to those furnished in homes or rest homes, emergency and critical care services. Services to new patients and initial hospital and nursing facility-level services, however, as well as radiation treatment management services and medical nutrition therapy, remain covered only if provided through a face-to-face visit.

CMS also clarified current policies for telehealth services, including that telehealth services may be covered when provided incident-to a distant site physician's (or authorized non-physician practitioner's ("NPP")) service under the direct supervision of the billing practitioner provided through telehealth.

Non-telehealth CTBS services. CMS also finalized separate payment for many CTBS services that are not considered telehealth, including services furnished by licensed clinical social workers, clinical psychologists, PTs, OTs, and SLPs. CMS emphasized, however, that outside of the PHE, CTBS services will be covered only for established patients. CMS also clarified that after the end of the PHE, there will be no separate payment for audio-only E/M services, since CMS considers these services replacements for in-person office visits and thus subject to the statutory restriction on telehealth modalities in Section 1834(m) of the Social Security Act ("SSA").[10]

Remote physiologic monitoring. CMS also clarified several RPM policies, including that once the PHE ends, RPM services may be furnished only to established patients and that temporary modifications made to data collection requirements during the PHE will not continue. It made clear that RPM devices must meet the U.S. Food and Drug Administration ("FDA") definition of a medical device as set forth in Section 201(h) of the Federal Food, Drug, and Cosmetic Act in order to be reimbursable under Medicare as an RPM device. It also clarified that RPM services may be

furnished to patients with acute conditions as well as chronic conditions. CMS finalized its proposal to allow patient consent for services to be obtained at the time RPM services are provided. It also finalized its proposal to allow auxiliary personnel, which includes leased employees and independent contractors, to furnish certain RPM data collection services under the general supervision of the billing practitioner, thereby eliminating the requirement that the billing practitioner be in the same office as the practitioner furnishing the data collection services.

The table below describes certain of the changes implemented by the Final Rule. While the Final Rule extends only a small portion of existing flexibilities on a permanent basis, other market drivers may influence the adoption and coverage of telehealth and remote monitoring services, both through prompting legislation and through changes to state and commercial payor policies. Commercial payors may decide, for example, to extend coverage of telehealth services to help reduce costs of care or to improve patient outcomes. States and state agencies also may adopt policies that encourage greater adoption of telehealth services either through their state Medicaid programs or through regulation of commercial payors.

If you have any questions, please contact one of the authors or your usual Ropes & Gray advisor.

Table of Key Telehealth Changes		
Category	**Existing COVID-19 Flexibility**	**Final Rule Changes**
Providers		
Medicare Telehealth Services List	During the PHE, CMS added certain services to the Medicare Telehealth Services List on an interim final basis.	**Permanent Additions to Telehealth Services** CMS has permanently added many services to the Medicare Telehealth Services List:[11] • Domiciliary, rest home, or custodial care evaluation and management services, established patient (CPT 99334-99335) • Home visits, evaluation and management services, established patient (CPT 99347- 99348) • Cognitive assessment and care planning services in the office or at home (CPT 99483) **Temporary Additions to Telehealth Services** CMS added certain services to the Medicare Telehealth Services List on a temporary basis through the later of either the end of the year in which the PHE ends or December 31, 2021:[12] • Domiciliary, rest home, or custodial care services, evaluation and management services, established patient (CPT 99336- 99337) • Home visits, evaluation and management services, established patient (CPT 99349-99350) • Emergency department visits, levels 1-5 (CPT 99281-99285)

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		• Nursing facilities discharge day management (CPT 99315-99316) • Critical care services (CPT 99291-99292) **Face-to-Face Still Required for Initial Services and New Patients** CMS decided not to add certain services to the Medicare Telehealth Services List:[13] • Initial nursing facility visits, all levels (low, moderate, and high complexity) (CPT 99304-99306) • Initial hospital care (CPT 99221-99223) • Domiciliary, rest home, or custodial care services, new patient (CPT 99324- 99328) • Home visits, new patient, all levels (CPT 99341-99345) CMS had added certain services associated with office-based treatment of opioid use disorder to the Medicare Telehealth Services List in CY 2020. In the Final Rule, CMS revised the descriptions to certain codes[14] added to the Medicare Telehealth Services List to include the treatment of any substance use disorder, rather than just opioid use disorder.
Interactive Telecommunication System Definition	During the PHE, CMS temporarily waived the prohibition on use of a telephone for telehealth services, but required that the telephone have "audio and video equipment permitting two-way, real-time interactive communication," allowing for synchronous patient interaction (e.g., Apple FaceTime, WhatsApp video chat, Zoom, Skype and Google Hangouts video). Notably, the statutory text that sets forth the telehealth services benefit does not explicitly define "telecommunications system." Thus, the Secretary has the ability to determine whether such "telecommunications system" must include both audio and video capabilities,	CMS permanently removed the regulatory reference that specified that telephones, fax machines, and email systems do not meet the definition of interactive telecommunications system for purposes of furnishing Medicare telehealth services.

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	and thus what is considered an "interactive telecommunications system."	
Billing of CTBS	During the PHE, CMS established that "e-visits" (a form of CTBS consisting of patient-initiated, non-face-to-face communications through an online portal) may be billed by licensed clinical social workers, clinical psychologists, PTs, OTs, and SLPs. • These practitioners also may provide virtual check-ins (brief telephone calls) and remote evaluation (evaluations of pre-recorded video and/or images submitted by a patient). • Consent for CTBS may be documented by auxiliary staff under general supervision. As CMS does not consider CTBS to be telehealth services, it has greater authority in deciding who may provide such services and where they may be provided.	Licensed clinical social workers, clinical psychologists, PTs, OTs, and SLPs may furnish the brief online assessment and management services, virtual check-ins and remote evaluation. New billing codes have been established to facilitate billing by these practitioners for the virtual check-ins and remote evaluations. In the Final Rule, CMS emphasized its view that, outside of the PHE, "CTBS services broadly should be billed only for *established* patients."
Reimbursement for Audio-Only Technology	During the PHE, reimbursement for audio-only telephone E/M visits for new and established patients, at payment rates that match rates under the PFS for office/outpatient visits with established patients.	Upon expiration of the PHE there will be no separate payment for the audio-only E/M visit codes. Outside of the PHE, CMS is unable to waive the statutory requirement that telehealth services be furnished using an interactive telecommunications system that includes two-way, audio and video communication. This is due to CMS's long-standing interpretation of audio-only assessments as inadequate replacements for face-to-face visits. Audio-only services will be bundled into E/M face-to-face visit codes. Even though, outside of the PHE, Medicare does not provide separate payment for a service furnished using synchronous audio-only technology, the Final Rule establishes additional coding and payment for an extended audio-only assessment service on an interim basis for CY 2021. The service is not a substitute for an in-person visit, but rather an assessment to determine the necessity of an in-person visit. CMS provides a 60-day public comment period on this interim final rule.
Direct Supervision Requirements	During the PHE, direct supervision by a supervising practitioner (traditionally	Through the later of December 31, 2021 or the end of the calendar year in which the PHE ends, direct supervision

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	defined to require the practitioner's physical presence in the office) could be met through virtual presence using interactive audio and video real-time communications technology.	requirements may be met using real-time interactive audio and video technology, based on the practitioner's clinical judgment. CMS clarified that telehealth services may be reimbursed when provided incident-to a distant site physician's (or authorized NPP's) service under the direct supervision of the billing professional provided through virtual presence.
RPM	During the PHE, RPM services may be furnished to *new and established* patients.	CMS clarified that after the PHE ends, there must be an *established* patient-practitioner relationship for RPM services to be furnished.
	During the PHE, consent for RPM services may be obtained at the time services are furnished and may be obtained by individuals providing RPM services under contract with the billing practitioner.	The Final Rule makes permanent that consent for RPM services may be obtained at the time they are furnished. Additionally, auxiliary personnel can furnish certain RPM services (CPT codes 99453 and 99454) under the *general* supervision of the billing physician/practitioner. Auxiliary personnel means any individual, whether an employee, leased employee or independent contractor, acting under the supervision of a physician/practitioner, who meets certain requirements.
	During the PHE, RPM codes may be billed for a minimum of two days of data collection over a 30-day period, rather than the required 16 days of data collection over a 30-day period.	CMS clarified that after the PHE ends, CMS will again require 16 days of data collection over a 30-day period for billing requirements.
	N/A	In its commentary, CMS noted its clarification in the proposed rule that the medical device for remote monitoring must automatically upload patient physiologic data; thus, data must not be patient self-recorded or self-reported.
	N/A	CMS clarified that RPM services can be ordered and billed only by physicians and NPPs who are eligible to bill Medicare for E/M services.
	N/A	CMS clarified that the CPT code descriptors indicate that a device supplied for RPM services must meet the FDA definition of a medical device under the Federal Food, Drug, and Cosmetic Act.
	N/A	CMS clarified that RPM services may be furnished to patients with acute conditions as well as those with chronic conditions.
	N/A	CMS clarified that for certain RPM services that require "interactive communication," the "interactive communication" requires, at a minimum, a real-time

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		synchronous, two-way audio interaction that can be enhanced with video or other data transmission.
End-Stage Renal Disease ("ESRD") Providers		
Face-to-Face Requirement for ESRD Patients	During the PHE, CMS waived the statutory requirement that an ESRD patient receiving home dialysis must receive certain face-to-face clinical assessments without the use of telehealth.	CMS finalized the addition of ESRD Monthly Capitation Payment services with a single face-to-face visit per month as a temporary addition to the Medicare Telehealth Services List for the later of the end of the year in which the PHE ends or December 31, 2021. However, CMS noted that, due to statutory restrictions, certain initial face-to-face clinical assessments must be provided in person following the expiration of the PHE.[15]
Nursing Facilities		
Frequency Limitations for Nursing Facility Telehealth Services	During the PHE, CMS waived the requirement for physicians and NPPs to perform required visits in person for nursing home residents to allow visits to be conducted via telehealth.	CMS permanently reduced frequency limitations for nursing facility care services delivered through telehealth from once every 30 days to once every 14 days.
Academic Medical Centers		
Virtual Presence of a Teaching Physician and Supervision of Residents	During the PHE, teaching physicians can be "present" through real-time, audio and video telecommunications technology, including telehealth services, except in certain complex cases. During the PHE, Medicare payment for teaching physician services, including telehealth services, may be made when a teaching physician reviews (in addition to directs or manages) a resident's service via audio and video real-time communications technology. During the PHE, services billed under the "primary care exception"[16] may include circumstances where the resident is furnishing services via telehealth.	CMS finalized these policies for the duration of the PHE. However, to improve rural access to care, CMS has made permanent these policies permitting teaching physicians to meet the requirements to bill for their services involving residents through virtual presence, but only for services furnished in residency training sites located outside of a metropolitan statistical area, as defined by the Office of Management and Budget.
Opioid Treatment Programs ("OTPs")		
Periodic Assessments	During the PHE, OTPs may furnish periodic assessments via two-way interactive audio and video	Periodic assessments must be furnished during a face-to-face encounter, but may be furnished via two-way interactive audio and video communication technology, as clinically

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	communication technology and, where beneficiaries do not have access to such, through audio-only telephone calls provided all other applicable requirements are met.	appropriate, provided all other applicable requirements are met. The flexibility to use audio-only telephone calls for periodic assessments will not be extended beyond the PHE.
ACOs and Value-Based Payment Participants		
Medicare Shared Savings Program ("MSSP") Primary Care Services Definition	CMS expanded the definition of primary care services in the MSSP to include codes for remote evaluations, virtual check-ins, e-visits, and telephone E/M services.	CMS will use the expanded definition of primary care services to determine beneficiary assignment when the assignment window for a benchmark or performance year includes any months during the PHE.
Consumer Assessment of Healthcare Providers and Systems ("CAHPS") Primary Care Services Definition	CMS expanded the definition of primary care services for purposes of the CAHPS for Merit-Based Incentive Payment Program ("MIPS") assignment methodology.	The Final Rule expands the definition to include CTBS and audio-only telephone E/M services in alignment with the MSSP definition of primary care services.
MIPS Cost Measures	N/A	CMS added costs associated with telehealth services to MIPS cost measures, beginning with the 2021 performance period.

[1] CMS, Medicare Program; CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; etc., *available at* https://public-inspection.federalregister.gov/2020-26815.pdf (scheduled to be published in the Federal Register on 12/28/2020).

[2] CMS, COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers 1 (December 1, 2020), *available at* https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf ("CMS Blanket Waiver"); April 6, 2020 interim final rule with comment (the "April IFC"), 85 Fed. Reg. 19230 (April 6, 2020), *available at* https://www.federalregister.gov/documents/2020/04/06/2020-06990/medicare-and-medicaid-programs-policy-and-regulatory-revisions-in-response-to-the-covid-19-public; May 8, 2020 interim final rule with comment (the "May IFC"), 85 Fed. Reg. 27550 (May 8, 2020), *available at* https://www.federalregister.gov/documents/2020/05/08/2020-09608/medicare-and-medicaid-programs-basic-health-program-and-exchanges-additional-policy-and-regulatory; September 2, 2020 interim final rule with comment (the "September IFC"), 85 Fed. Reg. 54820 (September 2, 2020), *available at* https://www.federalregister.gov/documents/2020/09/02/2020-19150/medicare-and-medicaid-programs-clinical-laboratory-improvement-amendments-clia-and-patient.

[3] CMS maintains a list of telehealth services for which Medicare will provide reimbursement so long as certain criteria are met; s*ee* the Final Rule, p. 143.

[4] *See* the Final Rule, p. 149.

[5] *See* the Final Rule, p. 149–150.

[6] For instance, the definition of primary care services for purposes of the Medicare Shared Savings Program ("MSSP") will be applicable retroactive to January 1, 2020.

[7] For example, policies used to identify inpatient services triggering an episode of care for treatment of COVID-19 will be effective retroactive to the start of the PHE on January 27, 2020.
[8] *See* 42 U.S.C. § 1395m(m).
[9] *See* Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116-123); Families First Coronavirus Response Act, 2020 (P.L. 116-127); and The Coronavirus Aid, Relief, and Economics Security Act, 2020 (P.L. 116-136) ("CARES Act").
[10] *See* 42 U.S.C. § 1395m(m).
[11] For a complete list, please see Table 16 of the Final Rule, p. 143, *available at* https://public-inspection.federalregister.gov/2020-26815.pdf.
[12] *Id*.
[13] *Id*.
[14] These include HCPCS codes for bundled payments (G2086, G2087, and G2088) for office-based treatment for opioid use disorder, which encompass development of the treatment plan, care coordination, individual therapy, group therapy and counseling.
[15] 42 U.S.C. 1395rr(b)(3)(B)(i) of the SSA provides that an ESRD patient receiving home dialysis may voluntarily elect to receive monthly ESRD-related clinical assessments through telehealth. However, the ESRD patient may elect such telehealth clinical assessments only if the ESRD patient already has received, without the use of telehealth, (i) a monthly face-to-face ESRD clinical assessment during the first three months of home dialysis, and (ii) after the initial three months, a face-to-face visit at least once for three consecutive months. *See* 42 U.S.C. 1395rr(b)(3)(B)(ii). The CARES Act provided the Secretary with the authority to waive 42 U.S.C. 1395rr(b)(3)(B)(ii) of the SSA during the PHE. For the duration of the later of either the end of the calendar year in which the PHE ends or December 31, 2021, CMS temporarily added the monthly recurring telehealth clinical assessments to the Medicare Telehealth Services List, effectively extending the waiver to ESRD patients who already have established the initial in-person clinical assessments. However, after the end of the PHE, the initial clinical assessments required under the SSA must be conducted in person.
[16] The "primary care exception" allows a teaching physician to bill for certain services furnished by residents in certain settings even when the teaching physician is not present with the resident. *See* 42 CFR § 415.174.