COVID-19: CMS RELEASES ADDITIONAL BLANKET WAIVERS AND FLEXIBILITIES

Date: 4 May 2020

U.S. Health Care Alert

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On 30 April 2020, the Centers for Medicare & Medicaid Services (CMS) released additional blanket waivers under Section 1135 of the Social Security Act and rules changes though an Interim Final Rule with Comment Period (IFC), as part of CMS's continuing efforts to support health care providers as they work to expand access to care and testing related to COVID-19. These waivers and rule changes impact health care providers across the spectrum—including hospitals, nursing facilities, durable medical equipment, prosthetics, orthotics, supplies supplier, home health agencies, hospices, and opioid treatment programs, to name a few. Some of these waivers and rule changes are new, while others update previous waivers and changes. CMS has also updated the provider specific guidance documents on its website.[1] A high-level summary of several notable waivers and regulatory changes is provided below.

ADDITIONAL BLANKET WAIVERS

CMS updated its "COVID-19 Emergency Declaration Blanket Waiver for Health Care Providers."[2] Notable waivers include the following:

Telehealth

The wavier updates add flexibilities for providing telehealth services, including the following:

- The restrictions imposed under 42 U.S.C. § 1395m(m)(4)(e) and 42 C.F.R. § 410.78(b)(2) on the types of practitioners that may furnish and bill for telehealth services as the distant site practitioner. The waiver permits all those that are eligible to bill for Medicare for their professional services to furnish and bill for Medicare telehealth services, including physical therapists, occupational therapists, speech-language pathologists, and other practitioner types that were previously ineligible.
- The requirements at 42 U.S.C. § 1395m(m)(1) and 42 C.F.R. § 410.78(a)(3) mandating the use of interactive telecommunications systems to furnish telehealth services to now allow audio-only equipment to be used for certain specified services.

Long-Term Care Facilities, Home Health Agencies (HHAs), and Hospices

For both long-term care facilities and HHAs, the update (1) modifies the quality assurance and performance improvement (QAPI) program to narrow its scope so that an emphasis is placed on infection control issues and the tracking of adverse events and (2) waives certain discharge planning requirements. The update also lengthens the time by which these entities must provide a resident his or her clinical records when requested to

10 days from the previous two-day requirement for long-term care facilities and the previous four-day period for HHAs. For long-term care facilities and HHAs, as well as hospices, the update postpones the deadline for their respective in-service nurse aide, home health aide, and hospice provider training.

Additionally, CMS also postpones the requirement for hospice and HHAs to conduct annual onsite supervisory visits for each aide that provides services on behalf of the agency. All postponed visits must be completed no later than 60 days after the expiration of the public health emergency (PHE).

Physical Environment Conditions of Participation

With respect to the physical environment conditions of participations for hospitals, critical access hospitals, inpatient hospice facilities, intermediate care facilities for individuals with intellectual disabilities, and skilled nursing facilities and nursing facilities, the update modifies requirements so that these facilities may adjust the frequency of scheduled inspection, testing, and maintenance and activities for facility and medical equipment, with the exception of certain activities deemed critical. Additionally, to accommodate the potential need to quarantine patients or provide care in a temporary area, the update also waives the requirement to have an outside window or door in every sleeping room in these facilities.

Ambulatory Surgical Centers (ASCs)

Regarding ASCs, during the PHE, the waiver allows those physicians whose privileges expire to continue practicing at the ASC without performing the reappraisal required at 42 C.F.R. § 416.45(b) and also permits the ASC to continue to operate without performing this administrative task.

Community Mental Health Centers (CMHCs)

For CMHCs, the update adds flexibilities to their QAPI requirements, waives prohibitions on partial hospitalization services and for providing certain services in patient's homes, and waives the “40 percent rule.”

REGULATORY CHANGES UNDER THE IFC

CMS released in prepublication form an IFC entitled *Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program*.[4] The IFC provides additional flexibilities to providers during the PHE, except where a different duration is specified in the IFC, and updates or clarifies policy changes in the prior IFC.[5] While the regulation changes will be effective on the date of publication in the Federal Register (scheduled for 8 May 2020), the policies in the IFC may be relied upon generally beginning on 1 March 2020 or 27 January 2020 (as set forth for each policy in the IFC), although certain alternative effective dates for specific policies are otherwise identified in the IFC[6] Below is a high-level summary of some notable regulatory and policy changes in the IFC.

- Scope of Practice.[7] Among other changes, permitting physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs), and certified nurse-midwives to supervise diagnostic tests if authorized to do so under applicable state law.

- Modified Requirements for Ordering COVID-19 Diagnostic Laboratory Tests.[8] Removing the requirement that COVID-19 tests, and in certain specified circumstances, tests for influenza virus and respiratory syncytial virus, be ordered by the patient's treating physician or non-physician practitioner (NPP) to be covered by Medicare.[9] CMS will publish a list of codes to which this change applies.[10] CMS indicates that when there is no physician or NPP order, the laboratory conducting the tests is required to directly notify the patient of the results consistent with other applicable laws, as well as meet other applicable test result reporting requirements.
- Treatment of Certain Relocating Provider-Based Departments (PBDs) During the COVID-19 PHE.[11] Permitting hospitals that temporarily relocate all or part of an on-campus PBD or off-campus PBD excepted under Section 603 of the Bipartisan Budget Act of 2015 to an alternative off-campus location (or, in limited circumstances, more than one alternative location) for purposes of addressing the COVID-19 PHE to seek a an extraordinary circumstances relocation exception so that they may bill at the Hospital Outpatient Prospective Payment System (OPPS) rate, as long as the relocation is not inconsistent with the state's emergency preparedness or pandemic plan. The IFC describes the process and timing for submitting such requests. If the request is denied, the hospital will be required to bill with modifier “PN” and receive the site-neutral payment rate (currently 40 percent of OPPS). This policy will end following the end of the PHE, and CMS anticipates that most, if not all, PBDs that relocate during the COVID-19 PHE will relocate back to their original location prior to, or soon after, the COVID-19 PHE concludes. On-campus PBDs that are permanently relocated off-campus would be considered new off-campus PBDs billing after 2 November 2015 and, therefore, would be required to bill using the “PN” modifier. Excepted off-campus PBDs that permanently relocate would be required to follow the standard relocation exception policy, and CMS indicates that the fact that a PBD relocated in response to the PHE will not, by itself, be considered an “extraordinary circumstance” to support a permanent relocation exception.
- Furnishing Outpatient Services in Temporary Expansion Locations of a Hospital or a CMHC (Including the Patient's Home).[12] Clarifying regulatory flexibilities and billing for three categories of hospital outpatient therapeutic services furnished to beneficiaries in their homes or other temporary expansion locations for the duration of the COVID-19 PHE: (1) hospital outpatient therapy, education, and training services, including partial hospitalization program services, which can be furnished other than in-person and are furnished in a temporary expansion location that is a PBD of the hospital or an expanded CMHC; (2) hospital outpatient clinical staff services furnished in person to the beneficiary in a temporary expansion location; and (3) hospital services associated with a professional service delivered by telehealth. The IFC explains the circumstances under which a patient's home may be considered a PBD of the hospital or a location of a CMHC during the PHE.
- Medical Education.[13] Describing approach to holding hospitals harmless from reductions in Indirect Medical Education (IME) payments due to increases in bed counts due to COVID-19 and holding Inpatient Rehabilitation Facilities and Inpatient Psychiatric Facilities harmless from reductions to teaching status adjustment payments due to COVID-19. CMS is also revising applicable IME and Direct Graduate Medical Education (DGME) regulations to permit teaching hospitals during the COVID-19 PHE to claim for purposes of IME and DGME payments the time spent by residents training at other hospitals where they may be most needed to treat COVID-19 or non-COVID-19 patients.

- Rural Health Clinics (RHCs).[14] Revising the bed count methodology used to determine the number of beds in a hospital for purposes of determining which provider-based RHCs are subject to the RHC payment limit due to the PHE.
- Care Planning for Medicare Home Health Services.[15] Making a permanent change to add a definition of "allowed practitioner" to applicable home health regulations to permit NPs, CNSs, and PAs to certify, establish, and periodically review the plan of care, as well as supervise the provision of items and services for beneficiaries under the Medicare home health benefit.
- Clarification of the "3-Hour Rule" Waiver and Modification of IRF Coverage and Classification Requirements for Freestanding IRF Hospitals.[16] Replacing the guidance in the IFC of 31 March 2020, in regard to the wavier of the IRF "3-hour" rule during the PHE, as the 31 March IFC did not account for Section 3711(a) of the Coronavirus Aid, Relief, and Economic Security Act, which more directly waives the "3-hour" rule. CMS amends certain IRF payment and classification requirements to add an exception for care furnished to patients admitted to freestanding IRFs solely to relieve acute care capacity during the COVID-19 PHE. Finally, CMS permits freestanding IRFs to admit acute care patients who must be discharged from the acute care hospitals to provide surge capacity at the acute care hospital. These flexibilities will apply only when a state is in Phase 1 or prior to Phase 1 under the Guidelines for Opening Up America.
- Medicare Shared Savings Program (MSSP). Making changes related to MSSP policies, including:
  - Application Cycle.[17] Forgoing the application cycle for a 1 January 2021 start date; allowing certain Accountable Care Organizations (ACOs) whose participation agreements are ending 31 December 2020 to elect an extension of their agreement for an additional 12-month performance year, permitting them to remain under their existing historical benchmark for an additional year.
  - BASIC Track ACOs Participation Level.[18] ACOs in the BASIC Track's glide path may elect to maintain their current level of participation for Performance Year (PY) 2021. ACOs that elect to maintain their current level will automatically advance two levels in PY 2022.
  - Adjustments to Shared Savings Program Calculations.[19] All Part A and Part B Fee-for-Service payment amounts for an episode of care for treatment of COVID-19, triggered by an inpatient service, and as specified on Part A and Part B claims with dates of service during the episode, will be excluded from Shared Savings Program calculations. Affected months will also be excluded from total person years used in per capita expenditure calculations.
  - Expansion of Codes Used in Beneficiary Assignment.[20] Expanding the definition of primary care services for purposes of determining beneficiary assignment to include certain additional codes as specified in the IFC related to virtual check-ins, e-visits, telephonic communication, and telehealth.
  - Track 1+ Model ACOs.[21] Unless specified otherwise, the changes to the Shared Savings Program regulations established in this IFC that are applicable to ACOs within a current agreement period will apply to ACOs in the Track 1+ Model in the same way that they apply to ACOs in Track 1, Track 2, or the Enhanced Track, so long as the applicable regulation has not been waived under the Track 1+ Model.

- Flexibility for Medicaid Laboratory Services.[22] Adding a new 42 C.F.R. § 440.30(d) that permits flexibility for coverage of COVID-19 tests, including those offered in non-office settings or that are self-collected during both the PHE and any subsequent period of active surveillance, as well as future communicable disease outbreaks.
- Changes to Modernize Requirements for Ordering Medicaid Home Health Nursing, Aide, and Therapy and Modernize Face-to-Face Encounter Requirements.[23] Permanently expanding the list of providers who can order home health services to include NPs, CNSs, and PAs, to the extent permitted under applicable state scope of practice laws, including the ordering of equipment, supplies, and appliances and removing the requirements to communicate clinical findings to the ordering physician.
- COVID-19 Serology Testing.[24] Finalizing on an interim basis that during the PHE, Medicare will cover FDA-authorized COVID-19 serology tests as they are reasonable and necessary for beneficiaries with known current or known prior COVID-19 infection or suspected current or suspected past COVID-19 infection and amending 42 C.F.R. § 410.32 to reflect this determination of coverage.
- Requirement for Facilities to Report Nursing Home Residents and Staff Infections, Potential Infections, and Deaths Related to COVID-19.[25] Adding a new provision at 42 C.F.R. § 483.80(g)(1) to require facilities to electronically report information about COVID-19, including, but not limited to, information on: suspected and confirmed COVID-19 infections among residents and staff, including residents previously treated for COVID-19; total deaths and COVID-19 deaths among residents and staff; personal protective equipment and hand hygiene supplies in the facility; ventilator capacity and supplies available in the facility; resident beds and census; access to COVID-19 testing while the resident is in the facility; staffing shortages; and other information specified by the Secretary of Health and Human Services. Also adding a new 42 C.F.R. § 483.80(g)(3) requiring facilities to inform residents, their representatives, and families of those residing in facilities of confirmed or suspected COVID-19 cases in the facility among residents and staff.
- Updating the Medicare Telehealth List.[26] Revising 42 C.F.R. § 410.78(f) to specify that, during the PHE, CMS will use a subregulatory process to modify the services included on the Medicare telehealth list, including posting new services to the web listing of telehealth services. While CMS states its belief that it has already added the vast majority of services that would be appropriate to add to the Medicare telehealth list for purposes of the PHE, if other services are identified, this change will permit an expedited process during the PHE for adding additional codes.
- Payment for COVID-19 Specimen Collection to Physicians, NPP, and Hospitals.[27] Finalizing on an interim basis that when the services described by CPT code 99211 for a level 1 evaluation and management (E/M) visit are furnished for the purpose of a COVID-19 assessment and specimen collection, the code can be billed for both new and established patients. Also, creating a new E/M code solely to support COVID-19 testing for the PHE, HCPCS code C9803 *(Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), any specimen source).*

The IFC should be consulted for more detailed guidance on these and other changes and clarifications, including related to quality reporting, value-based purchasing, durable medical equipment pricing, National Coverage Determination and Local Coverage Determination flexibilities, among others.

K&L Gates LLP has created a HUB webpage to address the legal implications of the COVID-19 outbreak on businesses generally and health care providers, in particular. K&L Gates' health care and FDA practice can provide guidance to providers and suppliers on these and other waivers and flexibilities provided by CMS as a result of the COVID-19 pandemic. Contact the authors of this article or your K&L Gates attorney for assistance or to receive updates on Medicare reimbursement during the COVID-19 emergency.

FOOTNOTES

[1] *See*, e.g., Coronavirus Waivers & Flexibilities. The website also includes a link to a zip file entitled List of Hospital Outpatient Services and List of Partial Hospitalization Program Services Accompanying the 4/30/2020 IFC.

[2] *See* COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers.

[3] This includes those services described by the codes for audio-only telephone evaluation and management services, behavioral health counseling, and educational services. *See* List of Telehealth Services. Unless provided otherwise, other services included on the Medicare telehealth services list must be furnished using, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.

[4] Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program [hereinafter, COVID-19 Additional Policy and Regulatory Revisions]. The CMS Coronavirus Waivers & Flexibilities website also includes a link to a zip file entitled “List of Hospital Outpatient Services and List of Partial Hospitalization Program Services Accompanying the 4/30/2020 IFC” and a PDF entitled “List of lab test codes for COVID-19, Influenza, RSV.”

[5] Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, 85 Fed. Reg. 19,230 (Apr. 6, 2020).

[6] COVID-19 Additional Policy and Regulatory Revisions at 4–5.

[7] *Id*. at 20–23.

[8] *Id*. at 23–31.

[9] CMS notes that “[u]nder this interim policy, during the COVID-19 PHE, COVID-19 tests may be covered when ordered by any healthcare professional authorized to do so under state law.” *Id*. at 30.

[10] *See* COVID-19, Influenza, and RSV Clinical Diagnostic Laboratory Tests for which Medicare Does Not Require a Practitioner Order During the PHE.

[11] COVID-19 Additional Policy and Regulatory Revisions at 33–43.

[12] *Id*. at 43–60.

[13] *Id*. at 60–68.

[14] *Id*. at 68–69.

[15] *Id*. at 76–79.

[16] *Id*. at 79–83.

[17] *Id*. at 86–90.

[18] *Id*. at 90–93.

[19] *Id*. at 97–112.

[20] *Id*. at 112–27.

[21] *Id*. at 127–30.

[22] *Id*. at 141–45.

[23] *Id*. at 146–49.

[24] *Id*. at 168–70.

[25] *Id*. at 178–82.

[26] *Id*. at 182–84.

[27] *Id*. at 184–92.

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