

Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the SNF Quality Reporting Program April 30, 2020

On Thursday, April 30, CMS issued an interim final rule that, for the duration of the COVID-19 public health emergency (PHE), ¹ offers providers flexibility by reinterpreting regulations related to telehealth, physician supervision, site of service and other regulatory requirements. CMS believes that providing additional flexibilities to Medicare and Medicaid regulations will help providers combat the COVID-19 pandemic. The following is a summary of key provisions included in the interim final rule.

1) Reporting Under the Home Health Value-Based Purchasing Model for CY20 During the COVID-19 PHE: During the PHE, to the extent that the data that participating home health agencies (HHAs) in the nine Home Health Value-based Purchasing (HHVBP) Model states are required to report are the same data that those HHAs are also required to report for the Home Health Quality Reporting Program (HH QRP), HHAs are required to report those data for the HHVBP Model in the same time, form and manner that HHAs are required to report those data for the HH QRP.

If CMS grants an exception or extension that either excepts HHAs from reporting certain quality data altogether, or otherwise extends the deadlines by which HHAs must report those data, the same exceptions and/or extensions apply to the submission of those same data for the HHVBP Model.

CMS issued supplemental public guidance² excepting HHAs from the requirement to report any HH QRP data for Q419, Q120, and Q220. Under the policy to align HHVBP data submission requirements with the HH QRP during the PHE for COVID-19, HHAs in the nine HHVBP Model states are not required to separately report measure data for these quarters for purposes of the HHVBP Model.

All Medicare-certified HHAs providing services in Arizona, Florida, Iowa, Nebraska, North Carolina, Tennessee, Maryland, Massachusetts and Washington are required to compete in the HHVBP. The HHVBP Model utilizes some of the same quality measure data that are reported by HHAs for the HH QRP, including Home Health Care Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) survey data. The other HHVBP measures are calculated using

¹ The definition identifies the PHE determined to exist nationwide by the Secretary of Health and Human Services under section 319 of the Public Health Service Act on January 31, 2020, as a result of confirmed cases of COVID-19, including any subsequent renewal.

² CMS. March 27, 2020. "Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID-19."



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Outcome and Assessment Information Set (OASIS) data, which are still required to be reported during the PHE; however, CMS has given providers additional time to submit OASIS data,³ claims-based data extracted from Medicare fee-for-service (FFS) claims and new measure data.

- 2) **Scope of Practice**: For the duration of the PHE, CMS is making several changes that will expand scope of practice for nonphysician providers.
 - Supervision of Diagnostic Tests by Certain Nonphysician Practitioners: While nurse practitioners (NPs), clinical nurse specialists (CNSs), physician assistants (PAs), and certified nurse midwives (CNMs) are permitted to furnish diagnostic tests to the extent they are otherwise authorized under state law to do, the regulations at § 410.32 does not address whether NPs, CNSs, PAs and CNMs may supervise others when furnishing diagnostic tests.

The interim final rule with comment period (IFC) finalizes a changes to the regulations at § 410.32(b) to add flexibility for NPs, CNSs, PAs, and CNMs, which are types of practitioners that have separately enumerated benefit categories under Medicare law that permit them to furnish services that would be physicians' services if furnished by a physician and be paid under Medicare Part B for the professional services they furnish directly and "incident to" their own professional services, to the extent authorized under their state scope of practice. The interim changes will ensure that these practitioners may order, furnish directly and supervise the performance of diagnostic tests, subject to applicable state law, during the PHE.

The rule amends the regulation at § 410.32(b)(1) to specify that diagnostic tests covered under § 1861(s)(3) of the Act and payable under the Physician Fee Schedule (PFS) must be furnished under the appropriate level of supervision by a physician as defined under § 1861(r) of the Act or, during the PHE, by a NP, CNS, PA and CNM. Additionally, CMS amends the regulation at § 410.32(b)(2)(iii)(B), which addresses supervision of COVID-19-related diagnostic psychological and neuropsychological testing.

Therapy – Therapy Assistants Furnishing Maintenance Therapy (PFS): The IFC synchronizes
Part B payment policies by permitting the physical therapist (PT) or occupational therapist
(OT) who established the maintenance program to delegate the performance of
maintenance therapy services to a physical therapy assistant or occupational therapy
assistant, when clinically appropriate.

³ CMS. "Home Health Agencies: CMS Flexibilities to Fight COVID-19"



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- Therapy Student Documentation (PFS): The IFC implements a general policy that creates broad flexibility for all members of the medical team to add documentation in the medical record which is then reviewed and verified (signed) by the appropriate clinician. Specifically, on an interim basis during the PHE for the COVID-19 pandemic, any individual who has a separately enumerated benefit under Medicare law that authorizes them to furnish and bill for their professional services, whether or not they are acting in a teaching role, may review and verify (sign and date), rather than re-document, notes in the medical record made by physicians, residents, nurses and students (including students in therapy or other clinical disciplines), or other members of the medical team.
- Pharmacists Providing Services Incident to a Physician's Service: The IFC clarifies that pharmacists fall within the regulatory definition of auxiliary personnel under CMS's regulations at § 410.26. As such, pharmacists may provide services incident to the services, and under the appropriate level of supervision, of the billing physician or NPP, if payment for the services is not made under the Medicare Part D benefit. This includes providing the services incident to the services of the billing physician or nonphysician practitioner (NPP) and in accordance with the pharmacist's state scope of practice and applicable state law. This clarification does not alter current payment policy for pharmacist services furnished incident to the professional services of a physician or NPP.
- 3) Modified Requirements for Ordering COVID-19 Diagnostic Laboratory Tests: The IFC amends CMS's regulation at § 410.32(a) to remove the requirement that certain diagnostic tests are covered only based on the order of a treating physician or NPP. Under 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.

Additionally, because the symptoms for influenza and COVID-19 might present in the same way, during the COVID-19 PHE, CMS is also removing the same ordering requirements for a diagnostic laboratory test for influenza virus and respiratory syncytial virus, a type of common respiratory virus. CMS will make a list of diagnostic laboratory tests for which it is removing the ordering requirements publicly available. The rule removes the treating physician or NPP ordering requirement for these additional diagnostic laboratory tests only when they are furnished in conjunction with a COVID-19 diagnostic laboratory test as medically necessary in the course of establishing or ruling out a COVID-19 diagnosis or of identifying patients with an adaptive immune response to SARS-CoV-2 indicating recent or prior infection. CMS does not expect there to be any medically necessary reason to use the specimen for unrelated or repeat testing.



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CMS is also making conforming amendments to its regulations at § 410.32(d)(2) and (3) to remove certain documentation and recordkeeping requirements associated with orders for COVID-19 tests during the COVID-19 PHE, as these requirements would not be relevant in the absence of a treating physician's or NPP's order. While no order is required under Medicare, CMS expects the entity submitting the claim to include the ordering or referring National Provider Identifier information on the claim form when an order is written for the test, consistent with current billing instructions.

4) Treatment of Certain Relocating Provider-Based Departments During the COVID-19 PHE: CMS is concerned that if an excepted provider-based department (PBD) that was previously paid the Outpatient Prospective Payment System (OPPS) rate relocates off-campus due to the COVID-19 PHE, some hospitals would have difficulty sustaining operations for necessary services during the COVID-19 PHE at the PBD if they were paid a reduced rate for services that would have otherwise been paid the OPPS rate but for the fact that the COVID-19 PHE necessitated the temporary relocation of the excepted off-campus or on-campus department. It is adopting a temporary relocation exception policy specific to the PHE for the COVID-19 pandemic so that hospitals can maintain treatment capacity and deliver needed care for patients.

The IFC temporarily implements an expanded version of the extraordinary circumstances relocation policy during the COVID-19 PHE to include on-campus PBDs that relocate off-campus during the COVID-19 PHE for the purposes of addressing the COVID-19 pandemic. CMS's policy has historically applied only to excepted off-campus departments that relocate to a different off-campus location for extraordinary circumstances outside of the hospital's control, that submit an extraordinary relocation exception request to their CMS Regional Office, and for which the CMS Regional Office evaluates and approves the request. However, on-campus departments that relocate on or after March 1, 2020 through the remainder of the PHE for the purposes of addressing the COVID-19 pandemic may also seek an extraordinary circumstances relocation exception so that they may bill at the OPPS rate, as long as their relocation is not inconsistent with the state's emergency preparedness or pandemic plan. CMS believes it is important for hospitals to align their PBD relocations with the state's emergency preparedness or pandemic plans to ensure continuity with state efforts, as well as efforts by other healthcare providers in their community, to mitigate the effects of the PHE for the COVID-19 pandemic.

CMS notes that this temporary extraordinary circumstances policy is time-limited to the PHE for COVID-19 to enable short-term hospital relocation of excepted off-campus and on-campus departments to improve access to care for patients during this time. The temporary extraordinary circumstances relocation policy established by the IFC will terminate following the end of the PHE for the COVID-19 pandemic, and CMS anticipates that most, if not all, PBDs that



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relocate during the COVID-19 PHE will relocate back to their original location prior to, or soon after, the COVID-19 PHE concludes. Hospitals that choose to *permanently* relocate these PBDs off-campus would be considered new off-campus PBDs billing after November 2, 2015, and therefore, would be required to bill using the PN modifier for hospital outpatient services furnished from that PBD location and would be paid the PFS-equivalent rate following the end of the COVID-19 PHE.

New Exception Process for Extraordinary Circumstances Relocation of Existing On-Campus and Excepted Off-Campus PBDs: Both excepted off-campus and on-campus PBDs may relocate to off-campus locations during the COVID-19 PHE and begin furnishing and billing for services under the OPPS in the new location prior to submitting documentation to the CMS regional office (RO) to support the extraordinary circumstances relocation request. If the relocation is denied by the RO under the extraordinary circumstances policy, and the hospital did not bill for them using the PN modifier, any claims billed under the OPPS in the new location would need to be reprocessed as having been billed by a non-excepted PBD and will instead be paid the PFS-equivalent rate.

Non-excepted off-campus departments will continue to be non-excepted during the COVID-19 PHE, even if they relocate, and thus, will continue to be paid the PFS-equivalent rate. They do not need to follow the process outlined below for relocation approval since they are already, and will continue to be, non-excepted.

- Hospitals with on-campus and excepted off-campus PBDs that relocate due to the COVID-19 PHE in a manner that is consistent with their state's emergency preparedness or pandemic plan should append the PO modifier to OPPS claims for services furnished at the relocated PBDs. This modifier indicates a service that is provided at an excepted off-campus PBD and is paid the OPPS payment rate.
- o In place of the process adopted in the CY17 OPPS/ambulatory surgical center final rule with comment period (81 FR 79704 through 79705) and included in the existing subregulatory guidance under which off-campus PBDs can apply for an extraordinary circumstance relocation exception, all hospitals that relocate excepted on- or off-campus PBDs to off-campus locations in response to the COVID-19 PHE should notify their CMS RO by email of their hospital's CMS certification number; the address of the current PBD; the address(es) of the relocated PBD(s); the date when they began furnishing services at the new PBD(s); a brief justification for the relocation and the role of the relocation in the hospital's response to COVID-19; and an attestation that the relocation is not inconsistent with their state's



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emergency preparedness or pandemic plan. CMS expects hospitals to include in their justification for the relocation why the new PBD location (including instances where the relocation is to the patient's home) is appropriate for furnishing covered outpatient items and services.

- To the extent that a hospital may relocate to an off-campus PBD that otherwise is the patient's home, only one relocation request during the COVID-19 PHE is necessary. In other words, the hospital would not have to submit a unique request each time it registers a hospital outpatient for a PBD that is otherwise the patient's home; a single submission per location is sufficient. Hospitals must send this email to their CMS RO within 120 days of beginning to furnish and bill for services at the relocated on- or off-campus PBD.
- To provide additional flexibility, for purposes of addressing the PHE for the COVID-19 pandemic, hospitals may divide their PBD into multiple locations during a relocation. That is, if a single excepted PBD location relocates to multiple off-campus PBD locations in response to the COVID-19 PHE and in a manner that is not inconsistent with the state's emergency preparedness or pandemic plan, it will be permissible for all of the off-campus PBDs to which the excepted PBD relocated to continue to bill under the OPPS under the temporary extraordinary circumstances policy that is in place during the COVID-19 PHE. In addition, for purposes of the COVID-19 PHE, hospitals may relocate part of their excepted PBD to a new off-campus location while maintaining the original PBD location.
- o If Medicare-certified hospitals will be rendering services in relocated excepted PBDs, but intend to bill Medicare for the services under the main hospital, no additional provider enrollment actions are required (for example, hospitals do not need to submit an updated CMS-855A enrollment form) for the off-campus relocated site during the COVID-19 PHE. Following the COVID-19 PHE, as noted in section II.E.4. of this IFC, hospitals that wish to permanently relocate their excepted PBD must file an updated CMS-855A enrollment form to reflect the new address(es) of the PBD(s).
- 5) Furnishing Outpatient Services in Temporary Expansion Locations of a Hospital or a Community Mental Health Center (Including the Patient's Home): Under ordinary circumstances, Medicare would not pay for hospital outpatient therapeutic services that are furnished to a beneficiary in the beneficiary's home or any other location that could not ordinarily be provider-based to the hospital.



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In response to the PHE, CMS has waived the requirements associated with becoming a PBD of a hospital at § 413.65, as well as certain requirements under the Medicare conditions of participation in §§ 482.41 and 485.623, to facilitate the availability of temporary expansion locations. Because of these waivers, during the COVID-19 PHE, temporary expansion locations, including beneficiaries' homes, can become PBDs of hospitals and therapeutic outpatient hospital services furnished to beneficiaries in these provider-based locations can meet the requirement that these services be furnished in the hospital so long as all other requirements are met, including the hospital conditions of participation, to the extent not waived, during the COVID-19 PHE.

 Partial Hospitalization Services: Effective as of March 1, 2020 and for the duration of the COVID-19 PHE, a temporary expansion location where the beneficiary may be located, including a beneficiary's home, may be a PBD of the hospital, or may be a temporary extension of the community mental health center.

The following types of services — to the extent they were already billable as partial hospitalization program (PHP) services in accordance with existing coding requirements prior to the COVID-19 PHE — can now be furnished to beneficiaries by facility staff using telecommunications technology during the COVID-19 PHE: (1) individual psychotherapy; (2) patient education; and (3) group psychotherapy. Because of the intensive nature of PHP, CMS expects PHP services to be furnished using telecommunications technology involving both audio and video. However, CMS recognizes that in some cases beneficiaries might not have access to video communication technology. In order to maintain beneficiary access to PHP services, only in the case that both audio and video are not possible can the service be furnished exclusively with audio. Services that require drug administration cannot be furnished using telecommunications technology.

To facilitate public understanding of the types of PHP services that can be furnished using telecommunications technology by the hospital to a patient in the hospital (including the patient's home if it is a PBD of the hospital) or by the CMHC to a patient in an expanded CMHC location, CMS has provided on its website a list of the individual psychotherapy, patient education and group psychotherapy services that hospital or CMHC staff can furnish during the COVID-19 PHE to a beneficiary in their home or other temporary expansion location that functions as a PBD of the hospital or expanded CMHC when the beneficiary is registered as an outpatient.

All other PHP requirements are unchanged and still in effect, including that all services furnished under the PHP still require an order by a physician, must be supervised by a



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physician, must be certified by a physician and must be furnished in accordance with coding requirements by a clinical staff member working within his or her scope of practice.

- Hospital In-Person Clinical Staff Services in a Temporary Expansion Location – Including the Home: Hospitals also provide services that are furnished by clinical staff under a physician's or qualified NPP's order that do not require professional work by the physician or qualified NPP, and thus, are billed only under the OPPS when furnished by the hospital and are not separately billable under the PFS. Wound care, chemotherapy administration and other drug administration are examples of these types of services. There are several other hospital outpatient therapeutic services that require the hospital's clinical staff's presence to furnish the service.

CMS is making the public aware of the flexibilities that exist during the COVID-19 PHE that enable hospitals to furnish these clinical staff services in the patient's home as an outpatient PBD and to bill and be paid for these services as hospital outpatient department (HOPD) services when the patient is registered as a hospital outpatient. Because these services have to be provided in person by clinical staff, these services cannot be furnished by telecommunication technology by the hospital. In these instances, hospital clinical staff must be physically present in the patient's home or other temporary expansion location that is provider-based to the hospital to furnish the hospital outpatient therapeutic service.

The physician supervision level must be met for these services, and CMS notes that for the vast majority of therapeutic hospital outpatient services, the required supervision level is currently general supervision under § 410.27. This means a service is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the service. This includes nonsurgical extended duration therapeutic services (NSEDTSs), which are services that can last a significant period of time, have a substantial monitoring component that is typically performed by auxiliary personnel, have a low risk of requiring the physician's or appropriate NPP's immediate availability after the initiation of the service and are not primarily surgical in nature.

During the time period that the patient is receiving services from the hospital clinical staff as a registered outpatient, the patient's place of residence cannot be considered a home for purposes of HHA services. This is because HHAs cannot bill for services furnished in PBDs of hospitals, and a patient's home has provider-based status when the patient is a registered hospital outpatient and HOPD services are being furnished. Hospitals should only consider the patient home to be provider-based to the hospital when the patient is registered as a hospital outpatient. When the patient is not receiving outpatient services by the hospital,



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the patient's home can be considered a home for purposes of the home health benefit and the HHA can furnish and bill for home health services. The hospital should be aware if the patient is under a home health plan of care, and it must not furnish services to the patient that could be furnished by the HHA while the plan of care is active.

Hospitals should bill for these services as they ordinarily bill for services along with any specific billing requirements for relocating PBDs specific to billing during a COVID-19 PHE (that is, appending the PO modifier for excepted items and services and the PN modifier for nonexcepted services).

- Hospital Services Accompanying a Professional Service Furnished Via Telehealth: During the COVID-19 PHE, when telehealth services are furnished by a physician or practitioner who ordinarily practices in the HOPD to a patient who is located at home or other applicable temporary expansion location that has been made provider-based to the hospital, CMS believes it would be appropriate to permit the hospital to bill and be paid the originating site facility fee amount for those telehealth services, just as they would have ordinarily done outside of the COVID-19 PHE in this circumstance. Effective March 1, 2020 and for the duration of the PHE, when a patient is receiving a professional service via telehealth in a temporary expansion location that is a PBD of the hospital, and the patient is a registered outpatient of the hospital, the hospital in which the patient is registered may bill the originating site facility fee for the service. As always, documentation in the medical record of the reason for the visit and the necessity of the visit is required.

In the March 31, 2020, COVID-19 IFC, CMS instructed physicians and other practitioners furnishing telehealth services to beneficiaries in their homes as permitted during the COVID-19 PHE to bill for those services in the same way they would if they were furnishing the services in person (85 FR 19233). For many professionals, the HOPD is the usual location where they furnish services. For the duration of the COVID-19 PHE and effective March 1, 2020, when a practitioner who ordinarily practices in a HOPD furnishes a telehealth service to a patient who is located at home (or otherwise not in a telehealth originating site), they would submit a professional claim with the place of service code indicating the service was furnished in the HOPD and using the CPT telehealth modifier, modifier 95. Medicare would pay the practitioner under the PFS at the facility rate as if the service were furnished in the HOPD.

When a registered outpatient of the hospital is receiving a telehealth service, the hospital may bill the originating site facility fee to support such telehealth services furnished by a physician or practitioner who ordinarily practices there. This includes patients who are at



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home, when the home is made provider-based to the hospital (which means that all applicable conditions of participation, to the extent not waived, are met), under the current waivers in effect for the COVID-19 PHE.

More specifically, when a telehealth service is furnished by a practitioner located at a distant site to a patient who is located in the HOPD, the hospital is presumed to provide administrative and clinical support resources. In such circumstances, section 1834(m)(2)(B) of the Act allows for an originating site facility fee to be paid to the hospital. Section 1834(m)(2)(B)(ii) of the Act further provides that no facility fee shall be paid to an originating site described in paragraph (4)(C)(ii)(X) (that is, the home). Hospitals should only furnish hospital outpatient services to a patient (who is registered as a hospital outpatient) after the patient's home has been made provider-based to the hospital for the provision of such services.

- Intersection with Payment Policy for Hospital Outpatient PBDs: For purposes of the COVID-19 PHE, on-campus or excepted off-campus PBDs can be considered to have relocated (or partially relocated) to a beneficiary's home, or other temporary expansion location of the hospital, when the beneficiary is registered as an outpatient of the hospital during service delivery. Under this policy, the PBD is still considered either an on-campus or excepted off-campus PBD that is not subject to section 603 of the Bipartisan Budget Act of 2015 and would bill with the PO modifier for services furnished to beneficiaries in their homes as a relocated (or partially relocated) PBD and will receive the full OPPS rate. However, CMS notes that if the hospital does not relocate (or partially relocate) an existing on-campus or excepted off-campus PBD to the patient's home and does not seek an exception under the temporary extraordinary circumstances relocation exception policy discussed in section II.E. of this IFC, the patient's home would be considered a new non-excepted off-campus PBD and the hospital would bill with the PN modifier and receive the PFS-equivalent rate.
- 6) Indirect Medical Education Payments to Teaching Hospitals: The indirect medical education (IME) payment formula (under section 1886(d)(5)(B) of the Act and § 412.105) is determined in part using each teaching hospital's ratio of allowable FTE residents in the numerator and available beds in the denominator. To accommodate the increase in COVID-19-related patients, many hospitals are increasing their number of inpatient beds. Using CMS's exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act, and to mitigate IME payment changes from pre-COVID levels, for the duration of the COVID-19 PHE, for purposes of determining a hospital's IME payment amount, the hospital's available bed count is considered to be the same as it was on the day before the COVID-19 PHE was declared.



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- 7) Holding IRFs and IPFs Harmless from Reductions to Teaching Status Adjustment Payments Due to COVID-19: To ensure that teaching inpatient rehabilitation facilities (IRFs) or teaching inpatient psychiatric facilities (IPFs) can alleviate bed capacity issues by taking patients from the inpatient acute care hospitals without being penalized by lower teaching status adjustments, CMS believes it is appropriate to freeze the IRF's or IPF's teaching status adjustment payments at their values prior to the COVID-19 PHE. Therefore, for the duration of the COVID-19 PHE, an IRF's or an IPF's teaching status adjustment payment amount will be the same as it was on the day before the COVID-19 PHE was declared.
- 8) Time Spent by Residents at Another Hospital During the COVID-19 PHE: Related to IME and direct graduate medical education (DGME) payments, for the timeframe that the PHE associated with COVID-19 is in effect, CMS is using its authority under section 1886(h)(4)(A) and (B) of the Act to suspend the requirement that a hospital cannot claim the time spent by residents training at another hospital so that a hospital that sends residents to another hospital can claim those FTE residents on its Medicare cost report while they are training at another hospital in its FTE count, if all of the following conditions and all other applicable requirements are met:
 - a. The sending hospital sends the resident to another hospital in response to the COVID-19 pandemic. This criterion would be met if either the sending hospital or the other hospital are treating COVID-19 patients. CMS would not require that the resident be involved in patient care activities for patients with COVID-19 for the sending hospital to demonstrate that it sent the resident to the other hospital in response to the COVID-19 pandemic.
 - b. Time spent by the resident at the other hospital would be considered to be time spent in approved training if the activities performed by the resident at the other hospital are consistent with any guidance in effect during the COVID-19 PHE for the approved medical residency program at the sending hospital.
 - c. The time that the resident spent training immediately prior to and/or subsequent to the timeframe that the PHE associated with COVID-19 was in effect was included in the sending hospital's FTE resident count.

Time spent by residents at these locations is not treated any differently from time spent by residents at locations established and operated by the hospital prior to the COVID-19 PHE.

Also, for the duration of the PHE related to COVID-19, CMS has adopted a policy that if routine services are provided under arrangements outside the hospital to its inpatients, these services are deemed to have been provided by the hospital (85 FR 19280). Similarly, time spent by



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residents at these locations is not treated any differently from time spent by residents at locations established and operated by the hospital prior to the COVID-19 PHE.

If the teaching hospital to which a resident is assigned sends the resident to another hospital and claims the resident's time, no other hospital, teaching or nonteaching, would be able to claim that time. During the COVID-19 PHE, the presence of residents in nonteaching hospitals will not trigger establishment of per-resident amounts or FTE resident caps at those nonteaching hospitals.

- 9) **Rural Health Clinics:** For the duration of the PHE, CMS will use the number of beds from the cost reporting period prior to the start of the PHE as the official hospital bed count for application of this policy. As such, rural health clinics (RHCs) with provider-based status that were exempt from the national per-visit payment limit in the period prior to the effective date of the PHE (January 27, 2020) would continue to be exempt for the duration of the PHE for the COVID-19 pandemic, as defined at § 400.200.
- 10) Care Planning for Medicare Home Health Services: Historically, a physician, who does not have a direct or indirect employment relationship with the HHA, must certify that home health services are required because the individual is confined to his or her home and is in need of skilled nursing care on an intermittent basis, physical or speech therapy, or a continued need for occupational therapy, in order for Medicare to cover it.

To align its regulations with the requirements of the CARES Act, CMS is amending its rules to define an NP, CNS and PA as an "allowed practitioner." This means that in addition to a physician, as defined at section 1861(r) of the Act, an "allowed practitioner" may 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. Additionally, CMS is amending the regulations to reflect that it would expect the allowed practitioner to also perform the face-to-face encounter for the patient for whom they are certifying eligibility; however, if a face-to-face encounter is performed by an allowed NPP, as set out at 42 CFR 424.22(a)(1)(v)(A), in an acute or post-acute facility, from which the patient was directly admitted to home health, the certifying practitioner may be different from the provider performing the face-to-face encounter. These regulation changes will become permanent and are not time limited to the period of the PHE for COVID-19.

11) Coverage and Classification Requirements for Freestanding IRF Hospitals for the PHE During the COVID-19 Pandemic: CMS is amending the requirements at §§ 412.29(d), (e), (h), and (i) and 412.622(a)(3), (4), and (5) to add an exception for care furnished to patients admitted to freestanding IRF hospitals solely to relieve acute care hospital capacity during the COVID-19



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PHE. The flexibilities in this IFC are available for freestanding IRF hospitals admitting patients in support of acute care hospitals when the state is in phase 1, or prior to entering phase 1, but are no longer available to the freestanding IRF hospital when the state is in phase 2 or phase 3 of the White House guidelines for a gradual reopening of the U.S. economy amid the COVID-19 pandemic, issued on April 16, 2020.⁴

These flexibilities apply to specific patients who must be discharged from the acute care hospitals to the freestanding IRFs to provide surge capacity for the acute care hospitals, and therefore apply only when those specific patients are admitted to the freestanding IRF hospitals and continue for the duration of that patient's care. Freestanding IRF hospitals must document the particular phase for the state when admitting the patient and electing to exercise these flexibilities.

For billing purposes, CMS is requiring freestanding IRF hospitals to append the DS modifier to the end of the IRF's unique patient identifier number (used to identify the patient's medical record in the IRF) to identify patients who are being treated in a freestanding IRF hospital solely to alleviate inpatient bed capacity in a state that is experiencing a surge during the PHE for the COVID-19 pandemic. The modifier will be used to identify those patients for whom the requirements in § 412.622(a)(3)(i), (iii), (iv), (4) and (5) do not apply. Freestanding IRF hospitals will be paid at the IRF PPS rates for patients with the DS modifier.

- 12) Medicare Shared Savings Program: The IFC modifies Shared Savings Program policies to: (1) allow accountable care organizations (ACOs) whose current agreement periods expire on December 31, 2020, the option to extend their existing agreement period by one year, and allow ACOs in the BASIC track's glide path the option to elect to maintain their current level of participation for performance year (PY) 2021; (2) clarify the applicability of the program's extreme and uncontrollable circumstances policy to mitigate shared losses for the period of the COVID-19 PHE; (3) adjust program calculations to mitigate the impact of COVID-19 on ACOs; and (4) expand the definition of primary care services for purposes of determining beneficiary assignment to include telehealth codes for virtual check-ins, e-visits and telephonic communication. CMS also addresses how these adjustments to program policies will apply to ACOs participating in the Track 1+ Model.
 - a. Application Cycle for January 1, 2021 Start Date and Extension of Agreement Periods Expiring on December 31, 2020: CMS is forgoing the application cycle for a January 1, 2021 start date (herein referred to as the 2021 application cycle).

⁴ White House. "Guidelines for Opening Up America Again."



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CMS will allow ACOs (including Track 1+) whose contract period ends on December 31, 2020 to continue participating in the program without a 2021 application cycle. ACOs that entered a first or second agreement period with a start date of January 1, 2018, may elect to extend their agreement period for an optional fourth performance year.

The fourth performance year would span 12 months from January 1, 2021, to December 31, 2021. This election to extend the agreement period is voluntary and an ACO could choose not to make this election, and therefore, conclude its participation in the program with the expiration of its current agreement period on December 31, 2020. Under this approach, eligible ACOs will be able to remain under their existing historical benchmark for an additional year, which will increase stability and predictability given the potential impact of the pandemic on beneficiary expenditures under FFS Medicare and help provide greater certainty for ACOs making determinations regarding their future participation in the Shared Savings Program. By forgoing the 2021 application cycle for new applicants, CY20 will not serve as benchmark year 3 for a cohort of ACOs that would otherwise be January 1, 2021 starters. Cancelling the 2021 application cycle would provide CMS with additional time to consider and develop approaches to further mitigate the role of 2020 as a benchmark year, given the unusual expenditure and utilization trends likely to result from the pandemic.

While CMS will forgo the application cycle for ACOs to apply to enter an agreement period beginning on January 1, 2021, eligible, currently participating ACOs will be able to apply for a skilled nursing facility (SNF) 3-day rule waiver, apply to establish a beneficiary incentive program, modify ACO participant and/or SNF affiliate lists, and elect to change their assignment methodology for PY21. Also, an ACO participating under the BASIC track's glide path may still elect to transition to a higher level of risk and potential reward within the BASIC track's glide path other than the level of risk and potential reward that the ACO would be automatically transitioned to for PY21, absent the ACO's election to maintain its current participation level for one year.

b. Allow BASIC Track ACOs to Elect to Maintain Their Participation Level for One Year: CMS is permitting ACOs participating in the BASIC track glide path to elect to maintain their current level under the BASIC track for PY21. Prior to the automatic advancement for PY21, an applicable ACO may elect to remain in the same level of the BASIC track's glide path that it entered for PY20. For PY22, an ACO that elects this advancement deferral option will be automatically advanced to the level of the BASIC track's glide path in which it would have participated during PY22 if it had advanced automatically to the next level for PY21 (unless the ACO elects to advance more quickly before the start of PY22).



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For example, if an ACO participating in the BASIC track, Level B, in PY20 elects to maintain its current level of participation for PY21, it will participate under Level B for PY21 and then will automatically advance to Level D for PY22, since the ACO would have moved automatically to Level C for PY21 under current program rules, absent this change. The ACO could also elect to advance more quickly by opting to move to Level E instead of Level D for PY22, in which case the ACO would participate under Level E for the remainder of its agreement period.

- c. Applicability of Extreme and Uncontrollable Circumstances Policies to the COVID-19 Pandemic: CMS clarifies that for purposes of the Shared Savings Program, the months affected by an extreme and uncontrollable circumstance will begin with January 2020, consistent with the COVID-19 PHE determined to exist nationwide as of January 27, 2020, by the Secretary on January 31, 2020, and will continue through the end of the PHE, as defined in § 400.200, which includes any subsequent renewals.
- d. Adjustments to Shared Savings Program Calculations to Address the COVID-19 Pandemic: CMS is revising its policies under the Shared Savings Program to exclude from Shared Savings Program calculations all Parts A and B FFS payment amounts for an episode of care for treatment of COVID-19, triggered by an inpatient service, and as specified on Parts A and B claims with dates of service during the episode. CMS is using authority under section 1899(d)(1)(B)(ii) of the Act to adjust benchmark expenditures for other factors in order to remove COVID-19-related expenditures from the determination of benchmark expenditures.

CMS will identify COVID-19 discharges as those with ICD-10 code B97.29 or U07.1. An episode of care starts in the month in which the inpatient stay begins as identified by the admission date, all months during the inpatient stay and the month following the end of the inpatient stay as indicated by the discharge date. This approach to measuring the length of the episode of care in units of months aligns with the Shared Savings Program's existing methodology for calculating benchmark year and performance year expenditures by performing separate calculations for each of four Medicare enrollment types (end stage renal disease, disabled, aged/dual eligible for Medicare and Medicaid, and aged/non-dual eligible for Medicare and Medicaid).

In addition to excluding Parts A and B payment amounts with dates of service in the months associated with an episode of care for treatment of COVID-19, CMS will also exclude the affected months from total person years used in per capita expenditure calculations.



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Further, CMS will retrospectively apply the historical benchmark update, which will be calculated based on factors that reflect actual expenditure and utilization changes nationally and regionally, other than expenditures for episodes of care for treatment of COVID-19. This will help to mitigate the potential for windfall savings due to potentially lower utilization of services not related to treatment for COVID-19. Specifically, CMS will adjust the following Shared Savings Program calculations to exclude all Parts A- and B-related COVID-19 spending:

- Calculation of Medicare Parts A and B FFS expenditures for an ACO's assigned beneficiaries for all purposes, including the following: establishing, adjusting, updating and resetting the ACO's historical benchmark and determining performance year expenditures.
- Calculation of FFS expenditures for assignable beneficiaries as used in determining county-level FFS expenditures and national Medicare FFS expenditures, including the following calculations:
 - Determining average county FFS expenditures based on expenditures for the assignable population of beneficiaries in each county in the ACO's regional service area for purposes of calculating the ACO's regional FFS expenditures.
 - Determining the 99th percentile of national Medicare FFS expenditures for assignable beneficiaries for purposes of the following: (1) truncating assigned beneficiary expenditures used in calculating benchmark expenditures, and performance year expenditures; and (2) truncating expenditures for assignable beneficiaries in each county for purposes of determining county FFS expenditures.
 - Determining 5% of national per capita expenditures for Parts A and B services under the original Medicare FFS program for assignable beneficiaries for purposes of capping the regional adjustment to the ACO's historical benchmark.
 - Determining the flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program for assignable beneficiaries, for purposes of updating the ACO's historical benchmark.
 - Determining national growth rates that are used as part of the blended growth rates used to trend forward benchmark year 1 and benchmark year 2 expenditures to benchmark year 3 and as part of the blended growth rates used to update the benchmark.



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- Calculation of Medicare Parts A and B FFS revenue of ACO participants for purposes of calculating the ACO's loss recoupment limit under the BASIC track.
- Calculation of total Medicare Parts A and B FFS revenue of ACO participants and total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries for purposes of identifying whether an ACO is a high revenue ACO or low revenue ACO and determining an ACO's eligibility for participation options.
- Calculation or recalculation of the amount of the ACO's repayment mechanism arrangement.

Additionally, CMS confirms that the Shared Savings Program expenditure calculations will not account for lump sum payments made to hospitals and other healthcare providers through the CARES Act Provider Relief Fund, that occur outside of Parts A and B claims.

- e. Use of Codes for Virtual Check-ins, Remote Evaluation e-Visits, Telephone Evaluation and Management Services, and Telehealth in Beneficiary Assignment: Based on feedback from ACOs and the expansion of payment, on an interim basis, for the virtual services discussed above, CMS is revising the definition of primary care services used in the Shared Savings Program assignment methodology for the performance year starting on January 1, 2020, and for any subsequent performance year that starts during the PHE for the COVID-19 pandemic, to include the following additions:
 - i. HCPCS code G2010 (remote evaluation of patient video/images) and HCPCS code G2012 (virtual check-in);
 - ii. CPT codes 99421, 99422 and 99423 (online digital evaluation and management (E/M) service (e-visit)); and (3) CPT codes 99441, 99442 and 99443 (telephone E/M services).

CMS also clarifies that CPT codes 99304, 99305 and 99306, 99315 and 99316, 99327 and 99328, 99334 through 99337, 99341 through 99345, and 99347 through 99350 will be included in the assignment methodology when these services are furnished using telehealth, consistent with additions to the Medicare telehealth list for the duration of the PHE for the COVID-19 pandemic as discussed in the March 31, 2020 COVID-19 IFC.

CMS also considered adding additional e-visit HCPCS codes which are used by clinicians who may not independently bill for E/M visits and who are not included in the definition of ACO professional (for example, PTs, OTs, speech-language pathologists and clinical pharmacists). However, because these services are not furnished by ACO professionals,



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CMS determined it was not necessary to include the following codes in its definition of primary care services for use in assignment: G2061 - G2063 and 98966 - 98968.

f. Applicability of Policies to Track 1+ Model ACOs: 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, so long as the applicable regulation has not been waived under the Track 1+ Model.

Similarly, to the extent that certain requirements of the regulations that apply to ACOs under Track 2 or the ENHANCED track have been incorporated for ACOs in the Track 1+ Model under the terms of the Track 1+ Model Participation Agreement, changes to those regulations as adopted in this IFC will also apply to ACOs in the Track 1+ Model in the same way that they apply to ACOs in Track 2 or the ENHANCED track. For example, the following policies apply to Track 1+ Model ACOs:

- Revisions to the definition of primary care services used in beneficiary assignment, to include telehealth codes for virtual check-ins, e-visits and telephonic communication.
- ii. Clarification that the total months affected by an extreme and uncontrollable circumstance for the COVID-19 pandemic will begin with January 2020 and continue through the end of the COVID-19 PHE, for purposes of mitigating shared losses for PY20
- iii. Adjustments to expenditure calculations to remove expenditures for episodes of care for treatment of COVID-19.
- iv. Adjustments to revenue calculations to remove expenditures for episodes of care for treatment of COVID-19.
- 13) Additional Flexibility under the Teaching Physician Regulations: On an interim basis for the duration of the PHE for the COVID-19 pandemic, the teaching physician may not only direct the care furnished by residents, but also review the services provided with the resident, during or immediately after the visit, remotely through virtual means via audio/video real time communications technology.

In addition, CMS is expanding the range of services added to the "primary care" exemption. For the duration of the COVID-19 PHE, Medicare may make PFS payment to the CPT codes listed in Appendix I.



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Finally, CMS clarifies that the office/outpatient E/M level selection for services under the primary care exception when furnished via telehealth can be based on medical decision-making or time, with time defined as all of the time associated with the E/M on the day of the encounter; and the requirements regarding documentation of history and/or physical exam in the medical record do not apply. The typical times for purposes of level selection for an office/outpatient E/M are the times listed in the CPT code descriptor. This policy is similar to the policy that will apply to all office/outpatient E/M services beginning in 2021 under policies finalized in the CY20 PFS final rule.

14) Payment for Audio-Only Telephone Evaluation and Management Services: In the March 31, 2020 COVID-19 IFC, CMS established separate payment for audio-only telephone E/M services. The telephone E/M services are CPT codes 99441, 99442, and 99443.

Based on feedback from providers, CMS is establishing new relative value units (RVUs) for the telephone E/M services based on crosswalks to the most analogous office/outpatient E/M codes, based on the time requirements for the telephone codes and the times assumed for valuation for purposes of the office/outpatient E/M codes.

Specifically, CMS is crosswalking CPT codes 99212, 99213 and 99214 to 99441, 99442 and 99443, respectively. CMS is finalizing, on an interim basis and for the duration of the COVID-19 PHE the following work RVUs: 0.48 for CPT code 99441; 0.97 for CPT code 99442; and 1.50 for CPT code 99443. CMS also finalizes the direct practice expense (PE) inputs associated with CPT code 99212 for CPT code 99441, the direct PE inputs associated with CPT code 99214 for CPT code 99443.

CMS is not finalizing increased payment rates for CPT codes 98966-98968 as these codes describe services furnished by practitioners who cannot independently bill for E/Ms and so these telephone assessment and management services, by definition, are not furnished in lieu of an office/outpatient E/M service.

Additionally, given CMS's understanding that these audio-only services are being furnished as substitutes for office/outpatient E/M services, CMS recognizes that they should be considered as telehealth services, and are adding them to the list of Medicare telehealth services for the duration of the PHE.

CMS notes that these codes describe medical discussions, and should not be used for administrative or other nonmedical discussion with the patient. Although practitioners have been provided flexibility around cost-sharing for the duration of the PHE, beneficiaries are still liable for cost-sharing for these services in instances where the practitioner does not waive cost-sharing. Practitioners should educate beneficiaries on any applicable cost-sharing.



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- 15) Flexibility for Medicaid Laboratory Services: CMS is amending § 440.30 to permit flexibility for coverage of COVID-19 tests, including coverage for tests administered in non-office settings, and coverage for laboratory processing of self-collected COVID-19 tests that are FDA-authorized for self-collection. The flexibility would apply not only during the current COVID-19 PHE, but also during any subsequent periods of active surveillance, to allow for continued surveillance as part of strategies to detect recurrence of the virus in individuals and populations to prevent further spread of the disease. CMS defines a period of active surveillance as an outbreak of communicable disease during which no approved treatment or vaccine is widely available. A period of active surveillance ends on the date the Secretary terminates it, or the date that is two incubation periods after the last known case of the communicable disease, whichever is sooner.
- 16) Changes to Modernize Requirements for Ordering Medicaid Home Health Nursing, Aide and Therapy Services; and Modernize Face-to-Face Encounter Requirements: CMS is amending the home health regulation at § 440.70(a)(3) to allow other licensed practitioners to order medical equipment, supplies and appliances in addition to physicians, when practicing in accordance with state laws. For other services covered under the Medicaid home health benefit, CMS is applying the new list of practitioners set forth in section 3708 of the CARES Act to who can order those services, specifically, part-time or intermittent nursing services, home health aide services, and if included in the state's home health benefit, therapy services. Specifically, § 440.70(a)(2) is amended to allow a NP, CNS and PA to order home health services described in § 440.70(b)(1), (2) and (4).

CMS is also amending the current regulation to remove the requirement that the NPPs described in § 440.70(a)(2) have to communicate the clinical finding of the face-to-face encounter to the ordering physician. With expanding authority to order home health services, the CARES Act also provides that such practitioners are now capable of independently performing the face-to-face encounter for the patient for whom they are the ordering practitioner, in accordance with state law. If state law does not allow such flexibility, the NPP is required to work in collaboration with a physician.

Flexibility allowed in this IFC to NPs, CNSs and PAs to order home health services must be done in accordance with state law. Individual states have varying requirements for conditions of practice, which determine whether a practitioner may work independently, without a written collaborative agreement or supervision from a physician, or whether general or direct supervision and collaboration is required.

17) Merit-based Incentive Payment System Qualified Clinical Data Registry Measure Approval Criteria: CMS is amending the Qualified Clinical Data Registry (QCDR) measure approval criteria previously finalized in the CY20 PFS final rule (84 FR 63065 through 63068), specifically: (1) completion of QCDR measure testing at § 414.1400(b)(3)(v)(C) as discussed in section II.R.1. of



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this IFC; and (2) collection of data on QCDR measures at § 414.1400(b)(3)(v)(D) as discussed in section II.R.2. of this IFC.

- a. Completion of QCDR Measure Testing: CMS is amending § 414.1400(b)(3)(v)(C) to state that beginning with the 2022 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination.
- b. Collection of Data on QCDR Measures: CMS is amending § 414.1400(b)(3)(v)(D) to state that beginning with the 2022 performance period, QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period.
- 18) Application of Certain National Coverage Determination and Local Coverage Determination Requirements during the PHE for the COVID-19 Pandemic: In the March 31, 2020 COVID-19 IFC, CMS finalized on an interim basis that for national coverage determinations (NCDs) or local coverage determinations (LCDs) (including articles) that require a face-to-face or in-person encounter or other implied face-to-face services, those requirements would not apply during the PHE for the COVID-19 pandemic. Additionally, CMS finalized on an interim basis that CMS will not enforce the clinical indications for coverage across respiratory, home anticoagulation management and infusion pump NCDs and LCDs (including articles), allowing for flexibility for practitioners to care for their patients. The IFC further clarifies that guidance.

The rule notes that nothing in guidance or the March 31 COVID-19 IFC, permanently or temporarily waives the reasonable and necessary statutory requirement, which is expressed in section 1862(a)(1)(A) of the Act and cannot be waived under the section 1135 PHE waiver authority. Except as expressly permitted by statute, CMS reminds physicians, practitioners and suppliers that most items and services must be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member to be paid under Part A or Part B of Title XVIII. Physicians, practitioners and suppliers are required to continue documenting the medical necessity for all services. Accordingly, the medical record must be sufficient to support payment for the services billed (that is, the services were actually provided, were provided at the level billed and were medically necessary).

Further, CMS finalizes on an interim basis that it will not enforce the clinical indications for therapeutic continuous glucose monitors in LCDs. For example, CMS will not enforce the current clinical indications restricting the type of diabetes that a beneficiary must have, or relating to the demonstrated need for frequent blood glucose testing, in order to permit COVID-19-infected patients with diabetes to receive a Medicare-covered therapeutic continuous glucose monitor.



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19) Delay of the Compliance Date of the Transfer of Health Information Quality Measures and Certain Standardized Patient Assessment Data Elements Adopted for the Inpatient Rehabilitation Facility QRP, Long-Term Care Hospital QRP and Home Health QRP: CMS is delaying the release of updated versions of the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI), Long-Term Care Hospital (LTCH) Continuity Assessment Record and Evaluation Data Set (LTCH CARE Data Set), and Home Health Agency Outcome and Assessment Information Set (OASIS) Instrument to reduce the burden that these providers would otherwise incur as a result of being required to incorporate the updated versions into their operations before October 1, 2020 (for IRFs and LTCHs) or January 1, 2021 (for HHAs). This delay will enable these providers to continue using the current versions of their assessment instruments, with which they are already familiar. The current version of the IRF-PAI has been in use since October 1, 2019 (IRF-PAI v. 3.0). The current version of the LTCH CARE Data Set has also been in use since October 1, 2019 (LTCH CARE Data Set v. 4.00). The current version of the OASIS Instrument has been in use since January 1, 2019 (OASIS-D).

This delay of the updated assessment instruments will impact the ability of IRFs, LTCHs and HHAs to collect and report data on the two Transfer of Health (TOH) Information Measures and Standardized Patient Assessment Data Elements (SPADEs) under their respective QRPs. Accordingly, CMS is delaying the compliance dates for the collection and reporting of these TOH Information Measures and SPADEs.

Specifically, CMS will require IRFs to use IRF-PAI V4.0 and LTCHs to use LTCH CARE Data Set V5.0 to begin collecting data on the two TOH Information Measures beginning with discharges on October 1 of the year that is at least one full fiscal year after the end of the COVID-19 PHE. For example, if the COVID-19 PHE ends on September 20, 2020, IRFs and LTCHs will be required to begin collecting data on these measures beginning with patients discharged on October 1, 2021. CMS will also require IRFs and LTCHs to begin collecting data on the SPADEs for admissions and discharges (except for the hearing, vision, race and ethnicity SPADEs, which would be collected for admissions only) on October 1 of the year that is at least one full fiscal year after the end of the COVID-19 PHE.

HHAs will be required to use OASIS-E to begin collecting data on the two TOH Information Measures beginning with discharges and transfers on January 1 of the year that is at least one full calendar year after the end of the COVID-19 PHE. For example, if the COVID-19 PHE ends on September 20, 2020, HHAs will be required to begin collecting data on those measures beginning with patients discharged or transferred on January 1, 2022. CMS will also require HHAs to begin collecting data on the SPADEs beginning with the start of care, resumption of care and discharges (except for the hearing, vision, race and ethnicity SPADEs, which would be collected at the start of care only) on January 1 of the year that is at least one full calendar year after the end of the COVID-19 PHE.



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- 20) Delay in the Compliance Date of the Transfer of Health Information Measures and Certain SPADEs Adopted for the SNF QRP: CMS will require SNFs to begin collecting data on the two TOH Information Measures beginning with discharges on October 1 of the year that is at least two full fiscal years after the end of the COVID-19 PHE. For example, if the COVID-19 PHE ends on September, 20, 2020, SNFs will be required to begin collecting data on these measures beginning with patients discharged on October 1, 2022. CMS will also require SNFs to begin collecting data on the SPADEs beginning with admissions and discharges (except for the hearing, vision, race and ethnicity SPADEs, which would be collected for admissions only) on October 1 of the year that is at least two full fiscal years after the end of the COVID-19 PHE.
- 21) Update to the Hospital Value-Based Purchasing Program Extraordinary Circumstance Exception Policy: CMS modifies the Hospital Value-Based Purchasing (VBP) Program's extraordinary circumstance exception (ECE) policy to allow it to grant ECE exceptions to hospitals which have not requested them when CMS determines that an extraordinary circumstance that is out of the hospital's control, such as an act of nature (for example, a hurricane) or PHE (for example, the COVID-19 pandemic), affects an entire region or locale, in addition to retaining the individual ECE request policy.

The rule notes that when CMS makes the determination to grant an exception to all hospitals in a region or locale, CMS will communicate this decision through routine communication channels to hospitals, vendors, and Quality Improvement Organizations (QIOs), including but not limited to issuing memos, emails and notices on the public QualityNet website.⁵

If CMS grants an ECE to hospitals located in an entire region or locale under this revised policy and, as a result of granting that ECE, one or more hospitals located in that region or locale does not report the minimum number of cases and measures required to enable CMS to calculate a Total Performance Score (TPS) for that hospital for the applicable program year, the hospital will be excluded from the Hospital VBP Program for the applicable program year.

A hospital that does not report the minimum number of cases or measures for a program year will not receive a 2% reduction to its base operating DRG payment amount for each discharge in the applicable program year, and will also not be eligible to receive any value-based incentive payments for the applicable program year.

In accordance with this updated policy and consistent with the ECE guidance CMS issued on March 22, 2020 and March 27, 2020, CMS is granting an ECE with respect to the COVID-19 PHE to all hospitals participating in the Hospital VBP Program for the following reporting requirements:

⁵ CMS QualityNet.



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- a. Hospitals will not be required to report National Healthcare Safety Network (NHSN) healthcare-acquired infections (HAI) measures and HCAHPS survey data for the following quarters: October 1, 2019 December 31, 2019 (Q419), January 1, 2020 March 31, 2020 (Q120), and April 1, 2020 June 30, 2020 (Q220). However, hospitals can optionally submit part or all of these data by the posted submission deadlines on the Hospital VBP QualityNet site.⁶
- b. CMS will exclude qualifying claims data from the mortality, complications, and Medicare spending per beneficiary measures for the following quarters: January 1, 2020 March 31, 2020 (Q120) and April 1, 2020 June 30, 2020 (Q220).
- 22) **COVID-19 Serology Testing:** CMS is finalizing on an interim basis that these FDA-authorized COVID-19 serology tests fall under the Medicare benefit category of diagnostic laboratory test (section 1861(s)(3) of the Act). Therefore, these tests are coverable by the Medicare program because they fall under at least one Medicare benefit category. This may not be an exhaustive list of benefit categories as CMS did not evaluate information about the test to identify additional benefit categories.

CMS is not aware of any professional society recommendations for confirmatory or repeat testing on the same sample. CMS would expect to be billed once per sample. Further, the agency would not expect such tests to be performed and billed unless clinically indicated.

23) Requirement for Facilities to Report Nursing Home Residents and Staff Infections, Potential Infections and Deaths Related to COVID-19: CMS is revising the requirements to establish explicit reporting requirements for confirmed or suspected cases of COVID-19. Specifically, CMS is revising its requirements by adding a new provision at § 483.80(g)(1), to require facilities to electronically report information about COVID-19 in a standardized format specified by the Secretary.

The report includes, but is 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. This information will be used to monitor trends in infection rates and inform public health policies.

Facilities are required to provide the information specified above at a frequency specified by the Secretary, but no less than weekly to the Center for Disease Control and Prevention's (CDC's)

⁶ CMS QualityNet. "Participation: How to Participate."



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National Healthcare Safety Network (NHSN). Furthermore, CMS notes that the information reported will be shared with CMS and it will retain and publicly report this information to support protecting the health and safety of residents, personnel and the general public.

CMS is also adding a new provision to require 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. Facilities must inform residents, their representatives and families by 5 p.m. the next calendar day following the occurrence of either: a single confirmed infection of COVID-19; or three or more residents or staff with new onset of respiratory symptoms that occur within 72 hours of each other. Also, cumulative updates to residents, their representatives and families must be provided at least weekly by 5 p.m. the next calendar day following the subsequent occurrence of either: each time a confirmed infection of COVID-19 is identified; or whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other.

- 24) Time Used for Level Selection for Office/Outpatient Evaluation and Management Services
 Furnished Via Medicare Telehealth: CMS is finalizing on an interim basis, for the duration of the
 PHE for the COVID-19 pandemic, that the typical times for purposes of level selection for an
 office/outpatient E/M are the times listed in the CPT code descriptor.
- 25) **Updating the Medicare Telehealth List:** For the duration of the PHE for the COVID-19 pandemic, CMS is revising its regulation to specify that, during a PHE it will use a subregulatory process to modify the services included on the Medicare telehealth list. Any additional services added using the revised process would remain on the list only during the PHE for the COVID-19 pandemic.
- 26) Payment for COVID-19 Specimen Collection to Physicians, Nonphysician Practitioners and Hospitals: The IFC provides additional payment for assessment and COVID-19 specimen collection to support testing by HOPDs, and physicians and other practitioners, to recognize the significant resources involved in safely collecting specimens from many beneficiaries during a pandemic.

For the duration of the PHE, CMS will recognize physician and NPP use of CPT code 99211 for all patients, not just patients with whom they have an established relationship, to bill for a COVID-19 symptom and exposure assessment and specimen collection provided by clinical staff incident to their services.

CMS notes that a physician or practitioner cannot bill for services provided by auxiliary clinical staff unless those staff meet all the requirements to furnish services "incident to" services, as described in 42 CFR 410.26 and further described in section 60 of Chapter 15, "Covered Medical and Other Health Services," in the Medicare Benefit Policy Manual 100-02. CMS further notes



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that CMS adopted an interim final policy to permit the direct supervision requirement to be met through virtual presence of the supervising physician or practitioner using interactive audio and video technology for the duration of the PHE.

For specimens collected by/in HOPDs, CMS is 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 code will be assigned to HCPCS code C9803 to APC 5731 Level 1 Minor Procedures. APC 5731 Level 1 Minor Procedures already contains many similar services to new HCPCS code C9803, including HCPCS code Q0091 (Obtaining screening pap smear) and G0117 (Glaucoma Screening for high risk patients furnished by an optometrist or an ophthalmologist).

CMS further established the payment for HCPCS code G2023 for specimen collection based on the resources required for CPT code 99211. Currently, the PFS pays a national unadjusted rate of \$23.46 for CPT code 99211. APC 5731 Level 1 Minor Procedures pays a national unadjusted rate of \$22.98. Because these payment amounts for APC 5731 Level 1 Minor Procedures approximates CMS's best estimate of the resource cost for this service, and because HCPCS code C9803 for a clinic visit dedicated to specimen collection is similar to other services in APC 5731, CMS assigns HCPCS code C9803 to APC 5731 for the duration of the PHE. CMS established HCPCS code C9803 only to meet the need of the PHE, and CMS expects to retire this code once the PHE concludes.

CMS is assigning a status indicator of "Q1" to HCPCS code C9803, indicating that this service will be conditionally packaged under the OPPS when billed with a separately payable primary service in the same encounter. The OPPS will only make separate payment to a hospital when HCPCS code C9803 is billed without another primary covered hospital outpatient service.

Because physicians and other practitioners will be using the level 1 E/M code for established patients, CPT code 99211, to conduct testing-related visits, there will not be beneficiary cost sharing when the practitioner's office bills for this service, provided it results in an order for or administration of a COVID-19 test. Similarly, because HOPDs will use HCPCS code C9803 to bill for a clinic visit for specimen collection, which CMS considers an E/M code in the office and other outpatient services category of HCPCS codes, beneficiary cost sharing will not apply for this service, provided it results in an order for, or administration of, a COVID-19 test and meets other requirements of the law.

27) Payment for Remote Physiologic Monitoring Services Furnished During the COVID-19 Public Health Emergency: For purposes of treating suspected COVID-19 infections, CMS is establishing a policy on an interim final basis for the duration of the COVID-19 PHE to allow remote physiologic monitoring (RPM) monitoring services to be reported to Medicare for periods of



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time that are fewer than 16 days of 30 days, but no less than 2 days, as long as the other requirements for billing the code are met. CMS is not proposing to alter the payment for CPT codes 99454, 99453, 99091, 99457 and 99458 because the overall resource costs for long-term monitoring for chronic conditions assumed under the current valuation would appropriately reflect those for short-term monitoring for acute conditions in the context of COVID-19 disease and exposure risks.

Payment for CPT codes 99454, 99453, 99091, 99457 and 99458 when monitoring lasts for fewer than 16 days of 30 days, but no less than 2 days, is limited to patients who have a suspected or confirmed diagnosis of COVID-19.

Appendix I: Expanded CPT Codes Subject to the Primary Care Exemption

CPT Code	Description
99441	Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion
99442	Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11-20 minutes of medical discussion
99443	Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 21-30 minutes of medical discussion.
99495	Transitional Care Management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within two business days of discharge; medical decision making of at least moderate complexity during the service period; face-to-face visit within 14 calendar days of discharge.
99496	Transitional Care Management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within two business days of discharge; medical decision making of at least high complexity during the service period; face-to-face visit within 7 calendar days of discharge
99421	Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5–10 minutes



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CPT Code	Description
99422	Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11–20 minutes
99423	Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes
99452	Interprofessional telephone/internet/electronic health record referral service(s) provided by a treating/requesting physician or qualified health care professional, 30 minutes
G2012	Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion);
G2010	Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment).