Summary – Interim Final Rule with Comment Period (IFC):

Additional Policy and Regulatory Revisions in Response to COVID-19 PHE and Delay of Certain Reporting Requirements for SNF Quality Reporting Program

85 Fed. Reg. 27550 (May 8, 2020)

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
I	Background/Purpose of Rule	Pg. 27552	• Secretary of Health & Human Services declared PHE Jan. 31, 2020, renewed April 21, 2020. • President declared national emergency March 13, 2020. • Waivers of Medicare rules have been granted pursuant to waiver authority under the PHE. • Additional flexibilities of Medicare rules granted under a previously issued interim final rule with comment period published in the Federal Register April 6, 2020, effective March 31, 2020 (March 31 IFC). • Current IFC is issued: ○ To ensure sufficient health care items and services are available to meet the needs of Medicare and Medicaid beneficiaries and others identified in the Affordable Care Act. ○ To implement provisions of recent legislation – Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (Pub. L. 116–123, March 6, 2020), the Families First Coronavirus Response Act (Pub. L. 116–127, March 18, 2020), and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136, March 27, 2020). • Intent of this IFC is: ○ To increase access to services in setting that could help to minimize transmission of disease and to improve infection control. ○ To amend the Shared Savings Program for the impact of the PHE and to encourage continued participation. ○ To provide flexibility to states operating Basic Health Programs BHPs). ○ To delay certain billing policies for qualified health plans (QHPs).

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
			○ To allow certain non-physician practitioners to certify the need for home health services. • The IFC provisions are only for the duration of this PHE, unless otherwise indicated. • The effective date of the IFC is May 8, 2020, but the policies in the IFC are applicable beginning March 1, 2020 or January 27, 2020, unless a different applicability date is expressly identified. • Comments are due to CMS no later than 5 p.m. ET on July 7, 2020.
II(A)	Reporting Under the Home Health Value-Based Purchasing Model for CY 2020 During the COVID-19 PHE	Pg. 27553	**Current Rule** Medicare certified home health agencies (HHAs) participating in the Home Health Value-Based Purchasing (HHVBP) Model are required to report data to CMS on certain quality measures that is used to adjust their Medicare payment rates. This data must be reported during designated submission periods in accordance with deadlines determined by the Secretary. **IFC Change** Extensions or exceptions CMS grants during the PHE to data submission requirements and deadlines for the Home Health Quality Reporting Program (HH QRP) will also apply to the HHVBP Model. Where the data that participating HHAs in the nine HHVBP Model states are required to report are the same data that those HHAs are also required to report for the HH QRP, such HHVBP Model data should be reported in the same time, form and manner that HHAs are required to report those data for the HH QRP. HHVBP participants are also excepted from New Measure reporting requirements for the April 2020 and July 2020 submission periods. HHAs may still optionally submit all or part of this data by the otherwise applicable submission deadlines. CMS is evaluating the impact of these exceptions and extensions on performance calculations for 2020 and considering whether changes to CY 2022 payment methodologies may be needed to account for the more limited data available.

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
II(B)	Scope of Practice	Pg. 27554	1. *Supervision of Diagnostic Tests by Certain Non-Physician Practitioners* **Current Rule** Nurse practitioners (NPs), clinical nurse specialists (CNSs), physician assistants (PAs) (to the extent generally supervised by a physician (42 CFR § 410.32(b)(1)), and certified nurse-midwives (CNMs) are permitted to furnish diagnostic tests to the extent that they are otherwise authorized to do so under state law, but the regulations at 42 CFR § 410.32 does not address whether NPs, CNSs, PAs and CNMs may supervise others when furnishing diagnostic tests. **IFC Change** • Amends 42 CFR § 410.32(b)(1) to specify that diagnostic tests can be furnished under the appropriate level of supervision, by an NP, CNS, PA and CNM so long as permitted under applicable state scope of practice laws. • Amends 42 CFR § 410.32(b)(2)(iii)(B) to permit diagnostic psychological and neuropsychological testing services to be supervised by NPs, CNSs, PAs and CNMs so long as permitted under applicable state scope of practice laws. • Adds 42 CFR § 410.32(b)(2)(viii) to allow diagnostic tests to be performed by a PA without physician supervision so long as the PA is authorized to perform the test. • Amends 42 CFR § 410.32(b)(3) to authorize NPs, CNSs, PAs and CNMs to provide the appropriate level of supervision assigned to diagnostic tests. 2. *Therapy—Therapy Assistants Furnishing Maintenance Therapy (PFS)* **Current Rule** In cases where it is medically necessary to maintain, prevent or slow the deterioration of a patient's condition, Medicare Part B policy permits only a physical therapist (PT) or occupational therapist (OT) (but not a physical therapy assistant (PTA) or occupational therapy assistant (OTA)) to carry out a therapist-established maintenance. However, PTAs and OTAs are permitted to furnish maintenance therapy services in skilled nursing facilities (SNFs) and home health Part A settings.

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
			IFC Change Medicare Part B payment policy will permit the PT or OT who established a maintenance program to delegate the performance of maintenance therapy services to a PTA or OTA. 3. *Therapy—Student Documentation (PFS)* **Current Rule** As of the CY 2020 Physician Fee Schedule final rule, CMS simplified medical record documentation requirements to allow the physician, PA, or NPs, CNS, CNMs and CRNAs who furnish and bill for their professional services to review and verify, rather than re-document information included in the medical record by physicians, residents, nurses, students or other members of the medical team. **IFC Change** Practitioners who are separately authorized to furnish and bill for their professional service, whether or not 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. 4. *Pharmacists Providing Services Incident to a Physician's Service* **IFC Clarification** Pharmacists fall within the regulatory definition of auxiliary personnel under 42 CFR § 410.26 and, therefore, may provide incident to services under the appropriate level of supervision by the billing physician or NPP (so long as payment for the services is not made under Medicare Part D benefit). Pharmacists may furnish services incident to a physician or NPP so long as the services are permitted under the pharmacists' state scope of practice and applicable state law. CMS's intent with the clarification is to encourage pharmacists to work with physicians and NPPs to expand the availability of health care services during the PHE and in particular to

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
			increase access to medication management of individuals with substance/opioid use disorder.
II(C)	Modified Requirements for Ordering COVID-19 Diagnostic Laboratory Tests	Pg. 27557	**Current Rule** 42 CFR § 410.32(a) provides coverage for diagnostic laboratory tests, such as tests for COVID-19, only when they are ordered by a physician or other practitioner who is treating the beneficiary and who uses the results of the test in managing the patient's specific medical condition. **IFC Change** The IFC amends removes the requirement that certain diagnostic tests are covered only based on the order of a treating physician or NPP. Certain tests, including those for COVID-19, influenza virus and respiratory syncytial virus, may be covered when ordered by any health care professional authorized to do so under state law. A list of diagnostic tests subject to this interim rule can be found at COVID-19, Influenza, and RSV Clinical Diagnostic Laboratory Tests for Which Medicare Does Not Require a Practitioner Order During the PHE. CMS makes clear its expectations that when COVID-19 tests are furnished without a treating physician's or NPP's order, the laboratory conducting the test will be required to directly notify the patient of the results (consistent with applicable law) and meet other reporting requirements, typically within 24 hours of receiving results.
II(D)	Opioid Treatment Programs (OTPs) – Furnishing Periodic Assessments via Communication Technology	Pg. 27558	**Current Rule** Periodic assessments would generally be performed in person. The current rules do not permit periodic assessments through two-way interactive audio-video communication technology or audio-only technology. **IFC Change** To ensure that beneficiaries with opioid use disorders are able to continue to receive important services during the PHE, CMS is revising § 410.67(b)(7) to allow periodic

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
			assessments to be furnished during the PHE period via two-way interactive audio-video communication technology. In situations where beneficiaries do not have access to two-way audio-video communications technology, periodic assessments may be furnished using audio-only telephone calls, provided all other applicable requirements are met. OTPs will use clinical judgment to determine whether they can adequately perform the periodic assessment over audio-only phone calls and if not, then they should perform the assessment using two-way interactive audio-video communication technology or in person as clinically appropriate. OTPs should document in the medical record the reason for the assessment and the substance of the assessment.
II(E)	Treatment of Certain Relocating Provider-Based Departments During the COVID-19 PHE	Pg. 27559	**Current Rule** The Medicare program has restricted which off-campus provider-based departments (PBDs) are paid pursuant to the outpatient prospective payment system (OPPS). On-campus and off-campus PBDs paid under OPPS that move to off-campus locations are typically no longer paid under OPPS, with an exception for extraordinary circumstances for off-campus PBDs. The Secretary recently issued a waiver of the provider-based rules at 42 CFR § 413.65 for the PHE. **IFC Change** To allow flexibility in using space and provide financial relief to providers, on-campus departments that relocate to off-campus sites on or after March 1, 2020, through the remainder of the PHE for the purposes of addressing the COVID-19 pandemic may also seek a temporary 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. The new exception process permits providers to begin furnishing services prior to submitting the requisite documents to the CMS Regional Office and applies to all hospitals that relocate an on-campus PBD or excepted off-campus PBD to an off-campus location in response to the PHE. Permissible relocation or partial relocation off-campus includes relocation to a patient's home. 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.

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
II(F)	Furnishing Hospital Outpatient Services in Temporary Expansion Locations of a Hospital or a Community Mental Health Center (CMHC) (including the Patient's Home)	Pg. 27562	**Initial PHE Policy** CMS previously waived the requirements associated with being provider-based to a hospital at 42 CFR § 413.65, as well the conditions of participation at 42 CFR § 482.41 and 42 CFR § 485.623, to facilitate the availability of temporary expansion locations. As a result, 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. **IFC Clarification** 1. *Hospital Outpatient and CMHC Therapy, Education and Training Services*: Hospital and CMHC staff can furnish certain outpatient therapy, counseling and educational services (including partial hospitalization program (PSP) services) incident to a physician's service during the COVID-19 PHE to a beneficiary in their home or other temporary expansion location using telecommunications technology, including when the staff is not present in the hospital or CMHC. In these circumstances, the hospital can furnish services to a beneficiary in a temporary expansion location (including the beneficiary's home) if that beneficiary is registered as an outpatient and the CMHC can furnish services in an expanded CMHC (including the beneficiary's home) to a beneficiary who is registered as an outpatient. CMS provided a list, which it will periodically update, of the applicable individual services. 2. *Hospital In-Person Clinical Staff Services in a Temporary Expansion Location (Which May Be the Patient's Home)*: Services that can safely be provided by hospital staff physically present in a patient's home that is a temporary expansion location may be billed by the hospital as hospital outpatient department (HOPD) services when the patient is a registered hospital outpatient. During the time period the patient is receiving these services, the patient's place of residence may not be considered a home for purposes of HHA services. 3. *Hospital Services Accompanying a Professional Service Furnished Via Telehealth*:

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
			Pursuant to the March 31 IFC, when a practitioner who ordinarily practices in a HOPD furnishes a telehealth service to a patient located at home, the practitioner would submit a professional claim with the place of service code indicating the service in the HOPD with the telehealth modifier 95. Pursuant to this new IFC, during the PHE, hospitals in this situation may also bill as the originating site.
II(G)	Medical Education	Pg. 27567	1. *Indirect Medical Education (IME):* **Current Rule** Hospitals, inpatient rehabilitation facilities (IRFs) and Inpatient Psychiatric Facilities (IPFs) receive a payment adjustment to account for the higher indirect patient care costs of teaching hospitals. This adjustment is based in part on a hospital's number of beds and an IRF's or IPF's average daily census. **IFC Change** To hold these facilities harmless to changes as a result of the PHE: (1) a hospital's beds temporarily added during the PHE will be excluded from its IME payment calculation; and (2) an IRF's or IPF's IME adjustment will be the same as it was on the day before the PHE was declared. 2. *Time Spent by Residents at Another Hospital during the PHE:* **Current Rule** Hospitals also receive a payment for the direct costs of approved graduate medical education programs (DGME payment). One of the elements in the both the IME and DGME calculations is the number of full-time equivalent (FTE) residents working in the hospital. **IFC Change** During the PHE, a hospital may continue to claim a resident for purposes of DGME and IME while they are training at another hospital if the applicable requirements are met, including (a) the sending or receiving hospital is treating COVID-19 patients, (b) activities performed by the resident at the other hospital are consistent with the

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
			guidance in effect during the PHE for the residency program at the sending hospital, and (c) the time spent by the resident immediately prior and/or subsequent to the timeframe the PHE was in effect was included in the sending hospital's FTE resident count.
II(H)	Rural Health Clinics (RHCs)	Pg. 27569	**Current Rule** RHCs are paid on the basis of an all-inclusive rate (AIR) for medically-necessary, face-to-face visits between an RHC practitioner and patient. Section 1833(f) of the Social Security Act establishes a payment limit (or cap) on the AIR. However, RHCs that are provider-based to a hospital with fewer than 50 beds are exempt from the national per-visit payment limit (or cap). **IFC Change** 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 determining the exemption to the per-visit payment limit. This means that RHCs that are exempt from the per-visit payment limit on the AIR because they are provider-based to a hospital that has fewer than 50 beds will not lose the exemption because the hospital expands bed capacity in response to the PHE.
II(I)	Durable Medical Equipment (DME) Interim Pricing in the CARES Act	Pg. 27569	**Current Rule** Medicare pays for durable medical equipment, prosthetics and orthotics (DMEPOS), including a separate payment for maintenance and servicing of the items on the basis of 80 percent of the lesser of the actual charge for the item or the fee schedule amount for the item. Fee schedule amounts for DME, enteral nutrition, and OTS orthotics in non-competitive bidding areas (CBAs) are set forth in 42 CFR § 414.210(g), which accounts for regional variations in price. **IFC Change** Pursuant to Section 3712 of the CARES Act, CMS is amending 42 CFR § 414.210(g) to revise payment rates for DMEPOS under the Medicare program through the duration of the PHE.

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
			For rural and noncontiguous areas, CMS is continuing its current policy at 42 CFR § 414.210(g)(9)(iii) of paying for DMEPOS items and services furnished in rural and noncontiguous non-CBAs based on a 50/50 blend of adjusted and unadjusted fee schedule amounts through December 31, 2020 or through the duration of the emergency, whichever is longer. This fee schedule adjustment results in fee schedule amounts that are approximately 66 percent higher than the fully adjusted fee schedule amounts that CMS currently pays for DMEPOS items and services furnished in non-rural areas in the contiguous U.S. For DMEPOS items and services furnished in non-CBAs other than rural and non-contiguous non-CBAs, the fee schedule amounts are based on 75 percent of the adjusted fee schedule amount and 25 percent of the historic, unadjusted fee schedule amount until the end of the emergency period. This increases payments so that they are approximately 33 percent higher than the payments at the fully adjusted fee schedule amounts. There is no adjustment for former CBAs, which will continue to be based on the single payment amounts from 2018 increased by update factors for subsequent calendar years until new competitive bidding contracts are in place. Retroactive effective date: March 6, 2020.
II(J)	Care Planning for Medicare Home Health Services	Pg. 27571	**Current Rule** Only a physician can certify need for home health services and the certifying physician is required to establish and periodically review the plan of care for furnishing the home health. The physician is also required to document a related face-to-face encounter personally performed by the physician or performed by a nurse practitioner (NP) or clinical nurse specialist (CNS) working in collaboration with the physician, certified nurse midwife (CNM) or physician assistant (PA) supervised by the physician.

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
			IFC Change CMS implements statutory changes made by the CARES Act that expand the authority for NPs, CNSs and PAs to certify eligibility for home health services, as well as establish and periodically review the home health plan of care, when consistent with their scope of practice under state law. The IFC amends parts 409, 424, and 484 to define an NP, a CNS, and a PA (as such qualifications are defined at §§ 410.74 through 410.76) as an "allowed practitioner." This will permit an NP, CNS or PA to certify, establish and periodically review the plan of care, perform the face-to-face encounter, as well as supervise the provision of items and services for beneficiaries under the Medicare home health benefit, so long as they comply with any applicable conditions of practice under state law. These provisions are applicable retroactively to March 1, 2020 and are permanent.
II(K)	CARES Act Waiver of the "3-Hour Rule" and Modification of IRF Coverage and Classification Requirements for Freestanding IRF Hospitals for the PHE During the COVID-19 Pandemic	Pg. 27572	1. *CARES Act Waiver of the "3-Hour Rule"*: The March 31 IFC provided clarification regarding the IRF 3-hour rule at 412.622(a)(3)(ii). The clarification was drafted before the adoption of the CARES Act on March 27, 2020, which requires waiver of 412.622(a)(3)(ii) during the PHE. Accordingly, the March 31 IFC clarification is rescinded. The waiver is not limited to particular IRFs or patients and is, therefore, applicable regardless of whether a patient was admitted for standard IRF care or to relieve acute care hospital capacity. 2. *Modification of IRF Coverage and Classification Requirements for Freestanding IRF Hospitals for the PHE*: The following IRF coverage criteria is waived for patients of freestanding IRFs admitted solely to relieve acute care hospital capacity in a state or region that is experiencing surge during the PHE, i.e., admitted prior to or during phase 1 pursuant to the Guidelines for Opening Up America Again, issued by the White House: (a) 412.622(a)(3)(i)-(iv) (multiple therapy disciplines, 3 hours of therapy per day, intensive rehabilitation therapy, rehabilitation physician supervision); (b) 412.622(a)(4) (documentation requirements); (c) 412.622(a)(5) (interdisciplinary team

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
			approach); (d) 412.29(d), (e), (h)(and (i) (preadmission screening, 3 face-to-face physician visits per week, plan of treatment and interdisciplinary approach).
II(L)	Medicare Shared Savings Program	Pg. 27573	**Current Situation** The COVID-19 pandemic and resulting PHE have created a lack of predictability for many accountable care organizations (ACOs) participating in the Medicare Shared Savings Program (MSSP) regarding the impact of expenditure and utilization changes on historical benchmarks and performance year expenditures, and for those under performance-based risk, the potential liability for shared losses, as well as disrupting population health activities. Thus, stakeholders have advocated for CMS to modify Shared Savings Program policies to address the impact of the COVID-19 pandemic since ACOs need to make participation decisions for PY 2020 and PY 2021 soon and may choose to terminate their participation in the Shared Savings Program on or before June 30, rather than face potential of pro-rated losses for PY 2020 if the COVID-19 PHE does not extend for the entire year or the program's policies do not adequately mitigate liability for shared losses. **IFC Change** CMS believes it is vital to the stability of the Shared Savings Program to encourage participation by ACOs by adjusting program policies as necessary to address the impact of the COVID-19 pandemic, including by offering certain flexibilities in program participation options to currently participating ACOs and addressing potential distortions in expenditures resulting from the pandemic to ensure that ACOs are treated equitably regardless of the degree to which their assigned beneficiary populations are affected by the pandemic. Please note that the modifications 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. The modifications include: (1) *Forgoing the application cycle for a January 1, 2021 start date to help ACOs and their ACO providers and suppliers currently participating in the Shared Savings*

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
			Program focus on treating patients during the pandemic. For ACOs that entered a first or second agreement period with a start date of January 1, 2018, these ACOs may elect to extend their agreement period for an optional fourth performance year (January 1, 2021 to December 31, 2021). This one-time election is voluntary and an ACO could choose not to make this election, thus concluding its participation in the program with the expiration of its current agreement period on December 31, 2020. Further, CY 2020 will not serve as a benchmark year 3 for a group of ACOs that would otherwise be January 1, 2021 starters. If an ACO elects to extend its agreement period, the ACO will be in compliance with 42 CFR § 425.210(a) (the requirement to provide a copy of its participation agreement with CMS to all ACO participants, ACO providers/suppliers, and other individuals and entities involved in ACO governance) if it notifies these parties that it will continue to participate in the program for an additional year; further, all parties must continue to comply with the program's requirements through December 31, 2021. An ACO participating under the BASIC track's glide path may still elect to transition to a higher level of risk and potential reward that the ACO would have automatically transitioned to for PY 2021, absent the ACO's election to maintain its current participation level for one year. CMS is seeking comment on this approach. Anticipated Election Date: June 18, 2020 through September 22, 2020. (2) *Permitting ACOs participating in the BASIC track glide path with a one-time exception to elect to maintain their current level under the BASIC track for PY 2021.* Prior to the automatic advancement for PY 2021, an applicable ACO may elect to remain in the same level of the BASIC track's glide path that it entered for PY 2020. For PY 2022, 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 PY 2022 if it had advanced automatically to the next level for PY 2021 (unless the ACO elects to advance more quickly before the start of PY 2022). The voluntary election to maintain its participation level must be made

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
			in the form and manner and by a deadline established by CMS. CMS is seeking comment on this approach. Anticipated Election Date: June 18, 2020 through September 22, 2020. (3) *Determining that 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 end of the PHE, which includes any renewals.* If the COVID-19 PHE extends through all of CY 2020, all shared losses for PY 2020 will be mitigated for all ACOs participating in a performance-based risk track (including track 2, the ENHANCED track, levels C, D and E of the BASIC track, and the Track 1+ Model). For example, the COVID-19 PHE has already covered four months (January through April 2020) meaning any shared losses an ACO incurs for PY 2020 will be reduced by at least one-third; if the COVID-19 PHE covers 6 months (January through June 2020), any shared losses an ACO incurs would be reduced by three-fourths. Extreme and uncontrollable circumstance begins January 2020. (4) *Revising Shared Savings Program financial calculations, as well as certain other program operations to mitigate the impact of unanticipated increased expenditures related to the treatment of COVID-19.* CMS will 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 (defined using the 20 percent DRG adjustment or discharges of an individual diagnosed with COVID-19 with particular diagnosis codes), and as specified on Parts A and B claims with dates of service during the episode (defined as the month of admission through the month following discharge). CMS will also remove COVID-19 related expenditures from the determination of benchmark expenditures since this approach will identify the most acutely ill patients with the highest costs associated with acute care

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
			treatment. Excluding those patients without an inpatient admission will therefore not generate unexpected performance year expenditures. CMS will also exclude the affected months from total person years used in per capita expenditure calculations. Finally, CMS will exclude all Parts A and B FFS payment amounts for a beneficiary's episode of care for treatment of COVID-19, which includes a number of different calculations, such as expenditures used in determining county-level FFS expenditures; revenue of ACO participants for purposes of calculating the ACO's loss recoupment limit under the BASIC track; revenue of ACO participants and expenditures 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; and ACO's repayment mechanism arrangement. This does not include recoupment of accelerated or advance payments or lump sum payments made to hospitals or other health care providers through the CARES Act Provider Relief Fund, which occurs outside of the FFS claims processing system. (5) *Expanding codes used in beneficiary 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: (1) HCPCS code G2010 (remote evaluation of patient video/images) and HCPCS code G2012 (virtual check-in) (which may also be used for new patients); (2) CPT codes 99421, 99422 and 99423 (online digital evaluation and management service (e-visit)); and (3) CPT codes 99441, 99442, and 99443 (telephone evaluation and management services).* Including these codes in the definition of primary care services used in assignment for performance years during the PHE for the COVID-19 pandemic will result in a more accurate identification of where beneficiaries have received the plurality of their primary care services. CPT codes 99304, 99305, 99306, 99315, 99316, 99327, 99328, 99334-99337, 99341-99345, and 99347-99350 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.

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
			Effective date: Expansion starts with January 1, 2020 performance year.
II(M)	Additional Flexibility under the Teaching Physician Regulations	Pg. 27587	**Initial PHE Policy** In the March 31 IFC, the Secretary adopted certain flexibilities for teaching physician supervision and E/M codes that may be furnished under the primary care exception, which permits services by a resident without the presence of the teaching physician. **IFC Changes** The current IFC includes clarifying technical edits for these flexibilities and new flexibilities during the PHE, including: (1) permitting a teaching physician to direct care and review resident services with the resident, during or immediately after the visit, remotely through virtual means via audio/video real-time communications technology; (2) adding services to the primary care exception; and (3) allowing the office/outpatient E/M level selection for services under the primary care exception furnished via telehealth to be based on medical decision making (MDM) or time, with time inclusive of all time associated with the E/M on the day of encounter and the requirements regarding documentation of history and/or physical exam in the medical record deemed inapplicable.
II(N)	Payment for Audio-Only Telephone Evaluation and Management Services	Pg. 27589	**Current Rule** Telephone E/M services described in CPT codes 98966-98968 and 99441-99443 are covered. These codes are meant to cover prolonged, audio-only communication between the practitioner and the patient, where clinically appropriate, and so providers are reimbursed in accordance with this expectation. The telephone E/M services are not meant to replace a face-to-face visit. **IFC Changes** CMS is increasing the reimbursement rates for audio-only telephone E/M services (CPT codes 99441, 99442 and 99443). CMS realizes that the audio-only services are being used primarily as a replacement for care that would otherwise be reported as an in-person or telehealth visit using the office/outpatient E/M codes.

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
			The new relative value units (RVUs) for the telephone E/M services are determined based on crosswalks that are similar to office/outpatient E/M codes, the time requirements for the telephone codes and the times assumed for valuation for purposes of the office/outpatient E/M codes. CMS is not increasing 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, cannot be furnished in lieu of an office/outpatient E/M service. CMS also adds audio-only also services that are being furnished as substitutes for office/outpatient E/M services to the list of telehealth services for the duration of the PHE. Pursuant to the 1135 waivers and the CARES Act, CMS will also be waiving the video technology requirement for telehealth services under §410.78, in certain instances. Specifically, CMS is permitting the use of audio only equipment to furnish the service codes for audio-only telephone E/M services and behavioral health counseling and educational services. Beneficiaries are still liable for cost-sharing where the practitioner does not waive cost-sharing. CMS seeks comments on ways to best minimize unexpected cost sharing for beneficiaries. Full list of Medicare Telehealth Service.
II(O)	Flexibility for Medicaid Laboratory Services	Pg. 27590	**Current Rule** Under the current regulations, • 42 CFR § 440.30(a) provides that Medicaid-covered laboratory and X-ray services must be ordered and provided by or under the direction of a physician or other licensed practitioner of the healing arts within the scope of his/her practice as defined by state law or ordered by a physician but provided by a referral laboratory.

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
			• 42 CFR § 440.30(b) specifies that Medicaid will cover laboratory tests and X-ray services only if provided in an office or similar facility; and • 42 CFR § 440.30(c) specifies that Medicaid will cover these services only if they are furnished by a laboratory that meets the requirements of 42 C.F.R. part 493. **IFC Change** CMS is amending 42 CFR § 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. This would apply during the current COVID-19 PHE, but also during any subsequent periods of active surveillance, to allow for continued surveillance to detect recurrence and prevent further spread of the disease. Active surveillance is defined 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. CMS seeks comments on this definition of active surveillance. These flexibilities would also apply to future PHEs resulting from outbreaks of communicable disease during which measures are necessary to avoid transmission of a communicable disease and when such measures might result in difficulty meeting the requirements of 42 CFR § 440.30(a) or (b). CMS is also soliciting comments on whether continuing to apply the requirements of section 440.30(c) would present any obstacle to providing Medicaid coverage for COVID-19 testing. Retroactive Effective Date: March 1, 2020.
II(P)	Improving Care Planning for Medicaid Home Health	Pg. 27591	**Current Rule** A beneficiary's physician must order Medicaid home health services as part of a written

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
	Services		plan of care that is reviewed by the physician annually. A face-to-face encounter must be documented by a physician or a nonphysician practitioner (NPP), acting within their scope of practice, within a reasonable timeframe of the order. An NPP performing the face-to-face must communicate the results to the ordering physician. The March 31 IFC amended these requirements to allow other licensed practitioners to order all components of Medicaid home health services, in accordance with state scope of practice laws, for the duration of the PHE. **IFC Change** The IFC amends the Medicaid 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. This change aligns Medicaid requirements with those now applied under Medicare. In addition, § 440.70(a)(2) is amended to allow an NP, CNS or PA to order Medicaid home health services, as described in § 440.70(b)(1), (2) and (4), when permitted under state law and subject to state conditions of practice. These practitioners may also independently perform the face-to-face encounter, if consistent with applicable state law. These changes are permanent.
II(Q)	Basic Health Program Blueprint Revisions	Pg. 27593	**Current Rule** States operating a Basic Health Program (BHP) that wish to implement significant program changes must submit a revised Blueprint to the Secretary for review and certification in advance. Revised Blueprints are also subject to public comment requirements. **IFC Change** CMS amends § 600.125 to provide states operating a BHP the ability to request retroactive certification of temporary revisions to program requirements related to the PHE and COVID-19 pandemic. These submissions will be excepted from normal public comment

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
			requirements in order to expedite certification of temporary changes that expand access to coverage. Currently, only Minnesota and New York operate BHPs.
II(R)	Merit-based Incentive Payment System (MIPS) Qualified Clinical Data Registry (QCDR) Measure Approval Criteria	Pg. 27594	**Current Rule** Under 42 CFR § 414.1400(b)(3)(v)(C), all QCDR measures must be fully developed and tested with complete testing results at the clinician level prior to submitting the QCDR measure at self-nomination for the 2021 performance period. In addition, 42 CFR § 414.1400(b)(3)(v)(D) requires QCDRs to collect data on a QCDR measure appropriate to the measure type, prior to submitting it for CMS consideration during self-nomination beginning with the 2021 performance year. **IFC Change** CMS is delaying the implementation of these current rules by one year. Specifically, CMS has amended § 414.1400(b)(3)(v)(C) to provide 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. Similarly, 42 CFR § 414.1400(b)(3)(v)(D) is amended to state that beginning with the 2022 performance period, QCDRs must collect data on a QCDR measure prior to submitting it for CMS consideration during self-nomination.
II(S)	Application of Certain National Coverage Determination and Local Coverage Determination Requirements during the PHE for the COVID-19 Pandemic	Pg. 27595	**Current Rule** National Coverage Determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under Title XVIII. Local Coverage Determinations (LCDs) are determinations by a Medicare Administrative Contractor (MAC) with respect to whether or not a particular item or service is covered under section 1862(a)(1)(A) of the Act in the particular MAC's geographic areas. Most items and services must be reasonable and necessary for the diagnosis or treatment of an

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
			illness or injury or to improve the functioning of a malformed body member to be paid under Part A or B of Title XVIII. **IFC Change** CMS will not enforce the clinical indications for therapeutic continuous glucose monitors (CGMs) in LCDs. For example, it 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 CGM. This enforcement discretion will only apply during the PHE for the COVID-19 pandemic.
II(T)	Delay in the Compliance Date of Certain Reporting Requirements Adopted for IRFs, LTCHs, HHAs and SNFs	Pg. 27595	**Current Rule** In the FY 2020 rulemaking process, CMS adopted two new transfer of health (TOH) information quality measures and certain standardized patient assessment data elements (SPADEs) for the quality reporting periods (QRPs) applicable to IRFs, LTCHs, HHAs and SNFs. For IRFs, LTCHs and SNFs, CMS adopted: • TOH Information to Provider-Post-Acute Care quality measure and TOH Information to Patient-Post-Acute Care quality measure beginning with the FY 2022 IRF, LTCH and SNF QRPs. These facilities are required to collect data on both measures beginning with patient discharges on/after October 1, 2020. • SPADEs for six categories on which IRFs, LTCHs and SNFs must report for patients beginning with FY 2022, with data collection beginning with admissions and discharges (except for hearing, vision, race, ethnicity SPADEs, which are collected for admissions only) on October 1, 2020. For HHAs, CMS adopted the same two TOH information measures discussed above for the CY 2022 HH QRP beginning with patients discharged or transferred January 1, 2021 and data collection on the same SPADEs beginning with the start of care, resumption of

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
			care and discharges (except for the hearing, vision, race and ethnicity SPADEs, which must be collected at the start of care) on or after January 1, 2021. **IFC Change** Under the IFC, CMS announced that it is delaying the compliance deadlines for data collection and reporting on the new TOH Information Measures and SPADEs required by these facilities as follows: • For IRFs and LTCHs, the new compliance date for data collection is October 1 of the year that is at least one full fiscal year after the PHE ends. • For HHAs, the new compliance date for data collection is January 1 of the year that is at least one full fiscal year after the PHE ends. • For SNFs, the new compliance date for data collection is October 1 of the year that is at least two full fiscal years after the PHE ends.
II(U)	Update to the Hospital Value-Based Purchasing (VBP) Program Extraordinary Circumstance Exception (ECE) Policy	Pg. 27597	**Current Rule** Under current policy, CMS may grant the request of an individual hospital participating in the Hospital VBP Program for a disaster/ECE. Under the ECE, CMS would not include any measures or cases for which a hospital has submitted data during a performance period for which the hospital has been granted a Hospital VBP Program ECE. **IFC Change** Under the IFC, CMS is codifying, at 42 CFR § 412.165(c), an update to its Hospital VBP Program ECE policy to include the ability to grant an ECE to all hospitals in a region, locale or the whole United States if affected by an emergency circumstance, without a hospital's individual request. Under the new policy and in consideration of the COVID-19 PHE, CMS is granting an ECE to all hospitals participating in the Hospital VBP program for two reporting requirements. First, the hospitals are not required to report National Healthcare Safety Network (NHSN) measures or Hospital Consumer Assessment of Healthcare Providers and Systems

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
			(HCAHPS) survey data for the quarters between October 1, 2019 and June 30, 2020. Second, CMS will exclude qualifying claims data from the mortality, complications and Medicare Spending per Beneficiary measures between January 1, 2020 and June 30, 2020. If a hospital under the ECE does not report a minimum number of cases and measures, the hospital will be excluded from the Hospital VBP Program for the applicable program year, will not receive a two percent reduction to its base operating DRG payment, and will not be eligible to receive any VBP incentive payments for the applicable year.
II(V)	COVID-19 Serology Testing	Pg. 27598	**Current Rule** Medicare covers the cost of tests that fall under a Medicare benefit. **IFC Change** CMS will now cover, on an interim basis, Food and Drug Administration-authorized COVID-19 serology tests under the Medicare Program as part of Medicare's diagnostic laboratory test benefit when reasonably necessary for beneficiaries with known current or known prior COVID-19 infection or suspected current or suspected past COVID-19 infection. CMS expects to be billed once per sample for these tests.
II(W)	Modification to Medicare Provider Enrollment Provision Concerning Certification of Home Health Services	Pg. 27598	**Current Rule** Under current 42 CFR § 424.507(b)(1), payment for covered Part A and B home health services requires (1) the provider's claim to include the legal name and National Provider Identifier (NPI) of the ordering/certifying physician, and (2) the ordering/certifying physician must be enrolled in Medicare in an approved status or have validly opted-out of the Medicare program. **IFC Change** CMS is amending 42 CFR § 424.507(b)(1) to provide that, during the PHE, the ordering/certifying physician, or the ordering/certifying physician assistant, nurse practitioner, or clinical nurse specialist (as those terms are defined in Section 1861(aa)(5)

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
			of the Act) working in accordance with state law may also certify the need for home health services. Effective Date: Applicable to services provided on or after March 1, 2020.
II(X)	Health Insurance Issuer Standards under the Affordable Care Act Including Standards Related to Exchanges: Separate Billing and Segregation of Funds for Abortion Services	Pg. 27599	**Current Rule** All qualified health plan (QHP) issuers must comply with the policy requiring the separate billing of policy holders for the portion of their premium attributable to coverage of non-Hyde abortion services beginning on or before the issuer's first billing cycle following June 27, 2020. **IFC Change** CMS is revising 45 CFR § 156.280(e)(2)(ii) to delay the implementation of the separate billing policy for 60 days. Therefore, QHP issuers must comply with the separate billing policy beginning on or before the issuer's first billing cycle following August 26, 2020. HHS will exercise its enforcement authority for QHP issuers and Exchanges that fail to timely comply with the requirement's new deadline despite good faith efforts but does not expect to formally extend the deadline again.
II(Y)	Requirement for Facilities to Report Nursing Home Residents and Staff Infections, Potential Infections, and Deaths Related to COVID-19	Pg. 27601	**Current Rule** Under 42 CFR § 483.80, Long Term Care Facilities (LTCFs) must maintain an infection prevention and control program designed to provide a safe, sanitary and comfortable environment and to help prevent the development and transmission of communicable diseases and infections. LTCFs must also have written standards, policies and procedures that include a system of surveillance designed to identify and report communicable diseases, health care-associated infections, and potential outbreaks to state and local health care departments. **IFC Change** CMS revises the LTCF infection prevention and control requirements to establish explicit reporting requirements for confirmed and suspected COVID-19 cases. The rule adds three

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
			salient provisions to the existing regulations at 42 CFR § 483.80(g). Specifically, CMS has added: • At § 483.80(g)(1), a requirement that LTCFs report information about COVID-19 in a standardized format determined by the Secretary. • At § 483.80(g)(2), a requirement that LTCFs electronically report resident and staff COVID-19-related information to the CDC through the NHSN at a frequency determined by the Secretary, but no less than weekly. The information will be shared with CMS, which will retain and publicly report it. • At § 483.80(g)(3), a requirement that LTCFs timely inform, and provide cumulative updates to, residents, their representatives, and their families of confirmed or suspected COVID-19 cases among the facilities' residents and staff.
II(Z)	Time Used for Level Selection for Office/Outpatient Evaluation and Management Services Furnished Via Medicare Telehealth	Pg. 27602	**Initial PHE Policy** In the first COVID-19 Interim Final Rule (85 FR 19268-19269), CMS revised its policy to allow practitioners to select the level of E/M office/outpatient services furnished via telehealth based on Medical Decision Making (MDM) or time, with time defined as all of the time associated with the E/M on the day of the encounter. CMS further instructed at that time that typical times associated with office/outpatient E/M visits were available in as a public file within the Medicare Physician Fee Schedule. **ICF Clarification** CMS has acknowledged that the typical times listed in the CMS public use file do not always align with the typical times included in the office/outpatient E/M code descriptors. Therefore, practitioners may use the typical times listed in the CPT code descriptor for purposes of level selection of an office/outpatient E/M service.
II(AA)	Updating the Medicare Telehealth List	Pg. 27602	**Current Rule** CMS requires an annual physician fee schedule rulemaking to add services to and delete services from the Medicare telehealth list.

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
			IFC Change CMS is modifying its regulations at § 410.78(f) to specify that, during a PHE, CMS would use a subregulatory process to modify the services included on the Medicare telehealth list. CMS would add services to the Medicare telehealth list on a subregulatory basis by posting new services to the CMS web listing of telehealth services, either when CMS receives a request to add new services or identifies a service that can be furnished in full, as described by the relevant code, by a distant site provider to a beneficiary in a manner that is similar to the in-person service.
II(BB)	Payment for COVID-19 Specimen Collection to Physicians, Nonphysician Practitioners and Hospitals	Pg. 27602	**Current Rule** When physicians and other practitioners collect specimens as part of their professional services, Medicare generally bundles the payment into the payment rate for other services, including office and outpatient visits. Typically, collection of a specimen via nasal swab or other method during the provision of a service might be reported as part of (bundled with) an office/outpatient E/M visit (CPT codes 99201-99205, 99211-99215). CMS pays for specimen collection that occurs when an established patient is having a face-to-face interaction with the billing professional. The services are reported with a level 2 through a level 5 visit (CPT codes 99212-99215). Where the specimen is collected during a face-to-face interaction with a clinical staff, the services are reported using CPT code 99211. For hospital outpatient departments (HOPDs), payments for clinical services such as specimen collection are included in a clinic or emergency room visit or in other primary services furnished in the HOPD, such as observation services or critical care services. **IFC Change** Under the IFC, CMS is providing additional payment for assessment and COVID-19 specimen collection to support testing by HOPDs, and physicians and other practitioners. Physicians and nonphysician practitioners (NPPs) may bill CPT code 99211 (a level 1 E/M

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
			visit, furnished for the purpose of a COVID-19 assessment and specimen collection) for both new and established patients. In addition, physicians and NPPs' may use CPT code 99211 to bill for services furnished incident to their professional services, when a clinical staff assess symptoms and collect specimens for purposes of COVID-19 testing. Cost-sharing for this service will be waived when the requirements under section 6002(a) of the Families First Coronavirus Response Act are met. CMS has created a new E/M code, HCPCS code C9803, under the outpatient perspective payment system (OPPS) for HOPDs to bill for a clinic visit dedicated to specimen collection and is adopting a policy to conditionally package payment for this code. CMS has assigned HCPCS code C9803 to APC 5731 for the duration of the PHE. HCPCS code C9803 will have a status indicator of Q1 to indicate that the services will be conditionally packaged under the OPPS when billed with a separately payable primary service in the same encounter. The OPPS will make a separate payment to the hospital when HCPCS code C9803 is billed without another primary covered hospital outpatient service or when it is billed with a clinical diagnostic laboratory test with a status indicator of "A."
II(CC)	Payment for Remote Physiologic Monitoring (RPM) Services Furnished During the COVID-19 Public Health Emergency	Pg. 27605	**Current Rule** Providers cannot report RPM services under CPT Codes 99454, 99454, 99453, 99091, 99457 and 99458 when monitoring a patient for fewer than 16 days during a 30-day period. **IFC Change** CMS will reimburse RPM services described by CPT code 99454, where the reporting period of time is fewer than 16 days out of a 30-day period, but not less than 2 days, as long as the other requirements for billing the RPM codes are met. CMS will also reimburse for RPM services under CPT codes 99454, 99453, 99091, 99457

IFC TOC	TOPIC / CATEGORY	IFC PAGE	SUBSTANCE
			and 99458 where the patient monitoring lasts for fewer than 16 days out of a 30-day period, but not less than 2 days. Reimbursement under these CPT codes is limited to patients who have a suspected or confirmed diagnosis of COVID-19.