Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program

[CMS-5531-IFC]

SUMMARY

On May 1, 2020, the Centers for Medicare and Medicaid Services (CMS) placed on public display an interim final rule with comment (IFC) to offer additional flexibilities in providing services during the COVID-19 pandemic and support the health and safety of Medicare beneficiaries, Medicaid recipients, and healthcare workers.

CMS believes it would be contrary to public interest to undertake normal notice and comment rulemaking; it waives both notice and comment rulemaking and the 30-day delay in the effective date of a final rule. **Policies in the IFC generally apply either as of January 27, 2020 or March 1, 2020**, except for those policies in the table in the IFC (reproduced below in the Background section). The IFC is scheduled to be published in the May 8, 2020 issue of the *Federal Register*, which is also the effective date of the IFC. The 60-day comment period for the IFC ends at close of business on July 7, 2020.[1]

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[1] The public display copy of this IFC indicates that comments must be received after the date of publication in the *Federal Register*.

I. BACKGROUND

On January 31, 2020, the Secretary of Health and Human Services (HHS) declared a Public Health Emergency (PHE) for the "coronavirus disease 2019" (known as COVID-19[2]) for the U.S.; the PHE was renewed effective April 26, 2020. On March 11, 2020, the World Health Organization (WHO) declared the COVID-19 outbreak as a pandemic. On March 13, 2020, the President declared the COVID-19 outbreak a national emergency.

A previous IFC published in the April 6, 2020 Federal Register (85 FR 19230) had an effective date of March 31, 2020 (referred to as the "March 31st COVID-19 IFC") and applied as of March 1, 2020. In the current IFC, CMS revises additional regulations in the programs under Title XVIII (Medicare) and Title XIX (Medicaid) of the Social Security Act (the Act), or in programs

[2] The virus causing COVID-19 has been named SARS-CoV-2.

under the Patient Protection and Affordable Care Act. CMS also implements regulations implementing recent legislation including the Coronavirus Preparedness and Response Supplemental Appropriations Act)[3], the Families First Coronavirus Response Act[4], and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act)[5].

In the current IFC, CMS addresses certain regulations with a goal to increase access to medically necessary services while minimizing the overall risk to health care providers and public health. All final provisions included in this IFC are only for the duration of the PHE, unless otherwise indicated. Policies in the IFC are effective as of January 27, 2020 or March 1, 2020, except for those policies shown in the following table reproduced without change from the IFC.

Provision	Applicability Date
Medicare Shared Savings Program – Expansion of Codes used in Beneficiary Assignment	We are revising §425.400 to expand the definition of primary care services used in the Shared Savings Program 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, as defined in §400.200, which includes any subsequent renewals.
Modification to Medicare Rules and Medicaid Concerning Certification and Provision of Home Health Services	We are revising §§ 409.41 through 409.48; 424.22; 424.507(b)(1); § 440.70(a)(2) and (3), and (b)(1), (2) and (4); and several sections of 42 CFR part 484 to include physician assistants, nurse practitioners, and clinical nurse specialists as individuals who can certify the need for home health services and order services. These changes are permanent, and applicable to services provided on or after March 1, 2020.
Flexibility for Medicaid Laboratory Services	We are revising § 440.30 to provide states with flexibility to provide Medicaid coverage for certain laboratory tests and X-ray services that may not meet certain requirements in § 440.30 (a) or (b) (such as the requirement that tests be furnished in an office or similar facility). This flexibility is retroactive to March 1, 2020, during the period of the COVID-19 PHE and for any subsequent periods of active surveillance. The flexibility also applies to future PHEs resulting from outbreaks of communicable disease and subsequent periods of active surveillance.
Requirement for Facilities to Report Nursing Home Residents and Staff Infections, Potential Infections, and Deaths Related to COVID-19	We are revising § 483.80 to establish explicit reporting requirements for long-term care (LTC) facilities to report information related to COVID-19 cases among facility residents and staff. These reporting requirements are applicable on the effective date of this IFC.
Separate Billing and Segregation of Funds for Abortion Services	We are delaying by 60 days the date when individual market qualified health plan (QHP) issuers must be in compliance with the separate billing policy for non-Hyde abortion services. Under this 60-day delay, individual market QHP issuers must comply with the separate billing policy beginning on or before the QHP issuer's first billing cycle following August 26, 2020.
DME Interim Pricing in the CARES Act	We are revising § 414.210 to provide increased fee schedule amounts in certain areas starting on March 6, 2020, and for the duration of the PHE for the COVID-19 pandemic.

[3] Pub. L. 116-123, March 6, 2020
[4] Pub. L. 116-127, March 18, 2020
[5] Pub. L. 116-136, March 27, 2020

Provision	Applicability Date
Merit-based Incentive Payment System (MIPS) Qualified Clinical Data Registry (QCDR) Measure Approval Criteria - Completion of QCDR Measure Testing - Collection of Data on QCDR Measures	For the reasons discussed in section II.R. of this IFC, we are delaying the implementation of the completion of QCDR measure testing policy by 1 year. Specifically, we are 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. This change is applicable on the effective date of this IFC. For the reasons discussed in section II.R. of this IFC, we are delaying the implementation of the collection of data on QCDR measures policy by one year. Specifically, we are 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
Hospital VBP Program	We are revising the extraordinary circumstances exception policy to allow CMS to grant an exception to hospitals located in an entire region or locale without a request and we are codifying the updated policy at § 412.165(c). This change is permanent and is applicable beginning on the effective date of this IFC.
Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP)	We are revising the compliance date for the IRF QRP to October 1st of the year that is at least one full fiscal year after the end of the PHE. This change is applicable on the effective date of this IFC.
Long-Term Care Hospital (LTCH) QRP	We are revising the compliance date for the LTCH QRP to October 1st of the year that is at least one full fiscal year after the end of the PHE. This change is applicable on the effective date of this IFC.
Home Health (HH) QRP	We are revising the compliance date for the HH QRP to January 1st of the year that is at least one full calendar year after the end of the PHE. This change is applicable on the effective date of this IFC.
Skilled Nursing Facility (SNF) QRP	We are revising the compliance date for the SNF QRP to October 1st of the year that is at least two full fiscal years after the end of the PHE. This change is applicable on the effective date of this IFC.

II. Provisions of the Interim Final Rule

CMS previously defined the term “Public Health Emergency” in the regulation at 42 CFR 400.200. This definition refers to the PHE determined to exist nationwide by the Secretary of HHS on January 31, 2020, under section 319 of the Public Health Service (PHS) Act and renewed effective April 26, 2020.

A. Reporting Under the Home Health Value-Based Purchasing Model for CY 2020 During the COVID-19 PHE

The Home Health Value-Based Purchasing (HHVBP) Model was established in the 2016 Home Health Prospective Payment System final rule (80 FR 68624) as a five-year test in nine states.[6] Participation of all Medicare-certified home health agencies (HHAs) providing services in those states is mandatory. The first payment adjustments under the HHVBP were applied to 2018 payments based on data for 2016. HHVBP Model measures include (1) measures drawn from those reported by HHAs under the Home Health Quality Reporting Program (HH QRP), including the Home Health Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) measure; (2) measures calculated from claims data or from data submitted through the Outcome and Assessment Information Set (OASIS) patient assessment instrument; and (3) three HHVBP "New Measures," which are process measures reported by HHAs through a web portal and are not included in the HH QRP.

In this IFC, CMS aligns the HHVBP Model data submission requirements with any exceptions or extensions it has provided under the HH QRP during the COVID-19 PHE. Current regulations (§484.245(c)) provide that an HHA may apply for an exception or extension of HH QRP data reporting under certain extraordinary circumstances, and that CMS may grant exceptions or extensions to HHAs without a request if it determines that an extraordinary circumstance affects an entire region or locale.

Specifically, the IFC provides that if CMS grants an exception from reporting of certain quality data for the HH QRP or extends the deadline for reporting those data during the COVID-19 PHE, the same exception or extension will apply to reporting those same data under the HHVBP Model. The IFC further provides (at a revised §484.315(b)) that reporting of New Measure data under the HHVBP Model is subject to any exceptions or extensions CMS may grant to HHAs during the COVID-19 PHE.

As announced in March 2020[7], CMS has exempted all HHAs from the HH QRP reporting requirements with respect to the period October 1, 2019 through June 30, 2020. HHAs that do not submit data for those quarters (i.e., Q4 of 2019 (October 1, 2019 – December 31, 2019); Q1 of 2020 (January 1, 2020 – March 31, 2020) and Q2 of 2020 (April 1, 2020 – June 30, 2020)) will not have their annual market basket percentage increase reduced by two percentage points. Under the IFC policy, HHAs in the nine HHVBP Model states do not have to report data for this period on the overlapping measures for purposes of the Model. Any future exceptions or extensions for other CY 2020 reporting periods would similarly be extended to the HHVBP

[6] The nine states (AZ, FL, IA, MD, MA, NE, NC, TN, and WA) were selected using a randomized selection methodology. More information on the HH VBP is available at https://innovation.cms.gov/innovation-models/home-health-value-based-purchasing-model.

[7] See the March 27, 2020 CMS guidance memo: https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf

Model. While the exception does not apply to OASIS data, CMS has separately provided for additional time to submit OASIS data.[8] CMS notes that while the exception includes Q4 2019 data, it does not anticipate difficulties calculating performance scores under the HHVBP Model for the 2019 reporting period because HHAs had the opportunity to submit these data on a rolling basis.

With respect to the three New Measures, the IFC provides an exception to all HHAs participating in the HHVBP Model from the following requirements for reporting on New Measures:

- April 2020 New Measures submission period (data collection period October 1, 2019 – March 31, 2020).
- July 2020 New Measures submission period (data collection period April 1, 2020 – June 30, 2020).

CMS notes that although the April 2020 submission period includes data for 2019, these data are used for calculating total performance scores under the HHVBP for the 2020 performance period. In addition, it notes that under the COVID-19 exceptions, HHAs still have the option to submit part or all of the required data by the submission deadlines.

If further exceptions are provided, CMS will communicate this decision to HHAs participating in the HHVBP Model through normal communication channels, including memos, emails and the HHVBP Connect website.

Finally, CMS acknowledges that the exceptions to reporting of HH QRP measures and New Measures under the HHVBP Model may impact the calculation of performance scores under the Model for the 2020 performance year. Even though claims-based measures would still be calculated, it will need to assess the appropriateness of using claims data for the period of the COVID-19 PHE in assessing performance under the HHVBP Model for 2022 payment. It is considering possible approaches, such as changing the weighting of measures, and is also evaluating possible changes to public reporting of CY 2020 performance year data. Any changes will be addressed in future rulemaking.

B. Scope of Practice

In December 2019, CMS issued a request for feedback in identifying Medicare regulations which contain more restrictive supervision requirements than existing state scope of practice laws, or that limit health professionals from practicing the complete scope of their license.[9] As discussed

[8] See CMS, "Home Health Agencies: CMS Flexibilities to Fight COVID-19," page 3. https://www.cms.gov/files/document/covid-home-health-agencies.pdf

[9] This request is available at https://www.cms.gov/files/document/request-information-reducing-scope-practice-burden.pdf.

below, on an interim basis, CMS finalizes some of the recommendations to ensure an adequate number of clinicians can provide critical services and testing during the PHE.

In order to understand the impact of these changes, CMS seeks input about the number of states having more flexible scope of practice rules than federal regulations.

1. Supervision of Diagnostic Test by Certain Nonphysician Practitioners (NPPs)

Physicians and certain NPPs ((nurse practitioners (NPs), physician assistants (PAs), clinical nurse specialist (CNSs), clinical psychologists (CPs), clinical social workers (CSWs), and certified nurse midwives (CNMs)) who are operating within the scope of their state law and their Medicare statutory benefit may order diagnostic tests when the results of the rests are used in the management of the beneficiary's specific medical problem (§410.32(a)(3)). The regulations at §410.32(b) generally only allow physicians to supervise diagnostic tests, with certain exceptions.

On an interim basis during the PHE, CMS finalizes changes to §410.32(b) to add flexibility for NPs, CNSs, PAs and CNMs, to supervise diagnostic test as authorized under state law and licensure. [10] These NPPs will need to continue the required statutory relationships with supervising or collaborating physicians. Specifically, CMS amends the following regulations:

- §410.32(b)(1) – to specify that diagnostic tests covered under section 1861(s)(3) of the Act and payable under the PFS must be furnished under the appropriate level of supervision by a physician as defined under section 1861(r) of the Act or, during the PHE, by a NP, CNS, PA and CNM;
- §410.32(b)(2)(iii)(B) – to specify that in addition to physicians and CPs, a NP, CNS, PA, and CNM can supervise COVID-19 related diagnostic psychological and neuropsychological testing;
- §410.32(b)(2)(viii) – to allow PA to perform diagnostic tests without physician supervision when authorized to perform the tests under the applicable state law[11]; and
- §410.32(b)(3) – to authorize NPs, CNSs, PAs, and CNMs, during the PHE to provide the appropriate level of supervision assigned to diagnostic tests.

2. Therapy – Therapy Assistants Furnishing Maintenance Therapy

Medicare Part B provides payment for outpatient occupational and physical therapy furnished by an individual meeting the qualifications in part 484 for an occupational therapist (OT) or physical therapist (PT), or an appropriately supervised OT assistant (OTA) or PT assistant

[10] CMS also corrects a typographical error in §410.32(d)(2)(i) to state that when ordering diagnostic tests, the physician (or qualified NPP) who orders the service must maintain documentation of medical necessity in the beneficiary's medical record.

[11] All services furnished by PAs are still required to meet the physician supervision requirements at §410.74 which generally defer to state law requirements that address the requisite practice relationship between PAs and physicians or requires certain documentation of the working relationship between PAs and physicians to supervise PA services not addressed in state law.

(PTA). When a maintenance therapy program is necessary to maintain, prevent or slow the deterioration of a patient's condition, a therapist is required to supervise the respective OTA and PTA therapy services; claim modifiers are required to indicate a supervised therapy assistant performed these therapy services.

For the duration of the PHE, the treating PT or OT who developed and is responsible for the maintenance program may delegate without supervision the performance of maintenance therapy, when clinically appropriate, to a therapy assistant.

3. Therapy – Student Documentation

In the 2020 Physician Fee Schedule (PFS) final rule, CMS simplified medical record documentation requirements and finalized a general principle to allow a physician, PA, or advanced registered nurse (APRN) who furnish and bill for their professional services to review and verify, instead of re-documenting, information included in the medical record by other members of the medical team, including residents, nurses and students.

During the PHE, on an interim basis, CMS expands this policy to allow broad flexibility for all members of the medical team. Specifically, any individual who has a separately enumerated benefit under Medicare law that authorizes them to furnish and bill for their professional services may review and verify (sign and date), rather than re-document notes in the medical record; these individuals do not need to be acting in a teaching role. CMS emphasizes that the information in the medical record should document that services are reasonable and medically necessary.

CMS notes that this policy will ensure that therapist can spend more time furnishing therapy services, instead of spending time documenting in the medical record.

4. Pharmacists Providing Services Incident to a Physician's Service

CMS clarifies that pharmacists fall within the regulatory definition of auxiliary personnel under the regulations at §410.26. As auxiliary personnel, pharmacists can provide services incident to and under the appropriate level of supervision, of the billing physician or NPP, if the incident to rules are met and payment for the service is not made under Medicare Part D. Services provided must be in accordance with the pharmacist's state scope of practice and applicable state laws.

CMS notes that methadone should continue to be dispensed from certified and accredited Opioid Treatment Programs (OTPs) under the supervision of clinicians who have received appropriate training and fully understand the risks as required by statute.

C. Modified Requirements for Ordering COVID-19 Diagnostic Laboratory Tests

Clinical diagnostic laboratory tests, including COVID-19 diagnostic tests, are paid under the Clinical Laboratory Fee Schedule (CLFS) without any beneficiary cost-sharing requirements.

COVID-19 tests are covered only when they are ordered by a physician or NPP treating the beneficiary and the test results will be used in managing the patient's medical condition. Under existing rules, Medicare would not cover a COVID-19 test performed at a community testing site without an order for the test.

CMS amends §410.32(a) to remove the requirement that certain diagnostic tests are covered only based on the order of a treating physician or NPP. During the PHE, COVID-19 tests may be covered when ordered by any healthcare professional authorized under state law. CMS will extend this interim policy to diagnostic laboratory tests for influenza virus and respiratory syncytial virus. A list of covered laboratory tests that do not require a practitioner order is available at https://www.cms.gov/files/document/covid-ifc-2-flu-rsv-codes.pdf. CMS notes that when COVID-19 diagnostic laboratory testing is sufficient, prevalent, sensitive, and specific such that additional tests for influenza and other respiratory conditions are no longer necessary, it would expect that this additional testing would no longer be medically necessary.

CMS makes conforming amendments at §410.32(d)(2) and (3) to remove certain documentation and recordkeeping requirements for COVID-19 related to the treating physician's or NPP's order. It notes that although no order is required under Medicare, consistent with current billing instructions it does expect the entity submitting the claim to include the ordering or referring National Provider Identifier (NPI) information on the claim when an order is written for the test.

When COVID-19 tests are furnished without a physician's or NPP's order, the laboratory conducting the test is required to directly notify the patient of the results and state health officials, consistent with state and local public health requirements.

D. Opioid Treatment Programs (OTPs) – Furnishing Periodic Assessments via Communication Technology

In the CY 2020 Physician Fee Schedule (PFS) final rule, CMS finalized allowing the use of interactive two-way audio/video communication technology to furnish the counseling and therapy portions of the weekly bundle of services furnished by OTPs. In the March 31st COVID-19 IFC, CMS revised §410.67(b)(3) and (4) to allow the therapy and counseling portions of the weekly bundles, as well as the add-on code for additional counseling or therapy, to be furnished using audio-only telephone calls for beneficiaries who do not have access to two-way audio/video communications technology.

CMS has determined that it is also necessary to revise §410.67(b)(7) to allow periodic assessments to be furnished during the PHE via two-way interactive audio-video communications technology. In cases where beneficiaries do not have access to two-way audio-video communications technology, the periodic assessments may be furnished using audio-only telephone communications, provided all other applicable requirements are met.

CMS notes that the Substance Abuse and Mental Health Services Administration (SAMHSA) has offered flexibilities to states to ensure that individuals continue to receive their medication during the PHE. Specific guidance for OTP is available on the SAMHSA website at https://www.samhsa.gov/coronavirus.

E. Treatment of Certain Relocating Provider-Based Departments During the COVID-19 PHE

Beginning January 1, 2017, Medicare does not pay under the outpatient prospective payment system (OPPS) for services provided in off-campus provider-based departments (PBD) that first began furnishing services on or after November 2, 2015. These services are paid at a site-neutral rate equal to 40 percent of the OPPS rate. CMS identifies this site-neutral rate as a physician fee schedule (PFS) payment and not payment under the OPPS.

There are exceptions to this policy that allow on-campus PBDs as well as services furnished in dedicated emergency departments to continue to be paid under the OPPS. In extraordinary circumstances, an off-campus PBD that relocates will not be considered new for purposes of this policy and will continue to be paid under the OPPS. Any PBD that is excepted from this policy is referred to as an excepted PBD. There is no statutory or regulatory provision to allow on-campus PBDs that move off-campus to continue to be paid the full OPPS rate.

In response to the COVID-19 pandemic public health emergency (PHE), the Secretary waived Medicare's provider-based rules in § 413.65 for the duration of the PHE. The waiver does not address whether a PBD is excepted or non-excepted from the payment provision described above.

Recognizing the urgency of the PHE, CMS is allowing on and off-campus departments to use the extraordinary circumstances policy to seek approval to relocate a PBD on or after March 1, 2020 through the remainder of the PHE and continue to be paid under the OPPS. The hospital's purpose must be addressing the COVID-19 pandemic and the relocation must be consistent with the state's emergency preparedness or pandemic plan.

CMS emphasizes that this policy will only apply during the PHE. Once the PHE is over, these PBDs must either return to their prior location or be paid for outpatient services at 40 percent of OPPS rates. While relocated PBDs can apply under the extraordinary circumstances policy to continue being paid full OPPS rates after the PHE, the COVID-19 PHE will not be a justification for permitting an off-campus PBD to continue being paid under the OPPS.

Under the extraordinary circumstances policy, a CMS Regional Office (RO) needs to approve an off-campus PBD's application for relocation before the hospital can bill and be paid for outpatient services under the OPPS. During the PHE, CMS will allow both on-campus PBDs relocating off-campus and off-campus PBDs relocating to another off-campus location to be paid under the OPPS prior to having RO approval.

Hospitals relocating an on-campus PBD to an off-campus location or relocating an off-campus PBD from one location to another should notify their CMS Regional Office by email of:

- their hospital's CCN;
- the address of the current PBD;
- the address(es) of the relocated PBD(s);
- the date which they began furnishing services at the new PBD(s);
- a brief justification for the relocation including 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 emergency preparedness or pandemic plan.

CMS' partial waiver of the conditions of participation and full waiver of the provider-based rules allows a hospital to treat a patient's home provider-based. The IFC describes the addition of a patient's home as a PBD as a "relocation" of the PBD. If the relocation is the patient's home, only one justification is needed for each home being considered an off-campus PBD. Hospitals must send the email to the CMS RO notifying it of a relocated PBD within 120 days of beginning to furnish and bill for services at the relocated on or off-campus PBD. If the relocation is ultimately not approved by the RO and the services were paid at the 100 percent of the OPPS rate, the claims will be reprocessed to pay claims at a site-neutral PFS rate.

Hospitals may divide a single PBD into multiple locations during a relocation. Alternatively, the hospital may move part of an excepted PBD to a new off-campus location while maintaining the original PBD location. For example, one PBD may need to utilize two locations to maintain separation between COVID-positive and COVID-negative patients or use a patient's home for providing outpatient services to a registered hospital outpatient. CMS expects hospitals exercising this flexibility to demonstrate that the excepted PBD is still the same PBD, just split into more than one location (i.e., an oncology clinic would continue to be providing oncologic services).

If Medicare-certified hospitals will be rendering services in relocated excepted PBDs, but intend to bill Medicare for the services under the main hospital identifier, hospitals do not need to submit an updated CMS 855A enrollment form. If hospitals wish to permanently relocate their excepted PBD, they must file an updated CMS-855A enrollment form to reflect the new address(es) of the PBD(s).

F. 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 in the beneficiary's home or any other location that would not ordinarily be provider-based to the hospital. However, CMS' waiver of the provider-based rules,

and some conditions of participation, allow temporary expansion locations to become provider-based to the hospital. This policy allows hospitals to bill for medically necessary hospital outpatient therapeutic services furnished at those locations, assuming all other applicable requirements are met (including, to the extent not waived, the hospital conditions of participation). CMS is classifying hospital outpatient services into 3 categories and clarifying how its policies will apply when furnished in a temporary expansion location:

- hospital outpatient therapy, education, and training services, including partial hospitalization program services, that can be furnished other than in-person,
- hospital outpatient clinical staff services furnished in-person to the beneficiary; and
- hospital services associated with a professional service delivered by telehealth.

1. Hospital Outpatient and Community Mental Health Services (CMHC) Therapy, Education, and Training Services

a. Outpatient Therapy, Education, and Training services
Outpatient therapy, education and training services require communication and interaction. Facility staff can effectively furnish these services using telecommunications technology and, unlike many hospital services, the clinical staff and patient are not required to be in the same location to furnish them. CMS will consider these services to be outpatient services when ordered by a physician or qualified non-physician practitioner; provided by hospital clinical staff to a patient in the hospital including any of its temporary expansion locations when the patient is a registered outpatient; and the physician supervision requirements are met.

CMS provides a list of services included in this category on its website. The list may not be exhaustive and will be updated periodically. The list is at: https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers and is titled: List of Hospital Outpatient Services and List of Partial Hospitalization Program Services Accompanying the 4/30/2020 IFC (ZIP).

b. Partial Hospitalization Program (PHP)
CMS will allow hospitals and CMHCs to provide the following PHP services using interactive telecommunications technology: individual psychotherapy; patient education; and group psychotherapy. While CMS expects PHP services to be furnished using telecommunications technology involving both audio and video, it will allow these services to be furnished exclusively with audio in cases where beneficiaries do not have access to video communication technology. Drug administration cannot be furnished using telecommunications technology.

The list of services subject to this policy can be found at the above hyperlink. All other PHP requirements are unchanged and still in effect, including that all services furnished under the PHP require an order by a physician, must be supervised by a 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-based PHP Providers. Like other outpatient hospital services, PHP services may be provided in temporary expansion locations when the PHP services are furnished by hospital clinical staff, when the beneficiary is registered as an outpatient of the hospital, and in accordance with the supervising practitioner's scope of practice so long as the temporary expansion location is made provider-based to the hospital. The hospital should bill for these services as if they were furnished in the hospital and consistent with any specific requirements for billing Medicare during the COVID-19 PHE.

Community Mental Health Centers. For the duration of the COVID-19 PHE, CMS is allowing temporary expansion locations where the beneficiary may be located, including a beneficiary's home, to be a part of the CMHC. The patient must be registered as an outpatient of the CMHC while PHP services are being furnished at that location by CMHC staff in accordance with the supervising practitioner's scope of practice. The CMHC should bill for these services as if they were furnished in the CMHC consistent with any specific requirements for billing Medicare during the COVID-19 PHE.

2. Hospital In-Person Clinical Staff Services in a Temporary Expansion Location Including the Patient's Home)

Examples of hospital outpatient services that do not require professional work by the physician or qualified practitioner but must be provided in person by hospital clinical staff include wound care, chemotherapy administration, and other drug administration services. CMS' waivers enable hospitals to furnish these services in the patient's home provided all other requirements of the regulations not waived continue to be met.

During the time period that the patient is receiving services from the hospital clinical staff as a registered hospital outpatient, the patient's place of residence cannot be considered a home for purposes of home health agency services. When the patient is not receiving outpatient services from the hospital, the patient's home can be considered a home for purposes of the home health benefit, and the home health agency 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 home health agency while the plan of care is active.

3. Hospital Services Accompanying a Professional Service Furnished Via Telehealth

Absent any waivers outside of a PHE, Medicare pays physicians and practitioners for telehealth services using the lower facility rate under the PFS irrespective of whether the physician/practitioner is located in an office setting or an institutional setting like a hospital outpatient department. If the telehealth service originates from a patient care site like a hospital, Medicare will pay the originating site a telehealth facility fee of $26.65 for providing administrative or clinical support for a telehealth service. CMS does not pay the telehealth

facility fee for a service originating from the patient's home. During the COVID-19 PHE, CMS is waiving the originating site requirements but is still not paying the telehealth facility fee when the telehealth service originates from the patient's home.

In the March 31st COVID-19 IFC, CMS instructed physicians and other practitioners furnishing telehealth services to beneficiaries in their homes to bill for those services in the same way they would if they were furnishing the services in person (85 FR 19233). That is, if the physician or practitioner normally furnished the service in an office, the professional claim would be billed with an office place of service and Medicare uses the higher non-facility PFS rate to pay the physician or practitioner. If the physician or practitioner normally furnished the service in a hospital outpatient department, Medicare would pay the physician or practitioner at the lower PFS facility rate. There was no provision in the March 31st COVID-19 IFC that indicated how the hospital is paid in this circumstance.

CMS acknowledges that when a physician or practitioner who ordinarily practices in the outpatient department furnishes a telehealth service to a patient who is located at home, the hospital would often still provide some administrative and clinical support for that service. In the circumstance where the telehealth service originates from the patient's home and that home is provider-based to the hospital under waivers of the conditions of participation and the provider-based rules, CMS will pay the originating site facility fee of about $26.65 to support such telehealth services furnished by the hospital to a physician or practitioner who ordinarily practices in the hospital. No OPPS payment is made.

4. Intersection with Payment Policy for Hospital Outpatient PBDs

CMS provides billing guidance for services provided in off-campus PBDs as follows:

- Excepted off-campus PBDs add modifier "PO" on claims to ensure payment under the OPPS. Excepted off-campus PBDs include on-campus PBDs that relocate off-campus, and relocated or expanded excepted off-campus PBD. Relocated or expanded off-campus PBDs include those that add beneficiary home locations to the hospital's off-campus PBD where the hospital has sought extraordinary circumstances waiver to allow the expansion or relocation of the PBD.
- Other off-campus PBDs would add modifier "PN" on claims to make payment based on the PFS at 40 percent of the full OPPS rate. These PBDs would include non-excepted PBDs as well as those on-campus PBDs that have expanded or relocated off-campus or excepted off-campus PBDs that have expanded or relocated to other off-campus locations but did not seek an exception under the temporary extraordinary circumstances relocation policy.

G. Medical Education

The IFC makes several changes involving Medicare payments to hospitals for the direct and indirect costs of medical education. Payments for the direct costs of operating approved graduate

medical education programs (DGME) are set forth in regulations at §413.75 through §413.83. These payments are made by multiplying a hospital-specific per resident amount (based on historical data updated for inflation) by the weighted number of FTE residents working in all areas of the hospital complex and non-provider sites, where applicable, and Medicare's share of total inpatient hospital days. Additional payments are also made to reflect the higher (indirect) costs of patient care borne by teaching hospitals relative to non-teaching hospitals. Under the hospital Inpatient Prospective Payment System (IPPS), an indirect medical education (IME) payment adjustment formula is based on the hospital's resident-to-bed ratio. This is the ratio of full time equivalent (FTE) residents training in the IPPS portion of the hospital, outpatient departments, and qualifying non-provider sites to the number of inpatient beds. Under the statutory formula, a hospital's IME payment adjustment grows with increases in the resident-to-bed ratio. For payments to inpatient rehabilitation facilities (IRFs) and inpatient psychiatric facilities (IPFs), CMS uses its authority to make a teaching status adjustment based on the ratio of FTE residents divided by a facility's average daily census (ADC), subject to a cap.

1. Indirect Medical Education

Under the IFC, CMS is using its exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to provide that, for the duration of the COVID-19 PHE, beds temporarily added during the COVID-19 PHE are excluded from the calculations to determine IME payment amounts under the IPPS. This policy is codified by amending §412.105(d)(1) and made in response to requests by teaching hospitals to be held harmless from an undue reduction in IME that would result from an increase in the available number of hospital beds occurring in response to the influx of COVID-19 patients.

Similarly, for IRFs and IPFs, CMS policy under the IFC is that for the duration of the COVID-19 PHE, the teaching status adjustment payment amount will be the same as it was the day before the PHE was declared. This policy is also made in response to IRF and IPF concerns, and CMS does not want IRFs and IPFs that accept patients from acute care facilities to alleviate bed capacity during the PHE to experience a decrease in the teaching status adjustment as a result.

2. Time Spent by Residents at Another Hospital during the COVID-19 PHE

The IFC provides that during the COVID-19 PHE, teaching hospitals may claim, for purposes of both IME and DGME payments, the time spent by residents assigned to them who are sent to other hospitals to meet COVID-19 surges in patient volume. Current regulations prohibit a teaching hospital from counting time spent by its residents while training at another hospital. CMS believes that in the unprecedented context of the nationwide COVID-19 PHE and associated workforce challenges teaching hospitals should be able to send residents on an emergency basis to other hospitals where they are most needed to treat COVID-19 patients or others without regard to financial considerations with respect to GME payments.

Specifically, the IFC provides at a new §413.78(i) that while the COVID-19 PHE is in effect, a sending hospital can include FTE residents training at another hospital in its FTE count if all the following conditions are met:

> (1) The sending hospital sends the resident to the other hospital in response to the COVID-19 pandemic.
> (2) The time spent by the resident training at the other hospital is in lieu of time that would have been spent in approved training at the sending hospital.
> (3) The time that the resident spent training immediately before and/or after the COVID-19 PHE is included in the FTE count for the sending hospital.

CMS emphasizes that it believes that its policies are appropriate under normal circumstances, and that this significant departure from current policy is being made only because of the unprecedented nature of the COVID-19 PHE. It notes that if a teaching hospital claims the time of a resident it sends to another hospital, no other hospital may claim that time. Furthermore, the presence of these residents will not trigger establishment of per-resident amounts or FTE resident caps at those non-teaching hospitals.

This IFC policy intersects with previously established CMS COVID-19 policies that waive certain Medicare conditions of participation to allow hospitals to establish and operate temporary locations as part of the hospital during the PHE[12] and deem routine services provided under arrangements outside the hospital to have been provided by the hospital.[13] Under the IFC, 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.

H. Rural Health Clinics (RHCs)

RHCs are clinics located in rural areas that are designated as medically underserved or as health professional shortage areas. They are paid an all-inclusive rate (AIR) based on reasonable costs per visit subject to a limit updated for inflation. Hospital-based RHCs are not subject to the limit on the AIR. To be a hospital-based RHC, the hospital must have fewer than 50 beds and the RHC must be an integral and subordinate part of a hospital or critical access hospital (CAH). The same methodology is used to count beds for the 50-bed limit as is used for the IME adjustment.

CMS recognizes that hospitals are appropriately increasing the number of beds to provide surge capacity for additional patients during the COVID-19 PHE. To avoid these bed increases from

[12] CMS is waiving certain requirements under the Medicare conditions of participation at 42 CFR §482.41 and §485.623 to allow for flexibilities during hospital, psychiatric hospital, and CAH surges. CMS will permit non-hospital buildings/space to be used for patient care and quarantine sites, provided that certain conditions are met. See https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf.
[13] See "Inpatient Hospital Services Furnished Under Arrangements Outside the Hospital During the PHE for the COVID–19 Pandemic," included in the IFC published on April 6, 2020, 85 FR 19280 (referenced in this IFC as the March 31st IFC).

disqualifying a hospital-based RHC from the exemption to the AIR limit during 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 for the duration of the PHE. 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) will continue to be exempt for the duration of the PHE for the COVID-19 pandemic.

I. Durable Medical Equipment (DME) Interim Pricing in the CARES Act

As required by Section 1847(a) of the Act, Medicare is required to pay for certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) items and services furnished within competitive bidding areas (CBAs) as part of its Competitive Bidding Program (CBP).[14] Areas in which the CBP are not implemented are known as non-competitive bidding areas (non-CBAs). Currently, there are no CBAs due to the 2-year temporary gap period in the DMEPOS CBP, allowing any Medicare-enrolled DMEPOS suppliers to furnish DMEPOS items.[15] CMS uses the term "former CBAs" to refer to areas that were CBAs prior to the 2-year gap, to distinguish those areas from non-CBAs in which the CBP has not previously been implemented.

Section 3712(a) of the CARES Act revises the fee schedule amounts for certain DME and enteral nutrients, supplies, and equipment furnished in non-CBAs other than former CBAs through the duration of the emergency period. CMS states that the fee schedule amounts in former CBAs 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. The CARES Act applies the following transition policies for non-CBAs other than former CBAs.

For rural areas and non-contiguous areas.[16] Beginning June 1, 2018 through December 31, 2020, Medicare is paying for DME based on a blend of 50 percent of the historical fee schedule rates for the local area and 50 percent of the rates derived from the competitive bidding program. Section 3712 requires the Secretary to apply this provision of the regulation as planned for the duration of the COVID-19 PHE, which may continue past December 31, 2020.

For areas other than rural areas and non-contiguous areas. From March 6, 2020 through the remainder of the COVID-19 public health emergency, section 3712 requires the Secretary to pay for DME based on rates that are a blend of 75 percent competitive bidding program rates adjusted for inflation and 25 percent based on historical local DME fee schedule amounts.

[14] Based on the payment rules that are set forth in section 1847 of the Act and 42 CFR Part 414, Subpart F.
[15] All DMEPOS CBP contracts expired on December 31, 2018. Round 2021 of the CBP is scheduled to begin again in January 2021.
[16] Non-contiguous areas include Alaska, Hawaii and the U.S. Territories

CMS notes a couple of discrepancies that it addresses in this IFC. First, CMS notes that section 3712(b) of the CARES Act references two dates on which CMS should implement the payment amount increases for items and services furnished in areas other than rural areas and non-contiguous areas: April 26, 2020 (30 days after the enactment of the CARES act) and March 6, 2020. CMS believes it is in the public's interest to implement the higher fee schedule amounts starting with the earlier date of March 6, 2020, and thus it is revising the regulations to implement the higher fee schedule amounts required under the CARES Act as of March 6, 2020. Second, CMS states that section 3712(b) of the CARES Act requires CMS to pay the higher fee schedule amounts for the duration of the emergency period, but it does not specify the fee schedule amounts that should be in effect if the emergency period ends before December 31, 2020. As such, CMS specifies in §414.210(g)(9)(v) that the fee schedule amounts in areas other than rural or noncontiguous areas will again be based on 100 percent of the fee schedule amounts if the emergency period described ends before December 31, 2020.

CMS makes conforming changes to §414.210(g)(9), consistent with sections 3712(a) and (b) of the CARES Act.

Regulatory Impact. These changes increase Medicare expenditures, as well as beneficiary cost-sharing, by increasing Medicare payment rates for certain DMEPOS items furnished in non-rural and contiguous non-competitively bid areas. The estimated Medicare cost against the FY 2021 President's Budget baseline is $140 million.

J. Care Planning for Medicare Home Health Services

For Medicare payment for home health services, sections 1814(a)(2)(c) and 1835(a)(2)(A) of the Act require a physician who does not have a direct or indirect employment relationship with the home health agency to certify that home health services are required because the individual is confined to their home and needs skilled nursing care on an intermittent basis, physical therapy, speech-language pathology, or continued occupational therapy services. The certifying physician must establish and periodically review a plan for furnishing services such individuals.

In addition to a physician, section 3708 of the CARES Act allows a Medicare-eligible home health patient to be under the care of an NP, CNS, or a PA who is working in accordance with state law. These NPPs can: (1) order home health services; (2) establish and periodically review a plan of care for home health services (e.g., sign the plan of care), and (3) certify and re-certify that the patient is eligible for Medicare home health services. The CARES Act also allows these NPPs to certify that an individual has a bone fracture related to post-menopausal osteoporosis and that the individual is unable to self-administer the osteoporosis drug. These changes, effective March 1, 2020, are effective for Medicare claims with a "claim through date" on or after March 1, 2020. **These changes are permanent and not time limited to the PHE. CMS will respond to any comments received on this issue in the 2021 Home Health Prospective Payment System final rule**.

CMS notes that NPs, CNSs, and PAs, are required to practice in accordance with laws of the state in which the services are performed, and that states have varying requirements for conditions of practice. Based on a review of state websites, CMS believes that the majority of states require physician collaboration for these NPPs.

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

1. CARES Act Waiver of the "3-Hour Rule"

Among other requirements, Medicare only provides coverage under the IRF PPS if a patient receives 3 hours of intensive rehabilitation services per day or 15 hours per week ("the 3-hour rule"). The March 31st COVID-19 IFC provided

> in cases where an IRF's intensive rehabilitation therapy program is impacted by the PHE for the COVID– 19 pandemic (for example, due to staffing disruptions resulting from self- isolation, infection, or other circumstances related to the PHE), the IRF should not feel obligated to meet the industry standards referenced in §412.622(a)(3)(ii), but should instead make a note to this effect in the medical record. (66 FR 19253).

CMS indicates that the waiver provided in the March 31st COVID-19 IFC did not take into account section 3711(a) of the CARES Act that was enacted into law just a few days earlier. In this IFC, CMS is replacing the waiver provided for in the March 31st COVID-19 IFC to reflect that section 3711(a) of the CARES Act waives the 3-hour rule without exception during the COVID-19 PHE.

2. Modification of IRF Coverage and Classification Requirements for IRF Hospitals for the PHE During the COVID-19 Pandemic

IRF care is only considered by Medicare to be reasonable and necessary if the patient meets all of the IRF coverage requirements outlined in §412.622(a)(3), (4), and (5). Of these requirements, CMS previously waived the requirement to complete a post-admission physician evaluation during the COVID-19 PHE (§412.622(a)(4)(ii)). For IRF hospitals only (identified as those facilities with the last 4 digits of their Medicare provider numbers between 3025 through 3099) and not distinct part inpatient rehabilitation units, CMS is further 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 IRF hospitals solely to relieve acute care hospital capacity during the COVID-19 PHE.

Consistent with the Guidelines for Opening Up America Again at: https://www.whitehouse.gov/openingamerica/, the flexibilities in this IFC are available only for IRF hospitals admitting patients in support of acute care hospitals when the state is in phase 1 or prior to entering phase 1, and are no longer available when the state is in phase 2 or phase 3 of the Guidelines. These flexibilities apply to specific patients who must be discharged from acute care hospitals to IRF hospitals to provide surge capacity for the acute care hospitals, and

therefore apply only when those specific patients are admitted to an IRF hospital and continue for the duration of that patient's care. These limitations only apply to the provisions in this IFC and not to any blanket waivers issued, which have their own conditions. IRF hospitals must document the particular Guidelines phase in effect for the state when admitting the patient and electing to exercise these flexibilities.

For billing purposes, IRF hospitals are directed 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 an IRF hospital solely to alleviate acute 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. IRF hospitals will be paid at the IRF PPS rates for patients with the "DS" modifier.

In summary, CMS is modifying the requirements for coverage in IRF hospitals (not including distinct part inpatient rehabilitation facilities) only for payment under the IRF PPS. The requirements for coverage will only apply when the IRF is located in state that is prior to or within phase I of the Guidelines for Opening Up America Again for patients are admitted to an IRF hospital to pro

L. Medicare Shared Saving Program

To encourage continued participation by Accountable Care Organizations (ACOs) in the Medicare Shared Savings Program (MSSP), CMS is adjusting program policies to address the impact of the COVID-19 pandemic. As of January 1, 2020, there are 517 MSSP ACOs, and 160 of these ACOs have agreements ending December 31, 2020 and must renew under the BASIC or ENHANCED track to continue in the program, including 20 ACOs participating in the Medicare ACO Track 1+ Model. ACOs and other program stakeholders have advocated for CMS to modify MSSP policies to address the impact of the COVID-19 pandemic.

As described further in this section, CMS modifies MSSP policies to (1) allow ACOs whose current agreement periods expire on December 31, 2020, the option to extend their existing agreement period by 1 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.

1. Application Cycle for January 1, 2021 Start Date and Extension of Agreement Periods Expiring on December 31, 2020

CMS is foregoing the application cycle for a January 1, 2021 start date (i.e., the 2021 application cycle) given the COVID-19 PHE to allow ACOs and their providers/suppliers to continue to focus on treating patients. It is revising §425.200(b)(3)(ii) to allow ACOs that entered a first or second agreement period with a start date of January 1, 2018, to elect to extend their agreement period for an optional fourth performance year. This impacts 160 ACOs whose participation agreements will end on December 31, 2020, including 20 ACOs participating in the Track 1+ Model. The fourth performance year would span 12 months from January 1, 2021 to December 31, 2021.

CMS notes that the election to extend the agreement period is voluntary and an ACO could choose not to make this election, and therefore, conclude its participation based on the expiration of its current agreement period. CMS believes that its approach is advantageous as it allows ACOs to remain under their existing historical benchmark for an additional year and thus increasing stability and predictability. By foregoing the 2021 application cycle, CY 2020 will not serve as benchmark year 3 for a cohort of ACOs that would otherwise be January 1, 2021 starters. This will also allow CMS 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.

CMS provides detail on how ACOs whose agreements expire on December 31, 2020 could make this voluntary election to extend their agreement period. It notes that this is a one-time exception and not available to other ACOs or to future program entrants. An ACO executive who has the authority to legally bind the ACO must certify the election. CMS anticipates that eligible ACOs will be able to extend their agreement starting June 18, 2020, and the anticipated final date to make the election will be September 22, 2020. CMS states it will provide additional guidance regarding the form and manner, and the timeframe (including any changes to the above dates), for making the election.

CMS will consider an ACO that elects to extend its agreement period for an additional year to be in compliance with §425.10(a) if it notifies all ACO participants, ACO providers/suppliers, and other individuals and entities involved in ACO governance. CMS also specifies that an ACO that elects to extend its participation agreement must require these parties to comply with the program's requirements through December 31, 2021. To remain in compliance with §425.116, an ACO may need to extend the duration of its agreements with ACO participants and ACO providers/suppliers.

CMS notes that while it 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 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 PY 2021.

CMS seeks comment on its approach to address the extension of the participation agreements that are scheduled to expire on December 31, 2020.

2. Allow BASIC Track ACOs to Elect to Maintain Their Participation Level for One Year

As background, CMS finalized a redesign of the MSSP participation options in a 2017 final rule, including a BASIC track (83 FR 67841).[17] The BASIC track includes an option for eligible ACOs to begin participation under a one-sided model and incrementally phase in risk and potential reward over the course of an agreement period, an approach referred to as a glide path. Over a five-year agreement period, a one-sided model is available for the first two consecutive agreement periods (Levels A and B) and a two-sided model is available for the next 3 agreement periods (Levels, C, D, and E) which offer progressively higher risk and potential reward. ACOs are automatically advanced along this glide path, unless the ACO elects to advance more quickly. ACOs have expressed concern that they may not continue participating in the program if they are automatically transitioned to downside risk or a higher level of downside risk in PY 2021. This affects 136 ACOs participating under Level B of the BASIC track that are scheduled to automatically advance to Level C on January 1, 2021. CMS also expressed concern that care coordination policies ACOs have been developing may be interrupted by the pandemic and that ACOs transitioning to Level C may not have the ability to establish a repayment mechanism, such as a letter of credit, given the COVID-19 PHE.

CMS will allow ACOs participating in the BASIC track glide path to elect to maintain their current participation level under the BASIC track for PY 2021.[18] If an ACO elects this advancement deferral option, then in PY 2022 CMS states that the ACO 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). If, for example, an ACO participating in the BASIC track Level B in PY 2020 elects to maintain its current participation for PY 2021, it would advance to Level D for PY 2022 (absent the ACO electing to advance more quickly to Level E).

CMS anticipates that eligible ACOs will be able to elect to maintain their participation level for PY 2021 starting June 18, 2020, and the anticipated final date to make the election will be September 22, 2020. An ACO executive who has the authority to legally bind the ACO must certify the election. CMS states that it will provide additional guidance regarding the form and manner, and the timeframe (including any changes to the above dates), for making the election;

[17] Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success and Extreme and Uncontrollable Circumstances Policies for Performance Year 2017 (83 FR 67816).
[18] §425.600(a)(4)(i)(B)(2)(iii)

ACOs not electing this option will automatically advance the next level of the glide path (unless they opt to advance more quickly).

CMS seeks comment on the advancement deferral option it is establishing with this IFC.

3. Applicability of Extreme and Uncontrollable Circumstances Policies to the COVID-19 Pandemic

CMS finalized the Medicare Shared Savings Program (MSSP) Extreme and Uncontrollable Circumstances (EUC) policy for performance year 2018 and subsequent performance years in the CY 2019 Physician Fee Schedule final rule (83 FR 59968-59979). The policy provides for mitigation of shared losses for ACOs on performance-based risk tracks. The COVID-19 PHE meets the criteria for triggering the MSSP EUC policy, and CMS states that changes in care delivery precipitated by the PHE are highly likely to impair the ability of MSSP ACOs to coordinate care of and control expenditures for their assigned beneficiaries.

In section II.V of the March 31st IFC, CMS reprised the shared loss mitigation formula and stated that the formula would be applied for the period beginning with March 2020 and extend through the duration of the PHE. CMS now clarifies that the formula instead will be applied beginning with January 2020, rather than March 2020 as previously stated, in order to be consistent with the Secretary's COVID-19 PHE declaration on January 27, 2020. CMS restates the shared loss mitigation formula and gives examples of its implementation for various PHE durations.

$$\text{Reduction} = \text{Shared Losses} * \left(\frac{\text{affected months}}{\text{total performance months in performance year}}\right) * \left(\frac{\text{affected assigned ACO beneficiaries}}{\text{total ACO assigned beneficiaries}}\right)$$

CMS notes that since the COVID-19 PHE applies nationwide, 100 percent of ACO beneficiaries will be affected, making the formula dependent only upon the number of months of the PHE's duration. If the PHE's duration were January 2020 through June 2020, performance year 2020 shared losses would be reduced by 50 percent (6/12 * 100%). If the PHE were to extend throughout 2020, all shared losses for the performance year 2020 would be reduced completely (12/12 * 100%).

4. Adjustments to Shared Savings Program Calculations to Address the COVID-19 Pandemic

CMS believes it is necessary to revise the policies governing MSSP 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 cites several reasons for its concerns: (1) the prospective CMS-HCC risk scores would not be expected to meaningfully adjust for variability related to COVID-19 because these models are prospective and use diagnoses from

2019 to predict costs in 2020; (2) increased expenditures related to treatment of COVID-19 in calculations of ACO benchmarks for which FY 2020 is a benchmark year could lead to higher than anticipated future historical benchmarks; and (3) increased payment amounts for treatment of acute care for COVID-19 in calculations for which CY 2020 is used as a reference year could distort repayment mechanisms and the identification of high and low volume ACOs and influence ACO participation options. CMS believes that revisions to its policies are of an urgent nature as ACOs participating under a two-sided model would need to provide notice to CMS no later than June 1, 2020 to avoid liability for a pro-rated share of any shared losses that may be determined for PY 2020 and not covered by the extreme and uncontrollable circumstances policy.

To address these concerns, CMS is revising its policies to exclude from its MSSP 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.[19] CMS believes that its approach that makes the triggering event for this adjustment the beneficiary's receipt of inpatient care for COVID-19, will identify the most acutely ill patients and, as a result, those patients with the highest costs associated with acute care treatment.

Under the approach CMS adopts in this IFC, CMS will identify an episode of care triggered by an inpatient service for treatment of COVID-19, based on either: (1) discharges for inpatient services eligible for the 20 percent DRG adjustment;[20] or (2) discharges for acute care inpatient services for treatment of COVID-19 from facilities that are not paid under the IPPS, such as CAHs, when the date of admission occurs within the COVID-19 PHE.

CMS will identify discharges of an individual diagnosed with COVID-19 using the following ICD-10-CM codes:

- B97.29 (Other coronavirus as the cause of diseases classified elsewhere) for discharges occurring on or after January 27, 2020, and on or before March 31, 2020.
- U07.1 (COVID-19) for discharges occurring on or after April 1, 2020, through the duration of the COVID-19 PHE period, as defined in §400.200.34.

Episodes of care for treatment of COVID-19 may be triggered by an inpatient admission for acute care either at an acute care hospital or other healthcare facility, which may include temporary expansion sites, Medicare-enrolled ASCs providing hospital services to help address the urgent need to increase hospital capacity to treat COVID-19 patients, CAHs, and potentially

[19] CMS cites its 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, and its authority under section 1899(i)(3) of the Act to apply this adjustment to certain other program calculations, including the determination of performance year expenditures.
[20] See section 1886(d)(4)(C)(iv) of the Act.

other types of providers.[21] It will define the episode of care as starting 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. CMS will exclude Parts A and B payment amounts with dates of service in the months associated with an episode of care for treatment of COVID-19; it will also exclude the affected months from total person years used in per capita expenditure calculations. Adjusting both expenditures and person years will ensure that both the numerator and denominator used to calculate per capita expenditures are based on the same number of months.

CMS believes that this approach will provide for a more equitable comparison between an ACO's performance year expenditures and its historical benchmark and will help to ensure that ACOs are not rewarded or penalized for having higher/lower COVID-19 spread in their assigned beneficiary populations. The specific calculations that CMS will adjust to exclude all Parts A and B FFS payment amounts for a beneficiary's episode of care for treatment of COVID-19 are summarized in the table below.

MSSP program calculations to exclude all Parts A and B FFS payment amounts for a beneficiary's episode of care for COVID-19	**Calculation details**
Calculation of Medicare Parts A and B FFS expenditures for an ACO's assigned beneficiaries for all purposes.	Includes establishing, 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.	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 percent of national per capita expenditures for Parts A and B services under the original Medicare FFS program for assignable beneficiaries for purposes of

[21] See CMS fact sheet, "Hospitals: CMS Flexibilities to Fight COVID-19", dated March 30, 2020, available at https://www.cms.gov/files/document/covid-hospitals.pdf.

MSSP program calculations to exclude all Parts A and B FFS payment amounts for a beneficiary's episode of care for COVID-19	Calculation details
	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.
Calculation of Medicare Parts A and B FFS revenue of ACO participants	Used in 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	Identifies 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	No additional detail.

CMS notes that there are certain payments related to the COVID-19 PHE that fall outside of Medicare FFS Parts A and B claims, and thus would not be used for determining beneficiary expenditures. CMS would not account, for example, for recoupment of accelerated or advance payments or lump sum payments made to hospitals and other healthcare providers through the CARES Act Provider Relief Fund.

CMS does not believe that excluding payment amounts for episodes of care for treatment of COVID-19 from the specified calculations will result in an increase in spending beyond expenditures that would have otherwise occurred. It acknowledges that some trends and longer lasting effects of the COVID-19 pandemic are unknown and that it will continue to evaluate whether additional rulemaking is necessary. CMS adds a new provision at §425.611 to describe the adjustments it will make to MSSP calculations to address the impact of the COVID-19 pandemic.

CMS seeks comment on its approach to adjusting program calculations to mitigate the financial impact of the COVID-19 pandemic on ACOs.

5. Expansion of Codes Used in Beneficiary Assignment

Each MSSP ACO may choose from two methods of beneficiary assignment to the ACO for baseline and performance year expenditure calculations: preliminary prospective assignment with retrospective reconciliation or prospective assignment. The election is made prior to the start of the upcoming performance year, applies for the entire year, and may be changed annually.[22] Under both methods, assignment is based upon which clinicians furnished the plurality of a beneficiary's primary care services over a 12-month period. The definition (list) of primary care services used during assignment was last modified for 2019 and subsequent performance years and codified at §425.400(c)(1)(iv).

CMS notes that care delivery patterns are rapidly changing during the COVID-19 PHE due to factors such as viral exposure risk reduction for beneficiaries and clinicians and clinician time reallocation from ongoing chronic care management to caring acutely for COVID-19 patients. CMS states a belief that the primary care service list used for beneficiary assignment should be modified to more accurately capture primary care service delivery and utilization during the PHE. CMS, therefore, makes changes to add services for which delivery via telehealth or other communication-based technologies (CBT) have been authorized by CMS during the PHE. The CBT services include virtual check-ins, remote image evaluation, e-visits, and Evaluation and Management (E/M) by telephone, and CMS finalized separate payment for these services beginning with CY 2019 for established patients. CMS is exercising enforcement discretion and relaxing the established patient requirement associated with CBT services during the COVID-19 PHE. The updated primary care service definition list will be used for beneficiary assignment beginning with performance year 2020 and for any subsequent year that starts during the COVID-19 PHE. The table below shows the MSSP primary care service list prior to the PHE and as updated by this rule.

CMS considered adding G0261-G0263 to the MSSP primary care service list; these codes are used by clinicians who may not independently bill for E/M visits when furnishing e-visits. Because these clinicians are not included in the definition of ACO professionals, CMS decided not to add these codes to the list. CMS similarly considered the addition of CPT 98966-98968, used for reporting telephone assessment and management by clinicians who may not independently bill for E/M visits. CMS likewise decided not to add these codes to the primary care list since the clinicians furnishing the services are not considered ACO professionals.

[22] A beneficiary who designates an ACO professional as their "primary clinician" is assigned to that ACO regardless of the assignment method chosen by the ACO; this "voluntary alignment" supersedes all other assignment methods. To date, fewer than 10% of beneficiaries have been voluntarily aligned.

Primary Care Services Used to Determine MSSP Beneficiary Assignment					
CPT/HCPCS	**Short Descriptor**	**MSSP Primary Care List Status (PC)**			
		PC pre-COVID	**PC New for COVID**	**PC pre-COVID + telehealth**	**PC New for COVID + new for telehealth[a]**
99201-99205	Office/outpatient visit new	☑		☑	
99211-99215	Office/outpatient visit established	☑		☑	
99304-99306	Nursing facility care, initial[b]	☑		✕	☑
99307-99310	Nursing facility care, subsequent[b]	☑		☑	
99315-99316	Nursing facility care, discharge day[b]	☑		✕	☑
99318	Nursing facility care, annual assessment[b]	☑		✕	✕
99324-99328	Domiciliary/rest home/custodial visit, new	☑		✕	☑ 99327-8 only
99334-99337	Domiciliary/rest home/custodial visit, established	☑		✕	☑
99339-99340	Home/Domiciliary/rest home/care plan oversight	☑		✕	✕
99341-99345	Home visit, new	☑		✕	☑
99347-99350	Home visit, established	☑		✕	☑
99487, 99489	Chronic care mgmt., by clinician	☑		✕	✕
99490	Chronic care mgmt., by clinical staff	☑		✕	✕
99495-99496	Transitional care mgmt	☑		☑	
99497-99498	Advance care planning	☑		☑	
96160-96161	Administer health risk assessment	☑		☑	
99354-99355	Prolonged office E/M or psychotherapy service	☑		☑	
99484, 99492, 99493, 99494	Behavioral health integration services	☑		✕	✕
G0402	Welcome to Medicare visit	☑		✕	✕
G0438-G0439	Annual wellness visit	☑		☑	
G0463	Hosp outpatient clinic visit	☑		✕	✕
G0506	Comp assess care plan chronic care mgmt	☑		☑	
G0444	Depression screening annual	☑		☑	
G0442	Alcohol misuse screening annual	☑		☑	
G0443	Brief alcohol misuse counseling	☑		☑	
99421-99423	Online digital E/M service	✕	☑	✕	✕ CBT[c]
99441-99443	Telephone E/M service	✕	☑	✕	✕ CBT[c]
G2010	Remote evaluation patient video/image	✕	☑	✕	✕ CBT[c]
G2012	Virtual check-in	✕	☑	✕	✕ CBT[c]

Primary Care Services Used to Determine MSSP Beneficiary Assignment					
CPT/HCPCS	**Short Descriptor**	**MSSP Primary Care List Status (PC)**			
		PC pre-COVID	**PC New for COVID**	**PC pre-COVID + telehealth**	**PC New for COVID + new for telehealth[a]**
[a] Services in this column with a check mark when delivered via telehealth will be used for beneficiary assignment beginning March 1, 2020.					
[b] These services are not considered MSSP primary care services when furnished in the SNF setting.					
[c] These services are delivered using CBT and do not meet the Medicare definition of telehealth technology.					

6. Applicability of Policies to Track 1+ Model ACOs

The Track 1+ Model is a time-limited Innovation Center model that is built on the MSSP Track 1 framework but also incorporates a low level of downside risk. ACOs under this model execute both Track 1+ and MSSP participation agreements. Unless otherwise specified, Track 1+ ACOs are subject to MSSP requirements and to regulatory changes that become effective during the term of their participation agreements. The following policies as adopted in this rule for MSSP ACOs will also apply to Track 1+ ACOs:

- For purposes of shared loss mitigation for Track 1+ ACOs under the MSSP Extreme and Uncontrollable Circumstances policy as applied to the COVID-19 PHE, the affected months will begin with January 2020 rather than March 2020, as stated in the March 31st IFC, and will continue for the duration of the PHE;
- Revisions made to the primary care service list utilized for beneficiary assignment to MSSP ACOs (e.g., addition of communication-based technologies) will apply to Track 1+ ACOs for performance year 2020 and any subsequent performance year that starts during the COVID-19 PHE;
- Adjustments to ACO expenditure calculations to remove expenditures for episodes of care for treatment of COVID-19 will be applicable to Track 1+ ACOs; and
- Revenue calculations for Track 1+ ACOs will be adjusted to remove expenditures for episodes of care for treatment of COVID-19 and this change will be implemented through an amendment to the Track 1+ Model Participation Agreement.

Regulatory Impact. CMS estimates that the changes to the MSSP described in this IFC are estimated to reduce program spending by $1.43 billion over the 2020 to 2025 period (ranging from a reduction of $790 million to $2.12 billion) with most of the reduction attributable to performance year 2020. The most significant policy impact is estimated to result from the new policy to adjust MSSP calculations to remove Parts A and B expenditures for episodes of care for treatment of COVID-19. Failure to remove such spending would likely create high variability in shared savings and losses, and likely produce windfall payments to certain ACOs while causing other ACOs with significant exposure to COVID-19 in their assigned beneficiary populations to leave the program. CMS estimates a reduction in program spending by $1.11 billion from this provision alone

M. Additional Flexibility Under the Teaching Physician Regulations

The "primary care exception" makes PFS payment in primary care settings for certain low and mid-level complexity services (shown in the table below) furnished by a resident without the physical presence of a teaching physician (§415.174). The teaching physician must not direct the care of more than four residents at a time; must provide direct supervision; and must review with each resident during or immediately after each visit, the beneficiary's history, physical examination, diagnosis, tests and treatments. The teaching physician is required not to have other responsibilities at the time; assume management responsibility for the beneficiaries; and ensure services furnished are appropriate.

Services Furnished Under the Primary Care Exception*	
Service	**HCPCS Code**
Office or other outpatient E/M visit for new patient	99201 - 99203
Office or other outpatient E/M visit for established patient	99211 - 99213
Initial preventive physical exam	G0402
Annual wellness visit, initial visit	G0438
Annual wellness visit, subsequent visit	G0439
* The services are specified in Section 12 of the Medicare Claims Processing Manual available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf	

In the March 31st COVID-19 IFC, CMS stated that during the PHE, the requirement for the presence of a teaching physician can be met, at a minimum, through direct supervision by audio/video real-time communications technology. CMS also revised the scope of E/M codes that can be furnished under the primary care exception to include all levels of office/outpatient E/M codes (shown in the table below).

Under this IFC, in response to stakeholders' requests, during the PHE, CMS will allow the teaching physician to remotely (through audio/video real time communications technology) not only direct the care furnished by residents, but also review the services provided with the resident, during or immediately after the visit. CMS notes this allows PFS payment for teaching physician services when a resident furnishes services permitted under the primary care exception, including via telehealth, and the teaching physician can provide the necessary direction, management and review of the resident's services using interactive audio/video real-time communications technology. The teaching physician is still required not to have other responsibilities at the time; assume management responsibility for the beneficiaries; and ensure services furnished are appropriate.

In addition, in response to stakeholders' requests, during the PHE CMS will allow PFS payment to the teaching physician for the following additional services furnished by a resident under the primary care exception:

Additional Services Eligible for the Primary Care Exception During the COVID-19 PHE	
Service	**HCPCS Code**
Telephone E/M services	99441 – 99443
Transitional Care Management services	99495 – 99496
Online digital E/M services	99421 – 99423
Interprofessional telephone/internet/electronic health record referral service	99452
Remote evaluation of recorded video and images	G2010
Brief communication technology-based service, e.g. virtual check-in	G2012
Office or other outpatient E/M visit for new patient	99204 & 99205
Office or other outpatient E/M visit for established patient	99214 & 99215

CMS also clarifies that the office/outpatient E/M level selected under the primary care exception when furnished via telehealth can be based on medical decision making (MDM) or time, with time including all of the time associated with the E/M on the day of the visit. The typical times for selecting the level of the E/M visit are the times listed in the CPT descriptor.

N. Payment for Audio-Only Telephone Evaluation and Management Services

In the March 31st COVID-19 IFC, during the PHE, CMS established separate payment for audio-only telephone E/M services (CPT codes 99441 - 99443) and finalized payment based on the relative value units (RVUs) recommended by the Relative Value Scale Update Committee (RUC).

Stakeholders have informed CMS that audio-only services are serving as substitutes for office/outpatient Medicare telehealth visits for beneficiaries not using video-enabled telecommunications technology. Because these audio-only services are being furnished primarily as a replacement for an in-person or telehealth visit using the office/outpatient E/M codes, CMS is establishing new RVUs for these services based on crosswalks to the most analogous office/outpatient E/M codes. Specifically, CMS crosswalks CPT codes 99212, 99213, and 99214 to 99441, 99442, and 99443 respectively for determining the work RVUs and the direct practice expense inputs. CMS notes that to the extent phone services are replacing office/outpatient E/M visits, the direct crosswalk of RVUs also better maintains overall budget neutrality and relativity under the PFS.

Finalized Work RVUs for Telephone E/M services During the COVID-19 PHE		
Service	**Prior Work RVUs***	**New Work RVUs**
CPT code 99441; Telephone E/M service, 5-10 min	0.25	0.48
CPT code 99442; Telephone E/M service, 11-20 min	0.50	0.97
CPT code 99443; Telephone E/M service, 21-30 min	0.75	1.5
*RVUs finalized in the March 31st COVID-19 IFC		

CMS does not increase payment rates for CPT codes 98966-90968 because these codes describe services provided by practitioners who cannot independently bill for E/M services and which by definition are not furnished in place of an office/outpatient E/M service.

Because these audio-services are being furnished as substitutes for E/M services, for the duration of the PHE, CMS considers them as telehealth services, and is adding them to the list of Medicare telehealth services.[23] The full list of Medicare telehealth services, including those added during the PHE, is available at https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.

CMS notes if a provider does not waive cost-sharing for these services during the PHE[24], beneficiaries are liable for cost-sharing for these services and should be educated about any applicable cost-sharing. **CMS seeks comments on how to minimize unexpected cost-sharing for beneficiaries.** It plans to monitor utilization of these services and will consider refinements to billing rules, documentation requirements or claim edits through future rulemaking.

O. Flexibility for Medicaid Laboratory Services

CMS amends regulations relating to Medicaid laboratory services to permit greater flexibility for the administration and coverage of COVID-19 tests, including permitting coverage of tests administered in non-office settings and for self-collected COVID-19 tests.

CMS describes the new statutory requirement for state Medicaid programs to cover in vitro diagnostic products for the detection of SARS-COV-2 or diagnosis of the virus that causes COVID-19, including serological tests for COVID-19. This requirement was enacted in section 6004(a) of the Families First Coronavirus Response Act and amended by section 3717 of the CARES Act. It is incorporated into section 1905(a)(3)(B) of the SSA. Section 1905(a)(3) has long required states to cover laboratory and X-ray services more generally.

Pre-existing regulations implementing Medicaid's coverage of laboratory tests and X-rays (in 42 CFR 440.30) include certain limitations and conditions that CMS believes should be lifted or made more flexible in order to provide for the coverage of COVID-19 tests. CMS states that the flexibilities will help to prevent the spread of infection and to eliminate obstacles to Medicaid coverage for administering and processing of tests in alternative settings.

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[23] For these audio-only E/M services, CMS will be separately issuing a waiver under section 1135(b)(8) of the Act, as amended by section 3703 of the CARES Act, of the requirements under section 1834(m) of the Act and its regulations at §410.78 that Medicare telehealth services must be furnished using video technology.

[24] In the March 31st COVID-19 IFC, CMS noted that the Office of the Inspector General issued a Policy Statement notifying physicians and other practitioners that they will not be subject to administrative sanctions for reducing or waiving any cost-sharing obligations for federal health care beneficiaries for a broad category of non-face-to-face services through various modalities including telehealth visits and virtual check-in services. (https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/policy-telehealth-2020.pdf.)

For example, existing §440.30(a) requires that Medicaid-covered laboratory and X-ray services be ordered and provided by or under the direction of a physician or other licensed practitioner within the scope of his or her practice as defined by state law or ordered by a physician but provided by a referral laboratory. Section 440.30(b) specifies that Medicaid will cover laboratory and X-ray services only if provided in an office or similar facility other than a HOPD or clinic.

CMS believes that those regulations could prevent patients from being able to self-collect a specimen even though self-collection could minimize transmission. Accordingly, it is amending §440.30 to add new paragraph (d) to specify that during the COVID-19 PHE or any future PHE resulting from an outbreak of communicable disease, and during any subsequent period of active surveillance, Medicaid coverage is available for laboratory tests and X-ray services that do not meet conditions specified in §440.30(a) or (b) so long as the purpose of the laboratory or X-ray service is to diagnose or detect SARS-CoV-2, antibodies to SARS-CoV-2, COVID-19, or the communicable disease named in the PHE or its causes, and so long as the deviation from the conditions specified in § 440.30(a) or (b) is intended to avoid transmission of the communicable disease.

The provision ensures that under those conditions, Medicaid coverage is available for laboratory processing of self-collected laboratory tests that the FDA has authorized for home use, even if those self-collected tests would not otherwise meet the requirements in §440.30(a) or (b).

CMS states that in addition to permitting states to cover laboratory processing of self-collected test systems that the FDA has authorized for home use, an order from a treating physician or other licensed non-physician practitioner (NPP) is not necessary. Laboratories that process such tests without an order must notify the patient and the patient's physician or NPP, if known by the laboratory, of the results.

The new flexibility would apply during the current COVID-19 PHE as well as during any subsequent periods of active surveillance which CMS is defining as a period of surveillance of a communicable disease where 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 solicits comment on the implications of applying this provision to future public health emergencies, and the specifications that should be included in doing so. CMS seeks comments on this definition of the period of active surveillance.**

CMS also notes that these flexibilities are available to apply to all Medicaid laboratory and X-ray services during the COVID-19 PHE effective retroactive to March 1, 2020.

Finally, CMS notes that existing §440.30(c) specifies that Medicaid can cover laboratory services only if they are furnished by a laboratory that meets the requirements of 42 CFR part 493 (regulations describing the standards, accreditation requirements, and conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical

Laboratory Improvement Amendments of 1988 (CLIA)). CMS does not propose any changes to this requirement but **solicits comment as to whether this requirement presents obstacles for coverage of COVID-19 testing services.**

P. Improving Care Planning for Medicaid Home Health Services

CMS implements section 3708 of the CARES Act by amending §440.70 to permit nurse practitioners, clinical nurse specialists, and physician assistants (in addition to physicians) to write orders for home health services and to review care plans for those services.

Section 3708 of the CARES Act requires those new flexibilities on ordering and care planning for home health services to Medicare and applies the flexibilities "in the same manner and to the same extent" to Medicaid. CMS notes that because the Medicare home health benefit and the Medicaid home health benefit are different, Section 3708 leaves some discretion for CMS to interpret what is meant by the applying section 3708 to Medicaid in the same manner and to the same extent as it applies to Medicare. For example, under Medicare, the durable medical equipment (DME) benefit is separate from home health and under regulations in place prior to the CARES Act and may be ordered by a more extensive list of other licensed non-physician practitioners (NPPs). Under Medicaid, DME is included under the Medicaid home health benefit.

CMS is interpreting the directive to apply section 3708 in the same manner and to the same extent to Medicaid as applying the current Medicare rules on who can order DME to the DME component of the Medicaid home health benefit. CMS states that it believes aligning the Medicaid program with Medicare regarding who can order medical supplies, equipment and appliances promotes access to services for Medicaid beneficiaries, and will reduce the burden on states and providers of dealing with inconsistencies between the Medicare and Medicaid programs. Specifically, CMS amends §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.

The provisions take effect on the same date as the parallel Medicare provision (described above in section J.) CMS notes that section 3708 of the CARES Act is not time limited to the period of the COVID-19 PHE; therefore, the parallel revisions to the Medicaid home health program will be permanently in effect.

Q. Basic Health Program Blueprint Revisions

The Affordable Care Act provided states with the option to operate a Basic Health Program (BHP) for individuals whose income is too high to qualify for Medicaid but does not exceed 200 percent of the federal poverty level. Two states, Minnesota and New York, are currently operating those programs. Regulations for the operation of a BHP program are in 42 CFR Part 600.

States operating a BHP are required to submit a BHP Blueprint that incorporates all of the information needed by the Secretary of HHS to certify a BHP. A state seeking significant revisions to their Blueprint are required (under 600.125(a)) to submit a revised Blueprint for review and certification before implementing those changes. CMS describes "significant" changes in the September 15, 2013 proposed rule (78 FR 59125) as including changes that have a direct impact on enrollee experience or program financing.

In recognition that some states may wish to make changes during this public health emergency to ensure that enrollees are able to access services without delay or without cost sharing, CMS is revising §600.125(b) and adding a new paragraph (c) to permit a state to submit a revised Blueprint that makes temporary significant changes in response to the PHE for the COVID-19 pandemic that are retroactive to the start of the PHE. Such changes will not be subject to the public comment process required under §600.115(c).

CMS notes that changes permitted under the new paragraph (c) may only be temporary revisions that increase access to coverage and cannot reduce or limit access or eligibility for BHP coverage. In addition to the revised Blueprint incorporating the temporary changes, a state must submit a cover letter to CMS that lists each change for which it is seeking certification with an explanation for how each change is directly related to the PHE for the COVID-19 pandemic and how each change is not restrictive in nature. The state should also specify the requested duration of each of the changes. If the state is seeking certification to implement temporary changes beyond the end of the COVID-19 pandemic, the state should specify why the later end date is needed.

R. Merit-based Incentive Payment System (MIPS) Qualified Clinical Data Registry (QCDR) Measure Approval Criteria

Qualified Clinical Data Registries (QCDRs) are one of several types of third-party intermediaries who may submit Merit-based Incentive Payment System (MIPS) data to the CMS Quality Payment Program (QPP) on behalf of a MIPS eligible individual clinician, group, or virtual group, and many QCDRs are sponsored by practitioners' professional specialty societies. CMS has been progressively increasing the sophistication of the requirements for quality measures for which QCDRs submit data (e.g., be evidence-based). In the CY 2020 Medicare Physician Fee Schedule final rule, CMS finalized that before a QCDR can submit a measure for approval, the QCDR must 1) have fully developed and tested the measure; and 2) be actively collecting data on the measure. Both requirements were adopted for implementation with the MIPS 2021 performance year.

Due to effects of the COVID-19 PHE on practitioners and hospitals, QCDRs anticipate being unable to meet the two new requirements. For some practitioners, their time and energy are being focused nearly exclusively on COVID-19 patient care rather than QCDR data reporting, while others will have little or no data to submit because the procedures they normally perform have been suspended. CMS agrees that the COVID-19 PHE will seriously and negatively impact

data collection and data reporting to QCDRs by many practitioners. Therefore, CMS is delaying the implementation of both new QCDR requirements until performance year 2022. In the interim, CMS will continue to review QCDR measures for reliability, validity, and risk of patient harm along with assessing whether the measures are implementable and collectible.

S. Application of Certain National Coverage Determination and Local Coverage Determination Requirements During the PHE for the COVID-19 Pandemic

In the March 31st COVID-19 IFC, CMS finalized on an interim basis that to the extent an NCD or LCD, including an article, requires a face-to-face or an in-person encounter for evaluations, assessments, certifications or other implied face-to-face services, these requirements would not apply. This interim policy change does not apply to face-to face encounters that are statutorily required, such as the face-to-face encounter requirement for Power Mobility Devices. CMS also finalized on an interim basis, that it that it would not enforce the clinical indications for coverage of respiratory, home anticoagulation management and infusion pump NCDs and LCDs, including articles. At the conclusion of the PHE, CMS will return to enforcement of the clinical indications for coverage

1. Applicability of Reasonable and Necessary Requirement for Covered Items and Services

Because of concerns that stakeholders might be misinterpreting statements in the March 31st COVID-19 as waiving medical necessity requirements, CMS states there is nothing in the March 31st COVID-19 IFC or in guidance, that could be interpreted to permanently or temporarily waive the reasonable and necessary requirement in section 1862(a)(1)(A) of the Act and cannot be waived under the section 1135 PHE authority. Except as expressly permitted by statute, 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 for payment under Part A or Part B of Title XVIII. CMS notes the medical record must be sufficient to support that services were provided and were medically necessary.

2. Enforcement Discretion of Clinical Indications for Additional LCDs

CMS finalizes, on an interim basis, it will not enforce the clinical indications for therapeutic continuous glucose monitors in LCDs. CMS states this discretion is intended to permit COVID-19 patients to closely monitor their glucose levels given they are at risk for unpredictable impacts of the infection on their glucose levels and health. This enforcement discretion will only apply during the PHE.

T. Delay in the Compliance Date of Certain Reporting Requirements Adopted for IRFs, LTCHs, HHAs and SNFs

During the rulemaking cycle for 2020 payment, CMS adopted new reporting requirements for IRFs, LTCHs, HHAs and SNFs. Specifically, data for two new post-acute care measures

involving transfer of health information to patients and to providers ("TOH measures") and for a set of six categories of standardized patient assessment data elements (SPADEs) were to be reported beginning October 1, 2020 for IRFs, LTCHs and SNFs, and beginning January 1, 2021 for HHAs. The new requirements involved CMS updates to the patient assessment instruments for each of these provider types, which it has completed. However, training providers on the new instruments has not been possible due to the COVID-19 PHE.

In this IFC, in order to reduce burden on providers, CMS:

- Delays release of the updated patient assessment instruments and continues the current versions of the IRF Patient Assessment Instrument (IRF-PAI v. 3.0), LTCH Continuity Assessment Record and Evaluation Data Set (LTCH CARE Data Set v. 4.00), and the HHA Outcome and Assessment Information Set (OASIS-D) Instrument.
- Delays the compliance dates for the collection and reporting of the TOH Information Measures and SPADEs.
    - IRFs will be required to use IRF-PAI V4.0 and LTCHs to use LTCH CARE Data Set V5.0 and begin collecting data on the two TOH Information Measures and the previously finalized SPADEs beginning on October 1st of the year that is at least 1 full fiscal year after the end of the COVID-19 PHE[25]. For example, if the COVID-19 PHE ends on September 20, 2020, IRFs and LTCHs will be required to begin collecting data on the TOH measures beginning on October 1, 2021.
    - HHAs will be required to use OASIS-E to begin collecting these data January 1st of the year that is at least 1 full calendar year after the end of the COVID-19 PHE[26]. For example, if the COVID-19 PHE ends on September 20, 2020, HHAs will be required to begin collecting these data beginning on January 1, 2022.
    - SNFs will be required to begin collecting data on the two TOH Information Measures and the SPADEs beginning on October 1st of the year that is at least 2 full fiscal years after the end of the COVID-19 PHE.[6] For example, if the COVID-19 PHE ends on September 20, 2020, SNFs will be required to begin collecting the data beginning on October 1, 2022.

With respect to IRFs, LTCHs, and HHAs, CMS believes that the delays will provide enough time for these providers to operationalize the updated versions of their respective assessment instruments, including taking any necessary training and ensuring that their vendors can make appropriate programming updates. CMS plans to release the drafts of the new instruments again for these programs shortly after the COVID-19 PHE ends to provide ample time for training and any vendor programming.

[25] For IRFs, LTCHs, and SNFs data collection for the TOH measures will begin with discharges occurring on or after the applicable October 1st date, while data collection for the SPADEs applies to admissions and discharges beginning on that date, except that the hearing, vision, race, and ethnicity SPADEs will be collected for admissions only.

[26] For HHAs, data collection for the TOH measures applies to discharges or transfers on or after the January 1st date, while data collection for the SPADEs applies to start of care, resumption of care, and discharges, except that the hearing, vision, race, and ethnicity SPADEs will be collected at the start of care only.

With respect to the longer delay for SNFs, CMS explains that in a notice posted on March 19, 2020 it had already delayed release of the updated Minimum Data Set (MDS) patient assessment instrument because stakeholders expressed concern with the implementation timeline and that the draft update did not adequately address the needs of states that use the MDS. SNFs will continue to use the current version (MDS 3.0 v1.17.1). The additional delay is designed to give CMS time to address stakeholder concerns as well as provide SNFs with reasonable time to engage in training and work with vendors to make necessary programming updates. Shortly after the COVID-19 PHE ends, CMS plans to work with stakeholders to develop a mutually agreeable timeline for releasing the updated MDS 3.0 v1.18.1 that provides enough time for SNFs to incorporate the updated version into their operations.

U. Update to the Hospital Value-Based Purchasing (VBP) Program Extraordinary Circumstance Exception (ECE) Policy

The Hospital VBP Program includes an ECE policy under which a hospital affected by a natural disaster or other extraordinary circumstance may apply for an exception from the VBP Program requirements (78 FR 50704). Under that policy, the required minimum number of cases and measures is interpreted to exclude data submitted by the hospital for a performance period for which it has been granted an exception. If a hospital meets the minimum requirements for a performance period without the excepted data, a total performance score will still be calculated. Otherwise, the hospital will be excluded from the VBP program for the applicable program year.

The IFC revises the extraordinary circumstances exception policy to allow CMS to grant an exception to hospitals located in an entire region or locale without having to submit requests and codifies this updated policy at §412.165(c). CMS notes that this will align the Hospital VBP Program extraordinary circumstances policy to policies adopted for the Hospital Inpatient Quality Reporting Program, the Hospital Readmissions Reduction Program, the Hospital Acquired Condition Reduction Program, and many other Medicare quality programs. The change is permanent and is applicable beginning on the publication date of the IFC, expected to be May 8, 2020. CMS believes that this change will reduce the burden on hospitals of submitting an ECE request form in cases where an extraordinary circumstance is known by CMS to apply across many hospitals.

Consistent with this policy and earlier announcements by CMS in response to the COVID-19 PHE[27], an ECE is granted for all hospitals participating in the Hospital VBP Program with respect to the following reporting requirements for the period October 1, 2019 through June 30, 2020, which includes three reporting quarters: October 1, 2019 – December 31, 2019 (Q4 2019), January 1, 2020 – March 31, 2020 (Q1 2020), and April 1, 2020 – June 30, 2020 (Q2 2020). Under the exception:

[27] https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf

- Hospitals will not be required to report National Healthcare Safety Network (NHSN) hospital-associated infection (HAI) and Hospital CAHPS (HCAHPS) survey data for the listed reporting quarters. However, hospitals can voluntarily submit part or all of these data by the posted submission deadlines.
- Qualifying claims data from the mortality, complications, and Medicare Spending per Beneficiary measures will be excluded for the listed quarters.

CMS says it is granting these exceptions to assist hospitals while they direct their resources toward caring for their patients and ensuring the health and safety of patients and staff during the PHE related to COVID-19. Furthermore, it believes that HAI measure data, HCAHPS survey data, and claims-based data for Q1 and Q2 2020 may be greatly impacted by the hospital's response to COVID-19. An exception is provided for Q4 2019 data because the reporting deadlines are in 2020 and fall during the PHE. As it continues to monitor the impact of the COVID-19 PHE, CMS will communicate any decision to provide additional exceptions or extensions through routine channels, including memos, emails and notices on the QualityNet.org website.

V. COVID-19 Serology Testing

A serology test can be used to detect whether a patient has antibodies specific to the SARS-CoV-2 virus. Patients with these antibodies may have developed an immune response to SARS-CoV-2 indicating a recent or prior infection, and potentially may not be at immediate risk for re-infection. An FDA-authorized serology test that detects antibodies to SARS-CoV-2 may potentially assist in identifying patients with an immune response to SARS-CoV-2 infection.

CMS uses the NCD process to establish a benefit category and establish that an item or service is reasonable and necessary under section 1862(a)(1)(A) of the Act. The NCD process requires the Secretary to make a proposed decision available for 30 days of public comment followed by a final decision 60 days after the close of the comment period.

Given the need to establish timely and uniform national policy coverage during the PHE, CMS has determined that coverage for FDA-authorized COVID-19 serology tests should be established in this IFC. CMS finalizes that these serologic tests fall under the Medicare benefit category of diagnostic laboratory test (section 1861(s)(3) of the Act) and can be covered by the Medicare program. CMS also finalizes that on an interim basis, during the PHE, Medicare will cover FDA-authorized COVID-19 serology tests as they are reasonable and necessary under section 1862(a)(1)(A) of the Act for beneficiaries with known current or known prior COVID-19 infection or suspected current or suspected past COVID-19 infection. CMS amends §410.32 to reflect this coverage determination.

W. Modification to Medicare Provider Enrollment Provision Concerning Certification of Home Health Services

As previously discussed in Section J of this IFC (and this summary), in addition to a physician, section 3708 of the CARES Act allows a NP, CNS, or a PA working in accordance with State law to certify the need for home health services. Section 3708(f) of the CARES Act authorizes CMS to promulgate an interim final rule, if necessary, to implement the section 3708 provisions. Given the need for flexibility in the COVID-19 PHE, CMS believes it is appropriate to implement these statutory changes in this IFC, instead of notice-and-comment rulemaking.

CMS revises §424.507(b)(1) to include ordering/certifying physicians, PAs, NPs, and CNSs as individuals who can certify the need for home health services. This change is applicable to services provided on or after March 1, 2020. CMS will respond to any comments in the 2021 HH PPS final rule or in another future rule.

X. Health Insurance Issuer Standards under the Affordable Care Act, Including Standards Related to Exchanges: Separate Billing and Segregation of Funds for Abortion Services

In 2019, CMS finalized the "Patient Protection and Affordable Care Act; Exchange Program Integrity" final rule (84 FR 71674). That rule included a policy, codified at §156.280(e)(2)(ii), requiring issuers of individual market qualified health plans (QHPs) offering coverage of non-Hyde abortion services to separately bill policy holders for the portion of their premium attributable to coverage of those services. In that rule, CMS explained that separately billing policy holders in this manner for non-Hyde abortion services is necessary to meet statutory requirements in section 1303 of the Affordable Care Act, which requires separate billing for coverage of those services.

CMS has received requests from issuers to delay the implementation of the separate billing policy, which was to begin with the first billing cycle following June 27, 2020, in light of the additional burden that issuers are experiencing related to the COVID-19 PHE. Issuers have fewer resources to handle the implementation and implementation is more challenging with issuers' workforce working remotely.

Y. Requirement for Facilities to Report Nursing Home Residents and Staff Infections, Potential Infections, and Deaths Related to COVID-19

The IFC includes new reporting requirements for long-term care (LTC) facilities, which include Medicare SNFs and Medicaid nursing facilities (NFs), with respect to confirmed or suspected cases of COVID-19, effective with the publication of the IFC (expected to be May 8, 2020). Federal participation requirements for LTC facilities are set forth in sections 1819 and 1919 of the Act and codified in the implementing regulations at 42 CFR part 483, subpart B, and include requirements that LTC facilities develop and maintain an infection control program to protect the

health and safety of residents, personnel, and the general public. Existing regulations regarding infection control are set forth at §483.80.

Specifically, under the IFC a new provision at §483.80(g)(1) requires facilities to electronically report information about COVID-19 in a standardized format specified by the Secretary. The information will be used to monitor trends in infection rates and inform public health policies. The report must include 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.

In addition, at §483.80(g)(2), facilities are required to provide the information at a frequency specified by the Secretary, but no less than weekly to the Center for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN). The information reported to the NHSN will be shared with CMS, which will retain and publicly report it. CMS notes that it has received, and expects to continue to receive requests for COVID-19 related data under the Freedom of Information Act (FOIA), which requires agencies to make available to the public copies of records, that because of the nature of their subject matter, the agency determines are likely to become the subject of subsequent requests for substantially the same information. These new requirements will support CMS' efforts to proactively inform interested parties and ensure that the most complete information on COVID-19 cases is publicly available. CMS reminds readers that LTC facilities must continue to comply with the existing requirement at §483.80(a)(2)(ii), which requires facilities to report possible incidents of communicable disease and infections, as well as comply with state and local reporting requirements for COVID-19.

A new provision added at §483.80(g)(3) requires facilities to inform residents, their representatives, and their families of confirmed or suspected COVID-19 cases in the facility among residents and staff and the mitigating steps the facility is taking to prevent and control the spread of COVID-19. Specifically, 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. Cumulative updates must be provided at least weekly by 5 p.m. the next calendar day following the subsequent occurrence of either a confirmed infection of COVID-19 or whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other.

This information must be reported in accordance with existing privacy regulations and statute, and must not include personally identifiable information. Facilities must include information on mitigating actions implemented to prevent or reduce the risk of transmission, including if normal operations in the nursing home will be altered, such as restrictions or limitations to visitation or group activities.

CMS notes that facilities are not expected to make individual telephone calls for purposes of this reporting requirement. Instead, facilities can utilize communication mechanisms that make this information easily available to all residents, their representatives, and families, such as paper notification, listservs, website postings, and/or recorded telephone messages.

CMS believes these reporting requirements along with public reporting of the data support the statutory requirements for infection control programs and are necessary for it to monitor whether individual nursing homes are appropriately tracking, responding to, and mitigating the spread and impact of COVID-19 on residents, personnel, and the general public.

As discussed in the "Waiver of Proposed Rulemaking" section of the IFC, CMS believes that because of the urgency of the COVID-19 PHE, waiver of the normal notice-and-comment process is in the public interest, because time is of the essence in informing residents, their families, and the general public of the incidence of COVID-19 and assisting public health officials in detecting outbreaks and saving lives.

Z. Time for Level Selection for Office/Outpatient Evaluation and Management Services Furnished Via Medicare Telehealth

In the March 31st COVID-19 IFC, CMS specified that the office/outpatient E/M level selection for services furnished by telehealth can be 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 stated that typical times associated with the office/outpatient E/M visits were available as a public use file.[28]

CMS agrees with stakeholders' concerns that the times in its public use file do not align with the typical times included in the office/outpatient E/M code descriptors. In response, CMS finalizes, on an interim basis for the duration of the PHE, that the typical times for purposes of level selection of an office/outpatient E/M times are the times listed in the CPT code descriptor.

AA. Updating the Medicare Telehealth List

In the March 31st COVID-19 IFC, CMS added services to the Medicare telehealth list on an interim final basis for the duration of the PHE. CMS believes that it has added the vast majority

[28] The public use typical E/M code time file is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Regulation-Notices-Items/CMS-1715-F

of services that are appropriate for the PHE but, it might identify other services that would be appropriate to add to the telehealth list during the PHE. For the duration of the PHE, CMS is revising §410.78(f) to specify that during a PHE, it will use a subregulatory process to modify the services included on the Medicare telehealth list.

During the PHE, CMS will add services to the Medicare telehealth list by posting new services to the web listing of telehealth services when it either identifies a service through internal review or through an external request. CMS states the service needs to be a completely furnished, as described by the relevant HCPCS code, by a distant practitioner to a beneficiary in a manner similar to the in-person service. Services added using this revised process would remain on the list only during the PHE.

The current list of Medicare telehealth services, including those added during the PHE, is available at https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.

BB. Payment for COVID-19 Specimen Collection to Physicians, Nonphysician Practitioners and Hospitals

In the March 31st IFC (85 FR 19256 through 19258), CMS provided payment for specimen collection and a travel allowance when independent laboratories collect specimens for COVID–19 clinical diagnostic laboratory testing from beneficiaries who are homebound or inpatients not in a hospital. Effective March 1, 2020, Medicare will pay a specimen collection fee for COVID-19 testing for homebound and non-hospital inpatients of $23.46. For individuals in a SNF or individuals whose samples will be collected by a laboratory on behalf of an HHA, payment will be $25.46. The March 31st IFC did not include a provision to pay for specimen collection for COVID-19 clinical diagnostic laboratory testing from patients in a physician's office or hospital.

1. Collection of Specimens in a Physician's Office

CPT code 99211 is typically reported by physicians and qualified non-physician practitioners for established patients when the service can be furnished by the ancillary staff and a face-to-face visit with the physician is unnecessary. Under existing policy, CPT code 99211 may be used to report specimen collection for an established patient when no other services are provided by the physician or qualified non-physician practitioner.

CPT code 99211 was used as the basis for the specimen collection fee that CMS established for independent laboratories described above. While CPT code 99211 is restricted to use for established patients, CMS will also allow it to be used to report specimen collection in a physician's or qualified non-physician practitioner's office for new patients. The payment rate will be $23.46.

To bill for CPT code 99211 for new as well as established patients, the requirements for billing for "incident to" services must be met. That is, the service must be furnished under the direct supervision of the physician or qualified non-physician practitioner employing the auxiliary staff. All other requirements for "incident to" described in 42 CFR § 410.26 and section 60 of Chapter 15 Covered Medical and Other Health Services in the Medicare Benefit Policy Manual 100-02 must also be met. Under prior policy established specifically for the COVID-19 PHE, CMS is allowing direct supervision through interactive audio and video technology.

In other circumstances where the specimen collection occurs in the physician's or qualified non-physician practitioner's office during a medically necessary visit that includes a service furnished by the physician or qualified non-physician practitioner, payment for specimen collection will continue to be bundled and not paid separately.

2. Collection of Specimens in a Hospital Outpatient Department

For COVID-19 specimen collection in the hospital outpatient department, CMS is establishing the following 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).

HCPCS code C9803 will be assigned to APC 5731 Level 1 Minor Procedures that pays a national unadjusted rate of $22.98. CMS expects to retire HCPCS code C9803 once the PHE concludes. The code will also be conditionally packaged meaning that it will only be paid separately if no other services are provided during the hospital outpatient encounter. Payment for the specimen collection will only be made when billed with a clinical diagnostic laboratory test paid under the clinical diagnostic laboratory fee schedule.

3. Deductible and Coinsurance

Section 6002(a) of the Families First Coronavirus Response Act (Pub. L. 116-127) amended section 1833 of the Act to waive the Part B deductible and coinsurance for provider or outpatient visits associated with the diagnosis of COVID-19. The waiver of deductible or coinsurance applies to the furnishing or administration of a COVID-19 test. Consistent with this statutory provision, CMS will pay 100 percent of the PFS or OPPS payment amount for CPT code 99211 when used for COVID-19 specimen collection and HCPCS code C9803 which is exclusively used for COVID-19 specimen collection.

CC. Payment for Remote Physiologic Monitoring (RPM) Services Furnished During the COVID-19 Public Health Emergency

In the March 31st COVID-19 IFC, CMS finalized on an interim basis during the PHE, that RPM services (listed in the table below) can be furnished to new and established patients.

Remote Physiologic Monitoring Codes	
CPT Code	**Description**
99091	Collection & interpretation of physiologic data digitally stored and/or transmitted
99453	Remote monitoring of physiologic parameter, initial
99454	Remote monitoring of physiologic parameter, each 30 days
99457	Remote physiologic monitoring treatment management services, first 20 minutes
99458	Remote physiologic monitoring treatment management services, additional 20 minutes
99473	Self-measured blood pressure
99474	Separate self-measurements of blood pressure readings

Stakeholders have notified CMS that many of the CPT code descriptors for the RPM services have a reporting duration requirement and that while it is possible that RPM would be used to monitor a patient with COVID-19 for 16 or more days, many patients with COVID-19 do not need to be monitored for 16 days. CMS establishes on an interim basis for the duration of the PHE, payment for CPT codes 99091, 99453, 99454, 99457, and 99458 when monitoring lasts for fewer than 16 days during a 30-day period, but no less than 2 days, for patients who have a suspected or confirmed diagnosis of COVID-19. Payments for these codes will not be altered because CMS believes the overall resource costs for long-term monitoring for chronic conditions appropriately reflect those for short-term monitoring for acute conditions in the context of COVID-19 disease and exposure risks.

III. Waiver of Proposed Rulemaking

In accordance with 5 U.S.C. 553(b) of the Administrative Procedure Act (APA) and section 1871 of the Act, CMS ordinarily publishes a notice of proposed rulemaking in the Federal Register and invites public comment on the proposed rule before the provisions of the rule take effect. Section 553(b)(3)(B) of the APA and section 1871(b)(2)(C) of the Act authorize the agency to waive these procedures, however, if the agency finds good cause that notice and comment rulemaking procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of finding and its reasons in the rule issued. Section 553(d) of the APA ordinarily requires a 30-day delay in the effective date of a final rule from the date of its publication in the Federal Register. This 30-day delay in effective date can be waived, however, if the agency finds good cause to support an earlier effective date, and such changes could be applied retroactively to items and services furnished before the effective date of the change if the failure to apply the changes retroactively would be contrary to the public interest.

In light of the COVID-19 pandemic, CMS finds good cause to waive notice and comment rulemaking as it believes it would be contrary to the public interest for it to undertake normal notice and comment rulemaking procedures. CMS states that this IFC offers healthcare

professional flexibilities in furnishing services while combatting the COVID-19 pandemic and ensuring that sufficient health care items and services are available to meet the needs of individuals enrolled in the Medicare and Medicaid programs. It also waives the 30-day delay in the effective date, and, moreover, makes certain policies in this IFC effective as of March 1, 2020—the date the President of the United States declared to be the beginning of the national emergency concerning the COVID-19 outbreak, or, if applicable, January 27, 2020 the date on which the PHE for the COVID-19 pandemic started. CMS is providing a 60-day comment period for this IFC.

IV. Regulatory Impact Analysis

OMB has determined that this IFC is "economically significant" within the meaning of Executive Order 12866. CMS states that given the potentially catastrophic impact to public health, it is difficult to estimate the economic impact of the spread of COVID-19 under current payment rules compared to the rules issued in this IFC. It highlights the following:

- Allows hospitals and CMHCs more flexibility to furnish certain outpatient services remotely in a manner that reduces the exposure risk to patients, hospital staff, and physicians.
- Changes to ensure teaching payments are not disadvantaged. This includes excluding surge capacity beds when determining a teaching hospital's IME payments, allowing RHCs to maintain their payment levels if the hospital temporarily adds additional beds, and maintaining IRF and IPF average daily census numbers so that related teaching adjustment payments do not decrease during pandemic.
- Changes to Medicaid's regulations to expand the circumstances under which certain laboratory tests can be covered during a PHE and subsequent periods of active surveillance.
- Temporary increase to certain DME payments, as required by section 3712 of the CARES Act, will increase Medicare expenditures as well as beneficiary cost sharing.

CMS also discusses the impact of certain provisions of the IFC in this section, which are summarized in each of the sections of this summary, respectively.

Of note, CMS is making changes to the MSSP program to prevent COVID-19 related treatment costs from causing distortions in the calculation of shared savings and shared losses for individual ACOs. These policy changes are anticipated to help retain ACO participation and reduce program spending by $1.43 billion over the 2020 to 2025 period. Changes to increase certain DME payment rates, as required by section 3712 of the CARES Act is expected to cost $140 million against the FY 2021 President's Budget Baseline. CMS did not expect most policy changes to have a significant impact. In the accounting statement CMS prepared for this IFC, it estimates $270 million in annualized savings from the 2020 to 2025 period.

Overall, CMS does not believe that this rule will have a significant impact on a substantial number of small entities, small rural hospitals, or a direct cost impact on state or local governments, preempt state law, or otherwise have federalism implications.