TO: Health Care Clients

FROM: Alston & Bird LLP

DATE: May 6, 2020

RE: A&B Summary – Additional Policy and Regulatory Provisions in Response to the COVID-19 Public Health Emergency (CMS-5531-IFC)

On April 30, 2020, the Centers for Medicare & Medicaid Services (CMS) released an interim final rule with comment period (IFC) entitled, *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* (the IFC).[1] This IFC follows an interim final rule with comment period CMS released on March 31, 2020 (CMS-1744-IFC).[2] Please refer to the Alston & Bird summary of that interim final rule for more details.[3]

This IFC is intended to provide additional flexibilities for individuals and entities that provide health care services to Medicare, Medicaid, Basic Health Program, and Exchange beneficiaries so that they can respond effectively to the public health threats associated with COVID-19.

CMS is finalizing regulatory changes impacting:

1. Coverage and payment rules;
2. Hospitals;
3. Rural health clinics
4. Physicians;
5. Post-acute care providers;
6. Durable Medical Equipment;
7. Clinical laboratories;
8. Medicare Shared Savings Program; and
9. Health care coverage and insurers.

In general, and unless otherwise noted below, these changes will apply on a temporary or interim basis (i.e., only during the COVID-19 PHE), and have retroactive applicability as described below. **Comments to the IFC are expected to be due no later July 7, 2020.**

[1] See: https://www.cms.gov/files/document/covid-medicare-and-medicaid-ifc2.pdf.
[2] See: https://www.govinfo.gov/content/pkg/FR-2020-04-06/pdf/2020-06990.pdf.
[3] See: https://www.alston.com/en/-/media/files/insights/publications/2020/04/ab-summary--cms-covid19-policy-and-regulatory-chan.pdf.

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I. Coverage and Payment Rules

a. Scope of Practice

CMS is finalizing provisions intended to ensure an adequate number of clinicians are able to furnish critical services and tests during the COVID-19 PHE. CMS notes that it is finalizing provisions that address several of the recommendations from nonphysician practitioners (NPPs) that were provided in response to CMS' request for feedback[4] following the President's Executive Order (EO) 13890 on *Protecting and Improving Medicare for Our Nation's Seniors*.[5] CMS also seeks public feedback on the number of states that have more flexible scope of practice rules than federal regulations.

i. Supervision of Diagnostic Tests by Certain Nonphysician Practitioners

CMS is finalizing on an interim basis changes to regulations at 42 CFR 410.32(b) to add flexibility for nurse practitioners (NPs), clinical nurse specialists (CNSs), physician assistants (PAs), and certified nurse midwives (CNMs) to allow them to furnish what would be physician services and be paid under Medicare Part B for the professional services furnished directly and "incident to" their own professional services, to the extent authorized under their State scope of practice. CMS states that this change will enable NPPs to order, furnish directly, and supervise the performance of diagnostic tests during the COVID-19 PHE (subject to applicable state law). This flexibility is provided for diagnostic tests covered under section 1861(s)(3) of the Social Security Act (SSA) (42 CFR 410.32(b)(1)) and COVID-19-related psychological and neuropsychological testing services (42 CFR 410.32(b)(2)(iii)(B)), such that these services can be supervised by an NP, CNS, PA, and CNM during the COVID-19 PHE.

In addition, CMS is permitting PAs to perform diagnostic tests without physician supervision when authorized to do so under applicable state law (42 CFR 410.32(b)(2)(viii)) and is authorizing NPs, CNSs, PAs, and CNMs to provide the appropriate level of supervision for diagnostic tests (42 CFR 410.32(b)(3)) during the COVID-19 PHE. CMS is making corresponding changes to 42 CFR 410.74, which continues to apply, by removing the parenthetical regarding general physician supervision of PAs furnishing diagnostic tests.

ii. Therapy – Therapy Assistants Furnishing Maintenance Therapy (Part B)

CMS is, for the duration of the COVID-19 PHE, permitting a physical therapist (PT) or occupational therapist (OT) who established a maintenance program to delegate the performance of therapy services to a physical therapy assistant (PTA) or occupational therapy assistant (OTA) when clinically appropriate. CMS states that this will synchronize Part B with the maintenance therapy flexibilities for services furnished in skilled nursing facility (SNF) and home health Part A settings where PTAs and OTAs are permitted to provide these services.

iii. Therapy – Student Documentation (Part B)

During the COVID-19 PHE, any individual authorized under Medicare to furnish and bill for their professional services (whether they are acting in a teaching role or not) may review and verify (i.e., sign and date), rather than redocument notes in the medical record made by physicians, residents, nurses, and students, including students in therapy or other clinical disciplines, or other members of the medical team.

[4] See: https://www.cms.gov/files/document/2019-12-26-enews-se.pdf.
[5] Available here: https://www.govinfo.gov/content/pkg/FR-2019-10-08/pdf/2019-22073.pdf.

This is an expansion of the policy finalized in the 2020 Physician Fee Schedule (PFS) final rule, which allows review and verification, rather than re-documentation. Pursuant to this IFC, the policy will now cover therapy and other clinical disciplines. CMS emphasizes that information entered into the medical record should document that the furnished services are reasonable and necessary.

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

CMS is clarifying that pharmacists fall within the regulatory definition of auxiliary personnel (42 CFR 410.26) and can therefore provide services incident to, and under the appropriate level of supervision, of the billing physician or NPP, if the payment for services is not made under Part D. This includes providing services incident to a billing physician's or NPP's services in accordance with the pharmacist's state scope of practice and applicable state law. CMS notes that this does not alter current payment policy, and therefore is not limited to the duration of the COVID-19 PHE.

CMS states that this is fully consistent with current CMS policy, but also believes that this clarification may encourage pharmacists to work with physicians and NPPs in new ways during the COVID-19 PHE, including increasing access to medication management of individuals with substance use disorder.

b. Telehealth

i. Payment for Audio-Only Telephone Evaluation and Management (E/M) Services

CMS revisits the changes made in CMS-1744-IFC related to audio-only telephone E/M services (CPT codes 98966-98968 and 99441-99443). The agency recognizes that the intensity of furnishing an audio-only visit during the COVID-19 PHE is not accurately captured by the previously finalized values of some of those services, specifically CPT codes 99441-99443. CMS also recognizes that these codes are serving as a replacement for care that would otherwise be reported as an in-person or telehealth visit using the office/outpatient E/M codes.

CMS, therefore, is establishing, for the duration of the COVID-19 PHE, new relative value units (RVUs) for the telephone E/M services and direct practice expense (PE) inputs based on crosswalks to the most analogous office/outpatient E/M codes (based on time requirements):

- 99212 → 99441 (0.48 RVUs)
- 99213 → 99441 (0.97 RVUs)
- 99214 → 99443 (1.50 RVUs)

In addition, CMS is adding these services to the list of Medicare telehealth services during the COVID-19 PHE and will be issuing an 1135 waiver to this effect. CMS is not increasing payment rates for CPT codes 98966-98968 as these codes describe services furnished by practitioners who cannot independently bill for E/M services, and therefore would not be provided in lieu of an office/outpatient E/M service.

ii. Time Used for Level Selection for Office/Outpatient E/M Services Furnished via Medicare Telehealth

CMS revisits changes made in CMS-1744-IFC specifying that office/outpatient E/M level selection when furnished via telehealth can be based on medical decision making (MDM) or time (defined as all of the time associated with the E/M on the day of the encounter). CMS is amending its prior policy under CMS-

1744-IFC for the duration of the COVID-19 PHE such that the typical times for purposes of level selection are the times listed in the CPT code descriptor instead of the times listed in CMS' public use file.

iii. Updating the Medicare Telehealth List

CMS notes that it added several services to the Medicare telehealth list for the duration of the COVID-19 PHE in CMS-1744-IFC. In light of the urgency of minimizing unnecessary contact during the COVID-19 pandemic, CMS is modifying its regulation at 42 CFR 410.78(f) to specify that during the COVID-19 PHE it will use a subregulatory process to modify the services included on the Medicare telehealth list. CMS is not codifying a specific process to be in effect and any codes added through this process will only remain during the COVID-19 PHE.

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

CMS notes that several of the RPM services (CPT codes 99091, 99453-99454, and 99457-99458) cannot be reported for fewer than 16 days during a 30-day reporting period. While it is possible to monitor a COVID-19 patient for 16 or more days, many COVID-19 patients do not need to be monitored for that length of time. Subsequently, CMS is making additional changes to those made in CMS-1744-IFC to allow RPM monitoring services to be reported to Medicare for periods of time that are fewer than 16 of 30 days, but no less than two days, as long as other requirements are met. CMS is not altering payment rates for these codes. However, CMS is limiting payments for monitoring that lasts for fewer than 16 days (but no less than two days) for patients suspected to have or have a confirmed COVID-19 diagnosis.

c. Application of Certain National Coverage Determination (NCD) and Local Coverage Determination (LCD) Requirements

CMS provides clarification and expands upon its changes made in CMS-1744-IFC, including with respect to the applicability of the "reasonable and necessary" requirement for covered items and services and enforcement discretion of clinical indications for additional LCDs.

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

CMS clarifies that CMS-1744-IFC provided no indication or interpretation that the reasonable and necessary statutory requirement (SSA 1862(a)(1)(A)) was permanently or temporarily waived. As such, CMS states that physicians, practitioners, and suppliers are required to continue documenting the medical necessity for all services and the medical record must be sufficient to support payment for the services billed.

ii. Enforcement Discretion of Clinical Indications for Additional LCDs

CMS is finalizing that for the duration of the COVID-19 PHE, it will not enforce the clinical indications for therapeutic continuous glucose monitors (CGMs) in LCDs. For example, CMS will not enforce the current clinical indications restricting the type of diabetes that a beneficiary must have or relating to the demonstrated need for frequent blood glucose testing in order to permit COVID-19 infected patients with diabetes to receive a Medicare-covered therapeutic CGM. In addition, CMS states that practitioners will have greater flexibility to allow more of their diabetic patients to better monitor their glucose and adjust insulin doses from home by using a therapeutic CGM.

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

Recognizing the importance of expanding COVID-19 testing, CMS is providing additional payment for assessment and COVID-19 specimen collection to support testing by hospital outpatient departments (HOPDs), physicians, and other practitioners. CMS states that this additional payment is to recognize the significant resources required to safely collect specimens from beneficiaries during the pandemic. CMS notes that when physicians and other practitioners collect specimens, Medicare generally pays for those services under the PFS, although payment is often bundled into the payment rate for other services (e.g., with an office/outpatient E/M visit).

CMS notes that the given the need for widespread testing, COVID-19 specimen collection may occur in circumstances other than typical interaction between patients and professionals or staff. However, there is no code that specifically describes the services furnished through large-scale, dedicated testing operations involving a physician or NPP. Thus, during the COVID-19 PHE, CMS will recognize physician and NPP use of CPT code 99211 for all patients (not just established patients) to bill for a COVID-19 symptom and exposure assessment and specimen collection provided by clinical staff incident to the physician's or NPP's services. CMS reiterates its policy in CMS-1744-IFC that direct supervision can be met through virtual presence of the supervising physician or practitioner via interactive audio and video technology during the COVID-19 PHE. The current national unadjusted PFS rate for CPT code 99211 is $23.46.

For HOPDs, CMS is creating a new E/M code solely to support COVID-19 testing during the PHE – HCPCS code C9803. During the COVID-19 PHE, this code will be assigned to APC 5731 Level 1 Minor Procedures, which CMS states contains many similar services, including obtaining screening pap smear (HCPCS code Q0091) and glaucoma screening for high risk patients furnished by an optometrist or an ophthalmologist (HCPCS code G0117). In addition, this new code will have a status indicator of "Q1", meaning the service is conditionally packaged under the Outpatient Payment Prospective System (OPPS) when billed with a separately payable primary service in the same encounter. A separate OPPS payment for HCPCS code C9803 will be made if it is billed without another primary covered hospital outpatient service or when it is billed with a clinical laboratory test with a status indicator of "A" on Addendum B of the OPPS. CMS anticipates that a COVID-19 test will always be ordered or administered with this code. APC 5731 pays a national unadjusted rate of $22.98.

CMS notes that there will be no beneficiary cost-sharing for these services, pursuant to section 6002(a) of the Families First Coronavirus Response Act. While CMS states that HCPCS code C9803 may result in beneficiary cost-sharing, such cost-sharing will not apply if the specimen collection results in a COVID-19 test, which CMS anticipates will occur every time.

II. Hospitals

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

i. Excepted Provider-Based Department Temporary Relocation Policy

Section 603 of the Bipartisan Budget Act (BBA) of 2015 modified the way that certain hospital outpatient provider-based departments (PBDs) were paid, reducing reimbursement by applying a payment system more closely aligned with PFS instead of applying the OPPS. Certain PBDs were "excepted" from this reimbursement methodology change, including on-campus PBDs and those that were in operation before the enactment of the BBA (November 2, 2015), and thus continue to receive reimbursement under the

OPPS. Under ordinary circumstances, excepted off-campus PBDs would lose excepted status upon relocation unless CMS Regional Offices approved the relocation under the extraordinary circumstances policy, which allows excepted off-campus PBDs to relocate for extraordinary circumstances outside of the hospital's control, such as natural disasters, significant seismic building code requirements, or significant public health and safety issues.

In the IFC, CMS adopts a temporary relocation exception policy during the COVID-19 PHE. This expands the extraordinary circumstances policy to include on-campus PBDs that relocate off-campus in response to COVID-19 on or after March 1, 2020 through the remainder of the COVID-19 PHE, so long as the relocation is not inconsistent with the state's emergency preparedness or pandemic plan. Hospitals may relocate a single PBD to multiple locations, or relocate only part of a PBD, during the COVID-19 PHE. Hospitals may also relocate or partially relocate an excepted PBD to a patient's home for the purposes of furnishing a covered outpatient service, which can be provider-based to the hospital during the COVID-19 PHE under the Hospitals without Walls initiative. CMS expects hospitals to be able to support that an excepted PBD relocated to multiple locations is still be the same PBD, just split into more than one location. For example, if the excepted PBD was an oncology clinic, the relocated PBD(s) during the COVID-19 PHE would still be providing oncologic services, including in the patient's home to the extent such location is made provider-based to the hospital.

CMS anticipates that this relocation would be temporary, and notes that at the conclusion of the COVID-19 PHE, excepted PBDs that are permanently relocated would lose excepted status unless they met the standard extraordinary circumstances criteria and received approval from their CMS Regional Office.[6] Because the standard extraordinary circumstances policy does not apply to on-campus PBDs, they would lose excepted status if their relocation was permanent. Non-excepted off-campus PBDs, including new off-campus PBDs established to address COVID-19, remain ineligible for OPPS reimbursement.[7]

ii. New Temporary Exception Process

CMS will permit relocation of excepted off-campus and on-campus PBDs, and continued billing under the OPPS with claims modifier "PO," prior to submitting documentation to the CMS Regional Office to support the extraordinary relocation request. The extraordinary circumstances request process is modified during the COVID-19 PHE. Hospitals that relocate PBDs to off-campus locations in response to COVID-19 should notify their CMS Regional Office by email of: (1) their hospital's CCN; (2) the address of the current PBD; (3) the address(es) of the relocated PBD(s); (4) the date they began furnishing services at the new PBD(s); (5) a brief justification for the relocation and the role of the relocation in the hospital's response to COVID-19; and (6) an attestation that the relocation is not inconsistent with their state's emergency preparedness or pandemic plan. Note that if a hospital will render services in relocated, excepted PBDs, but intends to bill to Medicare for the services under the main hospital, no additional enrollment actions are required (i.e., the hospital does not need to submit an updated CMS-855A enrollment form) for the off-campus relocated site during the COVID-19 PHE. If a hospital intends to permanently relocate the excepted PBD after the COVID-19 PHE, the hospital would have to file an updated CMS-855A enrollment form.

In addition, hospitals are expected to explain why the new PBD location (including instances where the relocation is to the patient's home) is appropriate for furnishing covered outpatient items and services in the justification. Relocations to an off-campus PBD that is otherwise a patient's home only require one relocation request during the COVID-19 PHE, meaning only one submission per excepted PBD is needed

[6] CMS notes that the fact that the off-campus PBD relocated in response to the pandemic will not, by itself, be considered an "extraordinary circumstance" for purposes of a permanent relocation exception.
[7] See: *Hospitals: CMS Flexibilities to Fight COVID-19* (https://www.cms.gov/files/document/covid-hospitals.pdf).

and a hospital does not have to submit a unique request each time a patient's home is registered as a PBD. This request must be emailed to the CMS Regional Office within 120 days of furnishing and billing services at the relocated PBD.

b. Furnishing Hospital Outpatient Services in Temporary Expansion Locations of a Hospital or a Community Mental Health Center (including the Patient's Home)

Under ordinary circumstances, Medicare does not pay for hospital outpatient services furnished to a beneficiary in locations that are not provider-based, including a beneficiary's home. However, CMS has issued numerous blanket 1135 waivers to facilitate the availability of temporary expansion locations. Specifically, CMS has waived the provider-based requirements at 42 CFR 413.65 and certain physical environment requirements at 42 CFR 482.41 (hospitals) and 42 CFR 485.623 (Critical Access Hospitals). These waivers permit temporary expansion locations, including beneficiaries' homes, to become hospital PBDs, so long as all other requirements – including hospital conditions of participation to the extent not waived – are met. These waivers are in effect during the COVID-19 PHE. Services provided at temporary expansion locations, including beneficiaries' homes, are paid as services provided at excepted or non-excepted PBDs, as set forth in the previous section. Services provided in a patient's home would only qualify for payment as an excepted PBD if the patient's home is a partial relocation of a current on-campus or excepted off-campus PBD.

In the IFC, CMS provides guidance on the provision of hospital outpatient therapeutic services furnished to beneficiaries in their homes or other temporary expansion locations for the duration of the COVID-19 PHE, as follows:

i. Hospital Outpatient and Community Mental Health Center (CMHC) Therapy, Education, and Training Services That Can Be Furnished Other Than In-Person

CMS is permitting the provision of hospital outpatient therapy (including behavioral health and partial hospitalization program (PHP) services), education, and training services by hospital clinical staff to registered outpatients located in the hospital (including patient homes and other temporary expansion locations) using telecommunications technology. Such services include psychoanalysis, psychotherapy, diabetes self-management training, and medical nutrition therapy. Hospital clinical staff may provide these services remotely as long as the appropriate level of physician supervision is met. CMS notes that the level of supervision required for the vast majority of hospital outpatient therapeutic services is general supervision, meaning that the service must be furnished under a physician's or NPP's overall direction and control, but the physician's or NPP's presence is not required during the performance of the service (42 CFR 410.27). All services furnished by the hospital still require an order by a physician or qualified NPP. CMS published a list of hospital therapy and other services that it believes may be furnished by a hospital to a patient incident to a physician's or qualified NPP's service using telecommunications technology during the COVID-19 PHE.[8] Hospitals may bill for these services as if they were furnished in the hospital. However, if these services are furnished by clinical staff of the physician or other practitioner and furnished incident to their own services (i.e., are not provided by the staff of the hospital), the hospital may not bill for these services.

[8] HCPCS codes: 97110, 97112, 97129-97130, 97139, 97150-97158, 97161-97168, 97530, 97533, 97535, 97802-97804, 99453-99454, 99458, 99483-99484, 99487-99490, 99492-99498, G0108-G0109, G0175, G0248-G0249, G0506, G2058, G0444. This list is not exhaustive and will be updated periodically. The list is available at https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers.

A PHP is a program furnished by a hospital to its outpatients or by a CMHC, as a distinct and organized intensive ambulatory treatment service, offering less than 24-hour daily care, in a location other than an individual's home or inpatient or residential setting.

During the COVID-19 PHE, providers can furnish certain partial hospitalization services (i.e., individual psychotherapy, patient education, and group psychotherapy) remotely to patients in a temporary expansion location of the hospital or CMHC, which may include a patient's home to the extent it is made provider-based to the hospital or an extension of the CMHC. CMS expects these services to be furnished using telecommunications technology that involve both audio and video. If, however, video is not possible, the service can be furnished exclusively with audio. CMS published a list of PHP services that it believes may be provided remotely.[9] Services that require drug administration cannot be furnished using telecommunications technology. All other PHP requirements are unchanged and still in effect, including that services are ordered, supervised, and certified by a physician, and furnished in accordance with coding requirements by clinical staff working within their scope of practice. Services provided by clinical staff of the physician or NPP incident to the physician or NPP's professional services, and not the hospital or CMHC's staff, cannot be billed by the hospital or CMHC.

CMS is expanding the locations at which a CMHC may provide PHP services. For the duration of the COVID-19 PHE, beginning March 1, 2020, CMS will consider temporary expansion locations where the beneficiary may be located, including a beneficiary's home, to be a part of the CMHC once a patient is registered as an outpatient of the CMHC. CMHCs should bill for these services as if they were furnished in the CMHC.

ii. Hospital In-Person Clinical Staff Services in a Temporary Expansion Location (which may include the Patient's Home)

Services that do not require professional work by a physician or qualified NPP furnished by a hospital's clinical staff may be furnished at a temporary expansion site, including at a patient's home if it is a PBD of a hospital. Examples of such services include wound care, chemotherapy administration, and other drug administration.[10] The patient must be registered as a hospital outpatient and the requisite level of supervision must be met. Non-surgical extended duration therapeutic services (NSEDTSs) can be furnished in this manner, and CMS changed the requisite level of supervision required for the initiation of NSEDTSs from direct supervision to general supervision in CMS-1744-IFC.

During the time period that a patient is receiving services from the hospital clinical staff as a registered outpatient, the patient's place of residence cannot be considered both a PBD of the hospital and a home for the purposes of home health services. If a patient is under a home health plan of care, a hospital may not furnish services to the patient that could be furnished by the home health agency (HHA) while the plan of care is active.

iii. Hospital Services Accompanying a Professional Service Furnished Via Telehealth

In CMS-1744-IFC, CMS instructed physicians and other practitioners furnishing telehealth services to beneficiaries in their homes to bill for services in the same way they would if they were furnishing the

[9] HCPCS codes: 90785, 90832, 90834, 90837, 90847, G0410-G0411, G0129, G0176-G0177. This list is not intended to be exhaustive and may be updated periodically. The list is available at https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers.

[10] CMS notes that with respect to billing for observation services, all existing requirements must be met as set forth in the Medicare Claims Processing Manual, Ch. 4, Sec. 290.

services in person, including practitioners that typically provide services in a hospital outpatient department. This policy is in effect from March 1, 2020 through the duration of the COVID-19 PHE. CMS-1744-IFC did not include any provision that would permit hospitals to submit any claim for such a service.

Under ordinary circumstances, a hospital receives an originating site facility fee when a patient receives telehealth services at a hospital outpatient department from a distant site practitioner. Through this IFC, during the COVID-19 PHE hospitals can bill and receive payment for the originating site facility fee when a practitioner that ordinarily practices in the hospital's outpatient department provides a telehealth service to a patient at home, if the home is made provider-based to the hospital. Hospitals should only furnish hospital outpatient services to a registered hospital outpatient at home after the patient's home has been made provider-based, due to the nontraditional nature of the home as a PBD and potential interactions with other types of providers or suppliers in the home.

c. Medical Education

Under ordinary circumstances, teaching hospitals, inpatient rehabilitation facilities (IRFs), and inpatient psychiatric facilities (IPFs) receive a formula-based increase in payment to account for higher costs of teaching facilities relative to non-teaching facilities. While the formulae differ for hospitals, IRFs, and IPFs, they include (among other factors) a ratio based on the number of full-time equivalent (FTE) residents training at the facility compared to a denominator. For hospitals, the denominator is the number of inpatient beds. For IRFs and IPFs, the denominator is the facility's average daily census (ADC). As such, an increase in inpatient beds or ADC would generally result in reduced payments for teaching facilities. In response to the COVID-19 pandemic, CMS is changing its policies to mitigate the effect of expanded operations on payments for teaching facilities.

i. Holding Hospitals Harmless from Reductions in Indirect Medical Education (IME) Payments Due to Increases in Bed Counts Due to COVID-19

Teaching hospitals receive an IME payment adjustment based on the ratio of the hospital's number of allowable FTE residents to the number of inpatient hospital beds. Many hospitals are increasing their number of inpatient beds to accommodate the increase in COVID-19-related patients. To mitigate IME payment changes from pre-COVID-19 levels, a hospital's IME payment amount will be calculated using the hospital's bed count from the day before the COVID-19 PHE was declared for the duration of the COVID-19 PHE.

ii. Holding IRFs and IPFs Harmless from Reductions to Teaching Status Adjustment Payments Due to COVID-19

IRFs and IPFs receive a teaching status adjustment payment based on the ratio of the facility's number of FTE residents to the facility's ADC. Many IRFs and IPFs are accepting patients from inpatient acute care hospitals to alleviate bed capacity during the COVID-19 PHE, which can result in an increase in the facility's ADC. To prevent payment reductions based on an artificial decrease to the IRF's or IPF's resident to ADC ratio, teaching status adjustment payments will be the same as it was on the day before the COVID-19 PHE was declared for the duration of the COVID-19 PHE.

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

In addition to IME payments, teaching hospitals receive Medicare payments for the direct costs of approved Graduate Medical Education (GME) programs. The formulae for IME and direct GME (DGME) payments both account for the number of allowable FTE residents. Generally, the greater the number of FTE residents

a hospital counts, the greater the amount of Medicare DGME and IME payments the hospital will receive, subject to a cap.

Under ordinary circumstances, a hospital cannot claim the time spent by residents training at another hospital for purposes of DGME or IME payments. In order to provide teaching hospitals flexibility to determine resident training on an emergency basis to respond to workforce challenges during the COVID-19 PHE, CMS is revising DGME and IME regulations to allow teaching hospitals to claim time spent by residents training at other hospitals during the COVID-19 PHE. If the teaching hospital to which a resident is assigned sends the resident to another hospital and claims the resident's time, no other hospital, teaching or non-teaching, would be able to claim that time. Also, during the COVID-19 PHE, the presence of residents in non-teaching hospitals will not trigger establishment of per resident amounts or FTE resident caps at those non-teaching hospitals.

Further, the following requirements must be met in order for a hospital that sends residents to another hospital to claim those FTE residents on its Medicare cost report:

- The resident must be sent from the teaching hospital to another hospital in response to the COVID-19 pandemic. This requirement would be met if either the sending or receiving hospital are treating COVID-19 patients. The resident does not have to be involved in patient care activities for patients with COVID-19.
- Time spent by the resident at the receiving hospital would be considered to be time spent in approved training if the activities performed by the resident at the other hospital are consistent with any guidance in effect during the COVID-19 PHE for the approved medical residency program at the sending hospital.
- The time that the resident spent training immediately prior to and/or subsequent to the timeframe that the PHE associated with COVID-19 was in effect was included in the sending hospital's FTE resident count.

Because of other flexibilities in effect for the duration of the COVID-19 PHE, resident time spent in temporary expansion sites of a receiving hospital and time spent at locations providing inpatient services under arrangements for a receiving hospital are not treated any differently than time spent at the receiving hospital generally.

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

The Hospital VBP Program ECE Policy is intended to mitigate any adverse impact on quality performance as a direct result of unforeseen extraordinary circumstances outside of the hospital's control, including natural disasters and other extraordinary circumstances, and the resulting impact on their value-based incentive payment amounts. In prior rulemaking, CMS interpreted the requirement related to the minimum number of cases and measures (SSA 1886(o)(1)(C)(ii)(III) and IV)) to not include any measures or cases for which a hospital has submitted data during a performance period for which the hospital is granted a Hospital VBP Program ECE. If a hospital that is granted an ECE still reports the minimum number of cases and measures required for the program year after excluding the excepted data, the hospital will still receive a Total Performance Score (TPS) calculated without the use of the excepted quality data.

Under ordinary circumstances, a hospital must submit the designated request form to obtain an ECE. CMS is revising ECE regulations to include the ability for CMS to grant exceptions to hospitals located in entire regions or locales, which could include the entire United States, without a request where it determines that

the extraordinary circumstance has affected the entire region or locale. This revision is not limited to the COVID-19 PHE.

If CMS grants an ECE to hospitals located in an entire region or locale under this revised policy and, as a result of granting that ECE, a hospital does not report the minimum number of cases and measures required to calculate a TPS for that hospital, the hospital will be excluded from the Hospital VBP Program for the applicable program year. A hospital that does not report the minimum number of cases or measures for a program year will not receive a two percent reduction to its base operating diagnosis-related group (DRG) payment amount for each discharge in the applicable program year, and will also not be eligible to receive any value-based incentive payments for the applicable program year.

Further, CMS is exercising this new authority to grant an ECE with respect to the COVID-19 PHE to all hospitals participating in the Hospital VBP Program for the following reporting requirements:

- Hospitals will not be required to report National Healthcare Safety Network (NHSN) Healthcare-associated Infection (HAI) measures and HCAHPS survey data for the following calendar quarters: Q4 2019; Q1 2020; and Q2 2020. However, hospitals can optionally submit part or all of these data.
- CMS will exclude qualifying claims data from the mortality, complications, and Medicare Spending per Beneficiary measures for the following calendar quarters: Q1 2020; and Q2 2020.

III. Rural Health Clinics (RHCs)

Under ordinary circumstances, RHCs are paid an all-inclusive per-visit rate for medically necessary, face-to-face visits with an RHC practitioner. Generally, RHCs are subject to a per-visit payment limit, but are exempt from such payment limit when the RHC is provider-based to a hospital that has less than 50 beds. To respond to the COVID-19 pandemic and the resulting surge in need for inpatient care, many hospitals are increasing inpatient bed capacity. For the duration of the COVID-19 PHE, hospital bed count for the purpose of determining whether a provider-based RHC is subject to the payment limit will be the number of beds from the cost reporting period prior to January 27, 2020 (the effective date of the COVID-19 PHE as determined by HHS).

IV. Physicians

a. Additional Flexibility under the Teaching Physician Regulations

Through CMS-1744-IFC, CMS provided flexibilities regarding PFS payment for teaching physicians and residents. Following stakeholder feedback to those changes, CMS is making the following changes to apply for the duration of the COVID-19 PHE:

- Clarifying technical edits to reflect the audio/video real-time requirement for communications technology (42 CFR 415.172, 415.174, 415.180, and 415.184).
- Reinstating 42 CFR 415.174(b), which was inadvertently deleted, and adding a new paragraph 415.174(c) to allow that the teaching physician may not only direct care furnished by residents, but also review the services provided with the resident, during or immediately after the visit, remotely through virtual means via audio/video real-time communications technology.
- Permitting PFS payment to the teaching physician for the following additional services when furnished by a resident under the primary care exception: CPT codes 99441-99443, 99495-99496, 99421-99423, and 99452; and HCPCS codes G2010 and G2012.
- Clarifying that the office/outpatient E/M level selection for services under the primary care exception when furnished via telehealth can be based on the MDM or time (defined as all of the

time associated with the E/M on the day of the encounter). The requirements regarding documentation of history and/or physical exam in the medical record do not apply. As noted above, the typical times for level selection are the times listed in the CPT code descriptor.

CMS also clarifies that the teaching physician: (1) must have no other responsibilities at the time; (2), assume management responsibility for the beneficiaries seen by the residents; (3) ensure the services furnished are appropriate; and (4) review with each resident during or immediately after each visit the beneficiary's medical history, physical examination, diagnosis, and record of tests and therapies (42 CFR 415.174(a)(3)).

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

CMS believes that clinicians treating COVID-19 patients should not be burdened with submitting data to a QCDR for purposes of measure assessment (i.e., testing and data collection). Therefore, CMS is amending the QCDR measure approval criteria previously finalized in the 2020 PFS final rule as follows:

i. Completion of QCDR Measure Testing

The 2020 PFS final rule required that beginning with the 2021 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 (42 CFR 414.1400(b)(3)(v)(C)). CMS is delaying implementation of this policy by one year so that it begins with the 2022 performance period.

ii. Collection of Data on QCDR Measures

Similar to the completion of QCDR measure testing, CMS also is delaying implementation of the QCDR measure data collection (originally scheduled to begin with the 2021 performance period), by one year (42 CFR 414.1400(b)(3)(v)(D)). The requirement for QCDRs to collect data on a QCDR measure prior to submitting the measure for CMS consideration during the self-nomination period will begin with the 2022 performance period.

iii. CMS Activity During Delay

During the delay of measure testing and data collection, CMS will continue to review QCDR measures as they have in past years, including assessing measures for potential risk of patient harm (e.g., QCDR measures that promote clinical practices related to overuse) and to ensure measures are valid and identify performance gaps in the area of measurement. CMS also will continue to review QCDR measures for feasibility and accuracy and reliability of results and review QCDR-provided evidence (e.g., clinical studies, scientific journals) that would support the need for measurement in lieu of insufficient data collection to demonstrate that there is a measurement gap.

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

In the 2020 PFS final rule, CMS finalized an add-on code describing periodic assessments furnished by OTPs. The finalized HCPCS add-on code is G2077 (periodic assessment; assessing periodically by qualified personnel to determine the most appropriate combination of services and treatment). These services can be furnished by a program physician, a primary care physician, or an authorized healthcare professional under the supervision of a program physician or qualified personnel such as NPs and PAs. Other assessments can be furnished by practitioners who are eligible to do so under their state law and

scope of licensure. To bill for the add-on code, the services must be medically reasonable and necessary and the OTP should document the rationale for billing the add-on code.

The CMS-1744-IFC revised 42 CFR 410.67(b)(3) and (4) to allow the therapy and counseling portions of the bundles to be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology during the COVID-19 PHE if beneficiaries do not have access to two-way audio/video communications technology, provided all other applicable requirements are met.

In addition to the flexibilities in the CMS-1744-IFC, CMS has determined it is necessary to revise 42 CFR 410.67(b)(7) to allow periodic assessments to be furnished during the COVID-19 PHE via two-way interactive audio-video communication technology. Additionally, 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 calls rather than via two-way interactive audio-video communication technology, provided all other applicable requirements are met.

CMS believes this change is necessary to ensure that beneficiaries with opioid use disorders are able to continue to receive these services during the COVID-19 PHE. CMS expects that OTPs will use clinical judgement to determine whether they can adequately perform the periodic assessment over audio-only phone calls, and if not, then they should perform the assessment with a two-way audio-video device or in person as clinically appropriate. The OTP should also document in the medical record the reason for and the substance of the assessment.

CMS also lists flexibilities offered to states from the Substance Abuse and Mental Health Services Administration to ensure that individuals being treated with medication for opioid use disorders can continue to receive their medication during the COVID-19 PHE. The list of guidance documents is below.

- OTP Guidance (March 16, 2020)[11]
- OTP Guidance for Patients Quarantined at Home with the Coronavirus[12]
- FAQs: Provision of Methadone and Buprenorphine for the Treatment of Opioid Use Disorder in the COVID-19 Emergency[13]
- COVID-19 Public Health Emergency Response and 42 CFR Part 2 Guidance[14]
- Considerations for the Care and Treatment of Mental and Substance Use Disorders in the COVID-19 Epidemic: March 20, 2020[15]

V. Post-Acute Care Providers

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

In the applicable fiscal year and calendar year 2020 payment rules, CMS adopted certain quality measures for IRFs, LTCHs, HHAs, and SNFs. These include Transfer of Health (TOH) Information to Provider-Post-Acute Care and TOH Information to Patient-Post-Acute Care quality measures (collectively, the TOH

[11] See: https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf.
[12] See: https://www.samhsa.gov/sites/default/files/otp-covid-implementation-guidance.pdf.
[13] See: https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf.
[14] See: https://www.samhsa.gov/sites/default/files/covid-19-42-cfr-part-2-guidance-03192020.pdf.
[15] See: https://www.samhsa.gov/sites/default/files/considerations-care-treatment-mental-substance-use-disorders-covid19.pdf.

Information Measures), and standardized patient assessment data elements (SPADEs). To reduce provider burden during the COVID-19 PHE, CMS is delaying the data collection start dates for these measures as set forth in the table below.

CMS is also delaying the release of updated versions of the IRF Patient Assessment Instrument (IRF-PAI), LTCH Continuity Assessment Record and Evaluation Data Set (LTCH CARE Data Set), and HHA's Outcome and Assessment Information Set (OASIS) Instrument to reduce the burden on these providers that would otherwise need to implement before the October 1, 2020 and January 1, 2021 data collection periods. CMS already delayed, and is further delaying, the release of the updated version of the SNF Minimum Data Set (MDS) that SNFs would need to implement before the October 1, 2020 data collection period.

Facility Type	Reporting Rule Source	Original Data Collection Start Date		Delayed Data Collection Start Date		Assessment instrument for new quality measures
		TOH Information Measures	SPADEs	TOH Information Measures	SPADEs	
IRF	FY 2020 IRF PPS final rule	10/1/2020 (discharges)	10/1/2020 (admissions & discharges)	10/1 at least 1 full FY after COVID-19 PHE ends[16]	10/1 at least 1 full FY after COVID-19 PHE ends	IRF-PAI V4.0[17]
LTCH	FY 2020 IPPS/ LTCH PPS final rule	10/1/2020 (discharges)	10/1/2020 (admissions & discharges)	10/1 at least 1 full FY after COVID-19 PHE ends	10/1 at least 1 full FY after COVID-19 PHE ends	LTCH CARE Data Set V5.0[18]
HHA	CY 2020 HH PPS final rule	1/1/2021 (discharges & transfers)	1/1/2021 (start/ resumption of care & discharges)	1/1 at least 1 full CY after COVID-19 PHE ends[19]	1/1 at least 1 full CY after COVID-19 PHE ends	OASIS-E[20]
SNF	FY 2020 SNF PPS final rule	10/1/2020 (discharges)	10/1/2020 (admissions & discharges)	10/1 at least 2 full FYs after COVID-19 PHE ends[21]	10/1 at least 2 full FYs after COVID-19 PHE ends	MDS 3.0 v1.18.1[22]

b. Home Health

i. Reporting Under the Home Health Value-Based Purchasing Model (HHVBP) for CY 2020 During the COVID-19 PHE

CMS is implementing a policy to align the Home Health Value-Based Purchasing (HHVBP) Model[23] data submission requirements with any exceptions or extensions granted for purposes of the Home Health

[16] For example, if the COVID-19 PHE ends on September 20, 2020, data collection would begin October 1, 2021.
[17] IRF Patient Assessment Instrument (IRF-PAI). IRF-PAI V3.0 has been in use since October 1, 2019.
[18] LTCH Continuity Assessment Record and Evaluation (LTCH CARE) Data Set. LTCH CARE Data Set V4.0 has been in use since October 1, 2019.
[19] For example, if the COVID-19 PHE ends September 20, 2020, data collection would begin January 1, 2022.
[20] Outcome and Assessment Information Set (OASIS) Instrument. OASIS-D has been in use since January 1, 2019.
[21] For example, if the COVID-19 PHE ends September 20, 2020, data collection would begin October 1, 2022.
[22] Minimum Data Set (MDS). MDS 3.0 v1.17.1 has been in use since October 1, 2019.
[23] The HHVBP Model is a mandatory model for HHAs in Arizona, Florida, Iowa, Nebraska, North Carolina, Tennessee, Maryland, Massachusetts, and Washington.

Quality Reporting Program (HH QRP) during the COVID-19 PHE. Where the data that are required to be reported for an HHVBP Model are the same data as those that are required to be reported for the HH QRP, the reporting timeframes for the HHVBP Model will be the same as for the HH QRP. As such, if CMS grants an exception or extension that either excepts HHAs from reporting certain quality data altogether, or otherwise extends the deadlines by which HHAs must report those data, the same exceptions and extensions apply to the submission of those data for the HHVBP Model.

On March 27, 2020, CMS issued guidance that excepted HHAs from reporting any HH QRP data for the following 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 policy set forth in the IFC, HHAs in the HHVBP Model are not required to separately report measure data for these quarters for the HHVBP Model.

Further, CMS is implementing a policy to allow CMS to grant exceptions or extensions to New Measure reporting for HHAs participating in the HHVBP Model during the COVID-19 PHE. In accordance with this policy, CMS is granting an exception to HHVBP Model participants for New Measure reporting requirements for the April 2020 and July 2020 New Measures submission periods (data from October 1, 2019 – March 31, 2020 and April 1, 2020 – June 30, 2020, respectively).

ii. Care Planning for Medicare Home Health Services

CMS is promulgating regulations to implement certain provisions of the Coronavirus Aid, Relief, and Economic Security (CARES) Act to allow NPs, CNSs, and PAs to practice at the top of their state licensure to certify eligibility for home health services, as well as establish and periodically review the home health plan of care. These regulations are effective retroactive to March 1, 2020 and are not time limited to the COVID-19 PHE. Specifically, CMS is implementing regulations as follows:

- NPs, CNSs, and PAs may order and certify patients for eligibility under the Medicare home health benefit.
- Physicians, NPs, CNSs, and PAs may establish and periodically review the home health plan of care where such services are or were furnished while the individual was under the care of a physician, NP, CNS, or PA.
- NPs, CNSs, PAs, and CNMs may establish HHA policies that govern the services (and supervision of such services) provided to patients under the Medicare home health benefit, as well as certify that an individual has suffered a bone fracture related to post-menopausal osteoporosis and that the individual is unable to self-administer the osteoporosis drug.
- NPs, CNSs, and PAs may prescribe items and services under the home health prospective payment system (HH PPS).

CMS is modifying regulations to reflect that it expects that the practitioner that certifies home health eligibility would also perform the face-to-face encounter for the patient; however, if a face-to-face encounter is performed by an allowed NPP in an acute or post-acute facility from which the patient was directly admitted to home health, the certifying practitioner may be different from the practitioner performing the face-to-face encounter. These changes are not limited in duration to the COVID-19 PHE.

NPs, CNSs, and PAs continue to be subject to state law with respect to licensure, scope of practice, and supervision requirements.

iii. Improving Care Planning for Medicaid Home Health Services

Section 3708(e) of the CARES Act requires that the Medicare home health services amendments under Section 3708 be applied in the same manner and to the same extent under Medicaid as well. Medicare and Medicaid home health benefits have structural differences which require some adaptation to implement this statutory directive. Significantly, the Medicare home health benefit does not include durable medical equipment (DME), because DME is a separate benefit under Medicare. Conversely, the Medicaid home health benefit includes DME.

In order to align the Medicare and Medicaid home health benefits, including with respect to the ordering requirements for DME, CMS is amending Medicaid home health regulations to expand the list of practitioners that may order home health services for Medicaid beneficiaries to include NPs, CNSs, and PAs. CMS is also amending the Medicaid home health regulations to expand the list of NPPs who may order DME to align with the Medicare DME benefit to include "a licensed practitioner of the healing arts acting within the scope of practice authorized under state law."

These regulatory amendments are not limited in duration to the COVID-19 PHE.

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

Consistent with the expanded role of NPPs in home health services as set forth above, CMS is amending the conditions for payment of claims for home health services at 42 CFR 424.507(b)(1) to permit PAs, NPs, and CNSs to order and certify home health services. This regulatory amendment is not limited in duration to the COVID-19 PHE.

c. Inpatient Rehabilitation Facilities (IRFs)

Through CMS-1744-IFC, CMS provided a clarification regarding the "3-hour rule" (42 CFR 412.622(a)(3)(ii)). Specifically, CMS-1744-IFC removed the requirement to complete a post-admission physician evaluation during the COVID-19 PHE (42 CFR 412.622(a)(4)(ii)). Section 3711(a) of the CARES Act requires HHS to waive the 3-hour rule during the COVID-19 PHE. This waiver was issued on April 15, 2020.[24] Because the CARES Act more directly and comprehensively addressed the 3-hour rule, the clarification in the CMS-1744-IFC is moot. Additionally, the waiver required by the CARES Act is not limited to particular IRFs or patients, and therefore, is available during the COVID-19 PHE regardless of whether a patient was admitted for standard IRF care or to relieve acute hospital capacity. In light of these changes, CMS is waiving the 3-hour rule to reflect the waiver required by the CARES Act.

IRF care is only considered by Medicare to be reasonable and necessary under federal law if the patient meets all of the IRF coverage requirements (42 CFR 412.622(a)(3), (4), and (5)). Failure to meet the IRF coverage criteria in a particular case results in denial of the IRF claim. Furthermore, CMS believes that all IRFs should have to comply with the requirements at 42 CFR 412.29(d), (e), (h), and (i) and 42 CFR 412.622(a)(3), (4), and (5). However, the agency also recognizes that there are certain institutional differences between freestanding IRF hospitals and IRF units in acute care hospitals that may impose barriers on freestanding IRF hospitals seeking to admit patients to relieve hospital capacity during the COVID-19 PHE. Specifically, freestanding IRF hospitals do not have the same close affiliations with acute care hospitals that IRF units in acute care hospitals have, and are not as able to establish billing procedures under the Inpatient Prospective Payment System (IPPS) as are IRF units in acute care hospitals by virtue of the fact the that the IRF units have access to their parent hospitals' billing departments. Therefore, CMS is amending the requirements at 42 CFR 412.29(d), (e), (h), and (i) and 42 CFR 412.622(a)(3), (4), and (5) to

[24] See: https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf.

add an exception for care furnished to patients admitted to freestanding IRF hospitals (identified as those facilities with the last 4 digits of their Medicare provider numbers between 3025 through 3099) solely to relieve acute care hospital capacity during the COVID-19 PHE.

CMS believes freestanding IRF hospitals need the flexibility during the COVID-19 PHE to determine the best care for each patient admitted solely for the purposes of relieving acute care hospital capacity consistent with the *Guidelines for Opening Up America Again* (Guidelines).[25] The flexibilities in this IFC are available for IRF hospitals admitting patients in support of acute care hospitals when the state is in phase 1 or prior to entering phase 1, but will not be available to freestanding IRF hospital when the state is in phase 2 or phase 3 of the Guidelines.[26] These flexibilities only apply to patients admitted to relieve acute care hospital capacity issues and will 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. Freestanding IRF hospitals must document the particular phase for the state when admitting the patient and electing to exercise these flexibilities.

For billing purposes, CMS is requiring freestanding IRF hospitals to append the "DS" modifier to the end of the IRF's unique patient identifier number to identify patients who are being treated solely to alleviate inpatient bed capacity in a state that is expecting a surge during the COVID-19 PHE. The modifier will be used to identify patients for whom the requirements at 42 CFR 412.622(a)(3)(i), (iii), (iv), (4), and (5) do not apply. Freestanding IRF hospitals will be paid at the IRF prospective payment system (PPS) rates for patients with the "DS" modifier.

CMS anticipates that freestanding IRF hospitals will take advantage of these flexibilities and allow freestanding IRF hospitals to aid in the response to the COVID-19 pandemic in several ways. First, CMS expects that some patients that freestanding IRF hospitals care for during the COVID-19 PHE in a state that is experiencing a surge would need high-acuity clinical care but may not need or be able to tolerate the intensive rehabilitation therapy typically provided in an IRF. Second, waiving the documentation requirements for patients alleviating acute care hospital bed capacity allows freestanding IRF hospitals to concentrate on providing care for surge patients from the acute care hospitals in a state that is experiencing a surge, instead of completing documentation. Third, CMS also believes this will help freestanding IRFs maximize their available beds.

To implement these changes, CMS is amending its regulations to state that the following requirements do not apply to care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge during the COVID-19 PHE:

- Certain IRF coverage criteria (42 CFR 412.622(a)(3)(i), (ii), (iii), and (iv))
- The requirement for IRF documentation to be present in the IRF medical record (42 CFR 412.622(a)(4))
- The requirement for an interdisciplinary team approach to care (42 CFR 412.622(a)(5))

CMS is also amending 42 CFR 412.29(d), (e), (h), and (i) to align the provisions waived in 42 CFR 412.622 with the classification criteria for payment to freestanding IRF hospitals under the IRF PPS. Lastly, CMS is amending 42 CFR 412.622(c) to add a definition of a state (or region, as applicable) that is experiencing a surge and 42 CFR 412.29 to cross-reference that definition where applicable. The definition of a "state (or region, as applicable) that is experiencing a surge" means a state or region that is in phase 1 of the

[25] See: https://www.whitehouse.gov/openingamerica/.
[26] The guidelines outline a three-phase approach for re-opening states. Phase 1 is the most restrictive phase while phases 2 and 3 are less restrictive.

Guidelines. Specifically, a state or region must implement all of the following state/region policies, as determined by applicable state and local officials:

- All vulnerable individuals continue to shelter in place.
- Individuals continue social distancing.
- Individuals avoid socializing in groups of more than 10.
- Non-essential travel is minimized.
- Visits to senior living facilities and hospitals are prohibited.
- Schools and organized youth facilities remain closed.

d. Nursing Homes

Federal law requires long-term care (LTC) facilities, including Medicaid nursing facilities and Medicare skilled nursing facilities (SNFs), to develop and maintain an infection control program that is designed, constructed, equipped, and maintained in a manner to protect the health and safety of residents, personnel, and the general public.

Also, HHS may issue necessary regulations to protect the health and safety of residents. Existing regulations require facilities to, among other things, establish and maintain an infection prevention and control program (PCP) designed to provide a safe, sanitary, and comfortable environment and to help prevent the transmission of communicable diseases. Furthermore, federal regulations require facilities to have written standards, policies, and procedures for the program to include a system that identifies communicable diseases and to whom to report when an incident arises.

In an effort to improve surveillance of COVID-19 cases, CMS is revising the requirements to establish reporting requirements for confirmed or suspected cases. Specifically, CMS is revising the requirements by adding a new provision at 42 CFR 483.80(g)(1), to require facilities to electronically report information about COVID-19 in a standardized format specified by HHS. The report must include, but is not limited to, information on:

- Suspected and confirmed COVID-19 infections among residents and staff, including residents previously treated for COVID-19;
- Total deaths and COVID-19 deaths among residents and staff;
- Personal protective equipment and hand hygiene supplies in the facility;
- Ventilator capacity and supplies available in the facility;
- Resident beds and census;
- Access to COVID-19 testing while the resident is in the facility;
- Staffing shortages; and
- Other information specified by the HHS Secretary.

This information will be used to monitor infection rates and inform public health policies.

Additionally, facilities are required to provide the information specified above at a frequency set by HHS, but not less than weekly, to the Centers for Disease Control and Prevention's National Healthcare Safety Network (42 CFR 483.80(g)(2)). This information will be shared with CMS and will be publicly reported.

CMS also notes that this policy may help the agency respond to the various COVID-19-related Freedom of Information Act requests. The new reporting requirements do not relieve LTC facilities of the existing obligations to report possible incidents of communicable disease and infections (42 CFR 483.80(a)(2)(ii)). LTCs must still comply with state and local reporting requirements for COVID-19.

CMS is also adding a new provision to require facilities to inform residents, their representatives, and families of those residing in facilities ("applicable parties") of confirmed or suspected COVID-19 cases in the facility among residents and staff (42 CFR 483.80(g)(3)). This reporting requirement is intended to support the overall health and safety of residents by ensuring they are informed participants in the care that they receive as well as providing assurances of the mitigating steps the facility is taking to prevent and control the spread of COVID-19. Facilities must inform the applicable parties by 5:00 p.m. the next calendar day following the occurrences 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" to the applicable parties must be provided weekly by 5:00 pm the next calendar day following the subsequent occurrence of either: (1) each time a confirmed infection of COVID-19 is identified; or (2) whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other. The information must be reported in accordance with existing privacy regulations and statutes and not include personally identifiable information. Facilities must include information on mitigating actions to prevent or reduce the risk of transmission, including if normal operations in the nursing home will be altered.

These requirements will be effective when the rule is published on the Federal Register (expected May 8, 2020). While these regulatory changes are specific to the COVID-19 disease, they are not limited in duration to the COVID-19 PHE.

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

CMS notes that section 3712 of the CARES Act revised the fee schedule amounts for certain DME and enteral nutrients, supplies, and equipment furnished in non-competitive bidding areas (CBAs) other than former CBAs during the COVID-19 PHE.

Specifically, CARES Act 3712(a) continues CMS' current policy of paying for DME, prosthetics, orthotics, and supplies (DMEPOS) items and services furnished in rural and non-contiguous non-CBAs based on a 50/50 blend of adjusted and unadjusted fee schedule amounts through December 31, 2020 (42 CFR 414.210(g)(9)(iii)), or through the duration of the emergency period, whichever is longer.

CARES Act 3712(b) directs HHS to increase the fee schedule amounts for DMEPOS items and services furnished in non-CBAs other than rural and non-contiguous non-CBAs through the duration of the COVID-19 PHE. In accordance with this change to 42 CFR 414.210(g)(9)(iv), CMS is required to pay for such DMEPOS items and services based on 75 percent of the adjusted fee schedule amount and 25 percent of the historic, unadjusted fee schedule amount for the duration of the COVID-19 PHE (instead of based on 100 percent of the unadjusted fee schedule amount). According to CMS, this will increase payments approximately 33 percent.

Fee schedule amounts in former CBAs (42 CFR 414.210(g)(10)) 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.

CMS believes the implementation date in CARES Act 3712(b) is ambiguous. However, because CMS believes the purpose of the law is to aid suppliers in furnishing items, 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. In addition, the CARES Act does not specify the fee schedule amounts that should be in effect if the emergency ends prior to December 31, 2020. Therefore, CMS is specifying at 42 CFR 414.210(g)(9)(v) that the fee schedule amounts in non-rural and contiguous non-CBAs will again be based on 100 percent of the adjusted fee schedule amounts should the COVID-19 PHE end before December 31, 2020 (instead of based on 75 percent of the adjusted payment amount and 25 percent of the unadjusted fee schedule amount).

VII. Clinical Laboratories

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

CMS anticipates needing to test many Medicare beneficiaries quickly as part of the rapid expansion of COVID-19 testing capacity, and it is concerned that not all Medicare beneficiaries have access to a doctor to obtain a COVID-19 laboratory test. CMS expects more states to authorize pharmacists and other qualified healthcare professionals to order COVID-19 testing in the near future. The agency is amending regulations to modify ordering and documentation requirements.

Under ordinary circumstances, a Medicare-covered diagnostic laboratory test must be ordered by a treating physician or NPP (42 CFR 410.32(a) and (a)(2)). During the COVID-19 PHE, CMS is amending its regulation at 42 CFR 410.32(a) regarding an order for a diagnostic laboratory test to remove the requirement that certain diagnostic tests are covered only based on the order of a treating physician or NPP. Under this interim policy, during the COVID19 PHE, COVID-19 tests may be covered when ordered by any healthcare professional authorized to do so under state law.

Additionally, because the symptoms for influenza and COVID-19 might present in the same way, during the COVID-19 PHE, CMS is also removing the same ordering requirements for a diagnostic laboratory test for influenza virus and respiratory syncytial virus, a type of common respiratory virus. CMS will make a list of diagnostic laboratory tests for which we are removing the ordering requirements publicly available. When COVID-19 diagnostic laboratory testing becomes sufficiently prevalent, sensitive, and specific such that laboratory tests for influenza or related respiratory conditions are no longer needed to establish a definitive COVID-19 diagnosis, CMS expects that additional testing for influenza or related respiratory viral illness no longer will be medically necessary.

b. Flexibility for Medicaid Laboratory Services

Section 6004(a) of the Families First Coronavirus Response Act requires Medicaid to cover in vitro diagnostic products for the diagnosis of COVID-19 or the detection of the SARS-CoV-2 virus, and subsequent guidance from CMS extended this requirement to SARS-CoV-2 serologic testing.[27] Under ordinary circumstances, a Medicaid-covered laboratory or X-ray service must be ordered and provided by or under the direction of a physician or other licensed practitioner of the healing arts within the scope of his or her practice as defined by state law, or ordered by a physician but provided by a reference laboratory. Further, Medicaid will cover a laboratory or X-ray service only if provided in an office or similar facility other than a hospital outpatient department or clinic, and only if they are furnished by a laboratory certified under the Clinical Laboratory Improvement Amendments (42 CFR part 493). CMS believes that these requirements could present an obstacle to Medicaid coverage of a test where specimen collection is done in non-office settings or for which a specimen is self-collected by a Medicaid beneficiary.

[27] See: FAQs on Families First Act and CARES Act (Apr. 12) (https://www.cms.gov/files/document/FFCRA-Part-42-FAQs.pdf.

CMS is adding a new subsection (d) at 42 CFR 440.30 to permit Medicaid coverage for laboratory tests and X-ray services that do not meet the physician or NPP order requirements or the in-office administration requirements so long as the purpose of the laboratory or X-ray service is to diagnose or detect SARS-CoV-2, antibodies thereof, COVID-19, or a communicable disease named in a future PHE, and so long as the deviation from such requirements is intended to avoid transmission of the communicable disease. Coverage includes laboratory processing of self-collected laboratory tests authorized by the FDA.

Coverage for such services during the COVID-19 PHE begins retroactive to March 1, 2020 and continues for the duration of the PHE, as well as during subsequent periods of active surveillance. The flexibilities in the new subsection (d) would be available during any future PHE resulting from an outbreak of communicable disease, and during any subsequent period of active surveillance.

i. Comment Solicitation

The IFC defines a "period of active surveillance" as an "outbreak of communicable disease during which no approved treatment or vaccine is widely available, and it ends on the date the Secretary terminates it, or the date that is two incubation periods after the last known case of the communicable disease, whichever is sooner." CMS seeks comment on the proposed definition.

The new regulatory text does not provide flexibility regarding the requirement that laboratory services must be furnished by a CLIA-certified laboratory, but CMS is soliciting comment on whether continuing to apply this requirement would present any obstacle to providing Medicaid coverage for COVID-19 testing.

c. COVID-19 Serology Testing

CMS is finalizing on an interim basis that FDA-authorized COVID-19 serology tests fall under the Medicare benefit category of diagnostic laboratory tests when furnished to those with known or suspected current or prior COVID-19 infection (42 USC 1395x(s)(3)). CMS believes that having COVID-19 serology test results is useful to individual patients, their practitioners, and their communities because it could change the decisions Medicare beneficiaries make for themselves and influences practitioner management of the beneficiaries' medical treatment. This policy is effective retroactive to January 27, 2020 through the duration of the COVID-19 PHE.

VIII. Medicare Shared Savings Program (MSSP)

CMS believes it is vital to encourage continued participation by accountable care organizations (ACOs) to ensure the MSSP remains stable. During the COVID-19 PHE, CMS is modifying MSSP policies to:

- Provide ACOs whose current agreement period expires on December 31, 2020 the option to extend their existing agreement period by one year, and allow BASIC Track ACOs the option to maintain their current level of participation for PY 2021;
- Clarify the applicability of the extreme and uncontrollable circumstances policy to mitigate shared losses during the COVID-19 PHE;
- Adjust program calculations to mitigate the impact of COVID-19 on ACOs; and
- Expand the definition of primary care services for determining beneficiary assignment to include telehealth codes for virtual check-ins, e-visits, and telephonic communication.

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

CMS is forgoing the application cycle for the January 1, 2021 start date (the 2021 application cycle). ACOs that entered a first or second agreement period with a start date of January 1, 2018 may extend their agreement period for an optional fourth performance year, from January 1, 2021 to December 31, 2021 (42 CFR 425.200(b)(3)(ii)). If extended, eligible ACOs will remain under their existing historical benchmark for an additional year. ACOs that choose not to extend the agreement period would conclude participation in the program once the current agreement period expires (December 31, 2020).

By forgoing the 2021 application cycle, 2020 will not serve as benchmark year 3 for the cohort of ACOs that would otherwise start January 1, 2021. Because benchmark year 3 is given the highest weight of the three benchmark years, CMS is canceling the 2021 application cycle for new applicants so there is additional time to consider and develop approaches to further mitigate the role of 2020 as a benchmark year given the COVID-19 PHE. CMS notes that the optional 12-month agreement period extension is a one-time exception for ACOs with agreements expiring on December 31, 2020, and will not be available to other ACOs or to future program entrants. CMS anticipates that eligible ACOs will be able to extend their agreements starting June 18, 2020, with the anticipated final date to make the election will be September 22, 2020. CMS will provide additional guidance for making this election.

An ACO that elects to extend its participation pursuant to this IFC must require its ACO participants, ACO providers/suppliers, and other individuals/entities performing functions or services related to ACO activities during performance year 2021 to comply with the program's requirements through December 31, 2021. Specifically:

- CMS will consider an ACO to be in compliance with 42 CFR 425.210(a) (that an ACO must provide a copy of its participation agreement with CMS to all ACO participants, individuals, and entities) if it notifies these parties that it will continue to participate for an additional year.
- All contracts or agreements must require compliance with the required MSSP conditions including, but not limited to, those specified in the participation agreement with CMS (42 CF 425.116(a)(3) and 425.116(b)(3)). To remain compliant, an ACO may need to extend the duration of its agreements with ACO participants and providers/suppliers.

While CMS is forgoing the 2021 application cycle, CMS notes that eligible, currently participating ACOs may apply for the SNF 3-day waiver rule (42 CFR 425.612(a)(1)(i)), apply to establish a beneficiary incentive program (42 CFR 425.304(c)(2)), modify ACO participant and/or SNF affiliate lists (42 CFR 425.118(b) and 425.612(a)(1)(i)(B)), and elect to change their assignment methodology for performance year 2021 (42 CFR 425.226(a)(1)). In addition, an ACO participating under the BASIC Track may elect to transition to a higher level of risk and potential reward other than what the ACO would automatically be transitioned to for performance year 2021 (absent the flexibility described in the following section).

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

CMS states that it has concerns that some ACOs, particularly those that would automatically transition to Level C of the BASIC Track, will not be able to establish a repayment mechanism prior to performance year 2021 due the resource intensity of responding to the COVID-19 PHE. CMS also is concerned that COVID-19 is interrupting ACO care coordination processes and believes that it is unknown how COVID-19 will impact expenditures or beneficiary populations and the potential for losses under risk arrangements.

Because of these concerns, CMS is permitting ACOs in the BASIC Track to elect to maintain their current level for performance year 2021. If an ACO elects to maintain its current level, it will be advanced to the regularly scheduled track in performance year 2022 as if the ACO did not stay in its current level. For example, an ACO in Level B that elects to stay in Level B for performance year 2021 would automatically

advance to Level D for performance year 2022 (skipping Level C). The ACO also may elect to advance more quickly by moving to Level E (instead of Level D) for performance year 2022.

Similar to the flexibility provided for the 2021 application cycle, CMS anticipates that ACOs will be able to elect to maintain their participation level for performance year 2021 starting June 18, 2020, with the anticipated final election date being September 22, 2020. CMS will provide additional guidance on this process. If an ACO does not make this election, it will automatically advance to the next level (unless it elects to advance more quickly). This is a one-time exception for current MSSP ACO participants in the BASIC Track. CMS seeks comment on this advancement deferral options.

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

CMS revisits the CMS-1744-IFC policy of reducing the amount of an ACO's shared losses for purposes of performance year 2020 financial reconciliation by multiplying the shared losses by the percentage of total months in the performance year affected by an extreme and uncontrollable circumstance and the percentage of assigned beneficiaries residing in an impacted area (all assigned beneficiaries). However, CMS states that it inadvertently listed the timeframe start date as March 2020, inconsistent with the first month of the COVID-19 PHE (January 2020). Therefore, CMS is clarifying that the affected months will begin with January 2020 and continue through the end of the COVID-19 PHE.

d. Adjustments to MSSP Calculations to Address the COVID-19 Pandemic

i. Background

In each year of an MSSP agreement period, an ACO is eligible to receive payment for shared savings only if the estimated average per capita Medicare expenditures for Medicare Part A and Part B services, adjusted for beneficiary characteristics, is at least the percent specified below the applicable benchmark (SSA 1899(d)(1)(B)(ii)). In addition, CMS has authority to use alternative methodologies for determining performance year expenditures (SSA 1899(i)(3)). CMS has used this authority to update the historical benchmark and calculate performance year expenditures, and to establish the two-sided payment models and mitigate shared losses owed by ACOs affected by extreme and uncontrollable circumstances.

ii. Removing Payment Amounts for Episodes of Care for Treatment of COVID-19 from Expenditure and Revenue Calculations

CMS references section 3710 of the CARES Act, which increased the weighting factor that would otherwise apply to a COVID-19 positive patient's DRG by 20 percent (DRG adjustment). This change can have multiple impacts for ACOs, including unanticipated increased expenditures and impacts on future historical baselines that would not otherwise be present absent COVID-19. Therefore, CMS is excluding all Part A and Part B fee-for-service (FFS) payment amounts for COVID-19 treatments triggered by an inpatient service. CMS will remove COVID-19 related expenditures from determining an ACO's benchmark as described in a new provision at 42 CFR 425.611.

Specifically, CMS will identify a COVID-19 episode of care based on either: (1) discharges for inpatient services eligible for the DRG adjustment; or (2) discharges for acute care inpatient COVID-19 treatment services from facilities not paid under the IPPS when such admission occurs within the COVID-19 PHE. CMS provides an example of the ICD-10-CM codes it will use to identify discharges: B97.29 for discharges occurring on or after January 27, 2020 and on or before March 31, 2020; and U07.1 for discharges occurring on or after April 1, 2020 until the end of the COVID-19 PHE period.

In addition to excluding these expenditures, CMS also will exclude the affected months from total person years used in per capita expenditure calculations. CMS believes adjusting both expenditures and person years will ensure the numerator and denominator used to calculate per capita expenditures are based on the same number of months of beneficiary experience and will treat ACOs equitably, regardless of the degree to which their assigned beneficiary population is affected by COVID-19.

To implement these changes, the following MSSP calculations will exclude Part A and Part B payment amounts for COVID-19 treatment:

- FFS expenditures for all purposes (i.e., establishing, adjusting, updating, and resetting the ACO's historical benchmark and determining performance year expenditures);
- FFS expenditures for assignable beneficiaries used in determining county-level and national Medicare FFS expenditures;
- FFS revenue of ACO participants (for purposes of calculating the ACO's loss recoupment limit under the BASIC Track);
- FFS revenue of ACO participants and FFS expenditures for an ACO's assigned beneficiaries (for purposes of identifying whether an ACO is a high or low revenue ACO and determining an ACO's eligibility for participation options); and
- The ACO's repayment mechanism arrangement.

CMS notes that COVID-19-related payments that fall outside of Medicare FFS would not be utilized under the MSSP methodology for determining beneficiary expenditures. CMS also acknowledges that there may be trends and longer lasting effects of the COVID-19 pandemic. CMS will continue to evaluate and issue additional changes as necessary to further adjust MSSP policies. CMS seeks comment on this approach.

e. Expansion of Codes used in Beneficiary Assignment

CMS is revising the definition of primary care services used in the MSSP assignment methodology for the 2020 performance year, and for any subsequent performance year that starts during the COVID-19 PHE to including the following: (1) HCPCS code G2010 and G2012; and CPT codes 99421-99423, and 99441-99443. These codes are discussed above and in CMS-1744-IFC.

CMS also clarifies that CPT codes 99304-99306, 9931-99316, 99327-99328, 99334-99337, 99341-99345, and 9937-99350 will be included in the assignment methodology when they are furnished using telehealth (consistent with the additions to the Medicare telehealth list during the COVID-19 PHE as discussed in CMS-1744-IFC). CMS considered adding certain telephone assessment and management CPT codes (98966-98968) used by clinicians who may not independently bill for E/M visits. However, because these services are not furnished by ACO professionals (e.g., PTs, OTs, speech-language pathologists, clinical psychologists), CMS does not believe it is necessary to include those codes in the definition of primary care services.

The codes that were included in the March 1, 2020 COVID-19 covered telehealth services list (99304-99306, 99315-99316, 99327-99328, 99334-99337, 9934199346, 99347-99350) will continue to be included in the definition of primary care services used for beneficiary assignment, including when they are furnished via telehealth during the COVID-19 PHE.

f. Applicability of Policies to Track 1+ Model ACOs

CMS notes that unless otherwise stated in the Track 1+ Model Participation Agreement, the requirements of the MSSP under 42 CFR part 425 continue to apply. Therefore, unless otherwise specified, the changes established in this IFC that apply to the MSSP also apply to Track 1+ ACOs in the same way that they

apply to Track 1 ACOs (so long as the applicable regulation has not been waived under the Track 1+ Model). Similarly, to the extent certain MSSP requirements apply to Track 2 or the ENHANCED Track ACOs and have been incorporated for Track 1+ ACOs, changes to those regulations in this IFC also will apply to Track 1+ ACOs in the same way they apply to Track 2 or ENHANCED Track ACOs.

CMS provides the following examples of policies that apply to Track 1+ ACOs:

- Revisions to the definition of primary care services used in beneficiary assignment.
- Clarification that the total months affected by an extreme and uncontrollable circumstance for the COVID-19 PHE will begin with January 2020.
- Removing expenditures for episodes of care for COVID-19 treatment.
- Adjustments to revenue calculations to remove expenditures for episodes of care for COVID-19 treatment (this will be accomplished through an amendment to the Track 1+ Model Participation Agreement).

IX. Health Care Coverage and Insurers

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

CMS is 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 extension, QHP issuers must comply with the separate billing policy beginning on or before the QHP's first billing cycle following August 26, 2020 (42 CFR 156.280(e)(2)(ii)).

In the Patient Protection and Affordable Care Act; Exchange Program Integrity final rule (2019 Program Integrity Rule), CMS required individual market QHPs offering coverage for non-Hyde abortion services[28] to separately bill policyholders for the portion of their premium attributable to coverage of the non-Hyde abortion services. This policy was intended to align with the statutory requirements in section 1303 of the Patient Protection and Affordable Care Act, which requires non-Hyde abortion services be treated differently than other covered services. The 2019 Program Integrity Rule specified that QHPs must separately bill policyholders for non-Hyde abortion services and other covered services on or before the QHP issuer's first billing cycle following June 27, 2020.

HHS had previously provided enforcement discretion in two scenarios related to policyholder nonpayment of the separate bill for coverage of non-Hyde abortion services. Under the first scenario, HHS will not take enforcement action against a QHP issuer that adopts and implements a policy, applied uniformly to all its QHP enrollees, under which an issuer does not place an enrollee into a grace period and does not terminate QHP coverage based solely on the policyholder's failure to pay the separate payment for coverage of non-Hyde abortion services. Further, QHP issuers would still be prohibited from using federal funds for non-Hyde abortion services as well as be required to collect the premium for the non-Hyde abortion service coverage and not relieve the policyholder's duty of paying the related premium. This enforcement posture

[28] Non-Hyde abortion services cannot receive federal funding. The Hyde amendment permits federal funds to be used for abortion services only in the limited cases of rape, incest, or if a women suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself that would place the woman in danger of death unless an abortion is performed. See: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQ-on-Providing-Consumers-with-Details-on-Plan-Coverage-of-Certain-Abortion-Services.pdf.

would have taken effect upon the effective date of the separate billing requirements on June 27, 2020. Under the second scenario, HHS would not take enforcement action against QHP issuers that, on or after the effective date of the 2019 Program Integrity Rule (February 25, 2020), modify the benefits of a plan either at the time of enrollment or during a plan year to effectively allow enrollees to opt out of coverage of non-Hyde abortion services by not paying the separate bill for such services, resulting in an enrollee effectively having a modified plan that does not cover non-Hyde abortion services.

CMS acknowledged that the QHP issuer's or Exchange's ability to comply with the separate billing policy by August 26, 2020 may depend on the particular impact the COVID-19 PHE has on the resources, systems, and operations of the issuer or Exchange. CMS also noted that it is unclear how long the COVID-19 PHE will last. Therefore, QHPs and Exchanges may be confronted with additional impediments to timely compliance after the 60-day policy finalized in this IFC.

Although HHS is considering exercising enforcement discretion after the August 26 date, HHS does not anticipate such discretion for an Exchange or QHP issuer that fails to meet the sperate billing requirements more than one year after the publication of the 2019 Program Integrity Rule – December 27, 2020 – or six months after the end of the COVID-19 PHE, whichever comes first. CMS does not anticipate it will extend the separate billing policy compliance requirements again since they believe QHPs should be able to come into compliance in time. Further, the agency has concluded they will not handle requests for additional time on a case-by-case basis and acknowledges that all QHPs and Exchanges are affected by the COVID-19 PHE.

CMS also noted that the enforcement discretion in this rule applies only to the first scenario described above. CMS is not making any additional revisions to the separate billing requirements finalized in the 2019 Program Integrity Rule.

b. Basic Health Program (BHP) Blueprint Revisions

This rule makes changes to the Basic Health Program (BHP), which was created by Section 1331 of the Patient Protection and Affordable Care Act, and allows states to set up a coverage option for individuals who do not qualify for Medicaid but also have an income below 200 percent of the federal poverty level (FPL). A BHP must have a "Blueprint" that describes the state's program and must be reviewed and certified by CMS. Minnesota and New York are the only states with a BHP.

If a state seeks to make significant changes to its certified BHP, it must first submit a revised BHP Blueprint for review and certification. For purposes of this provision, the types of changes that would be considered "significant" include changes that have a direct impact on the enrollee experience in BHP or program financing. However, during the COVID-19 PHE, states may need to make changes to their BHP Blueprints that would be considered "significant" to ensure that enrollees can access necessary services without delay or access the services without cost sharing. For example, states may need to temporarily waive limitations on certain benefits covered under their BHP or temporarily waive enrollee premiums and cost sharing.

Under this IFC, states may submit to HHS for review and certification a revised BHP Blueprint that makes temporary significant changes to respond to the COVID-19 PHE with the option for states to make such changes effective retroactive to the start of the COVID-19 PHE (42 CFR 600.125(b) and (c)). While CMS expects these new changes to be rescinded after the pandemic, there may be instances in which policies will need to be temporarily in effect for a longer period of time. For example, following the end of the COVID-19 PHE, a state may need time to process all of the renewals or changes that were not completed during the COVID-19 PHE. CMS will work with states to determine a reasonable amount of time after the COVID-19 PHE to return to normal course of business.

This new flexibility is only available for BHP Blueprint revisions that are directly related to the COVID-19 PHE and would increase access to coverage. In addition, CMS will not approve retroactive BHP Blueprint revisions that are restrictive in nature, such as revisions that increase enrollee cost sharing, reduce benefits, or reduce eligibility. To submit and receive certification, a state must submit a cover letter that lists each change along with an explanation for how each change is directly related to the COVID-19 PHE and is not restrictive. The state should also specify the requested duration of each of the changes. If the state is seeking certification to implement changes beyond the COVID-19 PHE, the state must certify why the later end date is needed. The state should also submit a revised BHP Blueprint that incorporates the requested temporary changes.

These changes will not be subject to the public comment requirements (42 CFR 600.115(c)). However, CMS encourages states to gather public input when appropriate.

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