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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 410, 412, 413, 414, 415, 424, 425, 440, 483, 484 and 600

Office of the Secretary

45 CFR Part 156

[CMS-5531-IFC]

RIN 0938-AU32

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

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period (IFC) gives individuals and entities that provide services to Medicare, Medicaid, Basic Health Program, and Exchange beneficiaries needed flexibilities to respond effectively to the serious public health threats posed by the spread of the coronavirus disease 2019 (COVID-19). Recognizing the critical importance of expanding COVID-19 testing we are amending several Medicare policies on an interim basis to cover FDA-authorized COVID-19 serology tests, to allow any healthcare professional authorized to do so

under State law to order COVID-19 diagnostic laboratory tests (including serological and antibody tests), and to provide for new specimen collection fees for COVID-19 testing under the Physician Fee Schedule and Outpatient Prospective Payment System, during the public health emergency (PHE) for the COVID-19 pandemic. Recognizing the urgency of this situation, and understanding that some pre-existing CMS rules may inhibit innovative uses of technology and capacity that might otherwise be effective in the efforts to mitigate the impact of the pandemic on beneficiaries and the American public, we are amending several CMS policies and regulations in response to the COVID-19 PHE and recent legislation, as outlined in this IFC. These changes apply to physicians and other practitioners, hospice providers, federally qualified health centers, rural health clinics, hospitals, critical access hospitals (CAHs), community mental health centers (CMHCs), clinical laboratories, teaching hospitals, providers of the laboratory testing benefit in Medicaid, Opioid treatment programs, and quality reporting programs (QRPs) for inpatient rehabilitation facilities (IRFs), long-term care hospitals (LTCHs), skilled nursing facilities (SNFs), home health agencies (HHAs) and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers. We are also adopting an extraordinary circumstances relocation exception policy for on-campus and excepted off-campus provider-based departments of hospitals that relocate in response to the PHE, as well as discussing the hospital outpatient services and community mental health care services that can be furnished in temporary expansion locations of a hospital (including the patient's home) or an expanded CMHC. We are also modifying the policy to allow a teaching hospital to claim, towards its resident fulltime equivalent count, residents that it sends to another hospital during the PHE associated with COVID-19. In addition, we are updating the Extraordinary Circumstances Exceptions policy under the Hospital Value-based Purchasing (VBP) Program to allow us to grant an exception to hospitals affected by an extraordinary circumstance without a request form, and we are granting exceptions under our updated policy to all hospitals participating in the Hospital VBP Program

with respect to certain 4th quarter 2019 measure data that hospitals would otherwise be required to report in April or May of 2020, and measure data that hospitals would otherwise be required to collect during the 1st and 2nd quarters of 2020. Additionally, in response to the PHE, we are also incorporating changes for accountable care organizations participating in the Medicare Shared Savings Program, as well as delaying by 1 year the implementation of certain qualified clinical data registry measure approval criteria under the Quality Payment Program's Merit-based Incentive Payment System.

This IFC also allows states operating a Basic Health Program (BHP) to seek certification of a revised BHP Blueprint for temporary, significant changes that are directly tied to the COVID-19 pandemic, including the ability to apply the changes retroactively to the start of the PHE for the COVID-19 pandemic. We are also implementing a policy to align Home Health Value-Based Purchasing (HHVBP) Model data submission requirements with any exceptions or extensions granted for purposes of the HH QRP during the PHE for the COVID-19 pandemic, as well as a policy for granting exceptions to the New Measures data reporting requirements under the HHVBP Model during the PHE for the COVID-19 pandemic. We are also addressing the waiver of the IRF "3-hour rule" required by section 3711(a) of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), as well as modifying the IRF coverage and classification requirements for freestanding IRF hospitals to exclude patients admitted solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge during the PHE. We are also making changes to the Medicare regulations to revise payment rates for certain durable medical equipment and enteral nutrients, supplies, and equipment as part of implementation of section 3712 of the CARES Act.

We are delaying the compliance date by which IRFs, LTCH, and HHAs must collect and report data on two Transfer of Health (TOH) Information quality measures and certain Standardized Patient Assessment Data Elements (SPADEs) adopted for the IRF QRP, LTCH

QRP, and HH QRP. Finally, this IFC delays by 60 days, when individual market qualified health plan issuers offering non-Hyde abortion services must comply with the separate billing provision.

DATES: Effective date*:* These regulations are effective on [Insert the date of publication at the Office of the **Federal Register**].

Applicability date: The policies in this IFC are applicable beginning on March 1, 2020, or January 27, 2020, except as further described in the following table:

Provision	Applicability Date
Medicare Shared Savings Program – Expansion of Codes used in Beneficiary Assignment	We are revising § 425.400 to expand the definition of primary care services used in the Shared Savings Program beneficiary assignment methodology for the performance year starting on January 1, 2020, and for any subsequent performance year that starts during the PHE for the COVID-19 pandemic, as defined in § 400.200, which includes any subsequent renewals.
Modification to Medicare Rules and Medicaid Concerning Certification and Provision of Home Health Services	We are revising §§ 409.41 through 409.48; 424.22; 424.507(b)(1); § 440.70(a)(2) and (3), and (b)(1), (2) and (4); and several sections of 42 CFR part 484 to include physician assistants, nurse practitioners, and clinical nurse specialists as individuals who can certify the need for home health services and order services. These changes are permanent, and applicable to services provided on or after March 1, 2020.
Flexibility for Medicaid Laboratory Services	We are revising § 440.30 to provide states with flexibility to provide Medicaid coverage for certain laboratory tests and X-ray services that may not meet certain requirements in § 440.30 (a) or (b) (such as the requirement that tests be furnished in an office or similar facility). This flexibility is retroactive to March 1, 2020, during the period of the COVID-19 PHE and for any subsequent periods of active surveillance. The flexibility also applies to future PHEs resulting from outbreaks of communicable disease and subsequent periods of active surveillance.
Requirement for Facilities to Report Nursing Home Residents and Staff Infections, Potential Infections, and Deaths Related to COVID-19	We are revising § 483.80 to establish explicit reporting requirements for long-term care (LTC) facilities to report information related to COVID-19 cases among facility residents and staff. These reporting requirements are applicable on the effective date of this IFC.
Separate Billing and Segregation of Funds for Abortion Services	We are delaying by 60 days the date when individual market qualified health plan (QHP) issuers must be in compliance with the separate billing policy for non-Hyde abortion services. Under this 60-day delay, individual market QHP issuers must comply with the separate billing policy beginning on or before the QHP issuer's first billing cycle following August 26, 2020.
DME Interim Pricing in the CARES Act	We are revising § 414.210 to provide increased fee schedule amounts in certain areas starting on March 6, 2020, and for the duration of the PHE for the COVID-19 pandemic.
Merit-based Incentive Payment System (MIPS) Qualified Clinical Data Registry (QCDR) Measure Approval Criteria - Completion of QCDR Measure Testing - Collection of Data on QCDR Measures	For the reasons discussed in section II.R. of this IFC, we are delaying the implementation of the completion of QCDR measure testing policy by 1 year. Specifically, we are amending § 414.1400(b)(3)(v)(C) to state that beginning with the 2022 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination. This change is applicable on the effective date of this IFC. For the reasons discussed in section II.R. of this IFC, we are delaying the implementation of the collection of data on QCDR measures policy by one year. Specifically, we are amending § 414.1400(b)(3)(v)(D) to state that beginning with the 2022 performance period, QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for

Provision	Applicability Date
	CMS consideration during the self-nomination period. This change is applicable on the effective date of this IFC.
Hospital VBP Program	We are revising the extraordinary circumstances exception policy to allow CMS to grant an exception to hospitals located in an entire region or locale without a request and we are codifying the updated policy at § 412.165(c). This change is permanent, and is applicable beginning on the effective date of this IFC.
IRF QRP	We are revising the compliance date for the IRF QRP to October 1st of the year that is at least one full fiscal year after the end of the PHE. This change is applicable on the effective date of this IFC.
LTCH QRP	We are revising the compliance date for the LTCH QRP to October 1st of the year that is at least one full fiscal year after the end of the PHE. This change is applicable on the effective date of this IFC.
HH QRP	We are revising the compliance date for the HH QRP to January 1st of the year that is at least one full calendar year after the end of the PHE. This change is applicable on the effective date of this IFC.
SNF QRP	We are revising the compliance date for the SNF QRP to October 1st of the year that is at least two full fiscal years after the end of the PHE. This change is applicable on the effective date of this IFC.

Comment date*:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [Insert date 60 days after date of publication in the **Federal Register**.]

ADDRESSES: In commenting, please refer to file code CMS-5531-IFC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to **http://www.regulations.gov**. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-5531-IFC,

P.O. Box 8016,

Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the

comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-5531-IFC,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Rebecca Cole, (410) 786-1589, for general information, or contact one of the following:

HHVBPquestions@cms.hhs.gov, for issues related to the HHVBP Model.

HAPG_COVID-19@cms.hhs.gov, for issues related to scope of practice issues; additional flexibilities for hospital outpatient departments and CMHCs to furnish outpatient services at temporary expansion sites, including the beneficiary's home and expanded CMHCs; expansion of the extraordinary circumstances relocation exception policy for on-campus and excepted off-campus provider-based departments (PBDs) that relocate in response to the COVID-19 PHE; teaching physician policies, including time spent by residents at another hospital and the medical education methodology of counting teaching hospital beds; counting beds for provider-based rural health clinic payment level; services furnished by opioid treatment programs; modified requirements for ordering COVID-19 diagnostic laboratory tests; payment to hospitals and physician's offices for specimen collection; counting time for telehealth evaluation and management visits; method for updating the telehealth list during the PHE; paying for

remote monitoring services; and increased payment for telephone evaluation and management visits (Note this email address has an underscore "_" between "HAPG" and "COVID-19".)

IRFCoverage@cms.hhs.gov, for issues related to the Medicare IRF benefits.

DMEPOS@cms.hhs.gov, for issues related to section 3712 of the CARES Act.

Hillary Loeffler, (410) 786-0456, HomeHealthPolicy@cms.hhs.gov, or HospicePolicy@cms.hhs.gov, for issues related to the Medicare home health and hospice benefits.

PHPPaymentPolicy@cms.hhs.gov, for issues related to the Partial Hospitalization Program (PHP) and CMHC issues.

MedicaidHomeHealthRule@cms.hhs.gov, for issues pertaining to the Medicaid home health benefit related to section 3708 of the CARES Act.

Kari Vandegrift, (410) 786-4008, and Elizabeth November, (410) 786-4518 or SharedSavingsProgram@cms.hhs.gov, for issues related to the Medicare Shared Savings Program.

Leigha Basini, (301) 492-4380, for issues related to the separate billing requirement.

Sheri Gaskins, (410) 786-9274, for issues related to Medicaid laboratory flexibilities.

Cassandra Lagorio, (410) 786-4554, for issues related to the BHP.

Molly MacHarris, (410) 786-4461, or QPP@cms.hhs.gov, for issues related to the Merit-based Incentive Payment System (MIPS).

NCDsPublicHealthEmergency@cms.hhs.gov, for issues related to national coverage determination and local coverage determination requirements.

Joan Proctor, (410) 786-0949, or HHQRPQuestions@cms.hhs.gov, for issues related to the following Post-Acute Care QRPs: HH QRP, IRF QRP, LTCH QRP, and SNF QRP.

Julia Venanzi, (410) 786-1471, for issues related to the Hospital VBP Program.

Adam Rubin, (410-786-1919), for issues related to Certification of Home Health

Services.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: http://regulations.gov. Follow the search instructions on that website to view public comments.

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CPT (Current Procedural Terminology) Copyright Notice

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I. Background

The United States is responding to an outbreak of respiratory disease caused by a novel (new) coronavirus that was first detected in China and which has now been detected in more than 190 countries internationally, and all 50 States and the District of Columbia. The virus has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2") and the disease it causes has been named "coronavirus disease 2019" ("COVID-19").

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a "Public Health Emergency of

international concern". On January 31, 2020, Health and Human Services Secretary, Alex M. Azar II, determined that a Public Health Emergency (PHE) exists for the United States to aid the nation's healthcare community in responding to COVID-19 (hereafter referred to as the PHE for the COVID-19 pandemic) and on April 21, 2020, Secretary Azar renewed, effective April 26, 2020, the determination that a PHE exists. On March 11, 2020, the WHO publicly declared COVID-19 a pandemic. On March 13, 2020, the President of the United States declared the COVID-19 pandemic a national emergency.

Coronaviruses are a large family of viruses that are common in people and many different species of animals, including camels, cattle, cats, and bats. Rarely, animal coronaviruses can infect people and then spread between people such as with MERS-CoV, SARS-CoV, and now with this new virus (SARS-CoV-2).

The complete clinical picture with regard to COVID-19 is not fully known. Reported illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that much COVID-19 illness is mild, the Centers for Disease Control and Prevention (CDC) reports find that in the United States, between March 1 and 28, 2020, the overall laboratory-confirmed COVID-19–associated hospitalization rate was 4.6 per 100,000 population.[1] A pandemic is a global outbreak of disease. Pandemics happen when a new virus emerges to infect people and can spread sustainably, from person-to-person. The virus, SARS-CoV-2, that causes COVID-19 is infecting people and spreading easily worldwide from person-to-person because there is little to no pre-existing immunity. This is the first pandemic known to be caused by the emergence of a new coronavirus.[2]

[1] https://www.cdc.gov/mmwr/volumes/69/wr/mm6915e3.htm.
[2] https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/summary.html.

People in places where ongoing community spread of the virus that causes COVID-19 has been reported are at elevated risk of exposure, with the level of risk dependent on the location. Healthcare workers caring for patients with COVID-19 are at elevated risk of exposure. Close contacts of persons with COVID-19 also are at elevated risk of exposure.

The CDC has reported that some people are at higher risk of getting very sick from this illness.[3] This includes:

- Older adults, with risk increasing by age.
- People who have serious chronic medical conditions like:

++ Obesity

++ Cardiovascular disease

++ Diabetes mellitus

++ Hypertension

++ Chronic lung disease.

The CDC has developed guidance to help in the risk assessment and management of people with potential exposures to COVID-19, including recommending that health care professionals make every effort to interview a person under investigation for infection by telephone, text monitoring system, or video conference.[4]

As the healthcare community establishes and implements recommended infection prevention and control practices, regulatory agencies under appropriate waiver authority granted by the PHE for the COVID-19 pandemic declaration are also working to revise and implement regulations that work in concert with healthcare community infection prevention and treatment practices. Based on the current and projected increase in the rate of incidence of the COVID-19 disease in the US population, and observed fatalities in the elderly population, who are

[3] https://www.cdc.gov/mmwr/volumes/69/wr/mm6915e3.htm.
[4] https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/summary.html.

particularly vulnerable due to age and co-morbidities, and additionally, the impact on health workers who are at increased risk due to treating the population, we believe that certain regulations should be reviewed and revised as appropriate to offer providers and suppliers additional flexibilities in furnishing services to combat the COVID-19 pandemic. We are addressing some of these regulations in a previous IFC which appeared in the April 6, 2020 **Federal Register** (85 FR 19230) with an effective date of March 31, 2020 (hereafter referred to as the "March 31st COVID-19 IFC"). In this interim final rule with comment period (IFC), we are revising additional regulations to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the programs under Title XVIII (Medicare) and Title XIX (Medicaid) of the Social Security Act (the Act), or in the identified programs authorized under the Affordable Care Act. In addition, we are implementing regulations in response to recent legislation including the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (Pub. L. 116-123, March 6, 2020), the Families First Coronavirus Response Act (Pub. L. 116-127, March 18, 2020), and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116-136, March 27, 2020).

In this extraordinary circumstance, we recognize that the COVID-19 pandemic greatly increases the overall risk to public health. We believe that this increased risk results in an immediate change, not only in the circumstances under which services can safely occur, but also in to the business relationships among providers, suppliers, and practitioners. By increasing access to hospital and community mental health services furnished in temporary expansion locations of the hospital including the patient's home, increasing access to laboratory and diagnostic testing in a patient's home or other settings that could help to minimize transmission of communicable disease, and improving infection control, this IFC will provide the necessary flexibility for Medicare and Medicaid beneficiaries to be able to receive medically necessary services without jeopardizing their health or the health of those who are providing those services,

while also minimizing the overall risk to public health. Notably, all final provisions included in this IFC are only for the duration of the PHE for the COVID-19 pandemic, unless otherwise indicated.

We also acknowledge that the COVID-19 PHE has created a lack of predictability for many ACOs regarding the impact of expenditure and utilization changes on historical benchmarks and financial performance, created uncertainty around future program participation, and disrupted population health activities as clinicians, care coordinators, and financial and other resources are diverted to address immediate acute care needs. We are amending the Shared Savings Program regulations in order to address the impact of the COVID-19 pandemic and encourage continued participation by ACOs. In addition, this IFC also provides flexibility to states operating a BHP to seek certification for temporary significant changes to its BHP Blueprint that are directly tied to the PHE for the COVID-19 pandemic, including the ability to apply the changes retroactively to the start of the PHE. Finally, in light of these extraordinary circumstances and the immediate need for QHP issuers to divert resources to responding to the COVID-19 PHE, we are delaying by 60 days the date when individual market issuers must be in compliance with the separate billing policy. Under this 60-day delay, QHP issuers must comply with the separate billing policy beginning on or before the QHP issuer's first billing cycle following August 26, 2020.

As QHP issuers and Exchanges work to respond to the COVID-19 PHE and implement and establish policies to ensure access to COVID-19-related care for enrollees, HHS is working to assess and extend regulatory flexibility to QHP issuers, Exchanges, and other health industry stakeholders where doing so may enable these stakeholders to divert existing resources to aiding the COVID-19 PHE response. We believe extending the deadline 60 days for QHP issuers and Exchanges to comply with the separate billing policy is appropriate so that they may adequately respond to and divert resources to address the COVID-19 PHE.

Also, consistent with section 3708 of the CARES Act, we are expanding 42 CFR parts 409, 424.22, 424.507(b), 440.70 and part 484 to permit nurse practitioners (NPs), clinical nurse specialists (CNSs), and physician assistants (PAs) to certify the need for home health services and to order services in the Medicare and Medicaid programs.

II. Provisions of the Interim Final Rule with Comment Period (IFC)

In this IFC, we use the term, "Public Health Emergency (PHE)," as defined at 42 CFR 400.200. The definition identifies the PHE determined to exist nationwide by the Secretary of Health and Human Services (the Secretary) under section 319 of the Public Health Service Act on January 31, 2020, and renewed effective April 26, 2020, as a result of confirmed cases of COVID-19.

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

Through this IFC, we are implementing a policy to align the Home Health Value-Based Purchasing (HHVBP) Model data submission requirements with any exceptions or extensions granted for purposes of the Home Health Quality Reporting Program (HH QRP) during the PHE for COVID-19. We are also implementing a policy for granting exceptions to the New Measures data reporting requirements under the HHVBP Model during the PHE for COVID-19. Specifically, during the PHE for COVID-19, to the extent that the data that participating HHAs in the nine HHVBP Model states are required to report are the same data that those HHAs are also required to report for the HH QRP, HHAs are required to report those data for the HHVBP Model in the same time, form and manner that HHAs are required to report those data for the HH QRP. 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/or extensions apply to the submission of those same data for the HHVBP Model. In addition, in this IFC, we are adopting a policy to allow exceptions or

extensions to New Measure reporting for HHAs participating in the HHVBP Model during the PHE for COVID-19.

As authorized by section 1115A of the Act and finalized in the CY 2016 HH PPS final rule (80 FR 68624), the HHVBP Model has an overall purpose of improving the quality and delivery of home health care services to Medicare beneficiaries. The specific goals of the Model are to: (1) provide incentives for better quality care with greater efficiency; (2) study new potential quality and efficiency measures for appropriateness in the home health setting; and (3) enhance the current public reporting process. All Medicare certified HHAs providing services in Arizona, Florida, Iowa, Nebraska, North Carolina, Tennessee, Maryland, Massachusetts, and Washington are required to compete in the Model. The HHVBP Model uses the waiver authority under section 1115A(d)(1) of the Act to adjust Medicare payment rates under section 1895(b) of the Act based on the competing HHAs' performance on applicable measures. The maximum payment adjustment percentage increases incrementally over the course of the HHVBP Model in the following manner, upward or downward: (1) 3 percent in CY 2018; (2) 5 percent in CY 2019; (3) 6 percent in CY 2020; (4) 7 percent in CY 2021; and (5) 8 percent in CY 2022. Payment adjustments are based on each HHA's Total Performance Score (TPS) in a given performance year (PY), which is comprised of performance on: (1) a set of measures already reported via the Outcome and Assessment Information Set (OASIS),[5] completed Home Health Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) surveys, and select claims data elements; and (2) three New Measures for which points are achieved for reporting data.

The HHVBP Model utilizes some of the same quality measure data that are reported by HHAs for the HH QRP, including HHCAHPS survey data. The other HHVBP measures are

[5] OASIS is the instrument/data collection tool used to collect and report performance data by HHAs.

calculated using OASIS data, which are still required to be reported during the PHE; however, we have given providers additional time to submit OASIS data (https://www.cms.gov/files/document/covid-home-health-agencies.pdf); claims-based data extracted from Medicare fee-for-service (FFS) claims; and New Measure data. To assist HHAs while they direct their resources toward caring for their patients and ensuring the health and safety of patients and staff, we are adopting a policy for the HHVBP Model to align the HHVBP data submission requirements with any exceptions or extensions granted for purposes of the HH QRP during the PHE for COVID-19. For the same reason, we are also establishing a policy for granting exceptions to New Measure reporting requirements for HHAs participating in the HHVBP Model during the PHE for COVID-19.

Under this policy, to the extent CMS has granted an exception to the HH QRP (for 2019 Q4 and 2020 Qs 1-2 as noted below in this section), or may grant any future exceptions or extensions under this same program for other CY 2020 reporting periods, HHAs in the nine HHVBP Model states do not need to separately report these measures for purposes of the HHVBP Model, and those same exceptions apply to the submission of those same data for the HHVBP Model. In accordance with this policy, if CMS grants an exception or extension under the HH QRP that either excepts HHAs from reporting certain quality data altogether, or otherwise extends the deadlines by which HHAs must report those data, the same exceptions and/or extensions apply to the submission of those same data for the HHVBP Model.

In response to the PHE for COVID-19, on March 27, 2020, we issued supplemental public guidance (https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf) excepting HHAs from the requirement to report any HH QRP data for the following quarters:

- October 1, 2019–December 31, 2019 (Q4 2019).
- January 1, 2020–March 31, 2020 (Q1 2020).

- April 1, 2020–June 30, 2020 (Q2 2020).

Under our policy to align HHVBP data submission requirements with any exceptions or extensions granted for purposes of the HH QRP during the PHE for COVID-19, HHAs in the nine HHVBP Model states are not required to separately report measure data for these quarters for purposes of the HHVBP Model. We note that with regard to the exception from the requirement to report Q4 2019 HH QRP data, we do not anticipate any issues in calculating the TPSs based on CY 2019 data under the HHVBP Model because HHAs had the opportunity to submit these Q4 2019 data on a rolling basis.

In addition, to ensure that HHAs are able to focus on patient care in lieu of data submission during the PHE for COVID-19, in this IFC, we are establishing a policy to allow us to grant exceptions to New Measure reporting for HHAs participating in the HHVBP Model during the PHE for COVID-19. We are codifying these changes at § 484.315(b). In accordance with this policy, we are granting an exception to all HHAs participating in the HHVBP Model for the following New Measure reporting requirements:

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

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

We note that although the data collection period for the April 2020 New Measures submission period began in 2019, the data collected during this period are used for the calculation of the TPSs for CY 2020 performance, not CY 2019 data. We further note that HHAs may optionally submit part or all of these data by the applicable submission deadlines. If we make the determination to grant an exception to New Measure data reporting for periods beyond the April and July 2020 submission periods, for example if the PHE for COVID-19 extends beyond the New Measure submission periods we have listed in this IFC, we will

communicate this decision through routine communication channels to the HHAs participating in the HHVBP Model, including but not limited to issuing memos, emails and posting on the HHVBP Connect website (https://app.innovation.cms.gov/HHVBPConnect).

We acknowledge that the exceptions to the HH QRP reporting requirements, as well as the modified submission deadlines for OASIS data and our exceptions for the New Measures reporting requirements, may impact the calculation of performance under the HHVBP Model for the performance year (PY) 2020. We also note that while we are able to extract the claims-based data from submitted Medicare FFS claims, we may need to assess the appropriateness of using the claims data submitted for the period of the PHE for COVID-19 for purposes of performance calculations under the HHVBP Model. We are evaluating possible changes to our payment methodologies for CY 2022 in light of this more limited data, such as whether we would be able to calculate payment adjustments for participating HHAs for CY 2022, including those that continue to report data during CY 2020, if the overall data is not sufficient, as well as whether we may consider a different weighting methodology given that we may have sufficient data for some measures and not others. We are also evaluating possible changes to our public reporting of CY 2020 performance year data. We intend to address any such changes to our payment methodologies for CY 2022 or public reporting of data in future rulemaking.

B. Scope of Practice

In December 2019, CMS issued a request for feedback in response to part of the President's Executive Order (EO) 13890 on "Protecting and Improving Medicare for Our Nation's Seniors," seeking the public's help in identifying additional Medicare regulations which contain more restrictive supervision requirements than existing state scope of practice laws, or which limit health professionals from practicing at the top of their license (for a link to this request for feedback see https://www.cms.gov/files/document/request-information-reducing-scope-practice-burden.pdf). In response to this request, we received several recommendations

from nonphysician practitioners (NPPs) that inform CMS policymaking to ensure an adequate number of clinicians are able to furnish critical services and tests during the COVID-19 PHE. According to the American Association of Nurse Practitioners, currently, twenty-two states and D.C. are considered Full Practice Authority (FPA) states because their licensure laws allow full and direct patient access to NPs. We are finalizing provisions that address several of those recommendations in this section of the IFC, on an interim basis for the duration of the PHE. We note that the responses to our request for information on these topics did not indicate the number of states having more flexible scope of practice rules than our federal regulations. In this rule, we are also seeking public feedback indicating the number of states to help us understand the scope of impact of these changes.

1. Supervision of Diagnostic Tests by Certain Nonphysician Practitioners

Rapid expansion of COVID-19-related diagnostic testing capacity (such as lab tests and respiratory imaging) is a top priority in the strategy to combat the pandemic. In response to the request for feedback discussed above, PAs and NPs recommended regulatory changes that would allow them to supervise diagnostic tests because they stated that they are currently authorized to do so under their State scope of practice rules. We also received feedback from radiologists who did not support making any changes to our regulations that would result in any inappropriate expansion of the role of NPPs. Currently, under 42 CFR 410.32(a)(3) of our regulations, physicians and NPPs who are treating a beneficiary for a specific medical problem may order diagnostic tests when they use the results of the tests in the management of the beneficiary's specific medical problem. Specifically, NPPs who furnish services that would be physicians' services if furnished by a physician (that is, NPs, PAs, CNSs, clinical psychologists (CPs), clinical social workers (CSWs), and certified nurse-midwives (CNMs)), and who are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefit may order diagnostic tests when they use the results of the tests in the

management of the beneficiary's specific medical problem. However, under our current regulation at § 410.32(b), only physicians are generally permitted to supervise diagnostic tests. The regulation at § 410.32(b)(1) provides as a basic rule that all diagnostic tests paid under the Physician Fee Schedule (PFS) must be furnished under an appropriate specified minimum level of supervision by a physician as defined in section 1861(r) of the Act. Section 410.32(b)(2) then provides for certain exceptions to which the general basic rule does not apply. For instance, under § 410.32(b)(2)(v), the requirement that diagnostic tests must be furnished under the appropriate level of supervision by a physician does not apply for tests performed by an NP or CNS authorized under applicable state law to furnish the test. (We note that, as for all services they furnish, the NP or CNS necessarily would be working in collaboration with a physician under §§ 410.75 and 410.76, respectively). Similarly, at § 410.32(b)(2)(vii), the requirement that diagnostic tests must be furnished under the appropriate level of supervision by a physician does not apply for tests performed by a CNM authorized under applicable state law to furnish the test. There are not currently any exceptions under § 410.32(b)(2) for services furnished by PAs. As such, any diagnostic tests furnished by PAs would need to be under the appropriate level of supervision by a physician in accordance with § 410.32(b)(1). We note further that our regulation at § 410.32(b)(3) specifies that only a general level of physician supervision is required for diagnostic tests performed by a PA that the PA is legally authorized to perform under state law. Of course, all services furnished by PAs must meet the physician supervision requirements under § 410.74, which generally defers to state law requirements that address the requisite practice relationship between PAs and physicians, or requires certain documentation of the working relationship between the PA and physicians to supervise PA services if the issue is not addressed in state law. Thus, while NPs, CNSs, PAs, and CNMs are permitted to furnish diagnostic tests to the extent they are otherwise authorized under state law to do so, the regulations at § 410.32 does not address whether NPs, CNSs, PAs and CNMs may supervise

others when furnishing diagnostic tests.

In light of the need to reinforce and increase COVID-19-related diagnostic testing capacity throughout the duration of the PHE, and to increase the flexibility and availability of health care professionals to provide needed care, we are finalizing on an interim basis changes to our regulation at § 410.32(b) to add flexibility for NPs, CNSs, PAs, and CNMs, which are types of practitioners that have separately enumerated benefit categories under Medicare law that permit them to furnish services that would be physicians' services if furnished by a physician and be paid under Medicare Part B for the professional services they furnish directly and "incident to" their own professional services, to the extent authorized under their State scope of practice. The interim changes will ensure that these practitioners may order, furnish directly, and supervise the performance of diagnostic tests, subject to applicable state law, during the PHE. As we observe how rapidly the COVID-19 virus is transmitted in the population, we believe this policy will help to ensure that an adequate number of health care professionals are available to support critical COVID-19-related and other diagnostic testing needs, and provide needed medical care. This policy will support the rapid expansion of COVID-19-related diagnostic testing capacity to quickly identify affected individuals and protect against transmission of the virus to vulnerable populations, and help to address potential clinical workforce shortages that may impact access to services and other diagnostic tests that still need to be furnished during the PHE.

Specifically, we are amending the regulation at § 410.32(b)(1) to specify in the basic rule that diagnostic tests covered under section 1861(s)(3) of the Act and payable under the PFS must be furnished under the appropriate level of supervision by a physician as defined under section 1861(r) of the Act or, during the PHE, by a NP, CNS, PA, and CNM, as described above. Additionally, we are amending the regulation at § 410.32(b)(2)(iii)(B) which addresses supervision of COVID-19-related diagnostic psychological and neuropsychological testing

services to allow these services to be supervised by a NP, CNS, PA and CNM as described above, during the PHE, in addition to physicians and CPs who are currently authorized to supervise these tests. We are also amending the regulation at § 410.32 by adding a new paragraph (b)(2)(viii) to allow diagnostic tests to be performed by a PA without physician supervision (although as noted above, the regulation at § 410.74 continues to apply) when authorized to perform the tests under applicable state law. Furthermore, we are amending the regulation at § 410.32(b)(3) regarding the levels of supervision, to also authorize NPs, CNSs, PAs, and CNMs, as described above, during the PHE to provide the appropriate level of supervision assigned to diagnostic tests. Since we are adding PAs under § 410.32(b)(2)(viii) to the list of exceptions to the general basic rule for supervision during the PHE, and given that the physician supervision requirement in the regulation at § 410.74 continues to apply, we are removing the parenthetical regarding general physician supervision for diagnostic tests furnished by PAs from § 410.32(b)(3). We are also correcting the typographical error under § 410.32(d)(2)(i) regarding documentation and recordkeeping requirements to state that when ordering diagnostic tests, the physician (or qualified NPP, as defined in paragraph (a)(2) of this section), who orders the service must maintain documentation of medical necessity in the beneficiary's medical record.

2. Therapy – Therapy Assistants Furnishing Maintenance Therapy (PFS)

We currently make payment under Medicare Part B for outpatient occupational and physical therapy (§§ 410.59(a) and 410.60(a), respectively) when they are furnished by an individual meeting qualifications in part 484 for an occupational therapist (OT) or physical therapist (PT), or an appropriately supervised occupational therapy assistant (OTA) or physical therapy assistant (PTA). This includes our policy for rehabilitative services for which improvement of the beneficiary's functional status is expected. However, in cases where it is medically necessary to maintain, prevent or slow the deterioration of a patient's condition, a

separate policy requires the skills of a physical or OT, not a PTA or OTA, to carry out a therapist-established maintenance program, which is generally known as "maintenance therapy." For services furnished by PTAs and OTAs, claims from therapists and providers are required to use the "CO" and "CQ" modifiers for their respective OTA and PTA therapy services, to indicate that a supervised therapy assistant performed the rehabilitative or maintenance therapy services.

In response to the request for feedback discussed above, therapists and therapy providers pointed out that our Part B policy specifying that maintenance therapy requires the skills of a therapist is not consistent with the policy for services furnished in SNF and Home Health Part A settings where PTAs and OTAs are permitted to furnish these services. They recommended that we revise our policy to permit the treating therapist who established or is responsible for the maintenance program plan to determine when it is clinically appropriate to delegate the performance of maintenance therapy services to PTAs and OTAs, as they are charged with overseeing a patient's course of treatment and assigning responsibilities to assistants. They suggested that permitting PTAs and OTAs to furnish maintenance therapy services would give Medicare patients greater access to care and permit therapists and therapy providers more flexibility for resource utilization.

To increase availability of needed health care services during the COVID-19 PHE, we believe it is appropriate to synchronize our Part B payment policies as suggested by the stakeholders, and to permit the PT or OT who established the maintenance program to delegate the performance of maintenance therapy services to a PTA or OTA when clinically appropriate. We believe that, by allowing PTAs and OTAs to perform maintenance therapy services, PTs and OTs will be freed up to furnish other services, including such services as non-medication pain management therapies that may reduce reliance on opioids or other medications, as well as those services related to the COVID-19 PHE that require a therapist's assessment and evaluation skills, including communication technology-based services (CTBS) that were made available for PTs,

OTs and speech-language pathologists (SLPs) during the PHE in the March 31st COVID-19 IFC (85 FR 19245 and 19265 through 19266).

3. Therapy – Student Documentation (PFS)

In the CY 2020 PFS final rule[6], we simplified medical record documentation requirements and finalized a general principle to allow the physician, PA, or the advanced practice registered nurses (APRNs), specifically, NPs, CNSs, CNMs, and certified registered nurse anesthetist (CRNAs) who furnish and bill for their professional services to review and verify, rather than re-document, information included in the medical record by physicians, residents, nurses, students or other members of the medical team. We explained that this principle would apply across the spectrum of all Medicare-covered services paid under the PFS. We noted that the policy was intended to apply broadly, and accordingly amended regulations for teaching physicians, other physicians, PAs, and APRNs to expressly provide for this flexibility for medical record documentation requirements for professional services furnished by physicians, PAs and APRNs in all settings.

To increase the availability of clinicians who may furnish healthcare services during the PHE, we are announcing a general policy that there is broad flexibility for all members of the medical team to add documentation in the medical record which is then reviewed and verified (signed) by the appropriate clinician. Specifically, on an interim basis during the PHE for the COVID-19 pandemic, any individual who has a separately enumerated benefit under Medicare law that authorizes them to furnish and bill for their professional services, whether or not they are acting in a teaching role, may review and verify (sign and date), rather than re-document,

[6] Medicare Program; CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations Final Rule; and Coding and Payment for Evaluation and Management, Observation and Provision of Self-Administered Esketamine Interim Final Rule (84 FR 62568-63563)

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. We note that although there are currently no statutory or regulatory documentation requirements that would impact payment for therapists when documentation is added to the medical record by persons other than the therapist, we are discussing this issue in response to stakeholder concerns about burden and in consideration of the current COVID-19 PHE. Specifically, this policy will ensure that therapists, as members of the clinical workforce, are able to spend more time furnishing therapy services, including pain management therapies to patients that may minimize the use of opioids and other medications, rather than spending time documenting in the medical record. We emphasize that our established principle is focused on the clinician, as described above who furnishes and bills for their professional services rather than the individuals who may enter information into the medical record. We want to emphasize that information entered into the medical record should document that the furnished services are reasonable and necessary.

4. Pharmacists Providing Services Incident to a Physicians' Service

In response to the request for feedback discussed above, numerous stakeholders asked us to clarify that pharmacists are permitted to provide services to Medicare beneficiaries incident to the professional services of a physician, like other clinical staff or certain other clinicians. These stakeholders have asked us, in particular, about pharmacists who provide medication management services. Medication management is covered under both Medicare Part B and Part D. We are clarifying explicitly that pharmacists fall within the regulatory definition of auxiliary personnel under our regulations at § 410.26. As such, pharmacists may provide services incident to the services, and under the appropriate level of supervision, of the billing physician or NPP, if payment for the services is not made under the Medicare Part D benefit. This includes providing the services incident to the services of the billing physician or NPP and in accordance with the pharmacist's state scope of practice and applicable state law. This clarification does not alter

current payment policy for pharmacist services furnished incident to the professional services of a physician or NPP.

Although fully consistent with current CMS policy, we believe this clarification may encourage pharmacists to work with physicians and NPPs in new ways that expand the availability of health care services during the COVID-19 PHE, and increase access to medication management of individuals with substance/opioid use disorder. We emphasize that consistent with the Controlled Substances Act (Pub. L. 91-513, enacted October 27, 1970), methadone should continue to be dispensed from certified and accredited Opioid Treatment Programs (OTPs) under the supervision of clinicians who have received appropriate training and fully understand the risks of that medication as is required by statute.

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

The rapid expansion of COVID-19 diagnostic laboratory testing capacity is a top priority in our strategy to combat the pandemic. To that end, several large clinical diagnostic laboratory and pharmacy businesses are operating community testing sites across the country in cooperation with state and federal authorities.[7] In combination with the availability of point of care tests that provide rapid results, these sites are a key component in the expansion of COVID-19 testing capacity.

Under Medicare Part B, clinical diagnostic laboratory tests, including COVID-19 diagnostic tests, are paid for under the Clinical Laboratory Fee Schedule (CLFS), without any beneficiary cost-sharing requirements (coinsurance or Part B deductible). See generally sections 1861(s)(3), 1833(a)(1)(D)(i)(II), (b)(3)(A), (h)(5)(C) and (D), and 1834A of the Act, and 42 CFR part 414, subpart G.

Under our current regulation at § 410.32(a), diagnostic laboratory tests such as the

[7] Guidance for Licensed Pharmacists, COVID-19 Test, and Immunity Under the PREP Act, HHS, April 8, 2020, https://www.hhs.gov/sites/default/files/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf.

COVID-19 tests are covered only when they are ordered by a physician or other practitioner who is treating the beneficiary, and who uses the results of the test in managing the patient's specific medical condition. If a patient arrives at a community testing site without an order for the test from his or her physician or practitioner, Medicare would not currently cover the test.

We have taken substantial steps to broaden access to safely-delivered care via telehealth and other communication technology-based services during the COVID-19 PHE in an attempt to ensure that a COVID-19 test could be ordered by a physician or other practitioner treating the beneficiary. Notwithstanding these flexibilities, not all beneficiaries have access to a doctor to obtain a COVID-19 diagnostic laboratory test. The most recently available results from the Medicare Current Beneficiary Survey indicated that only 70 percent of Medicare beneficiaries view a doctor's office as their source of care. In the same survey, 23 percent of beneficiaries indicated that a medical clinic, urgent care center, or hospital outpatient department (HOPD) was their source of care. HOPDs and urgent care clinics may not be able to furnish community patient visits because they are treating an excess number of patients already testing positive for the virus. The survey also indicated that 7 percent of beneficiaries reported no source of care.[8] We anticipate needing to test many Medicare beneficiaries quickly as part of the rapid expansion of COVID-19 testing capacity to combat the pandemic. Therefore, the need for a patient to first have a visit with a physician or practitioner to obtain an order for COVID-19 testing to meet Medicare ordering requirements could still present a significant barrier to patients who might otherwise seek a test.

Prior to the Guidance for Licensed Pharmacists, COVID-19 Test, and Immunity Under the PREP Act, which HHS issued on April 8, 2020 (April Guidance),[9] state governments had

[8] Centers for Medicare & Medicaid Services. Medicare Current Beneficiary Survey Chart Book 2016. https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/MCBS/Data-Tables-Items/2016Chartbook.
[9] HHS Statements on Authorizing Licensed Pharmacists to Order and Administer COVID-19 Tests, HHS, April 8, 2020, https://www.hhs.gov/about/news/2020/04/08/hhs-statements-on-authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.html.

sought to increase access to testing by removing prior authorization of COVID-19 tests in the commercial health insurance market.[10] States and State Boards of Pharmacy had also sought to increase physician capacity by permitting pharmacists to test for and treat influenza and streptococcus infections under protocols.[11] State Boards of Pharmacy have in turn sought to increase pharmacist capacity by relaxing pharmacist to pharmacy technician supervision ratios.[12] With growing supplies of tests and in light of the April Guidance we anticipate that States will look increasingly to pharmacists and other qualified healthcare professionals to order and furnish COVID-19 tests.

Information provided by the CDC shows that the likelihood of severe outcomes of COVID-19 illness is highest in adults aged 65 and older and people with underlying health conditions, which suggests that the Medicare beneficiary population is at particularly high risk from the disease.[13] Additionally, as noted by the CDC in guidance on how to protect against COVID-19 infection, some studies have suggested that COVID-19 may be spread by people who are not showing symptoms.[14] We believe it is vital for Medicare beneficiaries to have broad access to COVID-19 testing so that they can properly monitor their symptoms, make prompt decisions about seeking further care, and take appropriate precautions to prevent further spread of the disease.

Given the critical importance of expanding COVID-19 testing to combat the pandemic and the heightened risk that the disease presents to Medicare beneficiaries, we are amending our

[10] Karen Pollitz, "Private Health Coverage of COVID-19: Key Facts and Issues," Kaiser Family Foundation, March 18, 2020, https://www.kff.org/private-insurance/issue-brief/private-health-coverage-of-covid-19-key-facts-and-issues/.
[11] National Alliance of State Pharmacy Associations (NASPA), Pharmacist Prescribing: "Test and Treat," February 8, 2019, available at https://naspa.us/resource/pharmacist-prescribing-for-strep-and-flu-test-and-treat/
[12] NASPA. "COVID-19: Information from the States," April 14, 2020, available at https://naspa.us/resource/covid-19-information-from-the-states/.
[13] Preliminary Estimates of the Prevalence of Selected Underlying Health Conditions Among Patients with Coronavirus Disease 2019 — United States, February 12–March 28, 2020. MMWR Morb Mortal Wkly Rep 2020;69:382–386. DOI: http://dx.doi.org/10.15585/mmwr.mm6913e2.
[14] Coronavirus Disease 2019 (COVID-19): How to Protect Yourself & Others, CDC, https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html.

regulation at § 410.32(a) to remove the requirement that certain diagnostic tests are covered only based on the order of a treating physician or NPP. Under this interim policy, during the COVID-19 PHE, COVID-19 tests may be covered when ordered by any healthcare professional authorized to do so under state law. Additionally, because the symptoms for influenza and COVID-19 might present in the same way, during the COVID-19 PHE, we are 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. We are removing the treating physician or NPP ordering requirement for these additional diagnostic laboratory tests only when they are furnished in conjunction with a COVID-19 diagnostic laboratory test as medically necessary in the course of establishing or ruling out a COVID-19 diagnosis or of identifying patients with an adaptive immune response to SARS-CoV-2 indicating recent or prior infection. We would not expect there to be any medical necessary reason to use the specimen for unrelated or repeat testing. 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, we expect that additional testing for influenza or related respiratory viral illness would no longer be medically necessary. We are also making conforming amendments to our regulations at § 410.32(d)(2) and (3) to remove certain documentation and recordkeeping requirements associated with orders for COVID-19 tests during the COVID-19 PHE, as these requirements would not be relevant in the absence of a treating physician's or NPP's order. While no order is required under Medicare, we do expect the entity submitting the claim to include the ordering or referring NPI information on the claim form when an order is written for the test, consistent with current billing instructions.

When COVID-19 tests are furnished without a physician's or NPP's order as set forth in this regulation during the COVID-19 PHE, the laboratory conducting the tests is required to directly notify the patient of the results consistent with other applicable laws, as well as meet other applicable test result reporting requirements. Comprehensive and timely reporting of all testing results to local officials is critical to public health management of the pandemic, and we would expect any clinician or laboratory receiving results to report those results promptly, consistent with state and local public health requirements, typically within 24 hours.

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

In the CY 2020 PFS final rule (84 FR 62634), we finalized an add-on code describing periodic assessments furnished by OTPs. The finalized add-on code is Healthcare Common Procedure Coding System (HCPCS) code G2077 (*Periodic assessment; assessing periodically by qualified personnel to determine the most appropriate combination of services and treatment*). The medical services described by this add-on code 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. The other assessments, including psychosocial assessments can be furnished by practitioners who are eligible to do so under their state law and scope of licensure. We note that to bill for the add-on code, the services need to be medically reasonable and necessary and that OTPs should document the rationale for billing the add-on code in the patient's medical record (84 FR 62647).

In light of the PHE for the COVID-19 pandemic, during which the public has been instructed to practice self-isolation or social distancing, in the March 31st COVID-19 IFC, we revised § 410.67(b)(3) and (4) to allow the therapy and counseling portions of the weekly bundles of services furnished by OTPs, as well as the add-on code for additional counseling or therapy, to be furnished using audio-only telephone calls rather than via two-way interactive

audio-video communication technology during the PHE for the COVID-19 pandemic if beneficiaries do not have access to two-way audio/video communications technology, provided all other applicable requirements are met (85 FR 19258).

In addition to the flexibilities described above, we have determined that it is also necessary to revise § 410.67(b)(7) on an interim final basis to allow periodic assessments to be furnished during the PHE for the COVID-19 pandemic via two-way interactive audio-video communication technology. In addition, 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. We believe this change is necessary to ensure that beneficiaries with opioid use disorders are able to continue to receive these important services during the PHE for the COVID-19 pandemic. While we will allow this flexibility during the PHE for the COVID-19 pandemic, we expect that OTPs will use clinical judgment to determine whether they can adequately perform the periodic assessment over audio-only phone calls, and if not, then they should perform the assessment using two-way interactive audio-video communication technology or in person as clinically appropriate. Regardless of the format that is used, the OTP should document in the medical record the reason for the assessment and the substance of the assessment.

Additionally, we note that SAMHSA has offered flexibilities to states to ensure that individuals being treated with medication for opioid use disorders can continue to receive their medication during the PHE for the COVID-19 pandemic. SAMHSA provides specific guidance for OTPs on its website at SAMHSA.gov/coronavirus. The following is a list of resources posted on the SAMHSA website as of the time of publication of this rule:

- *Opioid Treatment Program (OTP) Guidance (March 16, 2020)* available at https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf.

- *OTP Guidance for Patients Quarantined at Home with the Coronavirus* available at https://www.samhsa.gov/sites/default/files/otp-covid-implementation-guidance.pdf.

- *FAQs: Provision of Methadone and Buprenorphine for the Treatment of Opioid Use Disorder in the COVID-19 Emergency* available at https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf.

- *COVID-19 Public Health Emergency Response and 42 CFR Part 2 Guidance* available at https://www.samhsa.gov/sites/default/files/covid-19-42-cfr-part-2-guidance-03192020.pdf.

- *Considerations for the Care and Treatment of Mental and Substance Use Disorders in the COVID-19 Epidemic: March 20, 2020* available at https://www.samhsa.gov/sites/default/files/considerations-care-treatment-mental-substance-use-disorders-covid19.pdf.

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

1. Background

In 2015, the Congress addressed payments for services furnished by certain off-campus provider-based departments (PBDs) through section 603 of the Bipartisan Budget Act of 2015 (BBA 2015) (Pub. L. 114-74, enacted November 2, 2015). In the CY 2017 Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center Payment System (ASC) proposed rule, we discussed the provisions of section 603 of the BBA 2015, which amended section 1833(t) of the Act (81 FR 45681). For the full discussion of our initial implementation of this provision, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719) and interim final rule with comment period (81 FR 79720 through 79729).

Section 603 of the BBA 2015 amended section 1833(t) of the Act by amending paragraph (1)(B) and adding a new paragraph (21). As a general matter, under sections 1833(t)(1)(B)(v)

and (t)(21) of the Act, applicable items and services furnished by certain off-campus outpatient departments (OPD) of a provider on or after January 1, 2017 are not considered covered OPD services as defined under section 1833(t)(1)(B) of the Act for purposes of payment under the OPPS and are instead paid "under the applicable payment system" under Medicare Part B if the requirements for payment are otherwise met.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719) and the interim final rule with comment period (81 FR 79720 through 79729), we established a number of policies to implement section 603 of the BBA 2015. Broadly, we finalized policies that define whether certain items and services furnished by a given off-campus PBD may be considered excepted, and thus, continue to be paid under the OPPS; established the requirements for the off-campus PBDs to maintain excepted status (both for the excepted off-campus PBDs and for the items and services furnished by excepted off-campus PBDs); and described the applicable payment system for non-excepted items and services (generally, the PFS).

We created the "PO" modifier in the CY 2015 Outpatient Prospective Payment System Final Rule (79 FR 66910-66914), which is reported with every HCPCS code for all outpatient hospital items and services furnished in an excepted off-campus PBD of a hospital. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719) and the interim final rule with comment period (81 FR 79720 through 79729), we created the "PN" modifier to collect data for purposes of implementing section 603 of the BBA 2015 and also to trigger payment under the newly adopted PFS-equivalent rates (50 percent of the OPPS for CY 2017) for non-excepted items and services. In the CY 2018 PFS final rule (82 FR 53023 through 53030), the PFS Relativity Adjuster was revised to be 40 percent of the OPPS rate beginning in CY 2018.

2. Definition of Off-Campus Outpatient Department (OPD)

Under section 603 of the BBA 2015, certain "off-campus departments of a provider" are considered "non-excepted" and paid under the "applicable payment system" instead of the OPPS. In defining the term "off-campus outpatient department of a provider," section 1833(t)(21)(B)(i) of the Act specifies that the term means a department of a provider (as defined at 42 CFR 413.65(a)(2) as that regulation was in effect on November 2, 2015, the date of enactment of the BBA 2015) that is not located on the campus (as defined in § 413.65(a)(2)), of the provider or within the distance (described in the definition of campus) from a remote location of a hospital facility (as defined in § 413.65(a)(2)). The definition of "campus" in § 413.65(a)(2) includes the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office (RO), to be part of the provider's campus.

We note that on March 30, 2020, the Secretary issued several waivers[15] under section 1135(b) of the Act in response to the PHE for the COVID-19 pandemic, including a waiver of Medicare's provider-based rules in § 413.65. Importantly, the waiver does not determine whether a PBD is excepted or non-excepted for purposes of section 603 of the BBA 2015, and the definitions in § 413.65 that section 603 cross-references, including the definition of campus at § 413.65(a)(2), remain relevant to that determination.

We note that the definition of "applicable items and services" specifically excludes items and services furnished by a dedicated emergency department as defined at 42 CFR 489.24(b). Section 1833(t)(21)(B)(ii) of the Act also excepts from the definition of "off-campus outpatient department of a provider," for purposes of paragraphs (1)(B)(v) and (21)(B) of the section, an off-campus PBD that was billing under section 1833(t) of the Act with respect to covered OPD

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

services furnished prior to November 2, 2015, the date of enactment of the BBA 2015. As a result, the definition of "off-campus outpatient department of a provider" *does not* include:

- Off-campus PBDs that were billing under the OPPS for covered OPD services furnished prior to November 2, 2015;
- PBDs located on the campus of a hospital;
- Those PBDs within the distance (described in the definition of campus at § 413.65(a)(2), as of November 2, 2015) of a remote location of a hospital facility; or
- Those PBDs determined by the CMS Regional Office to be part of the provider's campus.

The items and services furnished by these excepted off-campus PBDs on or after January 1, 2017 continue to be paid under the OPPS.

3. Extraordinary Circumstances Policy

In implementing section 603 of the BBA 2015, we recognized the need to determine the status of PBDs that had been excepted but subsequently relocated. In 42 CFR 419.48(a)(2), we established a policy that excepted off-campus PBDs that have not impermissibly relocated can remain excepted. Generally speaking, this means that excepted PBDs that relocate will typically lose their excepted status and be paid under the applicable payment system (generally the PFS) instead. In the CY 2017 OPPS/ASC final rule (81 FR 79705), we also explained that on-campus PBDs, which are considered excepted due to their on-campus status, that relocate off-campus would be considered non-excepted following their relocation. In other words, excepted on-campus and off-campus PBDs that relocate to an off-campus location are then typically paid the PFS-equivalent rate for items and services.

In the CY 2017 OPPS/ASC proposed rule (81 FR 45684), we sought comment on potential extraordinary circumstances outside of a hospital's control that may lead a hospital to relocate an off-campus PBD. In the CY 2017 OPPS/ASC final rule (81 FR 79704 through

79706), we finalized a policy to allow excepted off-campus PBDs to relocate, temporarily or permanently, without loss of excepted status, for extraordinary circumstances outside of the hospital's control, such as natural disasters, significant seismic building code requirements, or significant public health and public safety issues. We also finalized that CMS Regional Offices would evaluate and approve or deny these relocation requests. In 2017, we provided additional subregulatory guidance on the process to request an extraordinary circumstances relocation exception, including the requested minimum information hospitals should submit to support such a request.[16]

4. Extraordinary Circumstances for Relocating PBDs During the PHE for the COVID-19 Pandemic

We continue to believe that our current extraordinary circumstances policy is appropriate under normal circumstances. However, we wish to give hospitals that provide services to Medicare beneficiaries the flexibility to respond effectively to the serious public health threats posed by the COVID-19 PHE. We are aware that many hospitals are repurposing existing clinical and non-clinical space for use as temporary expansion sites to furnish inpatient and outpatient care during the PHE for the COVID-19 pandemic. In addition, we recognize that many hospitals are financially constrained due to the reduction in volume caused by the PHE for the COVID-19 pandemic.[17] We believe these constraints may have led, in certain cases, to hospitals furloughing or otherwise laying off clinical staff. Congress recognized these financial

[16] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Subregulatory-Guidance-Section-603-Bipartisan-Budget-Act-Relocation.pdf.

[17] For example, analysis of Medicare claims in the Integrated Data Repository paid through mid-April 2020 for hospital inpatient services furnished in the final week of March 2020 shows significant decreases (more than 50%), relative to claims paid through mid-April 2019 for hospital services furnished in the final week of March 2019, for certain high-volume elective procedures, like total knee arthroplasty and total hip arthroplasty. We note that any analysis of 2020 claims data is preliminary since providers have up to a year after a service is rendered to submit a claim.

constraints in the passage of the CARES Act and the $100 billion appropriation[18] for Medicare and Medicaid providers and suppliers for, among other things, health care-related expenses or lost revenues that are attributable to coronavirus. Nonetheless, we remain concerned that if an excepted PBD that was previously paid the OPPS rate relocates off-campus due to the COVID-19 PHE, some hospitals would have difficulty sustaining operations for necessary services during the COVID-19 PHE at the PBD if they were paid a reduced rate for services that would have otherwise been paid the OPPS rate but for the fact that the COVID-19 PHE necessitated the temporary relocation of the excepted off-campus or on-campus department. Recognizing the urgency of this situation and understanding that hospitals may need additional flexibilities and financial stability to quickly expand capacity to mitigate the impact of the pandemic on Medicare beneficiaries and the American public, we are adopting a temporary relocation exception policy specific to the PHE for the COVID-19 pandemic so that hospitals can maintain treatment capacity and deliver needed care for patients.

For purposes of enabling greater hospital flexibility, and, in particular, enabling hospitals to rapidly develop temporary expansion sites for patient care, we are temporarily adopting an expanded version of the extraordinary circumstances relocation policy during the COVID-19 PHE to include on-campus PBDs that relocate off-campus during the COVID-19 PHE for the purposes of addressing the COVID-19 pandemic. Our policy has historically applied only to excepted off-campus departments that relocate to a different off-campus location for extraordinary circumstances outside of the hospital's control, that submit an extraordinary relocation exception request to their CMS Regional Office, and for which the CMS Regional Office evaluates and approves the request. However, on-campus departments that relocate on or after March 1, 2020 through the remainder of the PHE for the purposes of addressing the

[18] This appropriation is included in Title VIII of the CARES Act as part of the Public Health and Social Services Emergency Fund.

COVID-19 pandemic may also seek an extraordinary circumstances relocation exception so that they may bill at the OPPS rate, as long as their relocation is not inconsistent with the state's emergency preparedness or pandemic plan. We believe it is important for hospitals to align their PBD relocations with the state's emergency preparedness or pandemic plans to ensure continuity with state efforts, as well as efforts by other health care providers in their community, to mitigate the effects of the PHE for the COVID-19 pandemic.

We note that this temporary extraordinary circumstances policy is time-limited to the PHE for COVID-19 to enable short-term hospital relocation of excepted off-campus and on-campus departments to improve access to care for patients during this time. The temporary extraordinary circumstances relocation policy established here will end following the end of the PHE for the COVID-19 pandemic, and we anticipate that most, if not all, PBDs that relocate during the COVID-19 PHE will relocate back to their original location prior to, or soon after, the COVID-19 PHE concludes. Hospitals that choose to *permanently* relocate these PBDs off-campus would be considered new off-campus PBDs billing after November 2, 2015, and therefore, would be required to bill using the PN modifier for hospital outpatient services furnished from that PBD location and would be paid the PFS-equivalent rate following the end of the COVID-19 PHE.

Following the COVID-19 PHE, hospitals may seek an extraordinary circumstances relocation exception for excepted off-campus locations that have permanently relocated, but these hospitals would need to follow the standard extraordinary circumstances application process we adopted in CY 2017[19] and file an updated CMS-855A enrollment form to reflect the new address(es) of the PBD(s). We note that our standard relocation exception policy only applies to excepted *off-campus* PBDs that relocate; on-campus PBDs that wish to permanently

[19] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Subregulatory-Guidance-Section-603-Bipartisan-Budget-Act-Relocation.pdf.

relocate off-campus will not be able to receive an extraordinary circumstances relocation exception under the standard extraordinary circumstances relocation request process after the conclusion of the COVID-19 PHE. We also note that hospitals should not rely on having relocated the off-campus PBD during the COVID-19 PHE as the reason the off-campus PBD should be permanently excepted following the end of the COVID-19 PHE. In other words, 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, although CMS Regional Offices will continue to have discretion to approve or deny relocation requests for hospitals that apply after the COVID-19 PHE, depending on if the relocation request meets the requirements for the normal extraordinary circumstances exception. Following the COVID-19 PHE, if temporarily relocated off-campus PBDs do not go back to their original location, they will be considered to be non-excepted PBDs and paid the PFS-equivalent rate.

5. New Exception Process for Extraordinary Circumstances Relocation of Existing On-Campus and Excepted Off-Campus PBDs

We are also taking steps to streamline the process for the extraordinary circumstances relocation exceptions for purposes of addressing the COVID-19 pandemic during the PHE. Specifically, using the process outlined below, both excepted off-campus and on-campus PBDs may relocate to off-campus locations during the COVID-19 PHE and begin furnishing and billing for services under the OPPS in the new location prior to submitting documentation to the RO to support the extraordinary circumstances relocation request.

Importantly, if the relocation is denied by the RO under the extraordinary circumstances policy, and the hospital did not bill for them using the "PN" modifier, any claims billed under the OPPS in the new location would need to be reprocessed as having been billed by a non-excepted PBD and will instead be paid the PFS-equivalent rate. Non-excepted off-campus departments will continue to be non-excepted during the COVID-19 PHE, even if they relocate, and thus, will

continue to be paid the PFS-equivalent rate. They do not need to follow the process outlined below for relocation approval since they are already, and will continue to be, non-excepted.

- Hospitals with on-campus and excepted off-campus PBDs that relocate due to the COVID-19 PHE in a manner that is not inconsistent with their state's emergency preparedness or pandemic plan should append modifier "PO" to OPPS claims for services furnished at the relocated PBDs. This modifier indicates a service that is provided at an excepted off-campus PBD and is paid the OPPS payment rate.

- In place of the process adopted in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79704 through 79705) and included in the existing subregulatory guidance under which off-campus PBDs can apply for an extraordinary circumstance relocation exception,[20] all hospitals that relocate excepted on- or off-campus PBDs to off-campus locations in response to the COVID-19 PHE should notify their CMS Regional Office by email of their hospital's CCN; the address of the current PBD; the address(es) of the relocated PBD(s); the date which they began furnishing services at the new PBD(s); a brief justification for the relocation and the role of the relocation in the hospital's response to COVID-19; and an attestation that the relocation is not inconsistent with their state's emergency preparedness or pandemic plan. We expect hospitals to include in their justification for the relocation why the new PBD location (including instances where the relocation is to the patient's home) is appropriate for furnishing covered outpatient items and services.

To the extent that a hospital may relocate to an off-campus PBD that otherwise is the patient's home, only one relocation request during the COVID-19 PHE is necessary. In other words, the hospital would not have to submit a unique request each time it registers a hospital outpatient for a PBD that is otherwise the patient's home; a single submission per location is

[20] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Subregulatory-Guidance-Section-603-Bipartisan-Budget-Act-Relocation.pdf.

sufficient. Hospitals must send this email to their CMS Regional Office within 120 days of beginning to furnish and bill for services at the relocated on- or off-campus PBD.

- To provide additional flexibility, for purposes of addressing the PHE for the COVID-19 pandemic, hospitals may divide their PBD into multiple locations during a relocation. That is, if a single excepted PBD location relocates to multiple off-campus PBD locations in response to the COVID-19 PHE and in a manner that is not inconsistent with the state's emergency preparedness or pandemic plan, it will be permissible for all of the off-campus PBDs to which the excepted PBD relocated to continue to bill under the OPPS under the temporary extraordinary circumstances policy that is in place during the COVID-19 PHE. In addition, for purposes of the COVID-19 PHE, hospitals may relocate *part* of their excepted PBD to a new off-campus location while maintaining the original PBD location. Said differently, if a hospital relocates part of an excepted PBD to one or more off-campus PBD locations, it would be permissible for the original excepted PBD location, as well as the relocated off-campus PBD location(s) of that excepted PBD, to continue to bill under the OPPS under the revised extraordinary circumstances policy that is in place during the COVID-19 PHE so long as the extraordinary circumstances policy in effect during the COVID-19 PHE (described earlier in this section) is followed. We believe these flexibilities are needed for hospitals to respond effectively to the COVID-19 PHE. For example, one PBD may need to utilize two locations to maintain separation between COVID-positive and COVID-negative patients. Further, the relocation or partial relocation of an excepted PBD for the extraordinary circumstance of the COVID-19 PHE could involve a single excepted PBD that relocates (or partially relocates) to a patient's home (for purposes of furnishing a covered OPD service), which under the Hospitals without Walls initiative, can be provider-based to the hospital during the COVID-19 PHE. We note that, during the COVID-19 PHE, a patient's home would be considered a PBD of the hospital when the patient is registered as a hospital outpatient (as discussed in section II.F. of this

IFC) and is receiving covered OPD services from the hospital.

However, in most cases we do not anticipate that excepted PBDs would need to relocate or partially relocate into many different new locations. Rather, we anticipate most multi-relocations or partial relocations would be to a *limited number* of locations as needed to respond to the COVID-19 PHE in a manner not inconsistent with the state's preparedness and pandemic plan, with the exception being multiple relocations to accommodate care in patient's homes. We also expect hospitals exercising this flexibility to be able to support that the excepted PBD is still the same PBD, just split into more than one location. For example, if the excepted PBD was an oncology clinic, we would expect that 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.

- If Medicare-certified hospitals will be rendering services in relocated excepted PBDs, but intend to bill Medicare for the services under the main hospital, no additional provider enrollment actions are required (for example, hospitals do not need to submit an updated CMS-855A enrollment form) for the off-campus relocated site during the COVID-19 PHE. Following the COVID-19 PHE, as noted in section II.E.4. of this IFC, hospitals that wish to permanently relocate their excepted PBD must file an updated CMS-855A enrollment form to reflect the new address(es) of the PBD(s).

In summary, and as discussed in more detailed above, we are adopting a temporary extraordinary circumstances relocation exception policy for excepted off-campus PBDs that relocate off-campus during the COVID-19 PHE. We are extending that temporary policy to on-campus PBDs that relocate off-campus during the COVID-19 PHE, and permitting the relocating PBDs to continue to be paid under the OPPS. Finally, we are streamlining the process for relocating PBDs to obtain the temporary extraordinary circumstances policy exception.

F. Furnishing Outpatient Services in Temporary Expansion Locations of a Hospital or a

Community Mental Health Center (including the Patient's Home)

Infection control is one of the primary goals of many initiatives CMS has undertaken during the COVID-19 PHE. Through all of the flexibilities offered, we have concentrated on increasing providers' ability to furnish services at temporary expansion locations, including the patient's home, to limit the need for patients to receive care in the hospital itself, which could unnecessarily expose the patients or providers to the pandemic contagion. Among the types of services that beneficiaries would benefit from receiving at temporary expansion locations are those critical outpatient services that hospitals, CMHCs, and CAHs furnish in their service areas. HOPDs, in particular, furnish a wide array of services, from clinic visits and counseling services, to complex surgical procedures and emergency care.

We have taken several actions to create regulatory flexibilities in response to the COVID-19 PHE, including publishing the March 31st COVID-19 IFC, issuing numerous blanket waivers of requirements for health care providers under section 1135 of the Act, and exercising the authority granted under section 1812(f) of the Act. Since that time, we have received many questions about how hospital outpatient services can be furnished when the patient is in a temporary expansion location, including his or her home, particularly for those hospital outpatient services that typically do not co-occur with a physician or NPP furnishing a professional service. Those services are billed only under the hospital OPPS when furnished by the hospital and there is no professional service that is separately billable under the PFS.

In addition, we have received questions about how the hospital should bill during the COVID-19 PHE when the practitioners typically furnishing services in HOPDs are now instead furnishing professional services as Medicare telehealth services under section 1834(m) of the Act under the flexibilities provided by both the waiver of requirements under section 1135(b)(8) of the Act and the March 31st COVID-19 IFC. Because we continue to believe that it is important for beneficiaries to be able to receive care in temporary expansion locations to maintain infection

control, we explain in this section the flexibilities that are available to hospitals to enable them to furnish outpatient services to beneficiaries in their homes (or other temporary expansion locations), when such a location is considered to be a PBD of the hospital, as permitted under the waivers in effect during the COVID-19 PHE.

Under ordinary circumstances, Medicare would not pay for hospital outpatient therapeutic services that are furnished to a beneficiary in the beneficiary's home or any other location that could not ordinarily be provider-based to the hospital. Our regulations at § 410.27(a)(1)(iii) explicitly include a requirement that therapeutic outpatient hospital services must be furnished in the hospital or CAH or in a department of the hospital or CAH.

However, as noted above, we have issued numerous blanket section 1135 waivers to give health care providers needed flexibility to address the COVID-19 PHE.[21] As part of this initiative, we have waived the requirements associated with becoming a PBD of a hospital at § 413.65, as well as certain requirements under the Medicare conditions of participation in §§ 482.41 and 485.623, to facilitate the availability of temporary expansion locations. Because of these waivers, during the COVID-19 PHE, temporary expansion locations, including beneficiaries' homes, can become PBDs of hospitals and therapeutic outpatient hospital services furnished to beneficiaries in these provider-based locations can meet the requirement that these services be furnished in the hospital so long as all other requirements are met, including the hospital conditions of participation, to the extent not waived, during the COVID-19 PHE. That is, while certain locations would not normally be permitted to be considered part of a hospital, during the COVID-19 PHE, the section 1135 waivers of the provider-based rules allow temporary expansion locations to become provider-based to the hospital to bill for medically necessary hospital outpatient therapeutic services furnished at those locations, assuming all other

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

applicable requirements are met (including, to the extent not waived, the hospital conditions of participation).

For purposes of clarifying regulatory flexibilities for hospital outpatient therapeutic services furnished to beneficiaries in their homes or other temporary expansion locations for the duration of the COVID-19 PHE, we considered hospital outpatient therapeutic services in three categories: (1) hospital outpatient therapy, education, and training services, including partial hospitalization program services, that can be furnished other than in-person, and are furnished in a temporary expansion location (which may be the patient's home) that is a PBD of the hospital or an expanded CMHC; (2) hospital outpatient clinical staff services furnished in-person to the beneficiary in a temporary expansion location; and (3) hospital services associated with a professional service delivered by telehealth. We address each of these three categories in more detail below.

1. Hospital Outpatient and CMHC Therapy, Education, and Training Services

In many cases, hospitals provide hospital outpatient therapy (including behavioral health), education, and training services that are furnished by hospital-employed counselors or other licensed professionals. Examples of these services include psychoanalysis, psychotherapy, diabetes self-management training, and medical nutrition therapy. With few exceptions, the Medicare statute does not have a benefit category that would allow these types of professionals (for example, counselors, nurses, and registered dieticians) to bill Medicare directly for their services. These services can, in many cases, be billed by providers such as hospitals under the OPPS or by physicians and other practitioners as services incident to their professional services under the PFS.

Potentially the most prominent of these services are partial hospitalization program (PHP) services, which comprise an intensive outpatient program of psychiatric services provided

as an alternative to inpatient psychiatric care for individuals who have an acute mental illness. We discuss treatment of PHP services separately within this section of this IFC.

Outpatient therapy, education, and training services require communication and interaction. Facility staff can effectively furnish these services using telecommunication technology and, unlike many hospital services, the clinical staff and patient are not required to be in the same location to furnish them. We have already stated that section 1135 blanket waivers in effect during the COVID-19 PHE allow the hospital to consider the beneficiary's home, and any other temporary expansion location operated by the hospital during the COVID-19 PHE, to be a PBD of the hospital, so long as the hospital can ensure the locations meet all of the conditions of participation, to the extent not waived. In light of the need for infection control and a desire for continuity of behavioral health care and treatment services, we recognize the ability of the hospital's clinical staff to continue to deliver these services even when they are not physically located in the hospital. Provided a hospital's clinical staff is furnishing hospital outpatient therapy, education, and training services to a patient in the hospital (which can include the patient's home so long as it is provider based to the hospital), and the patient is registered as an outpatient of the hospital, we will consider the requirements of the regulations at § 410.27(a)(1) to be met. We remind readers that the physician supervision level for the vast majority of hospital outpatient therapeutic services is currently general supervision under § 410.27. This means a service must be furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the service.

To facilitate public understanding of the types of services we believe can be furnished by the hospital to a patient in the hospital (including the patient's home if it is a PBD of the hospital) using telecommunications technology, we have provided on our website[22] a list of the

[22] www.cms.gov.

outpatient therapy, counseling, and educational services that hospital clinical staff can furnish incident to a physician's or qualified NPP's service during the COVID-19 PHE to a beneficiary in their home or other temporary expansion location that functions as a PBD of the hospital when the beneficiary is registered as an outpatient of the hospital. We note that this list may not include every service that falls into this category and we intend to update the list periodically, to the extent that would be helpful for public awareness.

All services furnished by the hospital still require an order by a physician or qualified NPP and must be supervised by a physician or other NPP appropriate for supervising the service given their hospital admitting privileges, state licensing, and scope of practice, consistent with the requirements in § 410.27. We note that hospitals may bill for these services as if they were furnished in the hospital and consistent with any specific requirements for billing Medicare in general, including any relevant modifications in effect during the COVID-19 PHE[23]. We note that when these services are provided by clinical staff of the physician or other practitioner and furnished incident to their professional services, and are not provided by staff of the hospital, the hospital would not bill for the services. The physician or other practitioner should bill for such services incident to their own services and would be paid under the PFS. As always, documentation in the medical record of the reason and necessity of the visit is required.

a. Partial Hospitalization Program (PHP)

A PHP is an intensive outpatient program of psychiatric services provided as an alternative to inpatient psychiatric care for individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression and schizophrenia. Section 1861(ff)(1) of the Act defines partial hospitalization services as the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph

[23] https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page.

(3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan. Section 1861(ff)(2) of the Act describes the items and services included in partial hospitalization services. Section 1861(ff)(3)(A) of the Act specifies that 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. Section 1861(ff)(3)(B) of the Act defines a CMHC for purposes of this benefit.

In CY 2018, which is the most recent period for which we have complete PHP claims data, there were a total of 482,973 paid PHP days, including 394,311 paid PHP days for hospital-based providers and 88,662 paid PHP days for CMHCs. In comparison, inpatient psychiatric facilities (IPFs) billed 4,291,461 utilization days in FY 2019, the most recent period for which we have complete IPF claims data. Based on this comparison, we estimate that IPF services are utilized between 8 and 9 times more frequently than PHP services.

Previously in this section, we identified that infection control is a primary goal of CMS initiatives undertaken during the COVID-19 PHE. We also believe continuity of behavioral health services is critical for those participating in a PHP, particularly at a time of heightened anxiety and uncertainty. As noted above, we have issued numerous blanket waivers under section 1135 of the Act, including for hospitals and CMHCs providing PHP services, to give health care providers needed flexibility to address the COVID-19 PHE and support the goal of infection control while maintaining access to partial hospitalization services and ensuring continuity of care for patients. Effective as of March 1, 2020 and for the duration of the COVID-19 PHE, a temporary expansion location where the beneficiary may be located, including a

beneficiary's home, may be a PBD of the hospital, or may be a temporary extension of the CMHC (discussed in more detail below).

Consistent with the goals of infection control and maintaining access, for the duration of the COVID-19 PHE only, providers can furnish certain partial hospitalization services remotely to patients in a temporary expansion location of the hospital or CMHC, which may include the patient's home to the extent it is made provider-based to the hospital or an extension of the CMHC. PHP services consist of unique combinations of services designated at section 1861(ff)(2) of the Act, including individual psychotherapy, patient education, and group psychotherapy. Certain PHP services such as these require communication and interaction, but do not require the clinical staff or patient to be in the same location, nor do clinical staff need to be in the hospital or CMHC when furnishing these PHP services. Therefore, the following types of services—to the extent they were already billable as PHP services in accordance with existing coding requirements prior to the COVID-19 PHE—can now be furnished to beneficiaries by facility staff using telecommunications technology during the COVID-19 PHE: (1) individual psychotherapy; (2) patient education; and (3) group psychotherapy. Because of the intensive nature of PHP, we expect PHP services to be furnished using telecommunications technology involving both audio and video. However, we recognize that in some cases beneficiaries might not have access to video communication technology. In order to maintain beneficiary access to PHP services, only in the case that both audio and video are not possible can the service be furnished exclusively with audio. To be clear, services that require drug administration cannot be furnished using telecommunications technology. To facilitate public understanding of the types of PHP services that can be furnished using telecommunications technology by the hospital to a patient in the hospital (including the patient's home if it is a PBD of the hospital) or by the

CMHC to a patient in an expanded CMHC location, we have provided on our website[24] a list of the individual psychotherapy, patient education, and group psychotherapy services that hospital or CMHC staff can furnish during the COVID-19 PHE to a beneficiary in their home or other temporary expansion location that functions as a PBD of the hospital or expanded CMHC when the beneficiary is registered as an outpatient. We note that this list may not include every service that falls into this category and we intend to update the list periodically, to the extent that would be helpful for public awareness.

Although these services can be furnished remotely, all other PHP requirements are unchanged and still in effect, including that all services furnished under the PHP still require an order by a physician, must be supervised by a physician, must be certified by a physician, and must be furnished in accordance with coding requirements by a clinical staff member working within his or her scope of practice. In accordance with the longstanding requirements that are detailed in the Medicare Benefit Policy Manual, Pub 100-02, chapter 6, section 70.3, documentation in the medical record of the reason for the visit and the substance of the visit is required. As noted above, when these services are provided by clinical staff of the physician or other practitioner and furnished incident to their professional services, and are not provided by staff of the hospital or CMHC, the hospital or CMHC would not bill for the services. The physician or other practitioner should bill for such services incident to their own services and would be paid under the PFS.

(i.) Hospital-based PHP Providers

As detailed above, in CY 2018, hospital-based providers furnished 394,311 paid PHP days to Medicare beneficiaries, approximately 81.6 percent of Medicare-paid PHP days in that year. As part of the initiative to promote infection control and maintain access to PHP services,

[24] www.cms.gov.

we have waived the requirements for being a PBD of the hospital in § 413.65, as well as certain requirements under the Medicare conditions of participation in §§ 482.41 and 485.623, to facilitate the availability of temporary expansion locations. As noted above, for purposes of the COVID-19 PHE and effective as of March 1, 2020, a temporary expansion location where the beneficiary may be located, including a beneficiary's home, may be a PBD of the hospital where the location meets the non-waived conditions of participation. Together, these waivers allow hospitals to consider a temporary expansion location where the beneficiary may be located, including their homes, an HOPD only in the context of the COVID-19 PHE. Thus, for the duration of the COVID-19 PHE, we will consider the PHP services furnished by hospital clinical staff, when the beneficiary is registered as an outpatient of the hospital and in accordance with the supervising practitioner's scope of practice, to the beneficiary in a temporary expansion location where the beneficiary may be located, including a beneficiary's home, to have been furnished in the hospital so long as the temporary expansion location is made provider-based to the hospital. The hospital should bill for these services as if they were furnished in the hospital and consistent with any specific requirements for billing Medicare during the COVID-19 PHE.

(ii.) Community Mental Health Centers

A CMHC is a provider of PHP services defined under section 1861(ff)(3)(B) of the Act. As detailed above, in CY 2018, CMHCs furnished 88,662 paid PHP days to Medicare beneficiaries, approximately 18.4 percent of Medicare-paid PHP days in that year. For the duration of the COVID-19 PHE, we are waiving the restriction at § 485.918(b)(1)(iii) for the purpose of providing PHP services to CMHC patients in their homes, which will be considered a temporary expansion location of a CMHC. A temporary expansion location where the beneficiary may be located, including the beneficiary's home, can be considered part of a CMHC, and certain therapeutic services furnished to beneficiaries, when the beneficiary is registered as an outpatient of the CMHC, in these temporary expansion locations can meet the

requirement that these services be furnished in the CMHC. Specifically, for the purposes of the COVID-19 PHE and effective as of March 1, 2020, we 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, while PHP services are being furnished at that location by CMHC staff in accordance with the supervising practitioner's scope of practice. Therefore, we will consider services furnished in that location to have been furnished in the CMHC. The CMHC should bill for these services as if they were furnished in the CMHC and consistent with any specific requirements for billing Medicare during the COVID-19 PHE.

2. Hospital In-Person Clinical Staff Services in a Temporary Expansion Location (which may the Home)

Hospitals also provide services that are furnished by clinical staff under a physician's or qualified NPP's order that do not require professional work by the physician or qualified NPP, and thus, are billed only under the OPPS when furnished by the hospital and are not separately billable under the PFS. Wound care, chemotherapy administration, and other drug administration are examples[25] of these types of services. We note that while surgical services also fall under this category, we would not anticipate that they would be furnished in a home that becomes provider-based to the hospital, due to infection control and operating room requirements. In addition, there are several other hospital outpatient therapeutic services that require the hospital's clinical staff's presence to furnish the service. The current section 1135 blanket waivers in place during the COVID-19 PHE allow the patient's home to be considered an outpatient PBD of the hospital. With a primary goal of infection control and understanding that hospitals must meet the conditions of participation, to the extent not waived during the

[25] With regard to observation services, we note that to bill for observation services all existing requirements must be met. These requirements are identified in Chapter 4, Section 290 of the Medicare Claims Processing Manual.

COVID-19 PHE, we are making the public aware of the flexibilities that exist during the COVID-19 PHE that enable hospitals to furnish these clinical staff services in the patient's home as an outpatient PBD and to bill and be paid for these services as HOPD services when the patient is registered as a hospital outpatient. Because these services have to be provided in person by clinical staff, these services cannot be furnished by telecommunication technology by the hospital. In these instances, hospital clinical staff must be physically present in the patient's home or other temporary expansion location that is provider based to the hospital to furnish the hospital outpatient therapeutic service. The physician supervision level must be met for these services, and we note that for the vast majority of therapeutic hospital outpatient services, the required supervision level is currently general supervision under § 410.27. This means a service is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the service. This includes non-surgical extended duration therapeutic services (NSEDTSs), which are services that can last a significant period of time, have a substantial monitoring component that is typically performed by auxiliary personnel, have a low risk of requiring the physician's or appropriate NPP's immediate availability after the initiation of the service, and are not primarily surgical in nature. Direct supervision is generally required for the initiation of these NSEDTs, followed by a general supervision requirement for the duration of the service. In the March 31st COVID-19 IFC, we changed the supervision requirement for NSEDTs to instead require a general level of supervision throughout the service, including at service initiation, for the duration of the COVID-19 PHE.

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

traditional PBD, and because there are interactions with other types of providers or suppliers who may furnish services in the home, but not in the "hospital," we note that hospitals should only consider the patient home to be provider-based to the hospital when the patient is registered as a hospital outpatient. When the patient is not receiving outpatient services by the hospital, the patient's home can be considered a home for purposes of the home health benefit and the HHA can furnish and bill for home health services. The hospital should be aware if the patient is under a home health plan of care, and it must not furnish services to the patient that could be furnished by the HHA while the plan of care is active. That is, to the extent that there is some overlap between the types of services a HHA and a HOPD can provide, and the patient has a current home health plan of care, the hospital should only furnish services that cannot be furnished by the HHA.

The fact that these services can be furnished in a patient's home or another temporary expansion location that is temporarily provider based to the hospital does not change the requirements that all services furnished by the hospital require an order by a physician or qualified NPP and must be supervised by a physician or other NPP appropriate for supervising the service given their hospital admitting privileges, state licensing, and scope of practice consistent with the requirements in § 410.27. Hospitals should bill for these services as they ordinarily bill for services along with any specific billing requirements for relocating PBDs specific to billing during a COVID-19 PHE as discussed in section II.D. of this IFC (that is, appending the PO modifier for excepted items and services and the PN modifier for nonexcepted services). Information regarding the application of section 603 of the BBA 2015 to relocating PBDs is available in section II.F.4. of this IFC, as well as section II.E. of this IFC.

3. Hospital Services Accompanying a Professional Service Furnished Via Telehealth

The majority of hospital services are furnished in conjunction with professional services of physicians and other practitioners. In these instances, practitioners furnish and bill separately

for their professional services indicating the place of service as a HOPD, and the hospital bills separately to be paid for the clinical labor, equipment, overhead, and capital to support the delivery of that professional service. In the March 31st COVID-19 IFC, we instructed physicians and other practitioners furnishing telehealth services to beneficiaries in their homes as permitted during the COVID-19 PHE to bill for those services in the same way they would if they were furnishing the services in person (85 FR 19233). For many professionals, the HOPD is the usual location where they furnish services. For the duration of the COVID-19 PHE and effective March 1, 2020, when a practitioner who ordinarily practices in a HOPD furnishes a telehealth service to a patient who is located at home (or otherwise not in a telehealth originating site), they would submit a professional claim with the place of service code indicating the service was furnished in the HOPD and using the Current Procedural Terminology (CPT) telehealth modifier, modifier 95. Medicare would pay the practitioner under the PFS at the "facility" rate as if the service was furnished in the HOPD. We adopted the aforementioned interim rule because we believed that, but for the COVID-19 PHE, the physician or practitioner would likely have furnished the service in person at their usual practice location; and that the service was instead furnished via telehealth for purposes of infection control. The March 31st COVID-19 IFC did not provide for the hospital to submit any claim for the service under the aforementioned scenario.

We acknowledge that when a physician or practitioner who ordinarily practices in the HOPD furnishes a telehealth service to a patient who is located at home, the hospital would often still provide some administrative and clinical support for that service. When a registered outpatient of the hospital is receiving a telehealth service, the hospital may bill the originating site facility fee to support such telehealth services furnished by a physician or practitioner who ordinarily practices there. This includes patients who are at home, when the home is made provider-based to the hospital (which means that all applicable conditions of participation, to the

extent not waived, are met), under the current waivers in effect for the COVID-19 PHE.

More specifically, when a telehealth service is furnished by a practitioner located at a distant site to a patient who is located in the HOPD, the hospital is presumed to provide administrative and clinical support resources. In such circumstances, section 1834(m)(2)(B) of the Act allows for an originating site facility fee to be paid to the hospital. Section 1834(m)(2)(B)(ii) of the Act further provides that no facility fee shall be paid to an originating site described in paragraph (4)(C)(ii)(X) (that is, the home). However, as described throughout this section, the patient's home may be considered a PBD of the hospital during the COVID-19 PHE if other applicable requirements (including the non-waived conditions of participation) are met. As noted above, because the home is not a traditional PBD, and because there are interactions with other types of providers or suppliers who may furnish services in the home, but not in the "hospital," we note that hospitals should only furnish hospital outpatient services to a patient (who is registered as a hospital outpatient) after the patient's home has been made provider-based to the hospital for the provision of such services. In that event, the home would be serving as a PBD of the hospital, and as the originating site for the telehealth service furnished by a physician or practitioner located at a distant site.

The originating site facility fee is the statutory payment that is made to the facility for providing the site where the patient is located, and any other administrative or clinical support, for a telehealth service. Therefore, during the COVID-19 PHE, when telehealth services are furnished by a physician or practitioner who ordinarily practices in the HOPD to a patient who is located at home or other applicable temporary expansion location that has been made provider based to the hospital, we believe it would be appropriate to permit the hospital to bill and be paid the originating site facility fee amount for those telehealth services, just as they would have ordinarily done outside of the COVID-19 PHE in this circumstance.

As such, for the duration of the COVID-19 PHE, we are making the public aware that

under the flexibilities already in effect, when a patient is receiving a professional service via telehealth in a temporary expansion location that is a PBD of the hospital, and the patient is a registered outpatient of the hospital, the hospital in which the patient is registered may bill the originating site facility fee for the service. As always, documentation in the medical record of the reason for the visit and the necessity of the visit is required.

4. Intersection with Payment Policy for Hospital Outpatient PBDs

As discussed previously, we have waived[26] the requirements for being a PBD of the hospital in § 413.65, as well as certain requirements under the Medicare conditions of participation in §§ 482.41 and 485.623, to facilitate the availability of temporary expansion sites. Importantly, these waivers do not determine whether a PBD is excepted or non-excepted for purposes of section 603 of the BBA 2015, and the definitions in § 413.65 that section 603 cross-references, including the definition of campus at § 413.65(a)(2), remain relevant to that determination. However, in section II.E. of this IFC, we discuss a temporary extraordinary circumstances relocation policy for on-campus and excepted off-campus hospital outpatient PBDs that relocate due to the COVID-19 PHE, under which these PBDs that relocate in accordance with that policy can continue to bill and be paid as an on-campus or excepted off-campus PBD at the full OPPS payment rate. The hospital's relocation must not be inconsistent with their state's emergency preparedness or pandemic plan. For purposes of the COVID-19 PHE, on-campus or excepted off-campus PBDs can be considered to have relocated (or partially relocated) to a beneficiary's home, or other temporary expansion location of the hospital, when the beneficiary is registered as an outpatient of the hospital during service delivery. Under this policy, the PBD is still considered either an on-campus or excepted off-campus PBD that is not subject to section 603 of the BBA 2015 and would bill with the "PO" modifier for services

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

furnished to beneficiaries in their homes as a relocated (or partially relocated) PBD and will receive the full OPPS rate. However, we note that if the hospital does not relocate (or partially relocate) an existing on-campus or excepted off-campus PBD to the patient's home and does not seek an exception under the temporary extraordinary circumstances relocation exception policy discussed in section II.E. of this IFC, the patient's home would be considered a new non-excepted off-campus PBD and the hospital would bill with the "PN" modifier and receive the PFS-equivalent rate.

Under section II.F.1. of this IFC, we have identified certain outpatient therapy, counseling, and educational services that hospital clinical staff can furnish (using telecommunications technology) incident to a physician's service during the COVID-19 PHE to a beneficiary who is registered as an outpatient when those services are furnished in the beneficiary's home, which functions as a PBD of the hospital. For example, hospital clinical staff can now remotely furnish psychotherapy (for example, HCPCS code 90832) to the beneficiary in their home, as long as the beneficiary is a registered outpatient of the hospital and the patient's home is made provider-based to the hospital. In this circumstance, if the hospital considers the beneficiary's home a relocated (or partially relocated) PBD, and follows the temporary extraordinary circumstances exception policy discussed in section II.E. of this IFC, the hospital would bill the applicable HCPCS code (for example, HCPCS code 90832) along with modifier "PO" to receive the full OPPS payment amount. The hospital will be paid under the PFS for services furnished to a beneficiary in their home if the hospital does not seek an extraordinary circumstances relocation exception for their PBD and, if applicable, include the patient's home address as one of the locations to which the PBD relocated and bill the claim for the services furnished in the patient's home using the PO modifier.

5. Summary

As discussed above, we clarified that hospital and CMHC staff can furnish certain

outpatient therapy, counseling, and educational services (including PHP services) incident to a physician's service during the COVID-19 PHE to a beneficiary in their home or other temporary expansion location using telecommunications technology. In these circumstances, the hospital can furnish services to a beneficiary in a temporary expansion location (including the beneficiary's home) if that beneficiary is registered as an outpatient; and the CMHC can furnish services in an expanded CMHC (including the beneficiary's home) to a beneficiary who is registered as an outpatient. We also clarified that hospitals can furnish clinical staff services (for example, drug administration) in the patient's home, which is considered provider-based to the hospital during the COVID-19 PHE, and to bill and be paid for these services when the patient is registered as a hospital outpatient. Further, we clarified that when a patient is receiving a professional service via telehealth in a location that is considered a hospital PBD, and the patient is a registered outpatient of the hospital, the hospital in which the patient is registered may bill the originating site facility fee for the service. Finally, we clarified the applicability of section 603 of the BBA 2015 to hospitals furnishing care in the beneficiaries' homes (or other temporary expansion locations), and whether those locations are considered relocated, partially relocated, or new PBDs.

G. Medical Education

1. Indirect Medical Education

a. Overview of Indirect Medical Education

Section 1886(d)(5)(B) of the Act provides for a payment adjustment known as the indirect medical education (IME) adjustment under the inpatient prospective payment system (IPPS) for hospitals that have residents in an approved Graduate Medical Education (GME) program, to account for the higher indirect patient care costs of teaching hospitals relative to non-teaching hospitals. The statute describes the calculation of the IME payment adjustment, which is applied to the (Medicare Severity-Diagnosis Related Group) MS-DRG payments based

on the ratio of the hospital's number of full-time equivalent (FTE) residents training in the portion of the hospital subject to the IPPS or in such hospital's outpatient departments (OPDs), as well as qualifying non-provider sites to the number of inpatient hospital beds. The regulation regarding the calculation of this additional payment is located at 42 CFR 412.105.

The calculation of IME payments is affected by a hospital's resident-to-bed ratio, which is the ratio of the number of FTE residents that a hospital is allowed to count to the number of available beds at the hospital. Generally, the greater the number of allowable FTE residents a hospital counts, the greater the amount of Medicare IME payments the hospital will receive. Conversely, the greater number of beds at the hospital for the same number of residents, the lower the amount of the IME payments the hospital will receive.

Similar payment adjustments to reflect the higher costs of facilities that train medical interns and residents are applied in the inpatient rehabilitation facility (IRF) and IPF contexts (referred to as "teaching status adjustments"). For IRFs, section 1886(j)(3)(A)(v) of the Act confers broad authority upon the Secretary to adjust the per unit payment rate by such factors as the Secretary determines are necessary to properly reflect variations in necessary costs of treatment. For example, we adjust the federal IRF prospective payment amount to account for facility-level characteristics such as an IRF's low-income percentage, teaching status, and location in a rural area, if applicable, as described in § 412.624(e). Under § 412.624(e)(4), for discharges on or after October 1, 2005, we adjust the Federal prospective payment on a facility basis by a factor as specified by CMS for facilities that are teaching institutions or units of teaching institutions. This adjustment is made on a claim basis as an interim payment and the final payment in full for the claim is made during the final settlement of the cost report.

Under the regulatory authority set out at § 412.624(e)(4), the IRF teaching adjustment is based on the ratio of the number of FTE residents training in the IRF divided by the facility's average daily census (ADC), subject to a cap. Specifically, the amount of the adjustment is

calculated by adding 1 to the ratio of interns and residents to the ADC, and then raising that sum to the 1.0163 power, as described in Chapter 3, Section 140.2.5.4 of the Medicare Claims Processing Manual (Pub. 100-04) at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.

For IPFs, section 1886(s) of the Act authorizes the Secretary to develop a per diem PPS for inpatient hospital services furnished in psychiatric hospitals and psychiatric units (IPFs) in accordance with section 124 of the Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113, November 29, 1999); section 124(a)(1) of the BBRA, in turn requires the Secretary to develop an adequate patient classification system that reflects the differences in patient resource use and costs among IPFs. Under this authority, we adjust the IPF federal per diem base rate to account for facility-level characteristics such as being located in a rural area, teaching status, and the cost of living for IPFs located in Alaska and Hawaii, if applicable, as described in § 412.424(d). For cost reporting periods beginning on or after January 1, 2005 under § 412.424(d)(1)(iii), we adjust the Federal per diem base rate by a factor to account for indirect teaching costs. This adjustment is made on a claim basis as an interim payment and the final payment in full for the claim is made during the final settlement of the cost report.

In accordance with § 412.424(d)(1)(iii), an IPF's teaching adjustment is based on the ratio of the number of FTE residents training in the IPF divided by the facility's ADC, subject to a cap. Specifically, the amount of the adjustment is calculated by adding 1 to the ratio of interns and residents to the ADC, and then raising that sum to the 0.5150 power, as described in Chapter 3, Section 190.6.3 of the Medicare Claims Processing Manual (Pub. 100-04) at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf.

We continue to believe that our current policies for calculating IME payments and the IRF and IPF teaching status adjustments are consistent with the statute and appropriate under normal circumstances. However, we wish to give hospitals, IRFs, and IPFs that provide services

to Medicare beneficiaries the flexibility to respond effectively to the serious public health threats posed by COVID-19. Recognizing the urgency of this situation, and understanding that hospitals may need additional flexibilities to expand capacity in the efforts to mitigate the impact of the pandemic on Medicare beneficiaries and the American public, we are changing our policies during the PHE for the COVID-19 pandemic so that hospitals, IRFs, and IPFs do not experience undue reductions in IME or teaching status adjustment payment amounts.

b. Holding Hospitals Harmless from Reductions in IME Payments Due to Increases in Bed Counts Due to COVID-19

We have been asked by multiple teaching hospitals if CMS can hold hospitals harmless from a reduction in IME payments resulting from the temporary increase in the number of available hospital beds due to the influx of COVID-19 patients. The IME payment formula (under section 1886(d)(5)(B) of the Act and § 412.105) is determined in part using each teaching hospital's ratio of allowable FTE residents in the numerator and available beds in the denominator. To accommodate the increase in COVID-19-related patients, many hospitals are increasing their number of inpatient beds. Using our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act, and to mitigate IME payment changes from pre-COVID levels, for the duration of the COVID-19 PHE, for purposes of determining a hospital's IME payment amount, the hospital's available bed count is considered to be the same as it was on the day before the COVID-19 PHE was declared. We are revising § 412.105(d)(1), to state that beds temporarily added during the timeframe of the COVID-19 PHE, as defined in § 400.200, is in effect, are excluded from the calculations to determine IME payment amounts.

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

We have been asked by IRFs and IPFs if CMS can hold facilities harmless from a reduction in teaching status adjustment payments resulting from the temporary increase in

facilities' ADC due to the influx of COVID-19 patients. We are concerned that, if a teaching IRF or IPF accepts patients from the inpatient acute care hospital to alleviate bed capacity during the PHE for the COVID-19 pandemic, the IRF's or IPF's ADC would increase, which would artificially decrease the IRF's or IPF's ratio of number of interns and residents to ADC and thereby decrease the facility's teaching status adjustment. To ensure that teaching IRFs or teaching IPFs can alleviate bed capacity issues by taking patients from the inpatient acute care hospitals without being penalized by lower teaching status adjustments, we believe it is appropriate to freeze the IRFs' or IPFs' teaching status adjustment payments at their values prior to the COVID-19 PHE. Therefore, for the duration of the COVID-19 PHE, an IRF's or an IPF's teaching status adjustment payment amount will be the same as it was on the day before the COVID-19 PHE was declared.

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

a. Overview of Graduate Medical Education

Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) (Pub. L. 99-272, enacted April 7, 1986), establishes a methodology for determining Medicare payments to hospitals for the direct costs of approved GME programs. Section 1886(h)(2) of the Act sets forth a methodology for the determination of a hospital-specific base-period per resident amount that is calculated by dividing a hospital's allowable direct costs of GME in a base period by its number of FTE residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, October 1, 1983 through September 30, 1984). The base year per resident amount is updated annually for inflation. In general, Medicare direct GME (DGME) payments are calculated by multiplying the hospital's updated per resident amount by the weighted number of FTE residents working in all areas of the hospital complex (and at non-provider sites, when applicable), and the hospital's Medicare share of total inpatient days. The

provisions of section 1886(h) of the Act are implemented in regulations at §§ 413.75 through 413.83.

As noted earlier, section 1886(d)(5)(B) of the Act provides for a payment adjustment known as the IME adjustment under the IPPS for hospitals that have residents in an approved GME program, to account for the higher indirect patient care costs of teaching hospitals relative to non-teaching hospitals. The regulation regarding the calculation of this additional payment is located at § 412.105. The hospital's IME adjustment applied to the MS-DRG payments is calculated based on the ratio of the hospital's number of FTE residents training in the portion of the hospital subject to the IPPS or the OPDs of such hospital, as well as qualifying nonprovider sites to the number of inpatient hospital beds.

The calculation of both DGME and IME payments is affected by the number of FTE residents that a hospital is allowed to count. 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. Congress, through the Balanced Budget Act of 1997 (Pub. L. 105-33, enacted August 5, 1997), established a limit (that is, a cap) on the number of allopathic and osteopathic residents that a hospital may include in its FTE resident count for DGME and IME payment purposes. Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of allopathic and osteopathic residents for purposes of DGME may not exceed the hospital's unweighted FTE count for DGME in its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the allopathic and osteopathic FTE count for IME during that cost reporting period is applied effective for discharges occurring on or after October 1, 1997. Dental and podiatric residents are not included in this statutorily mandated cap.

We continue to believe that our current policies for calculating DGME and IME payments are consistent with the statute and are appropriate under normal circumstances.

However, we wish to give hospitals that provide services to Medicare beneficiaries the flexibility to respond effectively to the serious public health threats posed by COVID-19. Recognizing the urgency of this situation, and understanding that our current policies may inhibit use of residents or capacity that might otherwise be effective in the efforts to mitigate the impact of the COVID-19 pandemic on Medicare beneficiaries and the American public, we are changing our policies during the PHE for the COVID-19 pandemic so that hospitals do not experience undue reductions in DGME or IME payment amounts.

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

We have been asked about the Medicare GME payment consequences of teaching hospitals sending residents assigned to them to other hospitals to meet COVID-19-related surges in patient volume.

Under our current regulations, a hospital cannot claim the time spent by residents training at another hospital for purposes of GME payments (§§ 412.105(f)(1)(iii)(A) for IME and 413.78(b) for DGME).

In the unprecedented context of the nationwide COVID-19 PHE, when teaching hospitals need flexibility to determine resident training on an emergency basis to respond to the COVID-19 pandemic and hospitals are facing significant workforce challenges, we believe that teaching hospitals should be able to send residents, on an emergency basis, without regard to GME financial considerations, to hospitals where they are most needed to treat COVID-19 or non-COVID-19 patients. Therefore, we are revising §§ 412.105(f)(1)(iii)(A) for IME and 413.78 for DGME to allow teaching hospitals during the COVID-19 PHE to claim for purposes of IME and DGME payments the time spent by residents training at other hospitals. We recognize this is a significant departure from existing policy and this action is being taken only during this PHE due to the unprecedented nature of 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. 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.

Specifically, for the timeframe that the PHE associated with COVID-19 is in effect, we are using our authority under section 1886(h)(4)(A) and (B) of the Act to suspend the requirement that a hospital cannot claim the time spent by residents training at another hospital so that a hospital which sends residents to another hospital can claim those FTE residents on its Medicare cost report while they are training at another hospital in its FTE count, if all of the following conditions and all other applicable requirements are met:

- The sending hospital sends the resident to another hospital in response to the COVID-19 pandemic. This criterion would be met if either the sending hospital or the other hospital are treating COVID-19 patients. We would not require that the resident be involved in patient care activities for patients with COVID-19 for the sending hospital to demonstrate that it sent the resident to the other hospital in response to the COVID-19 pandemic.

- Time spent by the resident at the other hospital would be considered to be time spent in approved training if the activities performed by the resident at the other hospital are consistent with any guidance in effect during the COVID-19 PHE for the approved medical residency program at the sending hospital.

- 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.

We believe that this policy will allow hospitals to react quickly and in "real time" to send residents to facilities where they are most needed during the PHE associated with COVID-19.

We are revising § 413.78(b), adding new § 413.78(i), and revising § 412.105(f)(1)(iii)(A) to state the conditions under which a hospital may claim, in its FTE resident count, residents that

it sends to another hospital during the PHE associated with COVID-19.

For the duration of the PHE related to COVID-19, CMS has waived certain requirements under the Medicare conditions of participation at §§ 482.41 and 485.623, and the PBD requirements at § 413.65, to the extent necessary, in order to allow hospitals to establish and operate as part of the hospital any location meeting those non-waived conditions of participation for hospitals that continue to apply during the PHE. (See https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf). Time spent by residents at these locations is not treated any differently from time spent by residents at locations established and operated by the hospital prior to the COVID-19 PHE.

Also, for the duration of the PHE related to COVID-19, CMS has adopted a policy that if routine services are provided under arrangements outside the hospital to its inpatients, these services are deemed to have been provided by the hospital (85 FR 19280). Similarly, time spent by residents at these locations is not treated any differently from time spent by residents at locations established and operated by the hospital prior to the COVID-19 PHE.

H. Rural Health Clinics (RHCs)

1. Revision of Bed Count Methodology for Determining Provider-Based RHCs Exemption to the RHC Payment Limit

RHCs furnish services in rural areas that have been determined to be medically underserved areas or health professional shortage areas. RHCs are paid an all-inclusive rate (AIR) for medically-necessary, face-to-face visits with an RHC practitioner. Section 1833(f) of the Act established an RHC payment limit, which is adjusted annually based on the Medicare Economic Index (MEI). Under section 1833(f) of the Act, an RHC that is provider-based to a hospital with fewer than 50 beds is exempt from the national per-visit payment limit.

To determine which provider-based RHCs are exempt from the payment limit, we use the same methodology that is used to calculate hospital bed count for the Indirect Medical Education

adjustment at § 412.105(b). Specifically, a provider-based RHC (as authorized by § 413.65(a)(1)(ii)(L)) that is an integral and subordinate part of a hospital (including a CAH) is excepted from the per-visit payment limit if the hospital has fewer than 50 beds. We have used the methodology set out at § 412.105(b) to make this calculation.

Due to the COVID-19 pandemic, health care providers such as hospitals have been or are planning to increase inpatient bed capacity to address the surge in need for inpatient care. Given this, we do not believe that RHCs that are currently exempt from the national per-visit payment limit should now be subject to the per-visit payment limit due to the COVID-19 PHE, and we do not want to discourage them from increasing bed capacity if needed. Allowing for these provider-based RHCs to continue to receive the payment amounts they would otherwise receive in the absence of the PHE will help maintain their ability to provide necessary health care services to underserved communities. We are implementing, on an interim basis, a change to the period of time used to determine the number of beds in a hospital at § 412.105(b) for purposes of determining which provider-based RHCs are subject to the payment limit. For the duration of the PHE, we will use the number of beds from the cost reporting period prior to the start of the PHE as the official hospital bed count for application of this policy. As such, RHCs with provider-based status that were exempt from the national per-visit payment limit in the period prior to the effective date of the PHE (January 27, 2020) would continue to be exempt for the duration of the PHE for the COVID-19 pandemic, as defined at § 400.200.

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

1. Background

a. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program

Section 1847(a) of the Act, as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173, enacted on December 8,

2003), mandates the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) for contract award purposes to furnish certain competitively priced DMEPOS items and services subject to the CBP:

- Off-the-shelf (OTS) orthotics, for which payment would otherwise be made under section 1834(h) of the Act;
- Enteral nutrients, equipment, and supplies described in section 1842(s)(2)(D) of the Act; and
- Certain DME and medical supplies, which are covered items (as defined in section 1834(a)(13) of the Act) for which payment would otherwise be made under section 1834(a) of the Act.

For a list of product categories included in the DMEPOS CBP, please refer to https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Round-2021/PCs.

Areas in which the CBP are not implemented are known as non-competitive bidding areas (non-CBAs). Currently, there are no CBAs due to the 2-year gap period in the DMEPOS CBP, allowing any Medicare-enrolled DMEPOS suppliers to furnish DMEPOS items.[27] However, we use the term "former CBAs" to refer to areas that were CBAs prior to the 2-year gap, to distinguish those areas from non-CBAs in which the CBP has not previously been implemented.

b. Fee Schedule Adjustment Methodology for Non-CBAs

Section 1834(a)(1)(F)(ii) of the Act requires the Secretary to use information on the payment determined under the Medicare DMEPOS CBP to adjust the fee schedule amounts for DME items and services furnished in all non-CBAs on or after January 1, 2016. Section

[27] All DMEPOS CBP contracts expired on December 31, 2018. There is currently a temporary gap in the DMEPOS CBP. Round 2021 of the CBP is scheduled to begin again in January 2021 and extend through December 31, 2023.

1834(a)(1)(F)(iii) of the Act requires the Secretary to continue to make these adjustments as additional covered items are phased in under the CBP or information is updated as new CBP contracts are awarded. Similarly, sections 1842(s)(3)(B) and 1834(h)(1)(H)(ii) of the Act authorize the Secretary to use payment information from the DMEPOS CBP to adjust the fee schedule amounts for enteral nutrition and OTS orthotics, respectively, furnished in all non-CBAs. Section 1834(a)(1)(G) of the Act requires the Secretary to specify the methodology to be used in making these fee schedule adjustments by regulation, and to consider, among other factors, the costs of items and services in non-CBAs (where the adjustments would be applied) compared to the single payment amounts for such items and services in the CBAs.

In accordance with the requirements of section 1834(a)(1)(G) of the Act, we conducted notice and comment rulemaking in 2014 to specify methodologies for adjusting the fee schedule amounts for DME, enteral nutrition, and OTS orthotics in non-CBAs in § 414.210(g). We refer readers to the proposed rule entitled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies," published on July 11, 2014 (79 FR 40208), (hereinafter CY 2015 ESRD PPS DMEPOS proposed rule), and the final rule entitled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies," published on November 6, 2014 (79 FR 66120), (hereinafter CY 2015 ESRD PPS DMEPOS final rule) for additional details.

The methodologies set forth in § 414.210(g) account for regional variations in prices, including for rural and non-contiguous areas of the United States. In accordance with § 414.210(g)(1), we determine regional adjustments to fee schedule amounts for each state in the contiguous United States and the District of Columbia, based on the definition of region in § 414.202, which refers to geographic areas defined by the Bureau of Economic Analysis (BEA) in the Department of Commerce for economic analysis purposes (79 FR 66226). Under

§ 414.210(g)(1)(i) through (iv), adjusted fee schedule amounts for areas within the contiguous United States are determined based on regional prices limited by a national ceiling of 110 percent of the regional average price and a floor of 90 percent of the regional average price (79 FR 66225). Under § 414.210(g)(1)(v), adjusted fee schedule amounts for rural areas are based on 110 percent of the national average of regional prices. Under § 414.210(g)(2), fee schedule amounts for non-contiguous areas are adjusted based on the higher of the average of the single payment amounts for CBAs in non-contiguous areas in the United States, or the national ceiling amount.

We use ZIP codes for rural, non-rural, and non-contiguous areas to establish geographic areas that are then used to define non-CBAs for the purposes of the DMEPOS fee schedule adjustments. A rural area is defined in § 414.202 as a geographic area represented by a postal ZIP code, if at least 50 percent of the total geographic area of the area included in the ZIP code is estimated to be outside any Metropolitan Statistical Area (79 FR 66228). A rural area also includes a geographic area represented by a postal ZIP code that is a low population density area excluded from a CBA in accordance with section 1847(a)(3)(A) of the Act at the time the rules in § 414.210(g) are applied. Non-contiguous areas refer to areas outside the contiguous United States – that is, areas such as Alaska, Guam, and Hawaii (81 FR 77936).

In the final rule entitled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS," published in the November 14, 2018 **Federal Register** (83 FR 56922), we established fee schedule adjustment methodologies for items and services furnished from January 1, 2019 through December 31, 2020.

For the fee schedule amounts for items and services furnished from January 1, 2019 through December 31, 2020, in all rural and non-contiguous non-CBAs, the fee schedule amounts are based on a blend of 50 percent of the unadjusted fee schedule amounts and 50 percent of the fee schedule amounts adjusted in accordance with the current methodologies under § 414.210(g)(1) through (8) (83 FR 57029). For items and services furnished from January 1, 2019 through December 31, 2020 in all non-CBAs other than rural or non-contiguous areas, the fee schedule amounts are based on 100 percent of the fee schedule amounts adjusted in accordance with the current methodologies under § 414.210(g)(1) through (8) (83 FR 57029). These rules are located at § 414.210(g)(9) and, again, apply to items and services furnished from January 1, 2019 through December 31, 2020 (83 FR 57039; 83 FR 57070 through 57071).

2. Current Issues

Section 3712 of the CARES Act revises the fee schedule amounts for certain DME and enteral nutrients, supplies, and equipment furnished in non-CBAs other than former CBAs through the duration of the emergency period described in section 1135(g)(1)(B) of the Act.

Section 3712(a) of the CARES Act directs the Secretary to implement § 414.210(g)(9)(iii) (or any successor regulation), to apply the transition rule described in such section to all applicable items and services as planned through December 31, 2020, and through the duration of the emergency period described in section 1135(g)(1)(B) of the Act, if longer. Therefore, section 3712(a) of the CARES Act continues our current policy at § 414.210(g)(9)(iii) of paying for 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, or through the duration of the emergency period, whichever is longer. This fee schedule adjustment in rural and non-contiguous areas results in fee schedule amounts that are approximately 66 percent higher than the fully adjusted fee schedule amounts that we currently pay for DMEPOS items and services furnished in non-rural areas in the contiguous United

States.

Section 3712(b) of the CARES Act states, for items and services furnished on or after the date that is 30 days after the date of the enactment of this legislation, the Secretary shall apply § 414.210(g)(9)(iv) (or any successor regulation), as if the reference to "dates of service from June 1, 2018 through December 31, 2020, based on the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section" were instead a reference to "dates of service from March 6, 2020, through the remainder of the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), based on the fee schedule amount for the area is equal to 75 percent of the adjusted payment amount established under this section and 25 percent of the unadjusted fee schedule amount." Therefore, section 3712(b) of the CARES Act directs the Secretary 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 PHE period described in section 1135(g)(1)(B) of the Act. In accordance with § 414.210(g)(9)(iv), the fee schedule amounts in these non-CBA areas are currently based on 100 percent of the adjusted fee schedule amount, but section 3712(b) of the CARES Act requires CMS to pay for these DMEPOS items and services based on 75 percent of the adjusted fee schedule amount and 25 percent of the historic, unadjusted fee schedule amount until the end of the emergency period. This increases payments so that they are approximately 33 percent higher than the payments at the fully adjusted fee schedule amounts.

Section 3712 of the CARES Act does not affect the current adjusted fee schedule amounts in former CBAs. In accordance with § 414.210(g)(10), the fee schedule amounts in the former CBAs will continue to be based on the single payment amounts from 2018 increased by update factors for subsequent calendar years until new competitive bidding contracts are in place.

Section 3712(b) of the CARES Act references two dates on which CMS should implement the payment amount increases for items and services furnished in non-rural and

contiguous non-CBAs: April 26, 2020 (April 26th is 30 days after March 27th, the date of the enactment of the CARES Act); and March 6, 2020. We believe that the law was written in a way that is ambiguous and essentially mandates two different and conflicting effective dates for the increase in the fee schedule amounts in non-rural and contiguous non-CBAs. Due to this ambiguity, we believe that we could implement the higher fee schedule amounts in non-rural and contiguous non-CBAs on either March 6, 2020 or April 26, 2020. Because we believe the purpose of the law is to aid suppliers in furnishing items under very challenging situations during the COVID-19 PHE, we believe it is in the public's interest to implement the higher fee schedule amounts starting with the earlier date of March 6, 2020. Therefore, we are revising the regulations to implement the higher fee schedule amounts required under the CARES Act as of March 6, 2020.

Additionally, section 3712(b) of the CARES Act requires CMS to pay the higher fee schedule amounts for the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), but it does not specify the fee schedule amounts that should be in effect if the emergency period ends before December 31, 2020. If not for section 3712(b) of the CARES Act, CMS would be paying the fully adjusted fee schedule amounts for DME items and services furnished in non-rural and contiguous non-CBAs until December 31, 2020. As such, we are specifying in § 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 fee schedule amounts adjusted in accordance with § 414.210(g)(9)(1) through (8) if the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)) ends before December 31, 2020.

In summary, we are making conforming changes to § 414.210(g)(9), consistent with section 3712(a) and (b) of the CARES Act, but we are omitting the language in section 3712(b) of the CARES Act that references an effective date that is 30 days after the date of enactment of the law. We are revising § 414.210(g)(9)(iii), which describes the 50/50fee schedule adjustment

blend for items and services furnished in rural and noncontiguous areas, to address dates of service from June 1, 2018 through December 31, 2020 or through the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later. We are also adding § 414.210(g)(9)(v) which will state that, for items and services furnished in areas other than rural or noncontiguous areas with dates of service from March 6, 2020, through the remainder of the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), based on the fee schedule amount for the area is equal to 75 percent of the adjusted payment amount established under "this section" (by which we mean § 414.210(g)(1) through (8)), and 25 percent of the unadjusted fee schedule amount. For items and services furnished in areas other than rural or noncontiguous areas with dates of service from the expiration date of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)) through December 31, 2020, based on the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under § 414.210(g)(1) through (8) (referred to as "this section" in the regulation text). In addition, we are revising § 414.210(g)(9)(iv) to specify for items and services furnished in areas other than rural and noncontiguous areas with dates of service from June 1, 2018 through March 5, 2020, based on the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under § 414.210(g)(1) through (8) ("this section" in the regulation text).

J. Care Planning for Medicare Home Health Services

Historically, sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act have stated that for Medicare to make payment for home health services, a physician, who does not have a direct or indirect employment relationship with the HHA, must certify that home health services are required because the individual is confined to his or her home and is in need of skilled nursing care on an intermittent basis, physical or speech therapy, or a continued need for occupational

therapy as defined at section 1861(m) of the Act. The certifying physician must establish and periodically review a plan for furnishing such services to such individual while the individual is under the care of a physician. The physician must document that the physician himself or herself or a NP or CNS (as those terms are defined in section 1861(aa)(5) of the Act), who is working in collaboration with the physician in accordance with State law, or a CNM (as defined in section 1861(gg) of the Act) as authorized by State law, or a PA (as defined in section 1861(aa)(5) of the Act) under the supervision of the physician, has had a face-to-face encounter related to the reason the home health services are needed.

Section 3708 of the CARES Act amended sections 1814(a) and 1835(a) of the Act to allow NPs, CNSs, and PAs (as those terms are defined in section 1861(aa) of the Act), to order and certify patients for eligibility under the Medicare home health benefit. Additionally, section 3708 of the CARES Act amended sections 1814(a)(2)(C), 1835 (a)(2)(A)(ii), and 1861(m) of the Act to allow the home health plan of care to be established and periodically reviewed by a physician, NP, CNS, or PA where such services are or were furnished while the individual was under the care of a physician, NP, CNS, or PA. The CARES Act also amended sections 1861(o)(2) and 1861(kk) of the Act to allow (CNMs, NPs, CNSs, or PAs to perform the role originally reserved for a physician in establishing 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 learn the skills needed to self-administer the osteoporosis drug or is otherwise mentally or physically incapable of self-administering such drug. Finally, section 3708 of the CARES Act amended section 1895(c) of the Act to allow payment for the furnishing of items and services under the home health prospective payment system (HH PPS) when these items and services are prescribed by an NP, CNS, or PA.

In accordance with section 3708 of the CARES Act, these changes are required to take

effect within 6 months of enactment of the law and the Secretary shall issue an IFC, if necessary to comply with the required effective date. Per the explicit statutory instructions at section 3708(f) of the CARES Act, we are addressing changes in the regulations in this IFC to ensure these requirements are issued within the timeframe required by statute. These regulations are effective on [OFR--insert date of publication], and will be retroactively applicable to March 1, 2020.We believe that enacting these provisions at this time will afford maximum flexibility for providers seeking to order home health care services during the PHE for the COVID-19 pandemic. That is, NPs, CNSs, and PAs would be able to practice to 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. This is imperative during the PHE for the COVID-19 pandemic as more beneficiaries may be considered "homebound", either because a practitioner has determined that it is medically contraindicated for a beneficiary to leave the home because he or she has a confirmed or suspected diagnosis of COVID-19, or because a practitioner has determined that it is medically contraindicated for a beneficiary to leave the home because the patient has a condition that may make the patient more susceptible to contracting COVID-19.

In accordance with section 1861(aa)(5) of the Act, NPs, CNSs, and PAs are required to practice in accordance with state law in the state in which the individual performs such services. Individual states have varying requirements for conditions of practice, which determine whether a practitioner may work independently without a written collaborative agreement or supervision from a physician, or whether general or direct supervision and collaboration is required. HHAs or other practitioners should check with the relevant state licensing authority websites to ensure that practitioners are working within their scope of practice and prescriptive authority. A review of these websites reveals that the majority of states require physician collaboration for these NPPs. We note that even in states that allow independent practice authority, many of these practitioners continue to work in a practice environment (inpatient facility or outpatient or

physician's office) that includes a physician.

Section 1861(aa)(5) of the Act allows the Secretary regulatory discretion regarding the requirements for NPs, CNSs, and PAs. As such, the regulations at §§ 410.74 through 410.76 set out in detail the qualifications needed and services provided by these practitioners under the Medicare program. We believe that we should align, for Medicare home health purposes, the definitions for such practitioners with the existing definitions in regulation at §§ 410.74 through 410.76 for consistency across the Medicare program and to ensure that Medicare home health beneficiaries are afforded the same standard of care. Therefore, we are amending the regulations at parts 409, 424, and 484 to define a NP, a CNS, and a PA (as such qualifications are defined at §§ 410.74 through 410.76) as an "allowed practitioner". This means that in addition to a physician, as defined at section 1861(r) of the Act, an "allowed practitioner" may certify, establish and periodically review the plan of care, as well as supervise the provision of items and services for beneficiaries under the Medicare home health benefit. Additionally, we are amending the regulations to reflect that we would expect the allowed practitioner to also perform the face-to-face encounter for the patient for whom they are certifying eligibility; however, if a face-to-face encounter is performed by an allowed NPP, as set out at 42 CFR 424.22(a)(1)(v)(A), in an acute or post-acute facility, from which the patient was directly admitted to home health, the certifying practitioner may be different from the provider performing the face-to-face encounter. These regulation changes will become permanent and are not time limited to the period of the PHE for COVID-19. We will review and respond to any comments received on this IFC in the CY 2021 HH PPS final rule.

K. CARES Act Waiver of the "3-Hour Rule" and Modification of IRF Coverage and Classification Requirements for Freestanding IRF Hospitals for the PHE During the COVID-19 Pandemic

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

In the March 31st COVID-19 IFC (85 FR 19252, 19287), we provided a clarification regarding § 412.622(a)(3)(ii) (commonly referred to as the "3-hour rule"). On March 27, 2020, the CARES Act was enacted and further addressed § 412.622(a)(3)(ii). Specifically, section 3711(a) of the CARES Act requires the Secretary to waive § 412.622(a)(3)(ii) during the emergency period described in section 1135(g)(1)(B) of the Act. This waiver was issued on April 15 2020, and is available at https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf. We note that the clarification provided in the March 31st COVID-19 IFC does not address section 3711(a) of the CARES Act as it was developed prior to the enactment of the CARES Act. Because § 412.622(a)(3)(ii) is more directly and comprehensively addressed by section 3711(a) of the CARES Act, the clarification provided in the March 31st COVID-19 IFC is moot and hereby rescinded.

We note that the waiver required by section 3711(a) of the CARES Act is not limited to particular IRFs or patients, and therefore, is available during the emergency period described in section 1135(g)(1)(B) of the Act regardless of whether a patient was admitted for standard IRF care or to relieve acute care hospital capacity. In this IFC, we are waiving § 412.622(a)(3)(ii) to reflect the waiver required by section 3711(a) of the CARES Act.

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

IRF care is only considered by Medicare to be reasonable and necessary under section 1862(a)(1) of the Act if the patient meets all of the IRF coverage requirements outlined in § 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. We note that the March 31st COVID-19 IFC removes the requirement at § 412.622(a)(4)(ii) to complete a post-admission physician evaluation during the COVID-19 PHE, as defined in § 400.200.

While we generally believe that all IRFs should have to comply with the requirements at

§ 412.29(d), (e), (h), and (i) and § 412.622(a)(3), (4), and (5), we recognize that there are certain institutional differences between freestanding IRF hospitals and IRF distinct part units of hospitals that may impose barriers on freestanding IRF hospitals seeking to admit patients to relieve acute care hospital capacity during the COVID-19 PHE. Specifically, freestanding IRF hospitals do not have the same close affiliations with acute care hospitals that IRF distinct part units of hospitals have, and are not as able to establish billing procedures under the IPPS as have IRF distinct part units by virtue of the fact that the distinct part units have access to (or at least affiliations with) their parent hospitals' billing departments. Therefore, we are amending the requirements at §§ 412.29(d), (e), (h), and (i) and 412.622(a)(3), (4), and (5) to add an exception for care furnished to patients admitted to freestanding IRF hospitals (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.

We believe that freestanding IRF hospitals need the flexibility during this COVID-19 PHE to determine the best care for each patient who is admitted solely to relieve acute care hospital capacity. Consistent with the Guidelines for Opening Up America Again at https://www.whitehouse.gov/openingamerica/, for the purposes of exercising these IRF flexibilities that are intended to provide broad flexibility for freestanding IRF hospitals to provide surge capacity in support of acute care hospitals in their state or community, CMS considers surge to be alleviated with regard to exercising these flexibilities when the state (or region, as applicable) in which the freestanding IRF is located is in phase 2 or phase 3. In other words, the flexibilities in this IFC are available for freestanding IRF hospitals admitting patients in support of acute care hospitals when the state is in phase 1 or prior to entering phase 1, but are no longer available to the freestanding IRF hospital when the state is in phase 2 or phase 3 of these Guidelines. These flexibilities apply to specific patients who must be discharged from the acute care hospitals to the freestanding IRFs to provide surge capacity for the acute care

hospitals, and therefore apply only when those specific patients are admitted to the freestanding IRF hospitals and continue for the duration of that patient's care. We believe this will allow for continuity of care and care planning consistency at admission and throughout a patient's stay if the same flexibilities apply for the duration of a patient's IRF stay. 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, we are requiring freestanding IRF hospitals to append the "DS" modifier to the end of the IRF's unique patient identifier number (used to identify the patient's medical record in the IRF) to identify patients who are being treated in a freestanding IRF hospital solely to alleviate inpatient bed capacity in a state that is experiencing a surge during the PHE for the COVID-19 pandemic. The modifier will be used to identify those patients for whom the requirements in § 412.622(a)(3)(i), (iii), (iv), (4) and (5) do not apply. Freestanding IRF hospitals will be paid at the IRF PPS rates for patients with the "DS" modifier.

We anticipate that freestanding IRF hospitals will take advantage of these flexibilities for those beneficiaries (who are surge patients from inpatient hospitals), while continuing to provide standard IRF-level care for those beneficiaries who would benefit from IRF-level care and would otherwise receive such care in the absence of the COVID-19 PHE. This will provide crucial flexibility to allow freestanding IRF hospitals to aid in the response to the COVID-19 pandemic in several ways. First, we expect that some of the 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, such as at least two types of therapy. Second, waiving the documentation requirements in § 412.622(a)(4) and (5) for patients alleviating inpatient 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 that may not be applicable to these acute patients during the PHE. Third, this flexibility allows freestanding IRF hospitals to maximize their available beds to take advantage of space where COVID-19 patients or surge patients could be safely managed. We believe this policy will allow freestanding IRF hospitals to make a clinical determination about what level of care each individual patient needs during the PHE for the COVID-19 pandemic.

To effectuate these changes, we are amending § 412.622(a)(3)(i), (ii), (iii), and (iv) to state that these IRF coverage criteria continue to be required, except for 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 PHE, as defined in § 400.200. Similarly, in § 412.622(a)(4), we are amending this paragraph to state that the IRF documentation requirements must be present in the IRF medical record, except for 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 PHE, as defined in § 400.200. In § 412.622(a)(5), we are amending this paragraph to state that an interdisciplinary team approach to care is required, except for 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 PHE, as defined in § 400.200. We are also amending § 412.29(d), (e), (h), and (i) to align the provisions we have waived in § 412.622 with the classification criteria for payment to freestanding IRF hospitals under the IRF prospective payment system. Finally, we are amending § 412.622(c) to add a definition of state (or region, as applicable) that are experiencing a surge and § 412.29 to cross-reference that definition where applicable.

L. Medicare Shared Savings Program

As of January 1, 2020, there are 517 Medicare Shared Savings Program (Shared Savings Program) Accountable Care Organizations (ACOs) serving approximately 11.2 million Medicare

FFS beneficiaries across the country: 37 percent of ACOs (192 of 517) are participating under two-sided shared savings and shared losses models; and 160 ACOs have agreements ending December 31, 2020, and must renew under the BASIC track or ENHANCED track to continue in the Shared Savings Program, including 20 ACOs participating in the Medicare ACO Track 1+ Model (Track 1+ Model).

The COVID-19 pandemic, and the resulting PHE as defined in § 400.200, have created a lack of predictability for many ACOs regarding the impact of expenditure and utilization changes on historical benchmarks and performance year expenditures, and for those under performance-based risk, the potential liability for shared losses, as well as disrupting population health activities, as clinicians, care coordinators and financial and other resources are diverted to address immediate acute care needs. ACOs and other program stakeholders have advocated for CMS to modify Shared Savings Program policies to address the impact of the COVID-19 pandemic including to:

- Adjust the methodology for determining shared savings and shared losses, such as by: reducing or eliminating liability for ACOs under performance-based risk for shared losses for PY 2020; not sharing savings or losses with ACOs for PY 2020; or adjusting program calculations to address the impact of COVID-19 on benchmark and PY expenditures, particularly for calendar year 2020.

- Eliminate or extend the deadline for ACOs to voluntarily terminate from the program without being financially reconciled for PY 2020, which under § 425.221(b)(2)(ii)(A) is June 30, 2020, with notification 30 days prior (no later than June 1).

- Maintain or "freeze" ACOs in their current participation options so that ACOs required to renew their participation for a new agreement period starting on January 1, 2021, are not burdened with meeting application deadlines and forgo the requirement that ACOs participating in the BASIC track's glide path advance to the next level for PY 2021.

- Account for changes in billing and care patterns in determining beneficiary assignment.

ACOs and other program stakeholders have indicated that there is an urgent need to address these concerns because ACOs need to make participation decisions for PY 2020 and PY 2021 soon and may choose to terminate their participation in the Shared Savings Program on or before June 30th, rather than face the potential of pro-rated losses for PY 2020 if the COVID-19 PHE does not extend for the entire year or the program's policies do not adequately mitigate liability for shared losses.

We believe it is vital to the stability of the Shared Savings Program to encourage continued participation by ACOs by adjusting program policies as necessary to address the impact of the COVID-19 pandemic, including by offering certain flexibilities in program participation options to currently participating ACOs and addressing potential distortions in expenditures resulting from the pandemic to ensure that ACOs are treated equitably regardless of the degree to which their assigned beneficiary populations are affected by the pandemic. The changes we are making in this IFC will help to ensure a more equitable comparison between ACOs' expenditures for PY 2020 and ACOs' updated historical benchmarks and that ACOs are not rewarded or penalized for having higher/lower COVID-19 spread in their patient populations which, in turn, will help to protect ACOs from owing excessive shared losses and the Medicare Trust Funds from paying out windfall shared savings. As described in this section of this IFC, we are modifying Shared Savings Program policies to: (1) allow ACOs whose current agreement periods expire on December 31, 2020, the option to extend their existing agreement period by 1-year, and allow ACOs in the BASIC track's glide path the option to elect to maintain their current level of participation for PY 2021; (2) clarify the applicability of the program's extreme and uncontrollable circumstances policy to mitigate shared losses for the period of the COVID-19 PHE; (3) adjust program calculations to mitigate the impact of COVID-19 on ACOs; and (4)

expand the definition of primary care services for purposes of determining beneficiary assignment to include telehealth codes for virtual check-ins, e-visits, and telephonic communication. We also address how these adjustments to program policies will apply to ACOs participating in the Track 1+ Model.

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

A renewing ACO is defined as an ACO that continues its participation in the program for a consecutive agreement period, without a break in participation, because it is an ACO whose participation agreement expired and that immediately enters a new agreement period to continue its participation in the program, or an ACO that terminated its current participation agreement under § 425.220 and immediately enters a new agreement period to continue its participation in the program (see § 425.20). Section 425.224 specifies application procedures for a renewing ACO applying to enter a new participation agreement with CMS for participation in the Shared Savings Program. We are seeking to reduce operational burden for ACOs and their health care providers while they respond to the serious health threats posed by the spread of the COVID-19. We have received feedback from ACO stakeholders requesting that CMS delay the Shared Savings Program application cycle for a January 1, 2021 start date (occurring in CY 2020), since they have reassigned staff and care coordinators to respond to the current pandemic. Due to COVID-19, stakeholders have expressed concern about focusing resources on applying to the Shared Savings Program rather than on patient care. Additionally, stakeholders have expressed uncertainty over their continued participation in the Shared Savings Program in 2021 given the lack of predictability of the impact of COVID-19 on expenditures used to establish an ACO's historical benchmark.

In response to stakeholder feedback, we are forgoing the application cycle for a January 1, 2021 start date (herein referred to as the 2021 application cycle). We believe it is appropriate

to forgo the 2021 application cycle as the COVID-19 PHE continues because this will allow ACOs and their ACO providers/suppliers currently participating in the Shared Savings Program to continue focusing on treating patients during the pandemic. There are 160 ACO Shared Savings Program participation agreements that will end on December 31, 2020, including 20 ACOs participating in the Track 1+ Model. These ACOs are eligible to apply to renew their participation agreement for the Shared Savings Program effective January 1, 2021. To reduce burden and allow these ACOs to continue participating in the program without a 2021 application cycle, ACOs that entered a first or second agreement period with a start date of January 1, 2018, may elect to extend their agreement period for an optional fourth performance year. The fourth performance year would span 12 months from January 1, 2021, to December 31, 2021. This election to extend the agreement period is voluntary and an ACO could choose not to make this election, and therefore, conclude its participation in the program with the expiration of its current agreement period on December 31, 2020. Under this approach, eligible ACOs will be able to remain under their existing historical benchmark for an additional year, which will increase stability and predictability given the potential impact of the pandemic on beneficiary expenditures under FFS Medicare and help provide greater certainty for ACOs making determinations regarding their future participation in the Shared Savings Program.

Additionally, by forgoing the 2021 application cycle for new applicants, CY 2020 will not serve as benchmark year 3 for a cohort of ACOs that would otherwise be January 1, 2021 starters. An ACO's historical benchmark is determined based on the 3 most recent years prior to the start of its agreement period. For ACOs in a first agreement period, benchmark year 3 is given the highest weight of the 3 benchmark years and, because CY 2020 is an anomalous year, we believe it could be disadvantageous to include CY 2020 expenditures as the third benchmark year for this cohort of ACOs. Cancelling the 2021 application cycle would provide us with additional time to consider and develop approaches to further mitigate the role of 2020 as a

benchmark year given the unusual expenditure and utilization trends likely to result from the pandemic.

The ACO's voluntary election to extend its agreement period must be made in the form and manner and by a deadline established by CMS, and an ACO executive who has the authority to legally bind the ACO must certify the election. We note that this optional 12-month agreement period extension is a one-time exception for all ACOs with agreements expiring on December 31, 2020; it will not be available to other ACOs or to future program entrants. We anticipate that eligible ACOs will be able to elect to extend their agreement starting June 18, 2020, and the anticipated final date to make the election will be September 22, 2020. We will provide additional guidance regarding the form and manner, and the timeframe (including any changes to the above dates), for making the election.

Under the existing provision at § 425.210(a), the ACO must provide a copy of its participation agreement with CMS to all ACO participants, ACO providers/suppliers, and other individuals and entities involved in ACO governance. In the case of an ACO that elects to extend its agreement period pursuant to this IFC, we will consider the ACO to be in compliance with § 425.210(a) if it notifies these parties that it will continue to participate in the program for an additional year. Further, under § 425.210(b), all contracts or arrangements between or among the ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities must require compliance with the requirements and conditions of the program's regulations, including, but not limited to, those specified in the participation agreement with CMS (see also §§ 425.116(a)(3) (as to agreements with ACO participants) and 425.116(b)(3) (as to agreements with ACO providers/suppliers)). Thus, an ACO that elects to extend its participation agreement pursuant to this IFC must require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities during PY 2021 to comply with the program's

requirements through December 31, 2021. We note that to remain in compliance with § 425.116, an ACO may need to extend the duration of its agreements with ACO participants and ACO providers/suppliers.

We believe there is good cause to address the extension of expiring participation agreements in this IFC. It would be impracticable and contrary to the public interest to undertake traditional notice and comment rulemaking for this policy because we previously announced on our website that the 2021 application cycle would begin on April 20, 2020 (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/for-acos/application-types-and-timeline). If we delayed finalizing this policy until after the public has had an opportunity to comment on it, ACOs might begin applying (or make preparations to apply) to the Shared Savings Program for an agreement period beginning January 1, 2021, rather than devote their scarce resources to care delivery and coordination activities.

We are revising § 425.200(b)(3)(ii) to allow ACOs that entered a first or second agreement period with a start date of January 1, 2018, to elect to extend their agreement period for an optional fourth performance year. Lastly, while we will forgo the application cycle for ACOs to apply to enter an agreement period beginning on January 1, 2021, we note that eligible, currently participating ACOs will be able to apply for a SNF 3-day rule waiver (§ 425.612(a)(1)(i)), apply to establish a beneficiary incentive program (§ 425.304(c)(2)), modify ACO participant (§ 425.118(b)) and/or SNF affiliate lists (§ 425.612(a)(1)(i)(B)), and elect to change their assignment methodology (§ 425.226(a)(1)) for PY 2021. Also, an ACO participating under the BASIC track's glide path may still elect to transition to a higher level of risk and potential reward within the BASIC track’s glide path other than the level of risk and potential reward that the ACO would be automatically transitioned to for PY 2021, absent the ACO’s election to maintain its current participation level for one year as described in section II.L.2. of this IFC. For example, an ACO participating in BASIC track Level B in PY 2020 can

still elect to transition to BASIC track level D or E in PY 2021.

We seek comment on the approach we are establishing with this IFC to address the extension of participation agreements that are scheduled to expire on December 31, 2020.

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

We finalized a redesign of Shared Savings Program's participation options in the final rule entitled "Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success and Extreme and Uncontrollable Circumstances Policies for Performance Year 2017", which appeared in the **Federal Register** on December 31, 2018 (83 FR 67816). We finalized the BASIC track, added as a new provision at § 425.605, which includes an option for eligible ACOs to begin participation under a one-sided model and incrementally phase-in risk (calculated based on ACO participant revenue and capped at a percentage of the ACO's updated benchmark) and potential reward over the course of a single agreement period, an approach referred to as the glide path (83 FR 67841). The glide path includes five levels: A one-sided model available only for the first 2 consecutive performance years of a 5-year agreement period, each year of which is identified as a separate level (Levels A and B); and three levels of progressively higher risk and potential reward in performance years 3 through 5 of the agreement period (Levels C, D, and E). ACOs are automatically advanced along the progression of risk/reward levels at the start of each participation year, over the course of a 5-year agreement period, unless the ACO elects to advance more quickly, until ACOs reach the BASIC track's maximum level of risk/reward (Level E) (83 FR 67844). For ACOs that entered the BASIC track's glide path for an agreement period beginning on July 1, 2019, the progression through the levels of risk and potential reward spans 6 performance years, including the ACO's first performance year from July 1, 2019, through December 31, 2019; these ACOs were not automatically advanced to the next risk/reward level at the start of PY 2020 (42 CFR 425.200(b)(4)(ii), (c)(3); § 425.600(a)(4)(i)(B)(*2*)(*i*)).

Stakeholders have expressed concern that due to the unpredictable impact of COVID-19 during PY 2020 and the uncertainty as to their ability to secure a repayment mechanism for PY 2021, ACOs are uncertain they will continue participating in the program if they are automatically transitioned to downside risk or a higher level of downside risk in PY 2021. Specifically, stakeholders have requested we "freeze," or forgo the automatic advancement of, BASIC track ACOs at their current level of participation for PY 2021. Additionally, per § 425.204(f)(3)(iii), an ACO entering an agreement period in Level A or Level B of the BASIC track must demonstrate the adequacy of its repayment mechanism prior to the start of any performance year in which it either elects to participate in, or is automatically transitioned to a two-sided model of the BASIC track, including Level C, Level D, or Level E. We have concerns whether some ACOs, particularly those that would automatically transition to Level C of the BASIC track, will have the ability to establish a repayment mechanism prior to the start of PY 2021 because the source of capital to cover potential losses may be uncertain for some ACOs given the resource intensity of responding to the pandemic. Currently, the Shared Savings Program has 136 ACOs participating under Level B of the BASIC track that are scheduled to automatically advance to Level C on January 1, 2021. Some stakeholders have indicated that they may be unable to secure a letter of credit at this time, while other stakeholders have indicated that their discretionary funds are currently fully committed to responding to the COVID-19 PHE.

We are also concerned that some of the care coordination processes ACOs have been developing may be interrupted by the pandemic. For example, ACOs may have reallocated funding and staff resources to respond to the COVID-19 PHE, thereby temporarily disrupting their ability to implement redesigned care processes that would support their transition to risk. We agree that most ACOs do not know the impact that COVID-19 will have on their expenditures or beneficiary population and the potential for losses under risk arrangements.

Therefore, through this IFC, we are permitting ACOs participating in the BASIC track glide path to elect to maintain their current level under the BASIC track for PY 2021. Prior to the automatic advancement for PY 2021, an applicable ACO may elect to remain in the same level of the BASIC track's glide path that it entered for PY 2020. For PY 2022, an ACO that elects this advancement deferral option will be automatically advanced to the level of the BASIC track's glide path in which it would have participated during PY 2022 if it had advanced automatically to the next level for PY 2021 (unless the ACO elects to advance more quickly before the start of PY 2022). For example, if an ACO participating in the BASIC track, Level B, in PY 2020 elects to maintain its current level of participation for PY 2021, it will participate under Level B for PY 2021 and then will automatically advance to Level D for PY 2022, since the ACO would have moved automatically to Level C for PY 2021 under current program rules, absent this change. The ACO could also elect to advance more quickly by opting to move to Level E instead of Level D for PY 2022, in which case the ACO would participate under Level E for the remainder of its agreement period.

The ACO's voluntary election to maintain its participation level must be made in the form and manner and by a deadline established by CMS, and an ACO executive who has the authority to legally bind the ACO must certify the election. We anticipate that eligible ACOs will be able to elect to maintain their participation level for PY 2021 starting June 18, 2020, and the anticipated final date to make the election will be September 22, 2020. We will provide additional guidance regarding the form and manner, and the timeframe (including any changes to the above dates), for making the election; an ACO that does not elect to maintain its current participation level for PY 2021 by the final date specified by CMS in this guidance will be automatically advanced to the next level of the glide path for that performance year (unless it elects to advance more quickly). This option is a one-time exception for ACOs currently participating in the Shared Savings Program under the BASIC track' glide path and will not be

available to other ACOs that are currently participating in the program or to future program entrants.

We believe there is good cause to address the automatic advancement of BASIC track ACOs along the glide path in this IFC. We believe we need to provide ACOs adequate time in 2020 to determine their participation options for PY 2021. It would be infeasible to finalize the necessary amendments to the program regulations with sufficient time for ACOs to be aware of the advancement deferral option, make related program participation decisions, and provide their election to CMS, if we did not implement this policy through this IFC. Additionally, this policy will provide further relief to ACOs that may not currently have the ability to establish a repayment mechanism prior to PY 2021 and that otherwise would be struggling during this period to establish one, or perhaps seeking to terminate their participation agreements early, rather than devoting scarce resources to care delivery and coordination and continuing in the program. Therefore, we are redesignating § 425.600(a)(4)(i)(B)(*2*)(*iii*) as § 425.600(a)(4)(i)(B)(*2*)(*iv*) and adding a new § 425.600(a)(4)(i)(B)(*2*)(*iii*) to allow ACOs currently participating in the BASIC track's glide path to elect to maintain their current participation level for PY 2021.

We seek comment on the advancement deferral option we are establishing with this IFC.

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

In December 2017, we issued an interim final rule with comment period entitled "Medicare Program; Medicare Shared Savings Program: Extreme and Uncontrollable Circumstances Policies for Performance Year 2017" (hereinafter referred to as the "December 2017 IFC"), which appeared in the **Federal Register** on December 26, 2017 (82 FR 60912 through 60919). The December 2017 IFC established a policy for mitigating shared losses for Shared Savings Program ACOs participating in a performance-based risk track, when the ACO's

assigned beneficiaries were located in geographic areas that were impacted by extreme and uncontrollable circumstances, such as hurricanes, wildfires, or other triggering events, during PY 2017. In the final rule entitled "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program-Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program-Accountable Care Organizations-Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act" (hereinafter referred to as the "CY 2019 PFS final rule") (83 FR 59452), we extended the extreme and uncontrollable circumstances policy finalized for PY 2017 to PY 2018 and subsequent performance years. Under the policy adopted in that final rule, for a given performance year, as set forth in §§ 425.605(f) (applicable to ACOs in two-sided models of the BASIC track), 425.606(i) (applicable to ACOs in Track 2) and 425.610(i) (applicable to ACOs in the ENHANCED track), CMS reduces the amount of the ACO's shared losses by an amount determined by multiplying the shared losses by the percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance, and the percentage of the ACO's assigned beneficiaries who reside in an area affected by an extreme and uncontrollable circumstance. Further, as specified in the Track 1+ Model participation agreement available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/track-1plus-model-par-agreement.pdf, CMS adjusts the amount of shared losses for Track 1+ Model ACOs for extreme and uncontrollable circumstances in the manner described in § 425.610(i).

As specified in the Shared Savings Program regulations at §§ 425.605(f), 425.606(i) and

425.610(i), CMS applies determinations made under the Quality Payment Program with respect to whether an extreme and uncontrollable circumstance has occurred and the affected areas. Further, CMS has sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred and the percentage of the ACO's assigned beneficiaries residing in the affected areas. In November 2017, we issued an interim final rule with comment period for the Quality Payment Program entitled "Medicare Program; CY 2018 Updates to the Quality Payment Program; and Quality Payment Program: Extreme and Uncontrollable Circumstance Policy for the Transition Year" IFC (hereinafter referred to the "Quality Payment Program IFC") (82 FR 53568), which appeared in the **Federal Registe**r on November 16, 2017. In the Quality Payment Program IFC (82 FR 53897), we explained that we anticipated that the types of events that could trigger the extreme and uncontrollable circumstances policies would be events designated a FEMA major disaster or a PHE declared by the Secretary, although we indicated that we would review each situation on a case-by-case basis.

In the CY 2019 PFS final rule (83 FR 59969), we explained our belief that the extreme and uncontrollable circumstance policies under the Shared Savings Program address stakeholders' concerns that ACOs participating under a performance-based risk track could be held responsible for sharing losses with the Medicare program resulting from catastrophic events outside the ACO's control given the increase in utilization, difficulty of coordinating care for patient populations leaving the impacted areas, and the use of natural disaster payment modifiers making it difficult to identify whether a claim would otherwise have been denied under normal Medicare FFS rules. Absent this relief, we explained that ACOs participating in performance-based risk tracks might reconsider whether they are able to continue their participation in the Shared Savings Program under a performance-based risk track.

In the March 31st COVID-19 IFC (85 FR 19230), we briefly addressed considerations related to applying the Shared Savings Program's extreme and uncontrollable circumstances

policies for mitigating shared losses for ACOs in PY 2020 because of the COVID-19 pandemic. We explained that for purposes of PY 2020 financial reconciliation, we will reduce the amount of an ACO's shared losses by an amount determined by multiplying the shared losses by the percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance, and the percentage of the ACO's assigned beneficiaries who reside in an area affected by an extreme and uncontrollable circumstance (85 FR 19268). We explained that the PHE for the COVID-19 pandemic applies to all counties in the country; therefore, 100 percent of assigned beneficiaries for all Shared Savings Program ACOs reside in an affected area. However, in describing the timeframe during which the extreme and uncontrollable circumstances policy would apply for mitigating shared losses because of the COVID-19 pandemic, we inadvertently stated that it would begin in March 2020 and continue through the end of the COVID-19 PHE, as defined in § 400.200. This statement was inconsistent with the beginning of the COVID-19 PHE as defined in § 400.200 (January 2020). Therefore, we are clarifying in this IFC that, for purposes of the Shared Savings Program, the months affected by an extreme and uncontrollable circumstance will begin with January 2020, consistent with the COVID-19 PHE determined to exist nationwide as of January 27, 2020, by the Secretary on January 31, 2020, and will continue through the end of the PHE, as defined in § 400.200, which includes any subsequent renewals.

Catastrophic events outside the ACO's control can also increase the difficulty of coordinating care for patient populations, and due to the unpredictability of changes in utilization and cost of services furnished to beneficiaries, may have a significant impact on expenditures for the applicable performance year and the ACO's benchmark in the subsequent agreement period (as further discussed in section II.L.4. of this IFC). These factors could jeopardize the ACO’s ability to succeed in the Shared Savings Program, and ACOs, especially those in performance-based risk tracks, may reconsider whether they are able to continue their participation in the

program.

Therefore, we believe it is important to make clear that, under the existing extreme and uncontrollable circumstances policies for the Shared Savings Program, the timeframe for the extreme and uncontrollable circumstance of the COVID-19 pandemic for purposes of mitigating shared losses will extend for the duration of the COVID-19 PHE as specified in § 400.200, which begins in January 2020. If the COVID-19 PHE extends through all of CY 2020, all shared losses for PY 2020 will be mitigated for all ACOs participating in a performance-based risk track: including Track 2, the ENHANCED track, Levels C, D and E of the BASIC track, and the Track 1+ Model (as discussed in section II.L.6. of this IFC). At this time, the COVID-19 PHE has already covered 4 months (January through April 2020) meaning any shared losses an ACO incurs for PY 2020 will be reduced by at least one-third. Further, if the COVID-19 PHE extends for a large portion, if not all of the year, the existing extreme and uncontrollable circumstances policy under the Shared Savings Program would mitigate a significant portion of, if not all, shared losses an ACO may owe for PY 2020. For example, if the COVID-19 PHE covers 6 months (January through June 2020) any shared losses an ACO incurs for PY 2020 would be reduced by one-half; if the COVID-19 PHE covers 9 months (January through September 2020) any shared losses an ACO incurs for PY 2020 would be reduced by three-fourths; and if the COVID-19 PHE covers the full year (January through December 2020) any shared losses an ACO incurs for PY 2020 would be reduced completely, and the ACO would not owe any shared losses.

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

a. Background

Section 1899(d)(1)(B)(ii) of the Act addresses how ACO benchmarks are to be established and updated under the Shared Savings Program. This provision specifies that the Secretary shall estimate a benchmark for each agreement period for each ACO using the most

recent available 3 years of per beneficiary expenditures for Parts A and B services for Medicare FFS beneficiaries assigned to the ACO. Such benchmark shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate, and updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B services. Section 1899(d)(1)(B)(i) of the Act specifies that, in each year of the agreement period, an ACO is eligible to receive payment for shared savings only if the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark under section 1899(d)(1)(B)(ii) of the Act.

Section 1899(i)(3) of the Act grants the Secretary the authority to use other payment models if the Secretary determines that doing so would improve the quality and efficiency of items and services furnished under Title XVIII and the alternative methodology would result in program expenditures equal to or lower than those that would result under the statutory payment model. The authority under section 1899(i)(3) of the Act to use other payment models includes authority to adopt alternatives to the benchmarking methodology set forth in section 1899(d)(1)(B)(ii) of the Act, and alternatives to the methodology for determining expenditures for each performance year as set forth in section 1899(d)(1)(B)(i) of the Act. As discussed in earlier rulemaking, we have used our authority under section 1899(i)(3) of the Act to adopt alternative policies to the provisions of section 1899(d)(1)(B) of the Act for updating the historical benchmark,[28] and calculating performance year expenditures.[29] We have also used our

[28] Such as using only assignable beneficiaries instead of all Medicare FFS beneficiaries in calculating the benchmark update based on national FFS expenditures (81 FR 37986 – 37989), calculating the benchmark update using factors based on regional FFS expenditures (81 FR 37977 – 37981), and calculating the benchmark update using a blend of national and regional expenditure growth rates (83 FR 68027 – 68030).

[29] Such as excluding indirect medical education and disproportionate share hospital payments from ACO performance year expenditures (76 FR 67921 – 67922), and determining shared savings and shared losses for the 6-month performance years (or performance period) in 2019 using expenditures for the entire CY 2019 and then pro-rating these amounts to reflect the shorter performance year or performance period (83 FR 59949 – 59951, 83 FR 67950 – 67956).

authority under section 1899(i)(3) of the Act to establish the Shared Savings Program's two-sided payment models,[30] and to mitigate shared losses owed by ACOs affected by extreme and uncontrollable circumstances during PY 2017 and subsequent performance years.[31]

Under the Shared Savings Program, providers and suppliers continue to bill for services furnished to Medicare beneficiaries and receive FFS payments under traditional Medicare. CMS uses payment amounts for Parts A and B FFS claims for a variety of Shared Savings Program operations, which include: calculations under the benchmarking methodology; determining an ACO's eligibility for shared savings and liability for shared losses for each performance year under the program's financial models as specified in the regulations in subpart G; determining an ACO's eligibility for certain participation options as set forth in § 425.600(d); and calculating the amount of the repayment mechanism required for ACOs participating in a two-sided model according to § 425.204(f)(4). These operations typically require the determination of expenditures for Parts A and B services under the original Medicare FFS program for a specified population of Medicare FFS beneficiaries or the Medicare Parts A and B FFS revenue of ACO participants. We note that the Medicare FFS beneficiary population for which expenditures are determined may differ depending on the specific program operation being performed and may reflect expenditures for the ACO's assigned beneficiaries, assignable beneficiaries as defined in § 425.20, or all Medicare FFS beneficiaries. The applicable Medicare FFS beneficiary population is specified in the regulations governing each program operation.

b. Removing Payment Amounts for Episodes of Care for Treatment of COVID-19 from Shared Savings Program Expenditure and Revenue Calculations

Section 3710 of the CARES Act amended section 1886(d)(4)(C) of the Act to specify that

[30] See earlier rulemaking establishing two-sided models: Track 2 (76 FR 67904 – 67909), Track 3 (subsequently renamed the ENHANCED track) (80 FR 32771 – 32772), and the BASIC track (83 FR 67834 – 67841).
[31] See earlier rulemaking establishing policies for mitigating shared losses owed by ACOs affected by extreme and uncontrollable circumstances (82 FR 60916 – 60917, 83 FR 59974 – 59977).

for discharges occurring during the emergency period described in section 1135(g)(1)(B) of the Act, in the case of a discharge of an individual diagnosed with COVID-19, the Secretary shall increase the weighting factor that would otherwise apply to the diagnosis-related group (DRG) to which the discharge is assigned by 20 percent. Further, the Secretary shall identify a discharge of such an individual through the use of diagnosis codes, condition codes, or other such means as may be necessary. In this section of this IFC, we refer to this increase in the weighting factor for DRGs as the "DRG adjustment."

We anticipate that the localized nature of infections (for example, rapid outbreaks in individual nursing facilities (NFs)) and the unanticipated increase in expenditures, along with the increased flexibilities that have been implemented to allow health care providers to identify and treat COVID-19 patients will affect the level of Medicare Parts A and B expenditures during 2020, both for the Medicare FFS beneficiaries assigned to ACOs and for the other populations of Medicare FFS beneficiaries whose expenditures are considered in performing calculations under the Shared Savings Program. The localized nature of outbreaks and the increased utilization of acute care occurring in PY 2020 and the associated higher costs are not reflected in ACOs' historical benchmarks, which are determined under §§ 425.601(b), 425.602(b), or 425.603(d), as applicable, based on Parts A and B expenditures for the beneficiaries who would have been assigned to that ACO during the three benchmark years. For some ACOs, the higher costs associated with COVID-19 may not be fully accounted for (or in other cases may be over-represented) by the retrospective application of the update factor to the benchmark at the time of financial reconciliation. In addition, the prospective CMS-HCC risk scores, which are used to adjust the historical benchmark each performance year for changes in severity and case mix (refer to §§ 425.601(a)(10), 425.602(a)(9) and 425.603(c)(10); and §§ 425.604(a)(1), 425.605(a)(1), 425.606(a)(1), 425.610(a)(1), (2)), would not be expected to meaningfully adjust

for such variability because they are prospective, and therefore, use diagnoses from 2019 to predict costs in 2020.

Furthermore, including the increased expenditures related to treatment of COVID-19 in calculations of ACO benchmarks for which CY 2020 is a benchmark year could lead to higher than anticipated future historical benchmarks unnecessarily advantaging some ACOs once the prevalence of COVID-19 in the population begins to decrease, and the corresponding reduction in expenditures is reflected in performance year expenditures. In contrast, we anticipate that the methodology used to update benchmarks will appropriately reflect any reduction in expenditures due to a cumulative yearlong decline in elective services and the deferral of other services as a result of regionally-uniform responses by beneficiaries and providers/suppliers to directives issued at federal, state, and local levels. Therefore, the retrospective application of the historical benchmark update (which for PY 2020 is either an update factor based on national growth rates, regional growth rates, or a blend of national and regional growth rates, depending on the start date of the ACO's agreement period) is expected to reasonably account for lower utilization of services by non-COVID-19 patients and prevent windfall shared savings payments to ACOs for PY 2020.

Including payment amounts for treatment of acute care for COVID-19 in calculations for which calendar year 2020 is used as a reference year could also distort repayment mechanism estimates and the identification of high and low revenue ACOs and influence ACO participation options. For example, ACOs could potentially be misclassified as either high revenue or low revenue, due to changes in expenditures arising from the COVID-19 pandemic, and either moved more quickly to higher levels of risk and reward if they are identified as high revenue ACOs or allowed additional time under a one-sided model (if eligible) or in relatively lower levels of performance-based risk if they are identified as low revenue ACOs.

ACOs currently participating in a performance-based risk track have an urgent need to

understand how we will address any distortions in expenditures resulting from the COVID-19 pandemic. Under the Shared Savings Program's regulations at § 425.221(b)(2)(ii)(A), an ACO under a two-sided model that voluntarily terminates its participation agreement with an effective date of termination after June 30th of the applicable performance year is liable for a pro-rated share of any shared losses determined for that performance year. Under § 425.220(a) of the regulations, ACOs are required to provide CMS at least 30 days' advance notice of their decision to voluntarily terminate from the program. As a result, ACOs that are participating under a two-sided model would need to provide notice to CMS no later than June 1, 2020, to avoid liability for a pro-rated share of any shared losses that may be determined for PY 2020. ACOs and other program stakeholders have expressed concern that ACOs need to make participation decisions in advance of this June 1, 2020 deadline, and may choose to terminate their participation in the Shared Savings Program on or before June 30th, rather than risk owing pro-rated shared losses for PY 2020. We note that as we explain in section II.L.3. of this IFC, the Shared Savings Program's extreme and uncontrollable circumstances policy will mitigate shared losses for these ACOs. However, given the uncertainty surrounding whether the COVID-19 PHE will cover the entire year and absent information regarding the steps that CMS intends to take to address the high costs associated with COVID-19 patients, many risk-based ACOs may choose to leave the program by June 30, 2020, to avoid the risk of owing shared losses.

We believe it is necessary to revise the policies governing Shared Savings Program financial calculations, as well as certain other program operations, to mitigate the impact of unanticipated increased expenditures related to the treatment of COVID-19. Given that ACOs in two-sided models have very limited time (less than 2 months at the time of development of this IFC) to decide whether to continue their participation in the program or voluntarily terminate without being liable for shared losses, we believe there is an urgent need to establish policies that address the impact of COVID-19 on Shared Savings Program financial calculations. More

generally, ACOs engage in care coordination and population-based activities for Medicare FFS beneficiaries, as they work towards achieving the Shared Savings Program's goals of lowering growth in Medicare FFS expenditures and improving the quality of care furnished to Medicare beneficiaries. We believe there is an urgency in taking steps to avoid adversely impacting ACOs, many of which have rapidly adapted to current circumstances in order to continue to coordinate care and deliver value-based care to Medicare FFS beneficiaries and meet program goals. In the absence of policies that adjust certain program calculations to remove payment amounts for episodes of care for treatment of COVID-19, ACOs may choose to leave the Shared Savings Program, setting back progress made in transitioning the health care system from volume-based to value-based payment. For these reasons, we find good cause to waive prior notice and comment rulemaking to establish policies to mitigate the impact of the COVID-19 pandemic on Shared Savings Program financial calculations.

We are revising our policies under the Shared Savings Program to exclude from Shared Savings Program calculations all Parts A and B FFS payment amounts for an episode of care for treatment of COVID-19, triggered by an inpatient service, and as specified on Parts A and B claims with dates of service during the episode. We are relying on our authority under section 1899(d)(1)(B)(ii) of the Act to adjust benchmark expenditures for other factors in order to remove COVID-19-related expenditures from the determination of benchmark expenditures. As discussed elsewhere in this section, we are also exercising our authority under section 1899(i)(3) of the Act to apply this adjustment to certain other program calculations, including the determination of performance year expenditures.

We believe an approach that makes the triggering event for this adjustment the beneficiary's receipt of inpatient care for COVID-19, will identify the most acutely ill patients and, as a result, those patients with the highest-costs associated with acute care treatment. In contrast, we believe that treatment for COVID-19 that does not result in an inpatient admission

does not raise the same level of concern in terms of generating unexpected performance year expenditures that are not appropriately reflected in the benchmark calculations. As William Bleser and colleagues have described,[32] citing a recent actuarial estimate of COVID-19 costs,[33] outpatient care was approximately 10 percent of the cost of hospital care, indicating that hospital costs are the dominant source of overall costs for treatment of COVID-19. We believe these findings support an approach that bases the exclusion of expenditures on the triggering event of an inpatient admission for treatment of COVID-19. Furthermore, we believe that some outpatient care will occur close-in-time to an eventual inpatient admission and following discharge. Under the approach we are establishing, where an episode of care includes the month of admission and the month following discharge, outpatient care occurring within the timeframe for an episode of care would also be excluded from financial calculations.

Accordingly, under the approach we are adopting in this IFC, we will identify an episode of care triggered by an inpatient service for treatment of COVID-19, based on either: (1) discharges for inpatient services eligible for the 20 percent DRG adjustment under section 1886(d)(4)(C) of the Act; or (2) discharges for acute care inpatient services for treatment of COVID-19 from facilities that are not paid under the IPPS, such as CAHs, when the date of admission occurs within the COVID-19 PHE as defined in § 400.200.

For example, we will identify discharges of an individual diagnosed with COVID-19 using the following ICD-10-CM codes:

- B97.29 (Other coronavirus as the cause of diseases classified elsewhere) for discharges occurring on or after January 27, 2020, and on or before March 31, 2020.

[32] Bleser WK, et al. Maintaining Progress Toward Accountable Care And Payment Reform During A Pandemic, Part 1: Utilization And Financial Impact. *Health Affairs*. April 14, 2020. Available at https://www.healthaffairs.org/do/10.1377/hblog20200410.281882/full/.

[33] COVERED California. The Potential National Health Cost Impacts to Consumers, Employers and Insurers Due to the Coronavirus (COVID-19). Policy / Actuarial Brief (March 22, 2020). Available at https://hbex.coveredca.com/data-research/library/COVID-19-NationalCost-Impacts03-21-20.pdf.

- U07.1 (COVID-19) for discharges occurring on or after April 1, 2020, through the duration of the COVID-19 PHE period, as defined in § 400.200.[34]

Episodes of care for treatment of COVID-19 may be triggered by an inpatient admission for acute care either at an acute care hospital or other healthcare facility, which may include temporary expansion sites, Medicare-enrolled ASCs providing hospital services to help address the urgent need to increase hospital capacity to treat COVID-19 patients, CAHs, and potentially other types of providers.[35]

We will define the episode of care as starting in the month in which the inpatient stay begins as identified by the admission date, all months during the inpatient stay, and the month following the end of the inpatient stay as indicated by the discharge date. This approach to measuring the length of the episode of care in units of months aligns with the Shared Savings Program's existing methodology for calculating benchmark year and performance year expenditures by performing separate calculations for each of four Medicare enrollment types (ESRD, disabled, aged/dual eligible for Medicare and Medicaid, and aged/non-dual eligible for Medicare and Medicaid). As described in the final rule entitled "Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations", which appeared in the **Federal Register** on June 10, 2016 (81 FR 37950), we account for circumstances where a beneficiary is enrolled in a Medicare enrollment type for only a fraction of a year (see 81 FR 37981). Specifically, we determine the number of months that an assigned beneficiary is enrolled in each specific Medicare enrollment type and

[34] See for example, MLN Matters, "New Waivers for Inpatient Prospective Payment System (IPPS) Hospitals, Long-Term Care Hospitals (LTCHs), and Inpatient Rehabilitation Facilities (IRFs) due to Provisions of the CARES Act" (April 15, 2020), available at https://www.cms.gov/files/document/se20015.pdf.
[35] See CMS fact sheet, "Hospitals: CMS Flexibilities to Fight COVID-19", dated March 30, 2020, available at https://www.cms.gov/files/document/covid-hospitals.pdf, describing flexibilities CMS specified for hospitals for the provision of inpatient care to fight COVID-19.

divide by 12. Summing these fractions across all assigned beneficiaries in each Medicare enrollment type results in total person years for the beneficiaries assigned to the ACO. Benchmark and performance year expenditures for each enrollment type are calculated on a per capita basis. The numerator of the per capita expenditure calculation for a particular enrollment type reflects the total Parts A and B expenditures incurred by all assigned beneficiaries in that enrollment type during the year, with adjustments made to exclude indirect medical education and disproportionate share hospital payments, to include individually beneficiary identifiable final payments made under a demonstration, pilot or time limited program, and to truncate beneficiary expenditures to minimize variation from catastrophically large claims. The denominator reflects total person years for the enrollment type.

In addition to excluding Parts A and B payment amounts with dates of service in the months associated with an episode of care for treatment of COVID-19, we will also exclude the affected months from total person years used in per capita expenditure calculations. For example, if a beneficiary had an episode of care for COVID-19 that lasted for 2 months, but was otherwise enrolled as an aged/non-dual eligible beneficiary for the full calendar PY, we will exclude their Parts A and B expenditures for those two months and compute their fraction of the year enrolled in the aged/non-dual eligible population as 10/12. Adjusting both expenditures and person years will ensure that both the numerator and denominator used to calculate per capita expenditures are based on the same number of months of beneficiary experience and allow ACOs to be treated equitably regardless of the degree to which their assigned beneficiary population is affected by the pandemic.

We believe that the approach described in this section will provide for a more equitable comparison between an ACO's performance year expenditures and its historical benchmark and will help to ensure that ACOs are not rewarded or penalized for having higher/lower COVID-19 spread in their assigned beneficiary populations which, in turn, will help to protect CMS against

paying out windfall shared savings and ACOs in two-sided models from owing excessive shared losses. Further, as described previously in this section of this IFC, we believe that the retrospective application of the historical benchmark update, which will be calculated based on factors that reflect actual expenditure and utilization changes nationally and regionally, other than expenditures for episodes of care for treatment of COVID-19, will also help to mitigate the potential for windfall savings due to potentially lower utilization of services not related to treatment for COVID-19.

We will adjust the following Shared Savings Program calculations to exclude all Parts A and B FFS payment amounts for a beneficiary's episode of care for treatment of COVID-19:

- Calculation of Medicare Parts A and B FFS expenditures for an ACO's assigned beneficiaries for all purposes, including the following: establishing, adjusting, updating, and resetting the ACO's historical benchmark and determining performance year expenditures.

- Calculation of FFS expenditures for assignable beneficiaries as used in determining county-level FFS expenditures and national Medicare FFS expenditures, including the following calculations:

++ Determining average county FFS expenditures based on expenditures for the assignable population of beneficiaries in each county in the ACO's regional service area according to §§ 425.601(c) and 425.603(e) for purposes of calculating the ACO's regional FFS expenditures. For example, for ACOs in agreement periods beginning on July 1, 2019, and in subsequent years, we will use county FFS expenditures from which we exclude all Parts A and B FFS payment amounts for a beneficiary's episode of care for treatment of COVID-19 in determining the regional component of the blended national and regional growth rates used to (1) trend forward benchmark year 1 and benchmark year 2 expenditures to benchmark year 3 according to § 425.601(a)(5)(iii), and (2) to update the benchmark according to § 425.601(b)(3). Further, we will use county expenditures from which we exclude all Parts A and B FFS payment

amounts for a beneficiary's episode of care for treatment of COVID-19 to update the ACO's rebased historical benchmark, according to § 425.603(d) for ACOs in a second agreement period beginning on or before January 1, 2019, based on regional growth rates in Medicare FFS expenditures.

++ Determining the 99th percentile of national Medicare FFS expenditures for assignable beneficiaries for purposes of the following: (1) truncating assigned beneficiary expenditures used in calculating benchmark expenditures (§§ 425.601(a)(4), 425.602(a)(4), 425.603(c)(4)), and performance year expenditures (§§ 425.604(a)(4), 425.605(a)(3), 425.606(a)(4), 425.610(a)(4)); and (2) truncating expenditures for assignable beneficiaries in each county for purposes of determining county FFS expenditures according to §§ 425.601(c)(3) and 425.603(e)(3).

++ Determining 5 percent of national per capita expenditures for Parts A and B services under the original Medicare FFS program for assignable beneficiaries for purposes of capping the regional adjustment to the ACO's historical benchmark according to § 425.601(a)(8)(ii)(C).

++ Determining the flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program for assignable beneficiaries, for purposes of updating the ACO's historical benchmark according to § 425.602(b)(2).

++ Determining national growth rates that are used as part of the blended growth rates used to trend forward benchmark year 1 and benchmark year 2 expenditures to benchmark year 3 according to § 425.601(a)(5)(ii) and as part of the blended growth rates used to update the benchmark according to § 425.601(b)(2).

- Calculation of Medicare Parts A and B FFS revenue of ACO participants for purposes of calculating the ACO's loss recoupment limit under the BASIC track as specified in § 425.605(d).

- Calculation of total Medicare Parts A and B FFS revenue of ACO participants and total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries for purposes of identifying whether an ACO is a high revenue ACO or low revenue ACO, as defined under § 425.20, and determining an ACO's eligibility for participation options according to § 425.600(d).

- Calculation or recalculation of the amount of the ACO's repayment mechanism arrangement according to § 425.204(f)(4).

We note that there are certain payments related to the COVID-19 PHE that fall outside of Medicare FFS Parts A and B claims, and by virtue of this fact, these payments would not be utilized under the Shared Savings Program methodology for determining beneficiary expenditures. For example, we would not account for recoupment of accelerated or advance payments,[36] which occurs outside of the FFS claims processing system. This is because the underlying Parts A and B claims used in Shared Savings Program expenditure calculations would continue to reflect the amount the providers/suppliers are eligible to be paid, although that payment may be subject to offset for repayment of accelerated or advance payments. Further, Shared Savings Program expenditure calculations would also not account for lump sum payments made to hospitals and other healthcare providers through the CARES Act Provider Relief Fund,[37] that occur outside of Parts A and B claims. We will continue to capture Medicare FFS Parts A and B payments to providers/suppliers in Shared Savings Program calculations from hospitals and other healthcare providers receiving these funds.

It is necessary to use our authority under section 1899(i)(3) of the Act to remove payment amounts for episodes of care for treatment of COVID-19 from the following calculations: (1)

[36] See CMS, "Fact Sheet: Expansion of the Accelerated and Advance Payments Program for Providers and Suppliers During COVID-19 Emergency," available at https://www.cms.gov/files/document/accelerated-and-advanced-payments-fact-sheet.pdf.
[37] See HHS website, CARES Act Provider Relief Fund, at https://www.hhs.gov/provider-relief/index.html.

performance year expenditures; (2) updates to the historical benchmark; and (3) ACO participants' Medicare FFS revenue used to determine the loss sharing limit in the two-sided models of the BASIC track. To use our authority under section 1899(i)(3) of the Act to adopt an alternative payment methodology to remove payment amounts for episodes of care for treatment of COVID-19 from these calculations, we must determine that the alternative payment methodology will improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without resulting in additional program expenditures. We believe that these adjustments, which will remove payment amounts for episodes of care for treatment of COVID-19 from the specified Shared Savings Program calculations, will capture and remove from program calculations expenditures that are outside of an ACO's control, but that could significantly affect the ACO's performance under the program. In particular, we believe that failing to remove this spending would likely create highly variable savings and loss results for individual ACOs that happen to have over-representation or under-representation of COVID-19 hospitalizations in their assigned beneficiary populations.

As described in the Regulatory Impact Analysis (section VI. of this IFC), we do not believe excluding payment amounts for episodes of care for treatment of COVID-19 from the specified calculations will result in an increase in spending beyond the expenditures that would otherwise occur under the statutory payment methodology in section 1899(d) of the Act. Further, we believe that these adjustments to our payment calculations to remove expenditures associated with treatment of COVID-19, in combination with the optional 1-year extension for ACOs whose current agreement periods expire on December 31, 2020 (as discussed in section II.L.1. of this IFC), and the option for ACOs in the BASIC track's glide path to elect to maintain their current level of risk and reward for PY 2021 (as discussed in section II.L.2. of this IFC) will provide greater certainty for currently participating ACOs. As a result, we expect these policies will support ACOs' continued participation in the Shared Savings Program in the face of

significant uncertainty arising from the disruptions due to the COVID-19 pandemic and the resulting PHE. This, in turn, means that these organizations would continue working towards meeting the Shared Savings Program's goals of lowering growth in Medicare FFS expenditures and improving the quality of care furnished to Medicare beneficiaries.

Based on these considerations, and as specified in the Regulatory Impact Analysis (section VI. of this IFC), we believe adjusting certain Shared Savings Program calculations to remove payment amounts for episodes of care for treatment of COVID-19 from the calculation of performance year expenditures, updates to the historical benchmark, and ACO participants' Medicare FFS revenue used to determine the loss sharing limit in the two-sided models of the BASIC track, meets the requirements for use of our authority under section 1899(i)(3) of the Act.

We also acknowledge that some trends and longer lasting effects of the COVID-19 pandemic are challenging to anticipate at the time of development of this IFC, and we will continue to evaluate the ongoing impact of the COVID-19 pandemic to determine whether additional rulemaking is necessary to further adjust Shared Savings Program policies. For example, it is unclear whether the COVID-19 pandemic may have longer-term effects into 2021, such as through rebounding elective procedure costs in 2021 following potentially sustained reductions in 2020 or to what extent the reduction in these procedures may persist. Further, we anticipate learning more about the potential longer-term implications of the COVID-19 pandemic on Medicare beneficiaries' health and the health care system.

We are adding a new provision at § 425.611 to describe the adjustments CMS will make to Shared Savings Program calculations to address the impact of the COVID-19 pandemic.

We seek comment on the approach to adjusting program calculations to mitigate the financial impact of the COVID-19 pandemic on ACOs that we are establishing with this IFC.

5. Expansion of Codes used in Beneficiary Assignment

a. Background

Section 1899(c)(1) of the Act, as amended by the 21st Century Cures Act (Pub. L. 114-255, enacted December 13, 2016) and the Bipartisan Budget Act of 2018 (BBA 2018) (Pub. L. 115-123, enacted February 9, 2018), provides that for performance years beginning on or after January 1, 2019, the Secretary shall assign beneficiaries to an ACO based on their utilization of primary care services provided by physicians participating in the ACO and all services furnished by RHCs and Federally Qualified Health Centers (FQHCs) that are ACO participants. However, the statute does not specify which kinds of services may be considered primary care services for purposes of beneficiary assignment.

For performance years beginning on January 1, 2019, and subsequent performance years, we defined primary care services in § 425.400(c)(1)(iv) for purposes of assigning beneficiaries to ACOs under § 425.402 as the set of services identified by the following HCPCS/ CPT codes:

CPT codes:

- 99201 through 99215 (*codes for office or other outpatient visit for the evaluation and management of a patient*).
- 99304 through 99318 (*codes for professional services furnished in a NF; services identified by these codes furnished in a SNF are excluded*).
- 99319 through 99340 (*codes for patient domiciliary, rest home, or custodial care visit*).
- 99341 through 99350 (*codes for evaluation and management services furnished in a patient's home for claims identified by place of service modifier 12*).
- 99487, 99489 and 99490 (*codes for chronic care management*).
- 99495 and 99496 (*codes for transitional care management services*).
- 99497 and 99498 (*codes for advance care planning*).

- 96160 and 96161 (*codes for administration of health risk assessment*).
- 99354 and 99355 (*add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code*).
- 99484, 99492, 99493 and 99494 (*codes for behavioral health integration services*).

HCPCS codes:

- G0402 (*code for the Welcome to Medicare visit*).
- G0438 and G0439 (*codes for the annual wellness visits*).
- G0463 *(code for services furnished in ETA hospitals)*.
- G0506 (*code for chronic care management*).
- G0444 (*code for annual depression screening service*).
- G0442 (*code for alcohol misuse screening service*).
- G0443 (*code for alcohol misuse counseling service*).

On March 17, 2020, we announced the expansion of payment for telehealth services on a temporary and emergency basis pursuant to waiver authority added under section 1135(b)(8) of the Act by the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 such that Medicare can pay for telehealth services, including office, hospital, and other visits furnished by physicians and other practitioners to patients located anywhere in the country, including in a patient's place of residence, starting March 6, 2020. In the context of the PHE for the COVID-19 pandemic, we recognize that physicians and other health care professionals are faced with new challenges regarding potential exposure risks, including for Medicare beneficiaries, for health care providers, and for members of the community at large. For example, the CDC has urged health care professionals to make every effort to interview persons under investigation for COVID-19 infection by telephone, text messaging system, or video conference instead of in-person. In the March 31st COVID-19 IFC, to facilitate the use of

telecommunications technology as a safe substitute for in-person services, we added, on an interim basis, many services to the list of eligible Medicare telehealth services, eliminated frequency limitations and other requirements associated with particular services furnished via telehealth, and clarified several payment rules that apply to other services that are furnished using telecommunications technologies that can reduce exposure risks (85 FR 19232).

Section 1834(m) of the Act specifies the payment amounts and circumstances under which Medicare makes payment for a discrete set of services, all of which must ordinarily be furnished in-person, when they are instead furnished using interactive, real-time telecommunication technology. When furnished under the telehealth rules, many of these specified Medicare telehealth services are still reported using codes that describe "face-to-face" services but are furnished using audio/video, real-time communication technology instead of in-person. As such, the majority of the codes for primary care services included in the additional telehealth services added in the March 31st COVID-19 IFC on an interim basis for the duration of the PHE for COVID-19 are already included in the definition of primary care services for purposes of the Shared Savings Program assignment methodology in § 425.400(c)(1)(iv).

The March 31st COVID-19 IFC also established flexibilities and separate payment for certain services that are furnished virtually using technologies but that are not considered Medicare telehealth services such as virtual check-ins, e-visits, and telephone E/M services, for which payment has been authorized during the COVID-19 PHE. The codes for these virtual services are not currently included in the definition of primary care services for purposes of the Shared Savings Program assignment methodology. We believe it is critical to include these additional codes in the definition of primary care services to ensure these services are included in our determination of where beneficiaries receive the plurality of their primary care for purposes of beneficiary assignment, so that the assignment methodology appropriately reflects the expanded use of technology that is helping people who need routine care during the PHE for the

COVID-19 pandemic and allowing vulnerable beneficiaries and beneficiaries with mild symptoms to remain in their homes, while maintaining access to the care they need. By including services provided virtually, either through telehealth, virtual check-ins, e-visits or telephone, in the definition of primary care services, we ensure that physicians and other practitioners can offer options to beneficiaries whom they treat, while also allowing this care to be included in our consideration of where beneficiaries receive the plurality of their primary care, for purposes of assigning beneficiaries to ACOs. As a result, revising the definition of primary care services used in assignment to include these services will further allow for continuity and coordination of care. We also reiterate our policy defined at § 425.404(b) that, for performance years starting on January 1, 2019, and subsequent performance years, under the assignment methodology in § 425.402, CMS treats a service reported on an FQHC/RHC claim as a primary care service performed by a primary care physician.

b. Use of Codes for Virtual Check-ins, Remote Evaluation E-Visits, Telephone Evaluation and Management Services, and Telehealth in Beneficiary Assignment

Based on feedback from ACOs and the expansion of payment, on an interim basis, for the virtual services discussed above, we are revising the definition of primary care services used in the Shared Savings Program assignment methodology for the performance year starting on January 1, 2020, and for any subsequent performance year that starts during the PHE for the COVID-19 pandemic, as defined in § 400.200, to include the following additions: (1) HCPCS code G2010 (*remote evaluation of patient video/images*) and HCPCS code G2012 (*virtual check-in*); (2) CPT codes 99421, 99422 and 99423 (*online digital evaluation and management service (e-visit)*); and (3) CPT codes 99441, 99442, and 99443 (*telephone evaluation and management services*).

Because the services listed above and described in detail in the preamble discussion below are similar to and may replace an E/M service for a beneficiary, we believe it is

appropriate to include these CPT and HCPCS codes in the definition of primary care services used for assignment because the services represented by these codes are being used in place of similar E/M services, the codes for which are already included in the list of codes used for assignment. We believe it is important to include these services in our assignment methodology because we determine assignment to ACOs based upon where beneficiaries receive the plurality of their primary care services or whether they have designated an ACO professional as their primary clinician, responsible for their overall care, and hold ACOs accountable for the resulting assigned beneficiary population. Including these codes in the definition of primary care services used in assignment for performance years during the PHE for the COVID-19 pandemic will result in a more accurate identification of where beneficiaries have received the plurality of their primary care services.

In preamble discussion below, we are also clarifying that CPT codes 99304, 99305 and 99306, 99315 and 99316, 99327 and 99328, 99334 through 99337, 99341 through 99345, and 99347 through 99350 will be included in the assignment methodology when these services are furnished using telehealth, consistent with additions to the Medicare telehealth list for the duration of the PHE for the COVID-19 pandemic as discussed in the March 31st COVID-19 IFC (85 FR 19235 through 19237). We use the assignment methodology described in §§ 425.402 and 425.404 for purposes of assigning beneficiaries to ACOs for a performance year or benchmark year based on preliminary prospective assignment with retrospective reconciliation (including quarterly updates) or prospective assignment.

With the emergence of the virus that causes COVID-19, there is an urgency to expand the use of technology to allow people who need routine care, vulnerable beneficiaries, and beneficiaries with mild symptoms to remain in their homes, while maintaining access to the care they need. Limiting community spread of the virus, as well as limiting beneficiaries' exposure to other patients and health care staff members, will slow viral spread. We anticipate that the

patterns and types of care provided during the COVID-19 PHE will be different and, in an effort to capture these changes in the methodology used to assign beneficiaries to ACOs as soon as possible, so that ACOs, particularly those that have elected preliminary prospective assignment with retrospective reconciliation for PY 2020, can understand the beneficiary population for which they will be responsible during PY 2020, we have determined that there is good cause to waive prior notice and comment rulemaking in order to implement these changes to the definition of primary care services in § 425.400(c) immediately.

As discussed in the March 31st COVID-19 IFC (85 FR 19244), in the CY 2019 PFS final rule, we finalized separate payment for a number of services that could be furnished via telecommunications technology, but that are not Medicare telehealth services. Specifically, beginning with CY 2019, we finalized separate payment for remote evaluation of video and/or images, HCPCS code G2010 *(Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment)*, and virtual check-in, HCPCS code G2012 *(Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report E/M services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion)*.

These codes were finalized as part of the set of codes that is only reportable by the physicians and practitioners who can furnish E/M services. Per the March 31st COVID-19 IFC, on an interim basis for the PHE for the COVID-19 pandemic, we will allow these codes to be used for new patients. In the March 31st COVID-19 IFC (85 FR 19244), we explained that, in

the context of the PHE for the COVID-19 pandemic, when brief communications with practitioners and other non-face-to-face services might mitigate the need for an in-person visit that could represent an exposure risk for vulnerable patients, we believe that these services should be available to as large a population of Medicare beneficiaries as possible. In some cases, use of telecommunication technology could mitigate the exposure risk, and in such cases, the clinical benefit of using technology to furnish the service is self-apparent. This would be especially true should a significant increase in the number of people or health care professionals needing treatment or isolation occur in a way that would limit access to brief communications with established providers. Therefore, on an interim basis, during the PHE for the COVID-19 pandemic, we finalized that these services, which may only be reported if they do not result in a visit, including a telehealth visit, can be furnished to both new and established patients

As discussed in the March 31st COVID-19 IFC (85 FR 19254), in the CY 2019 PFS final rule (83 FR 59452), we finalized payment for new online digital assessment services, also referred to as "E-Visits," beginning with CY 2020 for practitioners billing under the PFS. These are non-face-to-face, patient-initiated communications using online patient portals. These digital assessment services are for established patients who require a clinical decision that otherwise typically would have been provided in the office. Per the March 31st COVID-19 IFC (85 FR 19244), while the code descriptors for these e-visit codes refer to an "established patient", during the PHE for the COVID-19 pandemic, we are exercising enforcement discretion on an interim basis to relax enforcement of this aspect of the code descriptors. Practitioners who may independently bill Medicare for E/M visits (for instance, physicians and NPs) can bill the following codes:

- 99421 *(Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5–10 minutes.)*
- 99422 *(Online digital evaluation and management service, for an established patient,*

for up to 7 days cumulative time during the 7 days; 11– 20 minutes.)

- 99423 *(Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes.)*

We also considered adding additional e-visit HCPCS codes which are used by clinicians who may not independently bill for E/M visits and who are not included in the definition of ACO professional in § 425.20 (for example, PTs, OTs, SLPs, CPs). However, because these services are not furnished by ACO professionals, we determined it was not necessary to include the following codes in our definition of primary care services for use in assignment:

- G2061 *(Qualified nonphysician healthcare professional online assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 5-10 minutes.)*

- G2062 *(Qualified nonphysician healthcare professional online assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 11-20 minutes.)*

- G2063 *(Qualified nonphysician qualified healthcare professional assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes.)*

As discussed in the March 31st COVID-19 IFC (85 FR 19264 through 19265) and as discussed previously in this IFC, CMS finalized, on an interim basis for the duration of the PHE for the COVID-19 pandemic, separate payment for CPT codes 99441 through 99443 and 98966 through 98968, which describe E/M and assessment and management services furnished via telephone. While the code descriptors for these services refer to an "established patient" during the COVID-19 PHE we are exercising enforcement discretion on an interim basis to relax enforcement of this aspect of the code descriptors. Practitioners who may independently bill Medicare for E/M visits (for instance, physicians and NPs) can bill the following codes:

- 99441 *(Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion.)*

- 99442 *(Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11-20 minutes of medical discussion.)*

- 99443 *(Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 21-30 minutes of medical discussion.)*

We also considered adding the additional telephone assessment and management CPT codes which are used by clinicians who may not independently bill for E/M visits and who are not included in the definition of ACO professional in § 425.20 (for example, PTs, OTs, SLPs, CPs). However, because these services are not furnished by ACO professionals, we determined it was not necessary to include these codes in our definition of primary care services for use in assignment:

- 98966 *(Telephone assessment and management service provided by a qualified nonphysician health care professional to an established patient, parent, or guardian not originating from a related assessment and management service provided within the previous 7 days nor leading to an assessment and management service or procedure within the next 24*

hours or soonest available appointment; 5-10 minutes of medical discussion.)

- 98967 *(Telephone assessment and management service provided by a qualified nonphysician health care professional to an established patient, parent, or guardian not originating from a related assessment and management service provided within the previous 7 days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; 11-20 minutes of medical discussion.)*

- 98968 *(Telephone assessment and management service provided by a qualified nonphysician health care professional to an established patient, parent, or guardian not originating from a related assessment and management service provided within the previous 7 days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; 21-30 minutes of medical discussion.)*

Several codes, detailed below, that are included on the "Covered Telehealth Services for PHE for the COVID-19 pandemic, effective March 1, 2020" list available at https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes, are already included in the definition of primary care services used in the Shared Savings Program assignment methodology:

- 99304 *(Initial nursing facility care, per day, for the evaluation and management of a patient, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/ or family's needs. Usually, the problem(s) requiring admission are of low severity. Typically, 25 minutes are spent at the bedside and on the patient's facility floor or unit.)*

- 99305 *(Initial nursing facility care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive*

examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of moderate severity. Typically, 35 minutes are spent at the bedside and on the patient's facility floor or unit.)

- 99306 *(Initial nursing facility care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of high severity. Typically, 45 minutes are spent at the bedside and on the patient's facility floor or unit.)*
- 99315 *(Nursing facility discharge day management; 30 minutes or less.)*
- 99316 *(Nursing facility discharge day management; more than 30 minutes.)*
- 99327 *(Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/ or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity. Typically, 60 minutes are spent with the patient and/or family or caregiver.)*
- 99328 *(Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided*

consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant new problem requiring immediate physician attention. Typically, 75 minutes are spent with the patient and/ or family or caregiver.)

- 99334 *(Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self-limited or minor. Typically, 15 minutes are spent with the patient and/or family or caregiver.)*
- 99335 *(Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 25 minutes are spent with the patient and/or family or caregiver.)*
- 99336 *(Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent with the patient and/or family or caregiver.)*
- 99337 *(Domiciliary or rest home visit for the evaluation and management of an*

established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent with the patient and/or family or caregiver.)

- 99341 *(Home visit for the evaluation and management of a new patient, which requires these 3 key components: A problem focused history; A problem focused examination; and Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low severity. Typically, 20 minutes are spent face-to-face with the patient and/or family.)*

- 99342 *(Home visit for the evaluation and management of a new patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/ or family's needs. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent face-to-face with the patient and/or family.)*

- 99343 *(Home visit for the evaluation and management of a new patient, which requires these 3 key components: A detailed history; A detailed examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other*

physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 45 minutes are spent face-to-face with the patient and/or family.)

- 99344 *(Home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity. Typically, 60 minutes are spent face-to-face with the patient and/or family.)*

- 99345 *(Home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant new problem requiring immediate physician attention. Typically, 75 minutes are spent face-to-face with the patient and/or family.)*

- 99347 *(Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor. Typically, 15 minutes are spent face-to-face with the patient and/or family.)*

- 99348 *(Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 25 minutes are spent face-to-face with the patient and/or family.)*

- 99349 *(Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family.)*

- 99350 *(Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent face-to-face with the patient and/ or family.)*

Because these CPT codes are already included in the definition of primary care services used in the Shared Savings Program assignment methodology, we are clarifying that these CPT

codes will continue to be included in the definition of primary care services used for assignment, including when they are furnished via telehealth during the PHE for the COVID-19 pandemic, beginning March 1, 2020. We believe it is important to include these services in our assignment methodology, regardless of whether they are furnished in-person or via telehealth, because we determine assignment based upon where beneficiaries receive the plurality of their primary care services or whether they have designated an ACO professional as their primary clinician, responsible for their overall care, and hold ACOs accountable for the resulting assigned beneficiary population. Include these codes in the definition of primary care services used in assignment during the PHE for the COVID-19 pandemic, even when services are furnished via telehealth, will result in a more accurate identification of where beneficiaries have received the plurality of their primary care services.

Accordingly, we are adding a paragraph (c)(2) to our regulation at § 425.400, in which we specify additional primary care service codes that will be considered for purposes of beneficiary assignment for the performance year starting on January 1, 2020, and for any subsequent performance year that starts during the PHE for the COVID-19 pandemic, as defined in § 400.200. Under this provision the existing CPT codes and HCPCS codes included in the definition of primary care services at § 425.400(c)(1) will continue to apply for purposes of determining beneficiary assignment under § 425.402.

We seek comment on the revisions to the definition of primary care services that we are adopting in this IFC including the alternatives considered with regard to adding codes used by non-ACO professionals.

6. Applicability of Policies to Track 1+ Model ACOs

The Track 1+ Model was established under the Innovation Center's authority at section 1115A of the Act, to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care for Medicare, Medicaid, and

Children's Health Insurance Program beneficiaries. The Track 1+ Model, which is a time-limited model that began on January 1, 2018, is based on Shared Savings Program Track 1, but tests a payment design that incorporates more limited downside risk, as compared to Track 2 and the ENHANCED track. We discontinued all future application cycles for the Track 1+ Model, as explained in earlier rulemaking (83 FR 68032 and 68033). As of January 1, 2020, there are 20 Track 1+ Model ACOs participating in performance year 3 of a 3-year agreement under the model.

ACOs approved to participate in the Track 1+ Model are required to agree to the terms and conditions of the model by executing a Track 1+ Model Participation Agreement. See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/track-1plus-model-par-agreement.pdf. Track 1+ Model ACOs are also required to have been approved to participate in the Shared Savings Program (Track 1) and to have executed a Shared Savings Program Participation Agreement. As indicated in the Track 1+ Model Participation Agreement, in accordance with our authority under section 1115A(d)(1) of the Act, we have waived certain requirements of the Shared Savings Program that otherwise would be applicable to ACOs participating in Track 1 of the Shared Savings Program, as necessary for purposes of testing the Track 1+ Model, and established alternative requirements for the ACOs participating in the Track 1+ Model. Unless stated otherwise in the Track 1+ Model Participation Agreement, the requirements of the Shared Savings Program under part 425 continue to apply. Consistent with § 425.212, Track 1+ Model ACOs generally are subject to all applicable regulatory changes, including but not limited to, changes to the regulatory provisions referenced within the Track 1+ Model Participation Agreement that become effective during the term of the ACO's Shared Savings Program Participation Agreement and Track 1+ Model Participation Agreement, unless otherwise specified through rulemaking or amendment to the Track 1+ Model Participation Agreement.

We note that the terms of the Track 1+ Model Participation Agreement also permit the parties (CMS and the ACO) to amend the agreement at any time by mutual written agreement.

Therefore, unless specified otherwise, the changes to the Shared Savings Program regulations established in this IFC that are applicable to ACOs within a current agreement period will apply to ACOs in the Track 1+ Model in the same way that they apply to ACOs in Track 1, so long as the applicable regulation has not been waived under the Track 1+ Model. Similarly, to the extent that certain requirements of the regulations that apply to ACOs under Track 2 or the ENHANCED track have been incorporated for ACOs in the Track 1+ Model under the terms of the Track 1+ Model Participation Agreement, changes to those regulations as adopted in this IFC will also apply to ACOs in the Track 1+ Model in the same way that they apply to ACOs in Track 2 or the ENHANCED track. For example, the following policies apply to Track 1+ Model ACOs:

- Revisions to the definition of primary care services used in beneficiary assignment (section II.L.5. of this IFC), to include telehealth codes for virtual check-ins, e-visits, and telephonic communication. These codes are applicable beginning with beneficiary assignment for the performance year starting on January 1, 2020, and for any subsequent performance year that starts during the PHE for the COVID-19 pandemic, as defined in § 400.200.

- Clarification that the total months affected by an extreme and uncontrollable circumstance for the COVID-19 pandemic will begin with January 2020 and continue through the end of the COVID-19 PHE, for purposes of mitigating shared losses for PY 2020 (section II.L.3. of this IFC).

- Adjustments to expenditure calculations to remove expenditures for episodes of care for treatment of COVID-19 (section II.L.4. of this IFC).

We will also apply the following policies established in this IFC to Track 1+ Model ACOs through an amendment to the Track 1+ Model Participation Agreement executed by CMS

and the ACO:

- Adjustments to revenue calculations to remove expenditures for episodes of care for treatment of COVID-19 (section II.L.4. of this IFC).

M. Additional Flexibility under the Teaching Physician Regulations

In the March 31st COVID-19 IFC (85 FR 19258 through 19261), we introduced flexibilities in our regulations governing PFS payment for teaching physicians and residents. Since we published the March 31st COVID-19 IFC, stakeholders have asked us to relax additional requirements related to the provision of services furnished by a resident without the presence of a teaching physician under the so-called primary care exception specified in our regulation at 42 CFR 415.174.

For teaching physicians, section 1842(b) of the Act specifies that in the case of physicians' services furnished to a patient in a hospital with a teaching program, the Secretary shall not provide payment for such services unless the physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which payment is sought. Regulations regarding PFS payment for teaching physician services are codified in part 415. Under § 415.174, Medicare makes PFS payment in primary care settings for certain services of lower and mid-level complexity furnished by a resident without the physical presence of a teaching physician, referred to as the primary care exception. Our regulation at § 415.174(a)(3) requires that the teaching physician must not direct the care of more than four residents at a time, and must direct the care from such proximity as to constitute immediate availability (that is, provide direct supervision) and must review with each resident during or immediately after each visit, the beneficiary's medical history, physical examination, diagnosis, and record of tests and therapies. Section 415.174(a)(3) also requires that the teaching physician must have no other responsibilities at the time, assume management responsibility for the beneficiaries seen by the

residents, ensure that the services furnished are appropriate, and review with each resident during or immediately after each visit the beneficiary's medical history, physical examination, diagnosis, and record of tests and therapies.

As provided in the regulation at § 415.174(a), the E/M codes of lower and mid-level complexity that can be furnished under the primary care exception are specified in Section 100 of Chapter 12 of the Medicare Claims Processing Manual (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf). They are the following:

- CPT code 99201 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A problem focused history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family*);
- CPT code 99202 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 20 minutes are spent face-to-face with the patient and/or family*);
- CPT code 99203 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A detailed history; A detailed examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided*

consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent face-to-face with the patient and/or family);

- CPT code 99211 (*Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician or other qualified health care professional. Usually, the presenting problem(s) are minimal. Typically, 5 minutes are spent performing or supervising these services*);
- CPT code 99212 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family*);
- CPT code 99213 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent face-to-face with the patient and/or family*);
- HCPCS code G0402 *(Initial preventive physical examination; face-to-face visit, services limited to new beneficiary during the first 12 months of Medicare enrollment)*;
- HCPCS code G0438 (*Annual wellness visit; includes a personalized prevention plan of service (PPS), initial visit*); and

- HCPCS code G0439 (*Annual wellness visit, includes a personalized prevention plan of service (PPS), subsequent visit*).

In the context of the PHE for the COVID-19 pandemic, teaching hospitals have expressed a need to increase their capacity to respond to the increased demand for physicians to meet patient needs. Additionally, there are often circumstances where the teaching physician may be under quarantine or otherwise at home, or the physical proximity of the teaching physician might present additional exposure risks. In section II.E. the March 31st COVID-19 IFC (85 FR 19245 through 19246), we stated that as a general rule under § 415.172, the requirement for the presence of a teaching physician can be met, at a minimum, through direct supervision by audio/video real-time communications technology. We also revised the scope of E/M codes that can be furnished under the primary care exception and amended § 415.174 of our regulations to allow all levels of office/outpatient E/M services furnished in primary care centers under the primary care exception to be furnished under direct supervision of the teaching physician by interactive telecommunications technology. We are making clarifying technical edits to the regulation text at §§ 415.172, 415.174, 415.180, and 415.184 to reflect the audio/video real-time requirement for communications technology.

Since we published the March 31st COVID-19 IFC, stakeholders have requested that we also revise our regulations to allow the teaching physician to meet the requirement to review the service with the resident, during or immediately after the visit, through virtual or remote means via interactive audio/video real-time communications technology. Given the circumstances of the COVID-19 PHE, the teaching physician may be under quarantine or otherwise not physically available to review the service with the resident. We note that in the March 31st COVID-19 IFC, we inadvertently deleted the former § 415.174(b) which stated that, nothing in paragraph (a) of the section may be construed as providing a basis for the coverage of services not determined to be covered under Medicare, such as routine physical check-ups. We are reinstating the former

paragraph (b) and adding a new paragraph (c) to allow that, on an interim basis for the duration of the PHE for the COVID-19 pandemic, the teaching physician may not only direct the care furnished by residents, but also review the services provided with the resident, during or immediately after the visit, remotely through virtual means via audio/video real time communications technology.

We believe that permitting the teaching physician to interact with the resident remotely through virtual means would still allow the teaching physician to direct, manage, and review the care furnished by residents as specified in § 415.174(a). For example, this means that Medicare may make payment under the PFS for teaching physician services when a resident furnishes services permitted under the primary care exception, including via telehealth, and the teaching physician can provide the necessary direction, management and review of the resident's services using interactive audio/video real-time communications technology. The remainder of the policies at § 415.174(a)(3) continue to apply in that the teaching physician must have no other responsibilities at the time, assume management responsibility for the beneficiaries seen by the residents, ensure that the services furnished are appropriate, and review with each resident during or immediately after each visit the beneficiary's medical history, physical examination, diagnosis, and record of tests and therapies.

Since we published the March 31st COVID-19 IFC, stakeholders have requested that additional services be added to the primary care exception, such as the telephone E/M services we added for separate payment in the March 31st COVID-19 IFC, as well as transitional care management, and communication technology-based services. Adding services to the primary care exception would permit the resident to provide a more expansive array of services to patients who may be quarantined at home or who may need to be isolated for purposes of minimizing exposure risk based on presumed or confirmed COVID-19 infection. Consequently, on an interim basis for the duration of the COVID-19 PHE, Medicare may make PFS payment to

the teaching physician for the following additional services when furnished by a resident under the primary care exception:

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

- CPT code 99421 (*Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5–10 minutes*);
- CPT code 99422 (*Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11–20 minutes*);
- CPT code 99423 (*Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes*);
- CPT code 99452 (*Interprofessional telephone/internet/electronic health record referral service(s) provided by a treating/requesting physician or qualified health care professional, 30 minutes*);
- HCPCS code G2012 (*Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion*); and
- HCPCS code G2010 (*Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment*).

Finally, consistent with policy that we established in the March 31st COVID-19 IFC for selecting the level of Office/Outpatient E/M visits when furnished as Medicare Telehealth services, (85 FR 19268 through 19269), we are clarifying that the office/outpatient E/M level selection for services under the primary care exception when furnished via telehealth can be based on MDM or time, with time defined as all of the time associated with the E/M on the day of the encounter; and the requirements regarding documentation of history and/or physical exam

in the medical record do not apply. As described in section II.Z. of this IFC, the typical times for purposes of level selection for an office/outpatient E/M are the times listed in the CPT code descriptor. This policy is similar to the policy that will apply to all office/outpatient E/M services beginning in 2021 under policies finalized in the CY 2020 PFS final rule. Taken together, these policies mean that, on an interim basis for the duration of the PHE for the COVID-19 pandemic, Medicare may make PFS payment for teaching physician services when a resident furnishes a service included in this expanded list of services in primary care centers, including via telehealth, and the teaching physician can provide the necessary direction, management and review for the resident's services using audio/video real-time communications technology. We believe that these policies will increase the capacity of teaching settings to respond to the PHE for the COVID-19 pandemic as more practitioners are being asked to assist with the response.

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

In the March 31st COVID-19 IFC, we established separate payment for audio-only telephone evaluation and management services. The telephone evaluation and management (E/M) services are CPT codes:

- 99441 (*Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion*);

- 99442 (*Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next*

24 hours or soonest available appointment; 11-20 minutes of medical discussion); and

- 99443 (*Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 21-30 minutes of medical discussion*).

We noted that, although these services were previously considered non-covered under the PFS, in the context of PHE and with the goal of reducing exposure risks associated with the COVID-19 pandemic, especially in the case that two-way, audio and video technology required to furnish a Medicare telehealth service might not be available, we believed there are circumstances where prolonged, audio-only communication between the practitioner and the patient could be clinically appropriate, yet not fully replace a face-to-face visit. For example, an established patient who was experiencing an exacerbation of their condition could have a 25-minute phone conversation with their physician during which the physician determines that an adjustment to the patient's medication would alleviate their symptoms. The use of CPT code 99443 in this situation prevents a similar in-person service. We stated we believed that these telephone E/M codes, with their established description and valuation, were the best way to recognize the relative resource costs of these kinds of services and make payment for them under the PFS.

For these codes, we finalized on an interim basis during the PHE for the COVID-19 pandemic, work relative value units (RVUs) as recommended by the American Medical Association (AMA) Relative Value Scale Update Committee (RUC) as discussed in the CY 2008 PFS final rule (72 CFR 66371) of 0.25 for CPT code 99441, 0.50 for CPT code 99442, and 0.75 for CPT code 99443. We also finalized the RUC-recommended direct practice expense (PE) inputs which consist of 3 minutes of post-service Registered Nurse/Licensed Practical

Nurse/Medical Technical Assistant clinical labor time for each code.

In the time since we established these payment amounts, stakeholders have informed us that use of audio-only services is more prevalent than we had previously considered, especially because many beneficiaries are not utilizing video-enabled communication technology from their homes. In other words, there are many cases where practitioners would under ordinary circumstances utilize telehealth or in-person visits to evaluate and manage patients' medical concerns, but are instead using audio-only interactions to manage more complex care. While we previously acknowledged the likelihood that, under the circumstances of the PHE, more time would be spent interacting with the patient via audio-only technology, we are now recognizing that the intensity of furnishing an audio-only visit to a beneficiary during the unique circumstances of the COVID-19 pandemic is not accurately captured by the valuation of these services we established in the March 31st COVID-19 IFC. This is particularly true to the extent that these audio-only services are actually serving as a substitute for office/outpatient Medicare telehealth visits for beneficiaries not using video-enabled telecommunications technology contrary to the situation we anticipated when establishing payment for them in the March 31st COVID-19 IFC. Given our new understanding that these audio-only services are being furnished primarily as a replacement for care that would otherwise be reported as an in-person or telehealth visit using the office/outpatient E/M codes, we are establishing new RVUs for the telephone E/M services based on crosswalks to the most analogous office/outpatient E/M codes, based on the time requirements for the telephone codes and the times assumed for valuation for purposes of the office/outpatient E/M codes. Specifically, we are crosswalking CPT codes 99212, 99213, and 99214 to 99441, 99442, and 99443 respectively. We are finalizing, on an interim basis and for the duration of the COVID-19 PHE the following work RVUs: 0.48 for CPT code 99441; 0.97 for CPT code 99442; and 1.50 for CPT code 99443. We are also finalizing the direct PE inputs associated with CPT code 99212 for CPT code 99441, the direct PE inputs associated with

CPT code 99213 for CPT code 99442, and the direct PE inputs associated with CPT code 99214 for CPT code 99443. We are not finalizing increased payment rates for CPT codes 98966-98968 as these codes describe services furnished by practitioners who cannot independently bill for E/Ms and so these telephone assessment and management services, by definition, are not furnished in lieu of an office/outpatient E/M service.

We note that to the extent that these extended phone services are taking place instead of office/outpatient E/M visits (either in-person or via telehealth), the direct crosswalk of RVUs also better maintains overall budget neutrality and relativity under the PFS. We believe that the resources required to furnish these services during the PHE for the COVID-19 pandemic are better captured by the RVUS associated with the level 2-4 established patient office/outpatient E/M visits. Additionally, given our understanding that these audio-only services are being furnished as substitutes for office/outpatient E/M services, we recognize that they should be considered as telehealth services, and are adding them to the list of Medicare telehealth services for the duration of the PHE. We also note that, for these audio-only E/M services, we will be separately issuing a waiver under section 1135(b)(8) of the Act, as amended by section 3703 of the CARES Act, of the requirements under section 1834(m) of the Act and our regulation at § 410.78 that Medicare telehealth services must be furnished using video technology. The full list of Medicare telehealth services, including those added during the PHE, is available here https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes. We note that these codes describe medical discussion, and should not be used for administrative or other non-medical discussion with the patient. Although practitioners have been provided flexibility around cost-sharing for the duration of the PHE, beneficiaries are still liable for cost-sharing for these services in instances where the practitioner does not waive cost-sharing. Practitioners should educate beneficiaries on any applicable cost-sharing. We are seeking comment on how best to minimize unexpected cost sharing for beneficiaries. We plan to monitor

utilization of these services and will consider making refinements to billing rules, documentation requirements or claims edits through future rulemaking.

O. Flexibility for Medicaid Laboratory Services

Section 6004(a) of the Families First Coronavirus Response Act added a new mandatory benefit in the Medicaid statute at section 1905(a)(3)(B) of the Act, and this provision was amended by section 3717 of the CARES Act. Section 1905(a)(3)(B) of the Act provides that, for any portion of the COVID-19 emergency period defined in section 1135(g)(1)(B) of the Act that begins on or after March 18, 2020, Medicaid coverage must include in vitro diagnostic products (as defined in Food and Drug Administration (FDA) regulations at 21 CFR 809.3(a)) for the detection of SARS-CoV-2 or diagnosis of the virus that causes COVID-19, and the administration of such in vitro diagnostic products. As discussed in CMS guidance issued on April 13, 2020,[38] FDA has advised that serological tests for COVID-19 meet the definition in 21 CFR 809.3(a) of an in vitro diagnostic product for the detection of SARS-CoV-2 or the diagnosis of COVID-19. Therefore, coverage under section 1905(a)(3)(B) of the Act must include those serological tests. Section 1905(a)(3)(B) was an addition to the existing mandatory benefit for laboratory and X-ray services that was formerly at section 1905(a)(3) of the Act, and that is now at section 1905(a)(3)(A) of the Act.

The regulation currently implementing section 1905(a)(3) of the Act, at 42 CFR 440.30, includes certain limitations and conditions on Medicaid coverage of laboratory tests and X-rays, and describes who may provide laboratory tests and where laboratory tests may be administered. Specifically, § 440.30(a) requires that Medicaid-covered laboratory and X-ray services be ordered and provided by or under the direction of a physician or other licensed practitioner of the healing arts within the scope of his or her practice as defined by state law or ordered by a

[38] Families First Coronavirus Response Act, Pub. L. 116-127; Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. 116-136; Frequently Asked Questions (FAQs) (April 13, 2020) 5-6, at https://www.medicaid.gov/state-resource-center/downloads/covid-19-section-6008-CARES-faqs.pdf.

physician but provided by a referral laboratory. Section 440.30(b) specifies that Medicaid will cover laboratory and X-ray services only if provided in an office or similar facility other than a HOPD or clinic, and § 440.30(c) specifies that Medicaid will cover these services only if they are furnished by a laboratory that meets the requirements of 42 CFR part 493.

As the CDC noted when issuing advice on how to protect against COVID-19 infection, some recent studies have suggested that COVID-19 may be spread by people who are not showing symptoms.[39] We believe it is vital for Medicaid beneficiaries to have broad access to tests to detect the SARS-CoV-2 virus, antibodies to the SARS-CoV-2 virus, or COVID-19, so that they can properly monitor their symptoms, make decisions about seeking further care, and take appropriate precautions to prevent further spread of disease. The requirements at § 440.30(a) and (b) could present an obstacle to Medicaid coverage for administering and processing COVID-19 laboratory and diagnostic tests in certain non-office settings, such as parking lots or other temporary outdoor locations, where the setting is intended to maximize physical distancing and thereby minimize transmission of COVID-19. Given the nature and scope of the COVID-19 pandemic, the critical importance of expanding COVID-19 testing to combat the pandemic, and the heightened risk the disease presents to Medicaid beneficiaries, we also would like to accommodate evolving COVID-19 diagnostic mechanisms, such as FDA-authorized tests that allow for patients to self-collect a specimen in alternative locations (such as at home) to send to a laboratory, to detect the SARS-CoV-2 virus, antibodies to the SARS-CoV-2 virus, or COVID-19 (sometimes referred to as "self-collection"). Self-collection of tests at home is likely to minimize transmission of COVID-19, and the need for a Medicaid beneficiary to obtain an order for coverage of a self-collected COVID-19 test could present a significant barrier to beneficiaries who might otherwise seek a test that FDA authorizes as not requiring a

[39] https://www.cdc.gov/mmwr/volumes/69/wr/mm6913e2.htm; https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html.

prescription. We are using the term self-collection to encompass evolving mechanisms for testing that would be processed by a laboratory that can receive Medicaid payment.

Accordingly, we are amending § 440.30 to permit flexibility for coverage of COVID-19 tests, including coverage for tests administered in non-office settings, and coverage for laboratory processing of self-collected COVID-19 tests that are FDA-authorized for self-collection. The flexibility would apply not only during the current COVID-19 PHE, but also during any subsequent periods of active surveillance, to allow for continued surveillance as part of strategies to detect recurrence of the virus in individuals and populations to prevent further spread of the disease. State officials may continue to need the flexibility offered under this amendment during such periods of active surveillance after the COVID-19 PHE ends. We define a period of active surveillance as an outbreak of communicable disease during which no approved treatment or vaccine is widely available. A period of active surveillance ends on the date the Secretary terminates it, or the date that is two incubation periods after the last known case of the communicable disease, whichever is sooner. We seek comments on this definition of the period of active surveillance.

To allow similar flexibilities in future emergencies with similar circumstances, these amendments would not be limited to the COVID-19 PHE and any subsequent period of active surveillance (as defined above), but would also apply to future PHEs resulting from outbreaks of communicable disease (and subsequent periods of active surveillance, as defined above), during which measures are necessary to avoid transmission of the communicable disease, and when such measures might result in difficulty meeting the requirements of § 440.30(a) or (b). The flexibilities available under this amendment would be applicable as described below for the COVID-19 PHE, and with respect to future PHEs, would be applicable only upon formal declaration of a PHE that CMS determines meets these criteria, and would last for the duration of that future PHE and any subsequent period of active surveillance.

We are therefore adding a new § 440.30(d) that specifies that, during the COVID-19 PHE or any future PHE resulting from an outbreak of communicable disease, and during any subsequent period of active surveillance (as defined above), Medicaid coverage is available for laboratory tests and X-ray services that do not meet conditions specified in § 440.30(a) or (b) so long as the purpose of the laboratory or X-ray service is to diagnose or detect SARS-CoV-2, antibodies to SARS-CoV-2, COVID-19, or the communicable disease named in the PHE or its causes, and so long as the deviation from the conditions specified in § 440.30(a) or (b) is intended to avoid transmission of the communicable disease. We further specify that under these same circumstances and subject to these same conditions, Medicaid coverage is available for laboratory processing of self-collected laboratory test systems that the FDA has authorized for home use, if available to diagnose or detect SARS-CoV-2, antibodies to SARS-CoV-2, COVID-19, or the communicable disease named in the PHE or its causes, even if those self-collected tests would not otherwise meet the requirements in § 440.30(a) or (b). Among other flexibilities, these amendments would permit states to cover laboratory processing of self-collected test systems that the FDA has authorized for home use, without the order of a treating physician or other licensed non-physician practitioner (NPP). Laboratories that process such test systems without an order, as permitted under this new § 440.30(d), must notify the patient and the patient's physician or NPP, if known by the laboratory, of the results. Again, in order to protect the public, the flexibilities that would permit self-collection of testing will apply only for test systems authorized by the FDA for home use. We are soliciting comment on the implications of applying this provision to future public health emergencies, and the specifications that should be included in doing so.

These changes to § 440.30 apply not only to the benefit described at section 1905(a)(3)(B) of the Act, but also apply to the longstanding laboratory and X-ray services benefit that was formerly at section 1905(a)(3) of the Act, and is now at section 1905(a)(3)(A) of

the Act. In light of the urgent need to provide these flexibilities during the COVID-19 PHE, and because this provision will ease restrictions under existing law and make Medicaid coverage of testing more available, new paragraph (d) in § 440.30 will be effective retroactive to March 1, 2020.

Lastly, while § 440.30(d) does not provide flexibility regarding § 440.30(c), which provides that services under § 440.30 must be furnished by a laboratory that meets the requirements of part 493, we are soliciting comment on whether continuing to apply the requirements of § 440.30(c) would present any obstacle to providing Medicaid coverage for COVID-19 testing.

P. Improving Care Planning for Medicaid Home Health Services

1. Background

a. General Information

Title XIX of the Act requires that to receive federal Medicaid matching funds, a state must offer certain services to the categorically needy populations specified in the statute. Home health services for Medicaid-eligible individuals who are entitled to NF services is one of these mandatory services. Individuals entitled to NF services include the basic categorically needy populations that receive the standard Medicaid benefit package, and can include medically needy populations if NF services are offered to the medically needy within a state. Home health services include part-time or intermittent nursing, home health aide services, medical supplies, equipment, and appliances, and may include therapy services (physical therapy, occupational therapy, speech pathology and audiology services). Prior to 1997, Medicaid regulations required an individual's physician to order home health services as part of a written plan of care, and review the plan of care every 60 days. In 1997, Medicaid regulations (62 FR 47902), were amended to allow the plan of care for medical supplies, equipment and appliances to be reviewed by a physician annually.

Title XIX was amended in 2010, when section 6407 of the Patient Protection and Affordable Care Act of 2010[40] added the requirement that physicians document the occurrence of a face-to-face encounter (including through the use of telehealth) with the Medicaid beneficiary within reasonable timeframes when ordering home health services. Section 504 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10, enacted on April 16, 2015) amended Medicare requirements at section 1834(a)(11)(B)(ii) of the Act to allow certain authorized NPPs to document the face-to-face encounter and applied such changes to the Medicaid program. CMS finalized the implementing provisions on February 2, 2016, in the Medicaid Program; Face-to-Face Requirements for Home Health Services; Policy Changes and Clarification Related to Home Health final rule (81 FR 5529) became effective July 1, 2016.

In the March 31st COVID-19 IFC, we amended the Medicaid home health regulations to allow other licensed practitioners to order all components of home health services in accordance with state scope of practice laws, for the period of this COVID-19 PHE.

b. Changes to Modernize Requirements for Ordering Medicaid Home Health Nursing, Aide and Therapy Services; and Modernize Face-to-Face Encounter Requirements

When the Medicaid program was signed into law in 1965, most skilled medical professional services in the United States were provided by physicians, with the assistance of nurses. Over the decades, the medical professional field has diversified and allowed for a wider range of certifications and specialties, including the establishment of mid-level practitioners such as NPs and PAs that are also known as NPPs. Both Medicare and Medicaid policies and regulations have been updated over recent years to make changes to allow NPPs to provide certain services within the extent of their scope of practice as defined by state law.

[40] The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. In this IFC, we refer to the two statutes collectively as the "Patient Protection and Affordable Care Act".

The recognition of the advanced training and qualifications of these practitioners continues with the enactment of the CARES Act. Section 3708 of the CARES Act amended Medicare requirements at sections 1814(a) and 1835(a) of the Act to expand the list of practitioners who can order home health services. Specifically, sections 1814(a)(2)(C) of the Act under Part A and section 1835(a)(2)(A) of the Act under Part B of the Medicare program were amended to allow an NP, CNS or PA to order home health services in addition to physicians so long as these NPPs are permitted to provide such services under the scope of practice laws in the state. Section 3708(e) of the CARES Act also provides that the requirements for ordering home health services shall apply under title XIX in the same manner and to the same extent as such requirements apply under title XVIII of such Act. In accordance with this language on applying these requirements "in the same manner" as Medicare is, in light of the urgent need to provide these flexibilities during the COVID-19 PHE, and because this provision will increase flexibility in the delivery of benefits and make Medicaid coverage of home health services more available, the Medicaid regulations discussed in this section will take effect on the same date as the Medicare regulations implementing section 3708 discussed in section II.J. of this IFC, "Care Planning for Medicare Home Health Services." Further, the language in section 3708 of the CARES Act is not time limited to the period of the COVID-19 PHE; the revisions to the Medicaid home health program will be permanently in effect.

The purpose of this regulation is to implement this statutory directive in the CARES Act within the Medicaid program. In implementing the CARES Act home health provisions, it is important to note the structural differences between the Medicare home health benefit and the Medicaid home health benefit that require some adaptation for the requirement to apply the new Medicare rules in section 3708 of the CARES Act to Medicaid "in the same manner and to the same extent as such requirements apply" under Medicare. Under the Medicare program, the home health benefit includes skilled part-time or intermittent nursing, home health aide service,

therapies and medical social services. DME is a separate benefit under Medicare, and could already be ordered, prior to the enactment of section 3708 of the CARES Act, by a more extensive list of NPPs than the practitioners identified in section 3708 of the CARES Act for Medicare home health services. Comparatively, as noted previously in this section of the IFC, the Medicaid home health benefit includes part-time or intermittent nursing, home health aide services, and medical supplies, equipment and appliances, also known as DME. Therapy services can be included at the state's option.

Based on the statutory directive to apply section 3708 of the CARES Act changes to Medicaid in the same manner as Medicare, we had to determine whether to interpret this directive as applying the rules for who can order services under the more limited Medicare home health services benefit only to the subset of Medicaid home health services that align with Medicare, or to apply the Medicare rules on who can order services to the full range of Medicaid home health services. As discussed earlier in this section, Medicare allows a more extensive list of NPPs to order DME, than the practitioners identified for Medicaid or the practitioners identified in the CARES Act. Because DME ("medical supplies, equipment and appliances") is covered under the Medicaid home health benefit, this would mean applying the current Medicare rules on who can order DME under that Medicare benefit to that component of the Medicaid home health benefit. We believe that aligning the Medicaid program with Medicare regarding who can order medical supplies, equipment and appliances promotes access to services for Medicaid beneficiaries, including those who are dually eligible, and will eliminate burden to states and providers on dealing with inconsistencies between the Medicare and Medicaid programs. Specifically, we are amending the home health regulation at § 440.70(a)(3) to allow other licensed practitioners, to order medical equipment, supplies and appliances in addition to physicians, when practicing in accordance with state laws.

For other services covered under the Medicaid home health benefit, we are applying the new list of practitioners set forth in section 3708 of the CARES Act to who can order those services, specifically, part-time or intermittent nursing services, home health aide services, and if included in the state's home health benefit, therapy services. Specifically, § 440.70(a)(2) is amended to allow a NP, CNS and PA to order home health services described in § 440.70(b)(1), (2) and (4).

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

Finally, we note that the flexibility allowed in this IFC to NPs, CNSs and PAs to order home health services must be done in accordance with state law. Individual states have varying requirements for conditions of practice, which determine whether a practitioner may work independently, without a written collaborative agreement or supervision from a physician, or whether general or direct supervision and collaboration is required. State Medicaid Agencies can consult the specific practitioner association or relevant state agency website to ensure that practitioners are working within their scope of practice and prescriptive authority.

Q. Basic Health Program Blueprint Revisions

1. Background

Section 1331 of the Patient Protection and Affordable Care Act[41] provides states with a coverage option, the Basic Health Program (BHP), for specified individuals who do not qualify for Medicaid but whose income does not exceed 200 percent of the federal poverty level (FPL). More information about the BHP is available in the "Basic Health Program" final rule[42] which was published in the March 12, 2014 **Federal Register** (79 FR 14112). The BHP regulations are codified at part 600. As of April 2020, Minnesota and New York are the only states operating a BHP.

2. Changes to Requirements for Revisions of a Certified Blueprint

As we explain in § 600.110, the BHP Blueprint is a comprehensive written document submitted by the State to the Secretary for certification of a BHP. Section 600.110(a) specifies what content needs to be included in the BHP Blueprint that must be certified by HHS. Section 600.125(a) currently requires that a state that seeks to make significant changes to its BHP must submit a revised BHP Blueprint to the Secretary for review and certification.[43] We previously explained in the September 25, 2013 BHP proposed rule[44] (78 FR 59125) that, while not an exhaustive list, the types of changes that would be considered "significant" for purposes of this provision include changes that have a direct impact on the enrollee experience in BHP or the program financing. Section 600.125(b) currently requires that a state is responsible for continuing to operate under the terms of the existing Blueprint until and unless a revised

[41] The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. In this IFC, we refer to the two statutes collectively as the "Patient Protection and Affordable Care Act".

[42] Basic Health Program: State Administration of Basic Health Programs; Eligibility and Enrollment in Standard Health Plans; Essential Health Benefits in Standard Health Plans; Performance Standards for Basic Health Programs; Premium and Cost Sharing for Basic Health Programs; Federal Funding Process; Trust Fund and Financial Integrity; Final Rule (79 FR 14111through 14151, March 12, 2014).

[43] This provision states that "in the event that a State seeks to make significant change(s) that alter program operations the BHP benefit package, enrollment, disenrollment and verification policies described in the certified BHP Blueprint, the State must submit a revised Blueprint to the Secretary for review and certification."

[44] Basic Health Program: State Administration of Basic Health Programs; Eligibility and Enrollment in Standard Health Plans; Essential Health Benefits in Standard Health Plans; Performance Standards for Basic Health Programs; Premium and Cost Sharing for Basic Health Programs; Federal Funding Process; Trust Fund and Financial Integrity; Proposed Rule, 78 FR 59121 at 59125 (September 25, 2013).

Blueprint is certified. Taken together, these regulations require that states wishing to make significant changes to a certified Blueprint must do so on a prospective basis and such changes cannot be implemented until a revised Blueprint is certified by HHS.

We believe that during the PHE for the COVID-19 pandemic, it is not feasible for a state to receive certification by HHS prior to implementing certain necessary significant changes to their BHP. Specifically, during the PHE for the COVID-19 pandemic, states may need to immediately revise certain provisions of or add certain provisions to their BHP Blueprints that would be considered significant changes to ensure BHP enrollees can access necessary services without delay or access these services without cost sharing. For example, based on our experience with the PHE for the COVID-19 pandemic, we recognize that states operating a BHP may need to temporarily waive limitations on certain benefits covered under its BHP or temporarily waive enrollee premiums and cost sharing.

Therefore, at § 600.125, we are revising paragraph (b) and adding a new paragraph (c) to allow a state to submit to the Secretary for review and certification a revised Blueprint that makes temporary significant changes to respond to the PHE for the COVID-19 pandemic with the option for the states to make such changes effective retroactive to the start of the PHE for the COVID-19 pandemic as defined in § 400.200. While we would generally expect that revisions submitted under § 600.125(c) would no longer be in effect as of the end of the PHE for the COVID-19 pandemic as defined in § 400.200, there may be instances in which policies will need to temporarily be in effect for a longer period of time. For example, following the end of the PHE for the COVID-19 pandemic, a state may need additional time to process all of the renewals or changes in circumstance that were not completed during the PHE. A state may need an additional, temporary period of time (for example, 90 days), before resuming its usual processing standards. We will work with states to determine a reasonable amount of time after the PHE for returning to normal course of business.

Specifically, the flexibility in the new § 600.125(c) only applies to Blueprint revisions that make temporary significant changes that are directly tied to the PHE for the COVID-19 pandemic and would increase enrollee access to coverage.[45] States may not submit under § 600.125(c), and we will not certify, retroactive Blueprint revisions under this provision that are not directly tied to the PHE for the COVID-19 pandemic. In addition, states may not submit under § 600.125(c), and we will not certify, retroactive Blueprint revisions under this provision that are restrictive in nature, such as Blueprint revisions that increase enrollee cost sharing, reduce BHP benefits, or limit or reduce eligibility for BHP coverage. Revised Blueprints submitted under § 600.125(c) can only implement temporary revisions to increase access to coverage that would remain in effect only through the duration of the PHE for the COVID-19 pandemic, or a reasonable additional amount of time as discussed above. To submit and receive certification for a revised Blueprint under § 600.125(c), a state will need to submit a cover letter to CMS that lists each change for which it is seeking certification alongside an explanation for how each change is directly related to the PHE for the COVID-19 pandemic and how each change is not restrictive in nature. The state should also specify the requested duration of each of the changes. If the state is seeking certification to implement temporary changes beyond the end of the COVID-19 pandemic, the state should specify why the later end date is needed. The state should also submit a revised Blueprint that incorporates the temporary changes. In addition, as noted above, the process outlined in the new section § 600.125(c) does not apply to Blueprint revisions that do not make significant changes.

Revised Blueprints submitted under § 600.125(c) will not be subject to the public comment requirements under § 600.115(c), as we have determined that the existence of unforeseen circumstances resulting from the PHE for the COVID-19 pandemic warrants an

[45] These flexibilities are similar to those that are currently available in the Medicaid State Plan Amendment (SPA) template and instructions that CMS created in March 2020 to assist states in responding to the PHE for the COVID-19 pandemic and CHIP SPAs that allow for temporary adjustments to enrollment and redetermination policies during disaster events. More information about these Medicaid and CHIP flexibilities is available at https://www.medicaid.gov/resources-for-states/disaster-response-toolkit/state-plan-flexibilities/index.html.

exception to the normal public notice procedures to expedite the certification of a revised Blueprint that implements temporary changes to expand access to coverage. We have determined that it would not be practical to solicit public comment during the PHE for the COVID-19 pandemic, and we recognize that there is a need to ensure consumers have access to the care they need as expeditiously as possible. Nonetheless, we encourage states to seek public input, when appropriate, consistent with applicable state requirements.

If a state seeks to make a permanent, significant change to its BHP, such as permanently altering verification, enrollment, or disenrollment policies, the state must follow the usual process for submission of a revised Blueprint with a prospective effective date in accordance with § 600.125(a). In addition, when seeking to make permanent, significant changes to its BHP, the state must continue to operate under the terms of the existing certified Blueprint until HHS certifies the revision.

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

We have heard from third party intermediaries, specifically QCDRs, that due to the COVID-19 pandemic they anticipate being unable to complete QCDR measure testing or collect data on QCDR measures for the 2021 MIPS performance period as specified at § 414.1400(b)(3)(v)(C) and (D). Both QCDR measure approval criteria necessitate QCDRs collecting data from clinicians in order to assess the measure. Over 50 percent of the QCDRs approved for the 2020 performance period are supported by specialty societies that represent and support clinicians on the front lines of the COVID-19 pandemic, or are hospitals that are directly impacted by the pandemic. We also anticipate that there will be a lack of available data for some QCDR measures because clinicians who work in specialties that are not primarily caring for COVID-19 patients may have their cases or elective procedures canceled or delayed so that resources can be redistributed. As a result, we anticipate that QCDRs may be unable to collect,

and clinicians unable to submit, data on QCDR measures due to prioritizing the care of COVID-19 patients.

We believe that clinicians who are on the frontlines taking care of COVID-19 cases should not be burdened with having to submit data to a QCDR for purposes of QCDR measure assessment (testing and data collection). In consideration of clinicians' limited resources and in an effort to reduce burden on clinicians and health care organizations that are responding to the COVID-19 pandemic, we are amending the QCDR measure approval criteria previously finalized in the CY 2020 PFS final rule (84 FR 63065 through 63068), specifically: (1) completion of QCDR measure testing at § 414.1400(b)(3)(v)(C) as discussed in section II.R.1. of this IFC; and (2) collection of data on QCDR measures at § 414.1400(b)(3)(v)(D) as discussed in section II.R.2. of this IFC.

1. Completion of QCDR Measure Testing

In the CY 2020 PFS final rule (84 FR 63065 through 63067), we finalized at § 414.1400(b)(3)(v)(C) 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. For the reasons discussed in section II.R. of this IFC, we are delaying the implementation of this policy by 1 year. Specifically, we are amending § 414.1400(b)(3)(v)(C) to state that beginning with the 2022 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination.

During this 1 year delay, we will continue to review QDCR measures as in past years to ensure they are valid, reliable, and align with the goals of the Meaningful Measure initiative.[46]

[46] See https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.

This process includes review by quality measure experts; QCDR policy subject matter experts; clinicians, including physicians, nurses, and PTs/OTs, who work on our support contractor team; and CMS Medical Officers. We will continue to review QCDR measures for potential risk of patient harm (for example, QCDR measures that promote clinical practices related to overuse). We also will continue to review QCDR measures for feasibility and accuracy and reliability of results. For more information, we refer readers to the 2020 QCDR Measure Development Handbook.[47]

2. Collection of Data on QCDR Measures

In the CY 2020 PFS final rule (84 FR 63067 through 63068), we finalized at § 414.1400(b)(3)(v)(D) that beginning with the 2021 performance period, QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period. For the reasons discussed in section II.R. of this IFC, we are delaying the implementation of this policy by 1 year. Specifically, we are amending § 414.1400(b)(3)(v)(D) to state that beginning with the 2022 performance period, QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period.

During this 1-year delay, we will continue to review QDCR measures as in past years to ensure they are valid and identify performance gaps in the area of measurement. As described in the 2020 QCDR Measure Development Handbook[48], this process includes vetting the measures to ensure they are implementable and collectible, which includes an evaluation of the measure and coding constructs (for example, whether the measure is constructed as a ratio, proportional,

[47] Available at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/580/2020%20Self-Nomination%20Toolkit%20for%20QCDRs%20%26%20Qualified%20Registries.zip.
[48] Available at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/580/2020%20Self-Nomination%20Toolkit%20for%20QCDRs%20%26%20Qualified%20Registries.zip.

or inverse measure). Additionally, we will review the evidence provided by the QCDR (for example, clinical studies and/or scientific journals) that would support the need for measurement in lieu of insufficient data collection to demonstrate that there is a measurement gap.

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

National Coverage Determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under Title XVIII. Local Coverage Determinations (LCDs) are determinations by a Medicare Administrative Contractor (MAC) with respect to whether or not a particular item or service is covered under section 1862(a)(1)(A) of the Act in the particular MAC's geographical areas. Articles are often published alongside LCDs and contain coding or other guidelines that complement an LCD. NCDs and LCDs contain clinical conditions a patient must meet to qualify for coverage of the item or service.

In section II.U. of the March 31st COVID-19 IFC, we finalized on an interim basis that to the extent an NCD or LCD (including articles) would otherwise require a face-to-face or in-person encounter or other implied face-to-face services, those requirements would not apply during the PHE for the COVID-19 pandemic. Additionally, we finalized on an interim basis that we will not enforce the clinical indications for coverage across respiratory, home anticoagulation management and infusion pump NCDs and LCDs (including articles) allowing for flexibility for practitioners to care for their patients. This section provides clarification and expands upon section II.U. of the March 31st COVID-19 IFC.

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

Some external stakeholders appear to be misinterpreting statements that CMS made in the March 31st COVID-19 IFC as waiving medical necessity requirements; there are now questions as to whether items and services can be furnished or ordered without reason during the PHE for the COVID-19 pandemic. We note there is nothing in guidance or the March 31st COVID-19 IFC, that could be interpreted to permanently or temporarily waive the reasonable and necessary statutory requirement, which is expressed in section 1862(a)(1)(A) of the Act and

cannot be waived under the section 1135 PHE waiver authority. Except as expressly permitted by statute, we remind physicians, practitioners and suppliers that most items and services must be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member to be paid under Part A or Part B of Title XVIII. Physicians, practitioners, and suppliers are required to continue documenting the medical necessity for all services. Accordingly, the medical record must be sufficient to support payment for the services billed (that is, the services were actually provided, were provided at the level billed, and were medically necessary).

2. Enforcement Discretion of Clinical Indications for Additional LCDs

In the March 31st COVID-19 IFC, we finalized on an interim basis that we will not enforce the clinical indications for coverage across respiratory, home anticoagulation management and infusion pump NCDs and LCDs (including articles) allowing for more flexibility for practitioners to care for their patients. This enforcement discretion will only apply during the PHE for the COVID-19 pandemic.

In this IFC, we are finalizing on an interim basis that we will not enforce the clinical indications for therapeutic continuous glucose monitors in LCDs. For example, we will not enforce the current clinical indications restricting the type of diabetes that a beneficiary must have or relating to the demonstrated need for frequent blood glucose testing in order to permit COVID-19 infected patients with diabetes to receive a Medicare covered therapeutic continuous glucose monitor. This discretion is intended to permit COVID-19 patients to more closely monitor their glucose levels given that they are at risk for unpredictable impacts of the infection on their glucose levels and health. The use of therapeutic continuous glucose monitors may allow patients to proactively treat their diabetes and prevent the need for hospital-based diabetic care. Practitioners will also 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 continuous glucose monitor. This enforcement discretion will only apply during the PHE for the COVID-19 pandemic.

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

1. Delay of the Compliance Date of the Transfer of Health (TOH) Information Quality Measures and Certain Standardized Patient Assessment Data Elements (SPADEs) Adopted for the IRF QRP, LTCH QRP, and HH QRP.

In the FY 2020 IRF PPS final rule (84 FR 39100 through 39161), we adopted the TOH Information to Provider-Post-Acute Care and TOH Information to Patient-Post-Acute Care quality measures (collectively, the TOH Information Measures) beginning with the FY 2022 IRF QRP and finalized that IRFs would be required to collect data on both measures beginning with patients discharged on or after October 1, 2020. We also adopted standardized patient assessment data elements (SPADEs) for six categories that IRFs must report for patients beginning with the FY 2022 IRF QRP, with data collection beginning with admissions and discharges (except for the hearing, vision, race and ethnicity SPADEs, which would be collected for admissions only) on October 1, 2020 (84 FR 39114 through 84 FR 39149). In the FY 2020 Inpatient Prospective Payment System (IPPS)/Long-Term Care Hospital (LTCH) PPS final rule (84 FR 42526 through 84 FR 84534), we adopted the same two measures and SPADEs for reporting by LTCHs beginning with FY 2022 LTCH QRP with data collection beginning with patients discharged on October 1, 2020 and data collection on the SPADEs beginning with admissions and discharges (except for the hearing, vision, race, and ethnicity SPADEs, which would be collected for admissions only) on October 1, 2020.

In the CY 2020 HH PPS final rule (84 FR 60557 through 60610), we also adopted these measures for reporting by HHAs in the CY 2022 HH QRP beginning with patients discharged or transferred January 1, 2021 and data collection on the SPADEs beginning with the start of care,

resumption of care, and discharges (except for the hearing, vision, race, and ethnicity SPADEs, which would be collected at the start of care only) on January 1, 2021.

The current assessment instruments that IRFs, LTCHs, and HHAs use to submit data to meet the requirements of their respective QRPs do not include the data elements that these providers need to report the TOH Information Measures or the SPADEs that we previously finalized for data collection beginning either October 1, 2020 for IRFs and LTCHs or January 1, 2021 for HHAs. We have developed updated assessment instruments that include these new data elements, and under our current implementation timeline, we would be in the process of training providers on how to operationalize them. Each of these providers would also be in the process of training their staffs on how to use the updated versions, as well as working with their vendors to make programming changes necessary to implement them timely. However, we want to provide maximum flexibilities for these providers to respond to the public health threats posed by the COVID-19 PHE, and to reduce the burden in administrative efforts associated with attending training, training their staffs and working with their vendors to incorporate the updated assessment instruments into their operations. Accordingly, we are 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 that these providers would otherwise incur as a result of being required to incorporate the updated versions into their operations before October 1, 2020 (for IRFs and LTCHs) or January 1, 2021 (for HHAs). This delay will enable these providers to continue using the current versions of their assessment instruments, with which they are already familiar. The current version of the IRF-PAI has been in use since October 1, 2019 (IRF-PAI v. 3.0). The current version of the LTCH CARE Data Set has also been in use since October 1, 2019 (LTCH CARE Data Set v. 4.00). The current version of the OASIS Instrument has been in use since January 1, 2019 (OASIS-D).

This delay of the updated assessment instruments will impact the ability of IRFs, LTCHs and HHAs to collect and report data on the two TOH Information Measures and SPADEs under their respective QRPs. Accordingly, in this IFC, we are delaying the compliance dates for the collection and reporting of these TOH Information Measures and SPADEs. Specifically, we will require IRFs to use IRF-PAI V4.0 and LTCHs to use LTCH CARE Data Set V5.0 to begin collecting data on the two TOH Information Measures beginning with discharges on October 1st of the year that is at least 1 full fiscal year after the end of the COVID-19 PHE. For example, if the COVID-19 PHE ends on September 20, 2020, IRFs and LTCHs will be required to begin collecting data on these measures beginning with patients discharged on October 1, 2021. We will also require IRFs and LTCHs to begin collecting data on the SPADEs for admissions and discharges (except for the hearing, vision, race, and ethnicity SPADEs, which would be collected for admissions only) on October 1st of the year that is at least 1 full fiscal year after the end of the COVID-19 PHE. HHAs will be required to use OASIS-E to begin collecting data on the two TOH Information Measures beginning with discharges and transfers on January 1st of the year that is at least 1 full calendar year after the end of the COVID-19 PHE. For example, if the COVID-19 PHE ends on September 20, 2020, HHAs will be required to begin collecting data on those measures beginning with patients discharged or transferred on January 1, 2022. We will also require HHAs to begin collecting data on the SPADEs beginning with the start of care, resumption of care, and discharges (except for the hearing, vision, race, and ethnicity SPADEs, which would be collected at the start of care only) on January 1st of the year that is at least 1 full calendar year after the end of the COVID-19 PHE.

We believe that these delays will give IRFs, LTCHs, and HHAs enough time to operationalize the updated versions of their respective assessment instruments, including taking any necessary training and ensuring that their vendors can make appropriate programming updates. We plan to release the drafts of the new instruments again for these programs shortly

after the COVID-19 PHE ends to provide ample time for training and any vendor programming.

2. Delay in the Compliance Date of the Transfer of Health Information Measures and Certain SPADEs Adopted for the SNF QRP

In the FY 2020 SNF PPS final rule (84 FR 38755 through 84 FR 38764), we adopted the TOH quality measures beginning with the FY 2022 SNF QRP and finalized that SNFs would be required to collect data on both measures beginning with patients discharged on October 1, 2020. We also adopted SPADEs for six categories that SNFs must report for all patients beginning with the FY 2022 SNF QRP, with data collection for patients discharged October 1, 2020 for admissions and discharges (except for the hearing, vision, race, and ethnicity SPADEs, which would be collected for admissions only).

The current version of the Minimum Data Set (MDS), MDS 3.0 v1.17.1, that SNFs use to submit data in order to meet the requirements of the SNF QRP does not include the data elements that are needed to report the TOH Information Measures and the SPADEs that we previously finalized for data collection beginning October 1, 2020. We previously released a draft version of the updated MDS 3.0 v1.18.1 that includes these new data elements, and under our current implementation timeline, we would be in the process of training providers on how to operationalize them. Each of these providers would also be in the process of training their staffs on how to use the updated versions, as well as working with their vendors to make programming changes necessary to timely implement them. However, as we previously noted in a March 19, 2020 notice posted on our website[49] stakeholders have expressed concerns that the length of our planned implementation period is too short for SNFs to properly educate their staffs on how to operationalize the updated MDS given that the updated version did not adequately address the

[49] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Spotlights-and-Announcements.

needs of states that use the instrument for payment and to report data. For these reasons, we stated that we were delaying the release of the updated version of the MDS. This delay will enable SNFs to continue using the current version of the MDS, with which they are already familiar.

Our delay of the release of the updated version of the MDS 3.0 v1.18.1 will impact the ability of SNFs to collect and report data on the two TOH Information Measures and SPADEs. Accordingly, in this IFC, we are delaying the compliance dates for the collection and reporting of these measures and SPADEs. Although we did not originally delay the release of the updated version of the MDS because of the COVID-19 PHE, we believe that this PHE is appropriate to take into consideration when determining when it will be feasible to release the updated version, and when it will likewise be feasible to require SNFs to begin to report the new quality measure and SPADEs data.

Therefore, we will require SNFs to begin collecting data on the two TOH Information Measures beginning with discharges on October 1st of the year that is at least 2 full fiscal years after the end of the COVID-19 PHE. For example, if the COVID-19 PHE ends on September, 20, 2020, SNFs will be required to begin collecting data on these measures beginning with patients discharged on October 1, 2022. We will also require SNFs to begin collecting data on the SPADEs beginning with admissions and discharges (except for the hearing, vision, race, and ethnicity SPADEs, which would be collected for admissions only) on October 1st of the year that is at least 2 full fiscal years after the end of the COVID-19 PHE. Although this delay is longer than the delay we are adopting for IRFs, LTCHs and HHAs, we believe that the additional delay for SNFs is appropriate because it will give us enough time to work with stakeholders to ensure that their concerns are addressed while also allowing SNFs a reasonable amount of time to complete required training, train their staffs, and work with their vendors to make necessary programming updates. Shortly after the COVID-19 PHE ends, we plan to work with stakeholders

to develop a mutually agreeable timeline for releasing the updated MDS 3.0 v1.18.1that provides sufficient time for SNFs to incorporate the updated version into their operations.

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

In the FY 2014 IPPS/LTCH final rule (78 FR 50704 through 50707), we finalized a disaster/extraordinary circumstance exception (ECE) policy for the Hospital VBP Program. The intent of the Hospital VBP ECE policy is to mitigate any adverse impact on quality performance as a direct result of unforeseen extraordinary circumstances outside of the hospital's control and the resulting impact on their value-based incentive payment amounts.

Under the current policy and upon a hospital's request, we will consider providing an exception from the Hospital VBP Program requirements to hospitals affected by natural disasters or other extraordinary circumstances (78 FR 50704 through 50706). Specifically, in the FY 2014 IPPS/LTCH final rule, we stated that we interpreted the minimum number of cases and measures requirement in sections 1886(o)(1)(C)(ii)(III) and (IV) of the Act to not include any measures or cases for which a hospital has submitted data during a performance period for which the hospital has been granted a Hospital VBP Program ECE. We also stated that, if after the applicable quality measure data from a performance period has been excepted due to the granting of an ECE, the hospital still reports the minimum number of cases and measures required for the program year, the hospital will still receive a Total Performance Score (TPS) that has been calculated without use of the excepted quality data.

Based on our previously finalized policy, a hospital must submit the Hospital VBP Program ECE request form (OMB control #0938-1022), including any available evidence of the impact of the extraordinary circumstances on the hospital's quality measure performance, within 90 calendar days of the date on which the natural disaster or other extraordinary circumstance occurred (78 FR 50706).

We continue to recognize that unforeseen extraordinary circumstances, such as the current PHE for COVID-19, could substantially affect the ability of hospitals to perform under the Hospital VBP Program at the same level at which they might otherwise have performed if the natural disaster or extraordinary circumstance had not occurred. We also continue to acknowledge that using quality measure data from these periods to generate the Hospital VBP Program TPS might substantially impact the value-based incentive payment amount that the hospital would otherwise receive. Further, we believe that during an extraordinary circumstance that affects an entire geographic region or locale, which could include the entire United States (such as the COVID-19 PHE), the requirement for hospitals to submit individual ECE request forms along with supporting evidence to CMS within 90 days of the date the extraordinary circumstance occurred could be overly burdensome for hospitals by requiring additional administrative actions from hospital personnel, who may need to focus on care delivery and related priorities during and subsequent to the extraordinary circumstance.

Therefore, we believe it is necessary to update the Hospital VBP Program's ECE policy to include the ability for us to grant exceptions to hospitals located in entire regions or locales, which could include the entire United States, without a request where we determine that the extraordinary circumstance has affected the entire region or locale. Accordingly, in this IFC, we are modifying the Hospital VBP Program's ECE policy to allow us to grant ECE exceptions to hospitals which have not requested them when we determine that an extraordinary circumstance that is out of their control, such as an act of nature (for example, a hurricane) or PHE (for example, the COVID-19 pandemic), affects an entire region or locale, in addition to retaining the individual ECE request policy. We are codifying this updated ECE policy at § 412.165(c) of our regulations. When we make the determination to grant an exception to all hospitals in a region or locale, we will communicate this decision through routine communication channels to hospitals, vendors, and Quality Improvement Organizations (QIOs), including but not limited to issuing

memos, emails, and notices on the public QualityNet website (see https://www.qualitynet.org). This policy will more closely align the Hospital VBP Program ECE policy with the ECE policy adopted for other quality reporting and VBP programs, including the Hospital Inpatient Quality Reporting, Hospital Outpatient Quality Reporting, Inpatient Psychiatric Facility Quality Reporting, Ambulatory Surgical Center Quality Reporting, PPS-Exempt Cancer Hospital Quality Reporting, Hospital-Acquired Condition Reduction, and Hospital Readmissions Reduction Programs. If we grant an ECE to hospitals located in an entire region or locale under this revised policy and, as a result of granting that ECE, one or more hospitals located in that region or locale does not report the minimum number of cases and measures required to enable us to calculate a TPS for that hospital for the applicable program year, the hospital will be excluded from the Hospital VBP Program for the applicable program year. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42399 through 42400) for the minimum number of measures and cases that we currently require hospitals to report to receive a TPS for a program year under the Hospital VBP Program.

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

In accordance with this updated policy and consistent with the ECE guidance we issued on March 22, 2020 and March 27, 2020[50], we are granting 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)

[50] https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting, and https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf%20.

HAI measures and HCAHPS survey 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). However, hospitals can optionally submit part or all of these data by the posted submission deadlines on the HVBP QualityNet site (available at https://www.qualitynet.org/inpatient/iqr/participation). We refer readers to the March 27 guidance memo for more information on the HAI and HCAHPS measures in that are included in the Hospital-Acquired Condition Reduction Program.

- We will exclude qualifying claims data from the mortality, complications, and Medicare Spending per Beneficiary measures for the following quarters: January 1, 2020 – March 31, 2020 (Q1 2020) and April 1, 2020 – June 30, 2020 (Q2 2020).

We are granting these exceptions to assist hospitals while they direct their resources during the PHE related to COVID-19 toward caring for their patients and ensuring the health and safety of patients and staff. We believe it is appropriate to except hospitals from the requirement to report HAI measure data, HCAHPS survey data, and claims-based data for Q1 and Q2 2020 discharges because the data collected during that period may be greatly impacted by the hospital's response to COVID-19. While hospitals will continue to submit claims for reimbursement, we will not use discharge data from these quarters for measure calculations because we are concerned that these claims data may not be fully reflective of their quality or cost of care. For the Q4 2019 HAI and HCAHPS data, the exception is being granted because the April and May 2020 data submission deadlines for those data fall during the COVID-19 PHE, and we believe it is important to reduce the data collection and reporting burden so that hospitals can direct their resources toward responding to the COVID-19 PHE. We continue to closely monitor and analyze the impact that the COVID-19 PHE has on the HVBP program, and if necessary, will communicate any other exceptions and/or extensions that we believe are appropriate for the Hospital VBP Program through routine communication channels to hospitals,

vendors, and QIOs, including but not limited to issuing memos, emails, and notices on the public QualityNet website (see https://www.qualitynet.org).

V. COVID-19 Serology Testing

A blood-based serology test can be used to detect whether a patient may have previously been infected with the virus that causes COVID-19 by identifying whether the patient has antibodies specific to the SARS-CoV-2 virus. Patients who have these antibodies may have developed an immune response to SARS-CoV-2 indicating recent or prior infection, and therefore, potentially may not be at immediate risk for re-infection. It is expected that patients have been infected with COVID-19 who either had characteristic symptoms and were not tested or had minor or non-specific symptoms and did not seek testing. An FDA-authorized serology test that detects antibodies to SARS-CoV-2, the virus that causes COVID-19, may potentially aid in identifying patients who have had an immune response to current or prior SARS-CoV-2 infection.

Based on this information, we are finalizing on an interim basis that these FDA-authorized COVID-19 serology tests fall under the Medicare benefit category of diagnostic laboratory test (section 1861(s)(3) of the Act). Therefore, these tests are coverable by the Medicare program because they fall under at least one Medicare benefit category. This may not be an exhaustive list of benefit categories as CMS did not evaluate information about the test to identify additional benefit categories.

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.

If it can be determined that they are immune, these patients would possibly not be at risk for contracting COVID-19 and not be risking the health of their communities if they travel

outside of their home as they would not spread COVID-19. Among the biggest risks to the community are patients with COVID-19 infection who have not developed symptoms or had minor non-specific symptoms, yet are infectious[51].

Beneficiaries who are negative for COVID-19 antibodies through serology testing may need to take more preventive measures to reduce their personal risk of infection as some persons, based on age and other factors, are at higher risk of serious illness or death from the disease. Further, a practitioner should discuss the results of the serology test with the beneficiary to ensure that the beneficiary understands the results of the test and the results are considered in the overall management of the patient.

In circumstances outside of the COVID-19 PHE, we would ordinarily use the NCD process to establish a benefit category and establish that an item or service is reasonable and necessary under section 1862(a)(1)(A) of the Act. The NCD process is established in section 1862(l) of the Act and requires the Secretary to make a proposed decision available to the public for 30 days of public comment followed by issuing a final decision not later than 60 days after the close of the comment period. Given the need to establish timely and uniform national coverage that is relevant during the PHE for the COVID-19 pandemic, we have determined that coverage for FDA-authorized COVID-19 serology tests should be established in an interim final manner through this IFC. Since we are not aware of any professional society recommendations for confirmatory or repeat testing on the same sample, CMS would expect to be billed once per sample. Further, we would not expect such tests to be performed and billed unless clinically indicated.

We are finalizing on an interim basis, that during the PHE for the COVID-19 pandemic, Medicare will cover FDA-authorized COVID-19 serology tests as they are reasonable and

[51] Wei WE, Li Z, Chiew CJ, Yong SE, Toh MP, Lee VJ. Presymptomatic Transmission of SARS-CoV-2 — Singapore, January 23–March 16, 2020. MMWR Morb Mortal Wkly Rep 2020;69:411–415. DOI: http://dx.doi.org/10.15585/mmwr.mm6914e1.

necessary under section 1862(a)(1)(A) of the Act for beneficiaries with known current or known prior COVID-19 infection or suspected current or suspected past COVID-19 infection. We are amending § 410.32 to reflect this determination of coverage.

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

1. Background – Provider Enrollment

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers in the Medicare program. The overarching purpose of the enrollment process is to help ensure that providers and suppliers that seek to bill the Medicare program for services or items furnished to Medicare beneficiaries are qualified to do so under federal and state laws.

The applicable provider enrollment regulations are largely, though not exclusively, contained in part 424, subpart P (currently §§ 424.500 through 424.570). Several of our previous provider enrollment rulemaking efforts have focused on strengthening existing enrollment procedures and eliminating existing vulnerabilities; in other words, the objectives have been to enhance our ability to: (1) conduct strict screening activities; (2) take prompt action against problematic providers and suppliers; and (3) implement important safeguards against improper Medicare payments. Yet we believe that the current COVID-19 PHE requires us to undertake provider enrollment rulemaking for a different reason; specifically, the need to help providers and suppliers concentrate their resources on treating those beneficiaries affected by COVID-19. Therefore, as discussed in section III. of this IFC, "Waiver of Proposed Rulemaking," we believe the urgency of this COVID-19 PHE constitutes good cause to waive the normal notice-and-comment process under the Administrative Procedure Act and statute. Accordingly, this IFC contains an important revision to part 424, subpart P that will give providers and suppliers certain flexibilities in their activities during the existing COVID-19 PHE.

2. Certification of Home Health Services – Revision to § 424.507

Currently, § 424.507(b)(1) contains certain payment requirements for covered Part A or Part B home health services. Specifically, and consistent with section 6405(b) of the Patient Protection and Affordable Care Act (which amended sections 1814(a)(2) and 1835(a)(2) of the Act), to receive payment for such services, the provider's claim must meet all of the following requirements:

- The ordering/certifying physician must be identified by his or her legal name and National Provider Identifier (NPI) on the claim.
- The ordering/certifying physician must be enrolled in Medicare in an approved status or have validly opted-out of the Medicare program.

However, and as previously mentioned in this IFC, section 3708 of the CARES Act made several important amendments to sections 1814(a)(2) and 1835(a)(2) of the Act (as well as other related sections of the statute). One amendment was that NPs, CNSs, and PAs (as those terms are defined in section 1861(aa)(5) of the Act) working in accordance with state law may also certify the need for home health services. Section 3708(f) of the CARES Act authorizes us to promulgate an interim final rule, if necessary, to implement the provisions in section 3708 by the statutory deadline. Further, given the need for flexibility in the provision of health care services in the COVID-19 PHE, we believe it is appropriate to implement these statutory changes in this IFC, rather than through notice-and-comment rulemaking. Consequently, we are revising § 424.507(b)(1) to include ordering/certifying physicians, PAs, NPs, and CNSs as individuals who can certify the need for home health services. We note that, for reasons similar to those related to our other modifications to Medicare rules concerning the certification and provision of home health services, this change to § 424.507 is final and applicable to services provided on or after March 1, 2020. We will review and respond to any comments thereon in the CY 2021 HH PPS final rule or in another future rule.

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

In light of these extraordinary circumstances and the immediate need for qualified health plan (QHP) issuers to devote resources to respond to the COVID-19 PHE, we are revising 45 CFR 156.280(e)(2)(ii) to delay implementation of the separate billing policy for 60 days from the effective date we finalized in the "Patient Protection and Affordable Care Act; Exchange Program Integrity" final rule (84 FR 71674) ("2019 Program Integrity Rule").[52] Under this 60-day extension, QHP issuers must comply with the separate billing policy finalized at § 156.280(e)(2)(ii) beginning on or before the QHP issuer's first billing cycle following August 26, 2020.

To better align QHP issuer billing for coverage of non-Hyde abortion services with the separate payment requirement in section 1303 of the Patient Protection and Affordable Care Act,[53] we finalized a policy in the 2019 Program Integrity Rule requiring issuers of individual market QHPs offering coverage of non-Hyde abortion services to separately bill policy holders for the portion of their premium attributable to coverage of non-Hyde abortion services. We explained in the 2019 Program Integrity Rule that separately billing policy holders in this manner for coverage of non-Hyde abortion services is a necessary change to better align issuer billing with the statutory requirements specified in section 1303 of the Patient Protection and Affordable Care Act, which requires non-Hyde abortion services be treated differently from other covered services. Specifically, requiring separate billing for coverage of non-Hyde abortion services better aligns with Congress's intent for QHP issuers to collect two distinct premium payments

[52] A typographical error in the date in the regulation text promulgated in the 2019 Program Integrity Rule was corrected on January 17, 2020. 85 FR 2888.

[53] The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. In this IFC, we refer to the two statutes collectively as the "Patient Protection and Affordable Care Act".

for coverage of these services, one for the coverage of non-Hyde abortion services, and one for coverage of all other services covered under a QHP.

Under the separate billing policy finalized in the 2019 Program Integrity Rule at § 156.280(e)(2)(ii), issuers of individual market QHPs are required to begin separately billing policy holders for the portion of the policy holder's premium attributable to non-Hyde abortion services, as specified by the regulation, on or before the QHP issuer's first billing cycle following June 27, 2020.

To address the risk of coverage terminations related to failure on the part of policy holders to pay the separately billed amount for coverage of non-Hyde abortion services, we determined that HHS would exercise enforcement discretion in two scenarios related to policy holder nonpayment of the separate bill for coverage of non-Hyde abortion services. Under the first scenario, we explained that 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 policy holder's failure to pay the separate payment for coverage of non-Hyde abortion services. We further explained that the QHP issuer would: (1) be prohibited from using any federal funds for coverage of non-Hyde abortion services; (2) be required to collect the premium for the non-Hyde abortion coverage; and (3) not be able to relieve the policy holder of the duty to pay the amount of premium attributable to coverage for non-Hyde abortion services. We explained that this enforcement posture would take effect upon the effective date of the separate billing requirements on June 27, 2020.

Under the second scenario, we explained that HHS will not take enforcement action against QHP issuers that, on or after the effective date of the final 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.

We also stated in the 2019 Program Integrity rule that, for those State Exchanges and QHP issuers that may face uncommon or unexpected impediments to timely compliance, HHS would consider extending enforcement discretion to an Exchange or QHP issuer that fails to timely comply with the separate billing policy as required under the final rule, if we find that the Exchange or QHP issuer attempted in good faith to timely meet the requirements. However, we noted that HHS would be unlikely to exercise such discretion for an Exchange or QHP issuer that fails to meet the separate billing requirements after more than 1 year following publication of the 2019 Program Integrity Rule.

We have received a number of requests from QHP issuers requesting that HHS exercise its enforcement discretion for delayed implementation in light of the heightened burden QHP issuers are experiencing related to addressing the COVID-19 PHE. QHP issuers explained in their requests to HHS that the dedication of numerous cross-functional resources in response to the COVID-19 PHE has led to an overall reduction in resources available for other initiatives, such as preparatory arrangements to timely implement the separate billing policy. QHP issuers further explained how the already existing challenges to timely compliance with the separate billing policy pose an even greater obstacle when considered in conjunction with the mounting demands on QHP issuers in responding to the COVID-19 PHE. We are also aware that for many QHP issuers, some, if not all, of their daily work is being accomplished while staff is working remotely, adding yet another barrier to timely compliance.

We believe that despite timely QHP initiation of planning for compliance with the separate billing policy, there are circumstances outside of the control of QHP issuers, due to the COVID-19 PHE, that make timely compliance with the separate billing policy impractical by the deadline, on or before the first billing cycle following June 27, 2020. Moreover, we believe it is

imprudent to require QHP issuers to devote resources to timely compliance with the separate billing policy when these resources can instead be directed towards addressing the immediate needs associated with the COVID-19 PHE. Therefore, in light of these extraordinary circumstances and the immediate need for QHP issuers to divert resources to responding to the COVID-19 PHE, we are revising § 156.280(e)(2)(ii) to delay implementation of the separate billing policy for 60 days. Under this 60-day delay, QHP issuers must comply with the separate billing policy finalized at § 156.280(e)(2)(ii) beginning on or before the QHP issuer's first billing cycle following August 26, 2020.

We acknowledge that a particular QHP issuer's or Exchange's ability to comply with the separate billing policy by the extended deadline of August 26, 2020, may depend on the particular impact the COVID-19 PHE has on the resources, systems, and operations of that QHP issuer or Exchange. We also acknowledge that the timeline for how long the COVID-19 PHE continues to impact QHP issuers and Exchanges is uncertain, and therefore, QHP issuers and Exchanges may be confronted with additional unexpected impediments to timely compliance past the 60-day delay we are finalizing in this IFC. HHS will still consider exercising its enforcement discretion in connection with an Exchange or QHP issuer that fails to timely comply with the separate billing policy on or before the first billing cycle following August 26, 2020, if HHS finds that the Exchange or QHP issuer attempted in good faith to timely meet the requirements. We do not anticipate that HHS would exercise such discretion for an Exchange or QHP issuer that fails to meet the separate billing requirements after more than 1 year following publication of the 2019 Program Integrity Rule or more than 6 months after the end of the COVID-19 PHE, whichever comes later. However, we emphasize that QHP issuers and Exchanges should make good faith efforts to fully comply by the extended deadline of the first billing cycle following August 26, 2020. We believe the 60-day delay will sufficiently alleviate burden on resources in the short-term, as well as provide sufficient time for QHP issuers and

Exchanges, such that responding to the COVID-19 PHE and timely compliance with the separate billing policy are both practical. As a consequence, we do not anticipate formally extending the compliance deadline again.

As QHP issuers and Exchanges work to respond to the COVID-19 PHE, and implement and establish policies to ensure access to COVID-19-related care for enrollees, HHS is working to assess and extend regulatory flexibility to QHP issuers, Exchanges, and other health industry stakeholders, where doing so may enable these stakeholders to divert existing resources to the COVID-19 PHE response. We believe extending the deadline 60 days for QHP issuers and Exchanges to comply with the separate billing policy is appropriate, so that they may adequately respond to the COVID-19 PHE and divert resources to address the COVID-19 PHE that may otherwise have been used for timely compliance with the separate billing policy.

Although the 2019 Program Integrity Rule provides an existing framework for HHS to exercise its enforcement discretion in connection with QHP issuers and Exchanges unable to timely comply with the separate billing policy based on the circumstances of the particular Exchange or QHP issuer, based on reports from a number of QHP issuers and Exchanges, we have concluded that handling requests for additional time to come into compliance on a case-by-case basis is not an efficient mechanism to address these requests and does not adequately acknowledge the shared burden that the COVID-19 PHE is placing on QHP issuers and Exchanges. We believe that the COVID-19 PHE is an unexpected impediment to timely compliance with the separate billing policy for all QHP issuers and Exchanges alike. As a consequence, we have determined that it is appropriate to extend the deadline for compliance 60 days through this IFC, and to codify this change in the **Federal Register**.[54]

[54] In light of the ongoing litigation challenging the separate billing policy and the delayed briefing schedule for this litigation, delaying implementation of the separate billing policy by 60 days would also be justified, as the 60-day delay provides the court additional time to resolve the issues before compliance with the separate billing provision is required and offers regulated parties more certainty before dedicating limited resources to the necessary changes

As previously noted, we finalized in the 2019 Program Integrity Rule that HHS would exercise enforcement discretion in two scenarios related to policy holder nonpayment of the separate bill. We note that the extension for compliance we are finalizing here only impacts the first of those scenarios, by delaying when this enforcement posture becomes available by 60 days. As previously stated, 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 policy holder's failure to pay the separate payment for coverage of non-Hyde abortion services. This enforcement posture will now take effect on the earliest date on which QHP issuers will need to begin complying with the separate billing requirements, August 26, 2020. We are not making any additional revisions to the separate billing provisions finalized in the 2019 Program Integrity Rule other than extending the date for compliance with the separate billing policy by 60 days.

When explaining our rationale for the implementation deadline of the first billing cycle following June 27, 2020 in the 2019 Program Integrity Rule, we expressed the importance of QHP issuers implementing the separate billing policy changes at the earliest date feasible to better align QHP issuer billing of non-Hyde abortion services with the separate payment requirement in section 1303 of the Patient Protection and Affordable Care Act. Although expeditious implementation of this policy continues to be important, we believe the impact of the COVID-19 PHE on QHP issuer and Exchange operations has shifted the date by which it is operationally and administratively feasible to require QHP issuers to timely comply with the separate billing policy. We acknowledge that extending the date for compliance by 60 days also delays the added transparency the separate billing policy would provide for policy holders

during this PHE. This extension is also consistent with the representations made by the federal government to the federal court in lawsuits challenging the separate billing policy in response to requests that HHS delay implementation of the separate billing policy in light of COVID-19.

related to whether QHPs cover non-Hyde abortion services. However, we believe the delay in increasing transparency and better aligning QHP issuer billing with the separate payment requirement in section 1303 of the Patient Protection and Affordable Care Act is outweighed by the immediate need for QHP issuers and Exchanges to divert resources to respond to the current COVID-19 PHE.

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

Under sections 1866 and 1902 of the Act, providers of services seeking to participate in the Medicare or Medicaid program, or both, must enter into an agreement with the Secretary or the state Medicaid agency, as appropriate. Long-term care (LTC) facilities seeking to be Medicare and Medicaid providers of services must be certified as meeting federal participation requirements. LTC facilities include SNFs for Medicare and NFs for Medicaid. The federal participation requirements for SNFs, NFs, and dually certified facilities, are set forth in sections 1819 and 1919 of the Act and codified in the implementing regulations at 42 CFR part 483, subpart B.

Sections 1819(d)(3) and 1919(d)(3) of the Act explicitly require that LTC facilities 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. In addition, sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act explicitly authorize the Secretary to issue any regulations he deems necessary to protect the health and safety of residents. Infection prevention and control is a primary goal of initiatives taking place in LTC facilities during the COVID-19 PHE. Under the explicit instructions of Congress, existing regulations at § 483.80 require facilities to, among other things, establish and maintain an infection prevention and control program (IPCP) designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of

communicable diseases and infections. Furthermore, current § 483.80(a)(2) requires facilities to have written standards, policies, and procedures for the program, which among other things, must include a system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility and when and to whom possible incidents of communicable disease or infections should be reported. In an effort to support surveillance of COVID-19 cases, we are revising the requirements to establish explicit reporting requirements for confirmed or suspected cases. Specifically, we are revising our requirements by adding a new provision at § 483.80(g)(1), to require facilities to electronically report information about COVID-19 in a standardized format specified by the Secretary. The report includes, but is not limited to, information on: suspected and confirmed COVID-19 infections among residents and staff, including residents previously treated for COVID-19; total deaths and COVID-19 deaths among residents and staff; personal protective equipment and hand hygiene supplies in the facility; ventilator capacity and supplies available in the facility; resident beds and census; access to COVID-19 testing while the resident is in the facility; staffing shortages; and other information specified by the Secretary. This information will be used to monitor trends in infection rates, and inform public health policies.

In addition, at § 483.80(g)(2), facilities are required to provide the information specified above at a frequency specified by the Secretary, but no less than weekly to the Center for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) (OMB Control Number 0920-1290). Furthermore, we note that the information reported will be shared with CMS and we will retain and publicly report this information to support protecting the health and safety of residents, personnel, and the general public, in accordance with sections 1819(d)(3)(B) and 1919(d)(3) of the Act. The Freedom of Information Act (FOIA) (found in Title 5 of the United States Code, section 552) provides that, upon request from any person, a Federal agency must release any agency record unless that record falls within one of the nine statutory

exemptions and three exclusions (see https://www.foia.gov/faq.html for detailed information). Further, FOIA requires that agencies make available for public inspection copies of records, that because of the nature of their subject matter, the agency determines the records have become or are likely to become the subject of subsequent requests for substantially the same information. We have received, and expect to continue to receive, COVID-19 related FOIA requests. These requirements will support our efforts to proactively inform interested parties and ensure that the most complete information on COVID-19 cases is available. The new reporting requirements at § 483.80(g)(1) and (2) do not relieve LTC facilities of the obligation to continue to comply with § 483.80(a)(2)(ii), which requires facilities to report possible incidents of communicable disease and infections. This includes complying with state and local reporting requirements for COVID-19.

At § 483.80(g)(3), we are adding a new provision to require facilities to inform residents, their representatives, and families of those residing in facilities of confirmed or suspected COVID-19 cases in the facility among residents and staff. This reporting requirement supports 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 residents, their representatives, and families by 5 p.m. the next calendar day following the occurrence of either: a single confirmed infection of COVID-19; or three or more residents or staff with new-onset of respiratory symptoms that occur within 72 hours of each other. Also, cumulative updates to residents, their representatives, and families must be provided at least weekly by 5 p.m. the next calendar day following the subsequent occurrence of either: each time a confirmed infection of COVID-19 is identified; or whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other. This information must be reported in accordance with existing privacy regulations and statute, and must not include Personally

Identifiable Information (PII). Facilities must include information on mitigating actions implemented to prevent or reduce the risk of transmission, including if normal operations in the nursing home will be altered such as restrictions or limitations to visitation or group activities. For purposes of this reporting requirement, facilities are not expected to make individual telephone calls. Instead, facilities can utilize communication mechanisms that make this information easily available to all residents, their representatives, and families, such as paper notification, listservs, website postings, and/or recorded telephone messages.

These reporting requirements along with public reporting of the data support our responsibility to protect and ensure the health and safety of residents by enforcing the standards required to help each resident attain or maintain their highest level of well-being. As noted, sections 1819(d)(3)(B) and 1919(d)(3) of the Act requires that a facility must establish 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. We believe that these reporting requirements are necessary for CMS to monitor whether individual nursing homes are appropriately tracking, responding, and mitigating the spread and impact of COVID-19 on our most vulnerable citizens, personnel who care for them, and the general public. The information provided may be used to inform residents, families, and communities of the status of COVID-19 infections in their area. We believe that this action strengthens CMS' response to the PHE for the COVID-19 pandemic, and reaffirms our commitment to transparency and protecting the health and safety of nursing home residents.

As discussed in section III. of this IFC, "Waiver of Proposed Rulemaking", we believe the urgency of this COVID-19 PHE constitutes good cause to waive the normal notice-and-comment process under the Administrative Procedure Act and section 1871(b)(2)(C) of the Act. Waiving notice and comment is in the public interest, because time is of the essence in informing residents, their families, and the general public of the incidence of COVID-19; such information

will assist public health officials in detecting outbreaks and saving lives.

The applicability date for § 483.80(g)(1) through (3)(iii) is the date of the publication of this rule (that is, the effective date as noted in the "DATES" section of this notice).

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

In the March 31st COVID-19 IFC (85 FR 19268 through 19269), for the duration of the PHE for the COVID-19 pandemic, we revised our policy to specify that the office/outpatient E/M level selection for office/outpatient E/M services when furnished via telehealth can be based on MDM or time, with time defined as all of the time associated with the E/M on the day of the encounter. We stated that currently there are typical times associated with the office/outpatient E/M visits, and that those times are what should be met for purposes of level selection. We stated that typical times associated with the office/outpatient E/M visits were available as a public use file at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1715-F.

Members of the physician community have brought to our attention that the policy announced in the March 31st COVID-19 IFC relies on typical times listed in our public use file even when those times do not align with the typical times included in the office/outpatient E/M code descriptors. We agree that discrepancies between times can be confusing. We believe that, because the times are being used for the purpose of choosing which level of office/outpatient E/M CPT code to bill, the times listed in the codes themselves would be most appropriate for the purpose. Therefore, we are finalizing on an interim basis, for the duration of the PHE for the COVID-19 pandemic, that the typical times for purposes of level selection for an office/outpatient E/M are the times listed in the CPT code descriptor.

AA. Updating the Medicare Telehealth List

In the CY 2002 PFS final rule with comment period (64 FR 80041) we amended

regulations at § 410.78(f) to state that PFS annual rulemaking would serve as the process for adding and deleting services from the telehealth list as is required under section 1834(m)(4)(F)(ii) of the Act.

In the March 31st COVID-19 IFC (85 FR 19232-19253), we added a number of services to the Medicare telehealth list on an interim final basis for the duration of the PHE for the COVID-19 pandemic. While we believe that we have already added the vast majority of services that it would appropriate to add to the Medicare telehealth list for purposes of the PHE for the COVID-19 pandemic, it is possible that we might identify other services that would be appropriate additions to the telehealth list, taking into consideration infection control, patient safety, and other public health concerns resulting from the COVID-19 PHE. Due to the urgency of minimizing unnecessary contact between beneficiaries and practitioners, we believe that, for purposes of the PHE for the COVID-19 pandemic, we should modify the process we established for adding or deleting services from the Medicare telehealth services list under our regulation at § 410.78(f) to allow for an expedited process during the PHE that does not involve notice and comment rulemaking. Therefore, for the duration of the PHE for the COVID-19 pandemic, we are revising our regulation at § 410.78(f) to specify that, during a PHE, as defined in § 400.200 of this chapter, we will use a subregulatory process to modify the services included on the Medicare telehealth list.

While we are not codifying a specific process to be in effect during the PHE for the COVID-19 pandemic, we note that we could add services to the Medicare telehealth list on a subregulatory basis by posting new services to the web listing of telehealth services when the agency receives a request to add (or identifies through internal review) a service that can be furnished in full, as described by the relevant code, by a distant site practitioner to a beneficiary in a manner that is similar to the in-person service. We also note that any additional services added using the revised process would remain on the list only during the PHE for the COVID-19

pandemic.

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

In the March 31st COVID-19 IFC (85 FR 19256 through 19258), we changed Medicare payment policies for independent laboratories for specimen collection related to COVID-19 testing under certain circumstances. Specifically, under sections 1833(h)(3) and 1834A(b)(5) of the Act, we established a policy for the duration of the PHE for the COVID-19 pandemic to pay a nominal specimen collection fee and associated travel allowance to independent laboratories for collection of specimens for COVID–19 clinical diagnostic laboratory testing from beneficiaries who are homebound or inpatients not in a hospital. In that IFC, we stated that Medicare-enrolled independent laboratories can bill Medicare for the specimen collection fee using one of the two new HCPCS codes effective March 1, 2020, HCPCS code G2023(*specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2*) (*Coronavirus disease [COVID-19]), any specimen source*) and HCPCS code G2024 (*specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2*) (*Coronavirus disease [COVID-19]), from an individual in a SNF or by a laboratory on behalf of a HHA, any specimen source*).

To establish a payment amount for HCPCS code G2023 for the Clinical Laboratory Fee Schedule (CLFS) policy, we looked to similar services in other settings of care as a potential benchmark. In looking at other Medicare payment systems, we concluded that the PFS was the best source for assigning a payment amount since physicians and other practitioners often bill for services that involve specimen collection by trained, non-institutional staff. Additionally, we stated that under the PFS, a Level 1 established patient office visit (CPT code 99211) typically does not require the presence of a physician or other qualified health care professional and the usual presenting problem(s) are minimal and is typically reported by physician practices when the patient only sees clinical office staff for services like acquiring a routine specimen sample.

We also explained that we considered establishing a higher payment amount that considered the Level 1 E/M visit plus the payment amount for CPT code 89220, Sputum obtaining specimen aerosol induced technique. However, as noted in the March 31st COVID-19 IFC (85 FR 19257), we believe there are likely overlapping costs in staff time for these two services and the Level 1 office visit payment rate is adequate for HCPCS code G2023. The difference in payment for HCPCS code G2024 in comparison to HCPCS code G2023 represents the statutory payment increase under section 1834A(b)(5) of the Act for specimen collection when a sample is collected from an individual in a SNF or by a laboratory on behalf of an HHA. Under current CLFS policies, when an independent laboratory sends skilled laboratory staff to collect specimens from homebound individuals or non-hospital inpatients, the laboratory can bill Medicare for mileage in addition to specimen collection. The travel codes allow for payment either on a per mileage basis (P9603) or on a flat rate per trip basis (P9604). Payment of the travel allowance is made only if a specimen collection fee is also payable. The travel allowance is intended to cover the estimated travel costs of collecting a specimen including the laboratory technician's salary and travel expenses.

Unchecked spread of the coronavirus COVID-19 threatens to overwhelm healthcare resources in many areas of the country. The coronavirus is very contagious, spreading easily between people through communities largely through droplet transmission. The CDC considers it more contagious than influenza.[55] Widespread diagnostic testing for COVID-19 is a critical component of a public pandemic response to support infection control and proper treatment. Testing ensures individuals with positive diagnoses can be aware of their own condition and treatment they may need, and can isolate themselves to contain spreading. Testing on the scale that will be required to contain COVID-19 entails a tremendous commitment of labor,

[55] https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.

equipment, and capital resources. Assessment and specimen collection to support widespread COVID-19 testing will require extraordinary and resource-intensive measures for infection control, such as providing masks and protective equipment to staff and, setting up significant physical space to avoid additional spread when specimens are collected, among many other unique requirements. Recognizing the critical importance of expanding COVID-19 testing, in this IFC, we are providing additional payment for assessment and COVID-19 specimen collection to support testing by HOPDs, and physicians and other practitioners, to recognize the significant resources involved in safely collecting specimens from many beneficiaries during a pandemic. The majority of ambulatory care in any community is furnished by physicians and other practitioners in offices and HOPDs, and these are natural locations for COVID-19 testing in addition to laboratories.

When physicians and other practitioners collect specimens as part of their professional services Medicare generally makes payment for the services under the PFS, though often that payment is bundled into the payment rate for other services, including office and outpatient visits. Typically, collection of a specimen via nasal swab or other method during the provision of a service might be reported as part of (bundled with) an office/outpatient E/M visit (CPT codes 99201-99205, 99211-99215). In visits where a patient has face-to-face interaction with a billing professional with whom they have an established relationship, these services are generally reported with a level 2 through a level 5 visit (CPT codes 99212 – 99215). In cases where the specimen is collected during a visit where the face-to-face interaction only involves clinical staff of the billing professional with whom the patient has an established relationship, these services are generally reported using CPT code 99211. As noted previously, we referred to the PFS payment rate for CPT code 99211 in establishing a payment amount under section 1833(h)(3) of the Act for specimen collection for the COVID-19 tests described by G2023 (specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus

disease [COVID-19]), any specimen source)).

During this PHE, we understand that some professional practices are collecting specimens for COVID-19 tests. In many cases, we expect that these services are appropriately paid as part of the visit codes described above. Given the critical need for widespread testing as part of the pandemic response, we also expect that COVID-19 specimen collection may occur in circumstances other than the typical interaction between the patients and the professionals or staff of these practices. In our review of available HCPCS codes, we did not identify a code that would specifically describe the services that would be furnished in the context of large-scale dedicated testing operations involving a physician or NPP, specifically, assessment of COVID-19 symptoms and exposure, and specimen collection for new patients. In circumstances outside of the PHE, such a code would not be needed. We would ordinarily expect physicians and NPPs to establish a relationship with a patient before their clinical staff could effectively assist in managing care incident to their services. However, in the context of the widespread testing that is necessary during this COVID-19 PHE, we believe it is important to recognize such a service for new patients in addition to established patients. In considering possible codes for this purpose, we believe that CPT code 99211 for a level 1 E/M visit, appropriately describes the required clinical staff and patient interaction. However, billing for CPT code 99211is currently limited to patients with whom the billing practitioner has an established relationship. As discussed above, CPT code 99211 typically does not involve interaction with physician or other qualified health care professional and the usual presenting problem(s) are minimal. Thus, this CPT code typically is reported by a physician or practitioner when the patient only sees clinical office staff for services like acquiring a routine specimen sample. Additionally, as previously noted, we based our valuation of HCPCS code G2023 for specimen collection by independent laboratories on CPT code 99211. Therefore, for the duration of the PHE, we will recognize physician and NPP use of CPT code 99211 for all patients, not just patients with whom they have an

established relationship, to bill for a COVID-19 symptom and exposure assessment and specimen collection provided by clinical staff incident to their services.

For the duration of the COVID-19 PHE, we are therefore finalizing on an interim basis that when the services described by CPT code 99211 for a level 1 E/M visit are furnished for the purpose of a COVID-19 assessment and specimen collection, the code can be billed for both new and established patients. We believe this policy will support expanded access to COVID-19 testing, and provide appropriate payment for COVID-19 testing-related services furnished by physician and other practitioners. This policy will allow physicians and practitioners to bill for services provided by clinical staff to assess symptoms and take specimens for COVID-19 laboratory testing for all patients, not just established patients. We note that a physician or practitioner cannot bill for services provided by auxiliary clinical staff unless those staff meet all the requirements to furnish services "incident to" services, as described in 42 CFR 410.26 and further described in section 60 of Chapter 15 Covered Medical and other Health Services in the Medicare Benefit Policy Manual 100-02. We further note that we adopted an interim final policy to permit the direct supervision requirement to be met through virtual presence of the supervising physician or practitioner using interactive audio and video technology for the duration of the PHE (85 FR 19245).

During this COVID-19 PHE, we understand HOPDs also are engaging in significant additional specimen collection and testing for COVID-19 both at temporary expansion locations, as well as original locations of the hospital. As with the physician office clinical staff, hospital clinical staff are reviewing symptoms for patients relative to CDC guidelines and obtaining specimen samples for laboratory testing. As noted above, in our review of available HCPCS and CPT codes, we did not identify a code that explicitly describes the exact services that widespread testing efforts would require, assessment of symptoms and specimen collection. Such a uniquely auxiliary service would not normally be needed. Typically, clinical staff services such as

specimen collection are included in a clinic or emergency room visit or in other primary services furnished in the HOPD, such as observation services or critical are services. However, during this COVID-19 PHE, facilitating widespread testing requires recognizing such a service for the standalone work hospitals are undertaking to assess symptoms and collect specimens form a significant number of patients. In light of the tremendous need for testing created by this PHE and the resource needs to provide extensive symptom assessment for specimen collection, we are creating a new E/M code solely to support COVID-19 testing for the PHE, HCPCS code C9803 (*Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2*) (*coronavirus disease [covid-19]), any specimen source*). We believe this code is necessary to address the resource requirements hospitals face in establishing broad community diagnostic testing for COVID-19, including the significant specimen collection necessary to conduct that testing.

We will assign HCPCS code C9803 to APC 5731 Level 1 Minor Procedures. In assigning a service to an APC grouping, section 1833(t)(2)(B) of the Act requires that the groupings within the OPPS be comparable clinically and with respect to the use of resources. APC 5731 Level 1 Minor Procedures already contains many similar services to new HCPCS code C9803, including HCPCS code Q0091 (*Obtaining screening pap smear*) and G0117 (*Glaucoma Screening for high risk patients furnished by an optometrist or an ophthalmologist*). Earlier in this section, we established that clinical staff symptoms review and specimen collection is similar to the services described by, a Level 1 established patient office visit (CPT code 99211), which typically does not require the presence of a physician or other qualified health care professional, for which the usual presenting problem(s) are minimal and which is typically reported by physician practices when the patient only sees clinical office staff. We further established the payment for HCPCS code G2023 for specimen collection based on the resources required for CPT code 99211. Currently the PFS pays a national unadjusted rate of $23.46 for CPT code 99211. APC 5731

Level 1 Minor Procedures pays a national unadjusted rate of $22.98. Because these payment amounts for APC 5731 Level 1 Minor Procedures approximates our best estimate of the resource cost for this service, and because HCPCS code C9803 for a clinic visit dedicated to specimen collection is similar to other services in APC 5731, we will assign HCPCS code C9803 to APC 5731 for the duration of the PHE. We established HCPCS code C9803 only to meet the need of the PHE, and we expect to retire this code once the PHE concludes.

Under the OPPS, we pay for HOPD services through separate payment or through packaged payment when the service is integral, ancillary, supportive, dependent, or adjunctive to the primary service or services provided in the hospital outpatient setting during the same outpatient encounter and billed on the same claim to the OPPS. The clinical staff services described by HCPCS code C9803 are services that are integral and ancillary to other primary services, such as emergency room or clinic visits, or even observation or critical care services. We would not expect to make separate payment for a clinic visit dedicated to specimen collection (HCPCS code C9803) when the hospital furnished other more significant services in the same encounter. We are assigning a status indicator of "Q1" to HCPCS code C9803 indicating that this services will be conditionally packaged under the OPPS when billed with a separately payable primary service in the same encounter. The OPPS will only make separate payment to a hospital when HCPCS code C9803 is billed without another primary covered hospital outpatient service. The OPPS also will make separate payment for CPT code C9803 when it is billed with a clinical diagnostic laboratory test with a status indicator of "A" on Addendum B of the OPPS.

Finally, section 6002(a) of the Families First Coronavirus Response Act (Pub. L. 116-127) amended section 1833 of the Act by adding a new paragraph (DD) to section (a)(1) and a new paragraph (11) to section (b) to provide, respectively, that the payment amount for a specified COVID-19 testing-related service for which payment may be made under certain

outpatient payment provisions will be 100 percent of the payment amount otherwise recognized and that the deductible for such a service will not apply. These amendments mean that there is no beneficiary cost-sharing (coinsurance and deductible amounts) for COVID-19 testing-related services, which is defined in new section 1833(cc) of the Act as, among other requirements, are medical visits in any of several categories of HCPCS E/M service codes, including office and other outpatient services, that results in an order for or administration of a COVID-19 clinical diagnostic laboratory test described in section 1852(a)(1)(B)(iv)(IV) of the Act and relates to the furnishing or administration of such test or to the evaluation of such individual for purposes of determining the need of such individual for such test. Because physicians and other practitioners will be using the level 1 E/M code for established patients, CPT code 99211, to conduct testing related visits, there will not be beneficiary cost sharing when the practitioner's office bills for this service, provided it results in an order for or administration of a COVID-19 test. Similarly, because HOPDs will use HCPCS code C9803 to bill for a clinic visit for specimen collection, which we consider an E/M code in the office and other outpatient services category of HCPCS codes, beneficiary cost sharing will not apply for this service, provided it results in an order for or administration of a COVID-19 test and meets other requirements of the law. We anticipate that a COVID-19 test will always be ordered or administered with HCPCS code C9803 because the descriptor for this code includes specimen collection for COVID-19.

In summary, in the March 31st COVID-19 IFC, which created regulatory flexibilities to address the COVID-19 PHE, we finalized two codes to recognize the unique resource costs of specimen collection in a way that retains the integrity of infection control during a pandemic: CPT codes G2023 and G2024 for specimen collection for COVID-19 laboratory tests (85 FR 19257). In this IFC, to further support widespread community testing for COVID-19, we are finalizing on an interim basis that physicians and NPPs' may use CPT code 99211 to bill for services furnished incident to their professional services, for both new and established patients,

when clinical staff assess symptoms and collect specimens for purposes of COVID-19 testing. Cost-sharing for this service will be waived when all other requirements under section 6002(a) of the Families First Coronavirus Response Act are met. We are further creating a new code, CPT code C9803 under the OPPS for HOPDs to bill for a clinic visit dedicated to specimen collection and adopting a policy to conditionally package payment for this code. The OPPS will make separate payment for HCPCS code C9803 under the OPPS when no other primary service is furnished in the same encounter. Cost-sharing for this service will be waived when all other requirements under section 6002(a) of the Families First Coronavirus Response Act are met.

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

In the March 31st COVID-19 IFC, we changed several policies related to payment for Remote Physiologic Monitoring services under the PFS during the COVID-19 PHE. We had previously finalized payment in the CY 2018 PFS final rule for CPT code 99091 (*Collection and interpretation of physiologic data digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation requiring a minimum of 30 minutes of time*). In the CY 2019 PFS final rule the following year, we finalized payment for CPT codes 99453 (*Remote monitoring of physiologic parameter(s)(e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment*), 99454 (*Remote monitoring of physiologic parameter(s)(e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days*), and 99457 (*Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes*). Most recently, in the CY 2020 PFS final rule (84 FR 62645 and 62646), we finalized a treatment

management add-on code, CPT code 99458 (*Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes*) and two self-measured blood pressure monitoring codes, CPT code 99473 (*Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration*) and CPT code 99474 (*Separate self-measurements of two readings one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient*).

As we stated in the March 31st COVID-19 IFC, we believe that RPM services support the CDC's goal of reducing human exposure to the novel coronavirus while also increasing access to care and improving patient outcomes. RPM services could allow a patient with an acute respiratory virus to monitor pulse and oxygen saturation levels using pulse oximetry. Nurses or other auxiliary personnel, working with physicians, can check-in with the patient and then using patient data, determine whether home treatment is safe, all the while reducing exposure risk and eliminating potentially unnecessary emergency department and hospital visits. Based on these considerations, we established interim policies to eliminate as many unnecessary obstacles as possible to delivering these services as part of the response to the pandemic. To that end, a combination of our permanent and interim policies for the duration of the COVID-19 PHE allow RPM services to be furnished to new patients in addition to established patients; with beneficiary consent to be obtained at the time services are furnished and by auxiliary personnel for physiologic monitoring of patients with acute and/or chronic conditions; and under general supervision.

In recent weeks, we have been notified by stakeholders that CPT coding guidance states

that the RPM service described by CPT code 99454 cannot be reported for monitoring of fewer than 16 days during a 30-day period. In reviewing other RPM codes, we also observed that CPT codes 99091, 99453, 99457, and 99458, also have 30-day reporting periods. Stakeholders have alerted CMS that while it is possible that remote physiologic monitoring would be used to monitor a patient with COVID-19 for 16 or more days, many patients with COVID-19 who need monitoring do not need to be monitored for as many as 16 days. Consequently, and for all of the same reasons we articulated for establishing the other policies supporting use of RPM services as part of the pandemic response, for purposes of treating suspected COVID-19 infections, we are establishing a policy on an interim final basis for the duration of the COVID-19 PHE to allow RPM monitoring services to be reported to Medicare for periods of time that are fewer than 16 days of 30 days, but no less than 2 days, as long as the other requirements for billing the code are met. We are not proposing to alter the payment for CPT codes 99454, 99453, 99091, 99457, and 99458 because the overall resource costs for long-term monitoring for chronic conditions assumed under the current valuation would appropriately reflect those for short-term monitoring for acute conditions in the context of COVID-19 disease and exposure risks. Payment for CPT codes 99454, 99453, 99091, 99457, and 99458 when monitoring lasts for fewer than 16 days of 30 days, but no less than 2 days, is limited to patients who have a suspected or confirmed diagnosis of COVID-19.

III. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule before the provisions of the rule take effect, in accordance with the Administrative Procedure Act (APA), 5 U.S.C. 553, and section 1871 of the Act. Specifically, section 553(b) of the APA requires the agency to publish a notice of the proposed rule in the **Federal Register** that includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of

the subjects and issues involved. Section 553(c) further requires the agency to give interested parties the opportunity to participate in the rulemaking through public comment before the provisions of the rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rule in the **Federal Register** and a period of not less than 60 days for public comment. Section 553(b)(B) and section 1871(b)(2)(C) of the Act authorize the agency to waive these procedures, however, if the agency finds good cause that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

Section 553(d) ordinarily requires a 30-day delay in the effective date of a final rule from the date of its publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds good cause to support an earlier effective date. Section 1871(e)(1)(B)(i) of the Act also prohibits a substantive rule from taking effect before the end of the 30-day period beginning on the date the rule is issued or published. However, section 1871(e)(1)(B)(ii) of the Act permits a substantive rule to take effect before 30 days if the Secretary finds that a waiver of the 30-day period is necessary to comply with statutory requirements or that the 30-day delay would be contrary to the public interest. Furthermore, section 1871(e)(1)(A)(ii) of the Act permits a substantive change in regulations, manual instructions, interpretive rules, statements of policy, or guidelines of general applicability under Title XVIII of the Act to be applied retroactively to items and services furnished before the effective date of the change if the failure to apply the change retroactively would be contrary to the public interest. Finally, the Congressional Review Act (CRA) requires a delay in the effective date for major rules unless an agency finds good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, in which case the rule shall take effect at such time as the agency determines. 5 U.S.C. §§ 801(a)(3), 808(2).

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak of the 2019 Novel Coronavirus (2019-nCoV) to be a Public Health Emergency of International Concern.[56] On January 31, 2020, Health and Human Services Secretary Alex M. Azar II determined that a PHE exists retroactive to January 27, 2020[57] under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID-19), and on April 21, 2020, Secretary Azar renewed, effective April 26, 2020, the determination that a PHE exists.[58] On March 11, 2020, the WHO publicly declared COVID-19 to be a pandemic.[59] On March 13, 2020, the President declared that the COVID-19 pandemic in the United States constitutes a national emergency,[60] beginning March 1, 2020. This declaration, along with the Secretary's January 30, 2020 declaration of a PHE, conferred on the Secretary certain waiver authorities under section 1135 of the Act. On March 13, 2020, the Secretary authorized waivers under section 1135 of the Act, effective March 1, 2020.[61] Ensuring the health and safety of Medicare beneficiaries, Medicaid recipients, BHP enrollees, CHIP enrollees, and healthcare workers is of primary importance. As this IFC directly supports that goal by offering healthcare professionals flexibilities in furnishing services while combatting the COVID-19 pandemic and ensuring that sufficient health care items and services are available to meet the needs of individuals enrolled in the Medicare, Medicaid, CHIP and BHP programs, it is critically important that we implement this IFC as quickly as possible and for certain provisions, retroactive to either the start of the national emergency for the COVID-19 pandemic, beginning on March 1, 2020, or the start of the PHE for the COVID-19 pandemic on January 27, 2020. Not

56 https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov).
57 https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.
58 https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-21apr2020.aspx.
59 https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020.
60 https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.
61 https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx.

applying these revisions retroactive to either the start of the national emergency for the COVID-19 pandemic, beginning on March 1, 2020, or the start of the PHE for the COVID-19 pandemic on January 27, 2020 would be contrary to the public interest of supporting necessary flexibilities during the entire PHE. As we are in the midst of a PHE, we find good cause to waive notice and comment rulemaking as we believe it would be impracticable and contrary to the public interest for us to undertake normal notice and comment rulemaking procedures, as that would delay giving healthcare providers the flexibilities to provide critical care. For the same reasons, because we cannot afford any delay in effectuating this IFC, we find good cause to waive the 30-day delay in the effective date and, moreover, to make certain policies in this IFC applicable as of March 1, 2020—the date the President of the United States declared to be the beginning of the national emergency concerning the COVID-19 pandemic, or, if applicable, January 27, 2020, the date on which the PHE for the COVID-19 pandemic started.

In support of the imperative to contain and combat the virus in the United States, this IFC will give health care workers and hospitals additional flexibility to respond to the virus and continue caring for patients while minimizing exposure to COVID-19. CDC guidelines are clear that public exposure greatly increases the overall risk to public health and they stress the importance of containment and mitigation strategies to minimize public exposure and the spread of COVID-19. As of April 26th 2020, the CDC reports 957,875 cases of COVID-19 in the United States and 53,922 deaths.[62] Individuals such as healthcare workers who come in close contact with those infected with COVID-19 are at an elevated risk of contracting the disease. To minimize these risks, the CDC has urged healthcare professionals to make every effort to distance themselves from those who are potentially sick with COVID-19 by using modalities such as telephonic interviews, text monitoring systems, or video conference.[63] As the healthcare

[62] https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html.
[63] https://www.cdc.gov/coronavirus/2019-ncov/php/guidance-evaluating-pui.html.

community works to establish and implement infection prevention and control practices, we are also working to revise and implement regulations that function in concert with those healthcare community infection prevention and treatment practices.

This IFC offers flexibilities in certain Medicare, Medicaid, and BHP regulations that support measures to combat the COVID-19 pandemic and safeguard all interests by protecting healthcare providers and vulnerable beneficiaries. The provisions of this IFC better enable and facilitate physicians and other clinicians, to focus on caring for these beneficiaries during this PHE for the COVID-19 pandemic and minimize their own risks to COVID-19 exposure.

Furthermore, we are also adopting an extraordinary circumstances relocation exception policy for on-campus and excepted off-campus PBDs of hospitals that relocate in response to the PHE, as well as describing the hospital outpatient services and CMHC that can to be furnished in temporary expansion locations of a hospital (including the patient's home).

We are also establishing a national coverage policy under Medicare Part B for COVID-19 antibody diagnostic tests in order to ensure patients and practitioners have clinically relevant information to allow for ongoing health monitoring and isolation, as appropriate.

We are allowing Opioid Treatment Programs (OTPs) to furnish periodic assessments via communication technology.

In addition, we are allowing states that operate a BHP to seek certification of temporary BHP Blueprint revisions to make significant changes directly tied to the PHE for the COVID-19 pandemic and that increase access to necessary services without delay or other barriers (such as cost sharing) during the duration of the PHE for the COVID-19 pandemic.

We are modifying the methodology to determine IME payments teaching hospitals so that temporary increases in available beds or bed capacity during the PHE for the COVID-19 pandemic will not lower teaching hospitals' IME payments or impact provider-based RHC payments for those RHCs who are not currently subject to the national payment limit. We are

also implementing temporary policies to allow teaching hospitals to claim, in their resident FTE counts, residents that teaching hospitals send to other hospitals to respond to the PHE associated with COVID, which will allow teaching hospitals to maintain GME payments and will not trigger establishment of FTE counts or PRA caps at non-teaching receiving hospitals. Likewise, we are adopting a policy to hold, for the duration of the COVID-19 PHE, IRF and IPF average daily census numbers at their values prior to the COVID-19 PHE, so that IRF and IPF teaching status adjustment payments do not decrease during the pandemic. We are implementing various flexibilities for IRFs in this IFC so that IRFs may utilize their excess bed capacity to care for patients to alleviate capacity issues in acute care hospitals during the COVID-19 pandemic. Specifically, IRFs will still be required to meet requirements for IRF payment for patients who receive regular IRF care. However, for those patients who are cared for in an IRF solely to alleviate acute care hospital bed capacity, IRFs will not have to comply with some regulations governing documentation, therapy requirements, and other policies to maximize time spent on patient care during this pandemic.

We are also making changes to the Medicare regulations to revise payment rates for certain DME and enteral nutrients, supplies, and equipment as part of implementation of section 3712 of the CARES Act. We are also increasing flexibilities for hospitals participating in the Hospital VBP Program by expanding the Extraordinary Circumstances Exceptions (ECE) policy so that we can grant an ECE to hospitals within an entire region or locale, including the entire United States, that have been affected by an extraordinary circumstance, including the COVID-19 PHE, without requiring that each affected hospital individually submit an ECE request form.

Additionally, immediate implementation of section 3712 of the CARES Act is necessary to provide prompt relief, as intended by the CARES Act, in the form of higher Medicare payments to suppliers of DME in certain areas to ensure beneficiary access to necessary medical equipment and supplies during the PHE.

The COVID-19 pandemic PHE has created a lack of predictability for many ACOs participating in the Shared Savings Program regarding the impact of expenditure and utilization changes on financial benchmarks and performance year expenditures, and for those under performance-based risk, the potential liability for shared losses, as well as disrupting population health activities as clinicians, care coordinators and financial and other resources are diverted to address immediate acute care needs. ACOs and other program stakeholders have advocated that there is an urgent need to address these concerns because ACOs need to make participation decisions for PY 2020 and PY 2021 soon and may choose to terminate their participation in the Shared Savings Program on or before the June 30, 2020 deadline, rather than face the potential of pro-rated shared losses for PY 2020 if the PHE does not extend for the entire year and if the existing policies under the Shared Savings Program do not adequately mitigate liability for shared losses. We believe it is vital to the stability of the Shared Savings Program to encourage continued participation by ACOs by adjusting program policies as necessary to address the impact of the COVID-19 pandemic, including by offering certain flexibilities in program participation options to currently participating ACOs and addressing potential distortions in expenditures resulting from the COVID-19 pandemic. The changes included in this IFC will help to ensure a more equitable comparison between ACOs' expenditures for PY 2020 and their updated historical benchmarks and that ACOs are not rewarded or penalized for having higher/lower COVID-19 spread in their assigned beneficiary populations which, in turn, will help to protect ACOs from owing excessive shared losses and the Medicare Trust Funds from paying out windfall shared savings. For these reasons and the reasons set forth in section II.L. of this IFC, we find good cause to waive notice and comment procedures for the regulatory changes being made to the Shared Savings Program in this IFC.

Furthermore, changes effectuated in this rule to broaden the scope of practitioners who may order home health services and expand the availability of Medicaid coverage for certain

laboratory testing during a PHE and subsequent periods of active surveillance are being made to maximize beneficiary access to needed services and minimize the transmission of the disease, which is of critical importance in the current PHE. Additionally, during the PHE for the COVID-19 pandemic, we are adding flexibility for teaching physicians, NPPs, PTs, OTs, SLPs, and others in supervision, documentation, and other requirements of the Medicare program that could impact the availability and efficiency of care to ensure an adequate number of clinicians are able to furnish critical services and tests.

Section 3708 of the CARES Act is applicable to Medicare and Medicaid and allows a home health patient to be under the care of a NP or CNS or a PA and allows such practitioner to: (1) order home health services; (2) establish and periodically review a plan of care for home health services; and (3) certify and re-certify that the patient is eligible for home health services. Currently, these functions can only be paid for by Medicare when performed by physicians. However, these changes are not effective until CMS implements the changes in regulation, and pursuant to section 3708(f) of the CARES Act, may be implemented by an IFC. Implementing all of the conforming regulations changes in this IFC are needed to implement section 3708 of the CARES Act, and will allow us to meet the statutorily-required 6-month timeframe for implementation, but also allows us to act as expediently as possible to implement this new flexibility during the current PHE for the COVID-19 pandemic.

We are also permitting flexibility with respect to the administration of COVID-19 tests for purposes of Medicaid coverage, both during the COVID-19 PHE and any subsequent periods of active surveillance, to allow for continued surveillance as part of strategies to detect recurrence of the virus in individuals and populations to prevent further spread of the disease. These flexibilities related to Medicaid laboratory coverage, which are urgently needed during the COVID-19 PHE, will also apply during future PHEs resulting from outbreaks of communicable disease and any subsequent period of active surveillance. We are amending Medicare

regulations to remove the Medicare requirement for a physician or other practitioner's order for COVID-19 testing and certain related testing, as well as allowing increased flexibilities regarding documentation requirements for such tests, during the COVID-19 PHE.

We are also allowing flexibilities to HHAs in the HHVBP Model by aligning HHVBP Model data submission requirements with any exceptions or extensions granted for purposes of the HH QRP during the PHE for the COVID-19 pandemic, as well as a policy for granting exceptions to the New Measures data reporting requirements under the HHVBP Model during the PHE for the COVID-19 pandemic.

In addition, we are delaying the compliance dates for collecting and reporting the TOH Information to Provider-Post-Acute Care and TOH Information to Patient-Post-Acute Care quality measures and certain standardized patient assessment data with respect to six categories by IRFs, LTCHs, and HHAs under, respectively, the IRF QRP, LTCH QRP, and HH QRP.

Additionally, in regard to the Quality Payment Program, due to the PHE, we are amending § 414.1400(b)(3)(v)(C) and (D) to delay the implementation of these policies by 1 year. Both QCDR measure approval criteria necessitate QCDRs collecting data from clinicians in order to assess the measure, and we anticipate that QCDRs may be unable to collect, and clinicians unable to submit, data on QCDR measures due to prioritizing the care of COVID-19 patients.

We are also revising § 156.280(e)(2)(ii) to delay implementation of the separate billing policy for 60 days from the date finalized in the 2019 Program Integrity Rule (84 FR 71674). Under this 60-day extension, QHP issuers must comply with the separate billing policy finalized at § 156.280(e)(2)(ii) beginning on or before the QHP issuer's first billing cycle following August 26, 2020. We believe extending the deadline 60 days for QHP issuers and Exchanges to comply with the separate billing policy is appropriate so that they may adequately respond to the current national PHE and divert resources to address COVID-19 that may otherwise have been

used for timely compliance with the separate billing policy. Therefore, the 60-day delayed implementation for QHP issuers subject to the separate billing policy is effective immediately, such that QHP issuers are required to begin complying with the separate billing policy finalized at § 156.280(e)(2)(ii) beginning on or before the first billing cycle following August 26, 2020.

Finally, we are adding a new paragraph (g) to § 483.80, to require facilities to report information on COVID-19 incidence among residents and staff in LTC facilities to the CDC, without a previous opportunity for public comment. We believe we have good cause to waive the normal notice-and-comment process under the Administrative Procedure Act and section 1871(b)(2)(C) of the Act, because acting immediately to provide information to the CDC and the public can help control the spread of the virus. Waiving notice and comment is in the public interest, because time is of the essence in informing residents, their families, and the general public of the incidence of COVID-19 in the LTC facility population; such information will assist public health officials in detecting outbreaks and saving lives.

As noted in this IFC, it is critical in emergencies and disaster situations to respond as efficiently and effectively as possible to address immediate public health needs; as such, we may extend flexibilities in this IFC for future national emergencies, public health emergencies, or disasters. We welcome comments on whether some of these flexibilities should be extended to future situations.

We believe it would be impracticable and contrary to the public interest for us to undertake normal notice and comment procedures and to thereby delay the effective date of this IFC. We find good cause to waive notice of proposed rulemaking under the APA, 5 U.S.C. 553(b)(B), and section 1871(b)(2)(C) of the Act. For those same reasons, as authorized by section 808(2) of the CRA, we find it is impracticable and contrary to the public interest not to waive the delay in effective date of this IFC under section 801 of the CRA. We therefore find there is good cause to waive the CRA's delay in effective date pursuant to section 808(2) of the

CRA. Furthermore, as noted above, the President declared that the COVID-19 outbreak in the United States constituted a national emergency beginning March 1, 2020. In addition, the Secretary's declaration of a PHE for the COVID-19 pandemic took effect on January 27, 2020. To ensure the availability of the measures we are taking to address the COVID-19 pandemic, we believe it is vital that many of the Medicare policies in this IFC apply starting either with the first day of the national emergency or the start of the PHE for the COVID-19 pandemic, as applicable. It is also important to ensure that health care providers that acted expeditiously to implement appropriate physical and operational changes to their practices to adapt to emergency conditions, even in the absence of changes in our policies to address them, are not disadvantaged relative to other health care providers, and will not be discouraged from taking similar appropriate actions in the future. Specifically, in this IFC we have concentrated on increasing providers' ability to furnish services at temporary expansion locations, including the patient's home, that is a PBD of the hospital or an expanded CMHC to limit the need for patients to receive care in the hospital itself, which could unnecessarily expose the patients or providers to the pandemic contagion. For example, hospital staff can now remotely furnish psychotherapy to the beneficiary in their home, as long as the beneficiary is a registered outpatient of the hospital and the patient's home is made provider-based to the hospital. It is critical this provision be retroactive to the first day of the national emergency in order to ensure providers' have the necessary flexibilities to provide services at temporary expansion locations and to ensure beneficiaries continue to receive critical services, while limiting their exposure to the pandemic contagion. Both March 1, 2020, and January 27, 2020, precede the date of publication of this IFC in the **Federal Register**, which means that certain Medicare provisions of this rule have a retroactive effect. However, section 1871(e)(1)(A)(ii) of the Act permits the Secretary to issue a rule for the Medicare program with retroactive effect if the failure to do so would be contrary to the public interest. As we have explained above, we believe it would be contrary to the public

interest not to implement certain Medicare provisions of this IFC as soon as we are authorized to do so under the authority of section 1871(e)(1)(A)(ii) of the Act, that is, retroactively to either the start of the national emergency or the PHE for the COVID-19 pandemic, as applicable. Accordingly, the provisions in this IFC have retroactive applicability to March 1, 2020, or January 27, 2020, unless otherwise noted.

Separately, in light of the urgent need to provide the flexibilities under new paragraph (d) in § 440.30 during the COVID-19 PHE, and because this provision will ease restrictions under existing law and make Medicaid coverage of testing more available, this provision will also be effective on March 1, 2020. Similarly, in light of the urgent need to provide the flexibilities in the amendments to § 440.70 during the COVID-19 PHE, and because they will increase flexibility in the delivery of benefits and make Medicaid coverage of home health services more available, the amendments to § 440.70 will take effect on the same date as the Medicare regulations implementing section 3708 of the CARES Act, March 1, 2020. We are providing a 60-day public comment period for this IFC as specified in the DATES section of this document.

In this IFC, we are also delaying the date by which SNFs must start collecting and reporting data on the TOH Information to Provider–Post-Acute Care and TOH Information to Patient–Post-Acute Care quality measures and standardized patient assessment data elements (SPADEs) with respect to six categories for the SNF QRP. We are delaying these requirements because in response to stakeholder concerns, we have delayed the release of an updated version of the Minimum Data Set (MDS) that would have included the data elements that SNFs need to report these two quality measures and SPADEs. In the absence of a vehicle to report these data, SNFs cannot report them beginning with October 1, 2020 admissions and discharges. We have taken the COVID-19 PHE into consideration in selecting a new compliance date, which will be on October 1st of the year that is at least two fiscal years after the PHE ends.

We find the notice-and-comment procedure impracticable because SNFs cannot comply with the reporting requirements for the two quality measures and SPADEs until CMS releases the updated MDS and SNFs have had an opportunity to become familiar with the updated version. Also, this IFC does not impose any additional requirements, but rather delays the compliance date for collecting and reporting the two quality measures and SPADEs. Therefore, we find good cause to waive notice-and-comment procedures and to issue this IFC without a delay of effective date.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding Rules Relating to Separate Billing and Segregation of Funds for Abortion Services (§ 156.280)

This IFC does not impose any additional information collection burden under the PRA,

and does not contain any information collection activities beyond the information collection currently awaiting approval by OMB under the control number: 0938–1358 (Billing and Collection of the Separate Payment for Certain Abortion Services (CMS–10681)).

Based on 2020 QHP certification data in the Federally-facilitated Exchanges (FFEs) and State-based Exchanges on the Federal Platform (SBE–FPs), in the 2019 Program Integrity Rule (84 FR 71674), we estimated that 23 QHP issuers will offer a total of 338 plans with coverage of non-Hyde abortion services in 9 FFE and SBE–FP states. We also estimated that in the 12 State Exchanges that will operate their own technology platforms in 2020, 71 QHP issuers will offer a total of approximately 1,129 plans that include coverage for non-Hyde abortions services. Three of those State Exchanges perform premium billing and payment processing, while the other 9 have their issuers perform premium billing and payment processing. In total, we estimated that there will be 94 QHP issuers offering a total of 1,467 plans (representing approximately 32 percent of individual market, on-Exchange plans) covering non-Hyde abortion services across 21 states in plan year 2020. With the 60-day delay, we continue to believe the one-time burden QHP issuers will incur to complete the necessary technical build to implement the changes for the separate billing policy will be incurred primarily in 2020. Therefore, we are unable to quantify any additional cost or savings related to the one-time technical build that would be attributable to this rule.

In the 2019 Program Integrity Rule, we estimated that each issuer and State Exchange performing premium billing and payment processing will incur ongoing annual costs, such as those related to identifying impacted enrollees, ensuring billing accuracy, reconciliation, quality assurance, printing, recordkeeping, and document retention. The total burden for each issuer and State Exchange performing premium billing and payment processing was estimated to be 24,120 hours with an equivalent cost of $1.07 million. Delaying the implementation of the deadline for the separate billing policies by 60 days will result in a reduction in this burden. We estimate that

the burden for each issuer and State Exchange performing premium billing and payment processing will be reduced by 4,020 hours with an equivalent cost reduction of approximately $177,629 in 2020. For all 97 issuers and State Exchanges performing premium billing and payment processing, the total reduction in burden in 2020 will be 389,940 hours with an equivalent cost reduction of approximately $17.4 million.

In addition, we estimated that issuers and State Exchanges performing premium billing and payment processing will need to print and send approximately 1.82 million separate paper bills per month in 2020, incurring monthly costs of approximately $91,200. Delaying the implementation of the deadline for the separate billing policies by 60 days will reduce the cost of printing separate bills in 2020 by approximately $182,400.

The revised burden estimates will be included in the next submission of the information collection to OMB.

B. ICRs Regarding Temporary Extraordinary Circumstances Policy for Relocating Excepted Provider-based Departments During the COVID-19 PHE

In section II.E. of this IFC, for purposes of enabling greater hospital flexibility, and, in particular, enabling hospitals to rapidly develop temporary expansion sites for patient care, we are temporarily adopting an expanded version of the extraordinary circumstances relocation policy during the COVID-19 PHE to include on-campus PBDs that relocate off-campus during the COVID-19 PHE for the purposes of addressing the COVID-19 pandemic. We note that this temporary extraordinary circumstances policy is time-limited to the PHE for COVID-19 to enable short-term hospital relocation of excepted off-campus and on-campus departments to improve access to care for patients during this time. The temporary extraordinary circumstances relocation policy established here will end following the end of the PHE for the COVID-19 pandemic, and we anticipate that most, if not all, PBDs that relocate during the COVID-19 PHE will relocate back to their original location prior to, or soon after, the COVID-19 PHE concludes.

In place of the process adopted in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79704 through 79705) and included in the existing subregulatory guidance under which off-campus PBDs can apply for an extraordinary circumstance relocation exception, all hospitals that relocate excepted on- or off-campus PBDs to off-campus locations in response to the COVID-19 PHE should notify their CMS Regional Office by email of their hospital's CCN; the address of the current PBD; the address(es) of the relocated PBD(s); the date which they began furnishing services at the new PBD(s); a brief justification for the relocation and the role of the relocation in the hospital's response to COVID-19; and an attestation that the relocation is not inconsistent with their state's emergency preparedness or pandemic plan. We expect hospitals to include in their justification for the relocation why the new PBD location (including instances where the relocation is to the patient's home) is appropriate for furnishing covered outpatient items and services. To the extent that a hospital may relocate to an off-campus PBD that otherwise is the patient's home, only one relocation request during the COVID-19 PHE is necessary.

We estimate that 450 hospitals will request the temporary extraordinary circumstances exception for one or more excepted PBDs during the PHE. There are roughly 500 hospitals as identified by a unique CMS Certification Number (CCN) in the states of New York, New Jersey, Michigan, Washington, Massachusetts, and Louisiana. These states have some of the counties with the highest per-capita incidence of COVID-19, and we estimate that roughly 50 percent of the hospitals in those states will apply for an exception (roughly 250 hospitals) due to their need to relocate an on-campus or excepted off-campus PBD in response to the PHE. In the remaining states, we believe a smaller percent of hospitals in each state may also apply for the exception – resulting in a total of 450 hospitals.

We estimate that it will take each hospital 15 minutes to complete and submit the request to the CMS Regional Office. We believe that all hospitals will submit a maximum of one

relocation request email (even though the request may include more than one location) and this request can include some of the same information (for example, the same CCN, original PBD address, and justification) for multiple sites as deemed appropriate by the hospital. We believe a Medical and Health Services Manager will develop and submit the relocation request to the CMS Regional Office. These employees have an average hourly wage rate of $55.35 based on the May 2019 Bureau of Labor and Statistics' Occupation Employment Statistics. (Citation: BLS code 11-9111, website for May 2019 data here: ≥https://www.bls.gov/oes/current/oes119111.htm≤).

We estimate 450 total submissions (one per hospital) x 0.25 hours per submission = 113 total burden hours associated with this requirement and a total labor cost of $6,257 (113 hours x $55.37/hr).

The information collection requirements in this section associated with § 419.48 have been submitted to OMB for emergency review and approval in accordance with the implementing regulations of the PRA at 5 CFR 1320.13.

C. ICRs Regarding Changes to § 424.507

As previously explained, under section 3708 of the CARES Act, we are revising § 424.507(b)(1) to allow NPs, CNSs, and PAs to certify the need for home health services. This, in turn, would require these three NPP types to be enrolled in or opted-out of Medicare to certify such services. The following discusses our burden estimates for this requirement.

Based on internal data from our Provider Enrollment, Chain, and Ownership System (PECOS), we generally estimate that approximately:

- 5,000 currently unenrolled or non-opted out NPs, CNSs, and PAs will elect to enroll in or opt-out of Medicare solely for the purpose of certifying home health services. We believe they will do so in the first year following the effective date of this IFC.

- 1,000 new NPs, CNSs, and PAs each year will enroll in or opt-out of Medicare for the same purpose.

Physicians and practitioners complete the Form CMS-855O (Medicare Enrollment Application - Registration for Eligible Ordering and Referring Physicians and Non-Physician Practitioners) if they are enrolling in Medicare not to obtain Medicare billing privileges but strictly to order, refer, or certify certain Medicare items and services. The information collection for Form CMS-855O is currently approved under OMB control number 0938-1135 with an expiration date of December 31, 2021.

According to the most recent wage data provided by the Bureau of Labor Statistics (BLS) for May 2019 (see http://www.bls.gov/oes/current/oes_nat.htm#43-0000), the mean hourly wage for the general category of ‘‘Health Diagnosing and Treating Practitioners, All Others’’ is $49.26. With fringe benefits and overhead, the per hour rate are $98.52. We also project that, on average, it takes individuals approximately .5 hours to complete and submit the Form CMS–855O or an opt-out affidavit.

Given the foregoing, we estimate a first-year burden of 3,000 hours (0.5 hr x (5,000 + 1,000)) at a cost of $295,560. The annual burden in Year 2 and in Year 3 is 500 hours (0.5 hr x 1,000) at a cost of $49,260. This results in a total burden of 4,000 hours (3,000 hr + 500 hr + 500 hr) at a cost of $394,080. When averaged over the typical 3-year OMB approval period, we estimate an annual burden of 1,333 hours (4,000 hr/3) at a cost of $131,360 ($394,080/3).

The information collection requirements in this section associated with § 424.507 have been submitted to OMB for emergency review and approval in accordance with the implementing regulations of the PRA at 5 CFR 1320.13.

D. ICRs for Merit-based Incentive Payment System (MIPS) Qualified Clinical Data Registry (QCDR) Measure Approval Criteria § 414.1400

In section II.R. of this IFC, we are amending § 414.1400(b)(3)(v)(C) and (D) to delay the implementation of these policies by 1 year. Both QCDR measure approval criteria necessitate QCDRs collecting data from clinicians in order to assess the measure, and we anticipate that

QCDRs may be unable to collect, and clinicians unable to submit, data on QCDR measures due to prioritizing the care of COVID-19 patients. Because these policies are not modifying the approval criteria for QCDR measures but are instead amending the timeline for implementation of previously finalized policies, we are not making any changes to our previously approved burden estimates.

E. ICRs for the Hospital Value-Based Purchasing (VBP) Program

In section II.U. of this IFC, we are updating the Extraordinary Circumstance Exception (ECE) policy for the Hospital VBP Program to allow us to grant exceptions to hospitals which have not requested them when we determine that an extraordinary circumstance, such as PHE, including the current PHE for COVID-19, affects an entire region or locale. In a situation where we are granting such an exception for an entire region or locale, hospitals are not required to complete any forms or submit any additional information, therefore the program does not anticipate any change in burden associated with this IFC.

F. ICRs for COVID-19 Reporting in Nursing Homes

We are revising the regulations by adding a provision at § 483.80(g) to require LTC facilities to electronically report information related to confirmed or suspected COVID-19 cases in a standardized format and frequency specified by the Secretary, but no less frequent than weekly. This information will be reported to the CDC's National Healthcare Safety Network (NHSN). As of April 14, 2020, there are approximately 15,446 LTC facilities listed in the CMS Nursing Home Compare database. As CMS will require these facilities to participate in data collection and reporting, we estimate that 95% of these facilities will report COVID-19 case data.

We have estimated that the COVID-19 LTC facility forms will take an average of 55 minutes to complete weekly, knowing that the reporting burden includes surveillance and data entry. We further estimate that LTC facility users will report these data on a weekly basis. The

Module allows retrospective data collected from previous dates to be entered. Because OMB PRA approval is requested for 180 days, the total number of responses per respondent is 26. This burden will be submitted under the ICR titled National Healthcare Safety Network (NHSN) Patient Impact Module for Coronavirus (COVID-19) Surveillance in Healthcare Facilities (OMB Control Number 0920-1290). Details of this burden can be found in Table 1.

TABLE 1: Burden and Responses

Type of Respondent	Form Name	No. of Respond-ents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)	Hourly Wage Rate	Total Respondent Costs
LTCF personnel	COVID-19 Module, Long-Term Care Facility: Staff and Personnel Impact form	9,782	26	15/60	63,583	$50.91	$3,237,011
Business and financial operations occupations	COVID-19 Module, Long-Term Care Facility: Staff and Personnel Impact form	2,446	26	15/60	15,899	$37.56	$597,166
State and local health department occupations	COVID-19 Module, Long-Term Care Facility: Staff and Personnel Impact form	2,446	26	15/60	15,899	$40.21	$639,299
LTCF personnel	COVID-19 Module, Long-Term Care Facility: Resident Impact and Facility Capacity form	9,782	26	20/60	84,777	$50.91	$4,315,997
Business and financial operations occupations	COVID-19 Module, Long-Term Care Facility: Resident Impact and Facility Capacity form	2,446	26	20/60	21,199	$37.56	$796,234
State and local health department occupations	COVID-19 Module, Long-Term Care Facility: Resident Impact and Facility Capacity form	2,446	26	20/60	21,199	$40.21	$852,412
LTCF personnel	COVID-19 Module, Long-Term Care Facility: Ventilator Capacity & Supplies form	9,782	26	5/60	21,194	$50.91	$1,078,987
Business and financial operations occupations	COVID-19 Module, Long-Term Care Facility: Ventilator Capacity & Supplies form	2,446	26	5/60	5,300	$37.56	$199,068
State and local health department occupations	COVID-19 Module, Long-Term Care Facility: Ventilator Capacity & Supplies form	2,446	26	5/60	5,300	$40.21	$213,113
LTCF personnel	COVID-19 Module, Long-Term Care Facility: Supplies & Personal Protective Equipment form	9,782	26	15/60	63,583	$50.91	$3,237,011
Business and financial operations occupations	COVID-19 Module, Long-Term Care Facility: Supplies & Personal Protective Equipment form	2,446	26	15/60	15,899	$37.56	$597,166
State and local health department occupations	COVID-19 Module, Long-Term Care Facility: Supplies & Personal Protective Equipment form	2,446	26	15/60	15,899	$40.21	$639,299
Total					349,731		$16,402,763

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Statement of Need

Throughout this IFC, we discuss several changes to payment and coverage policies intended to allow health care providers maximum flexibility to minimize the spread of COVID-19 among Medicare and Medicaid beneficiaries, health care personnel, and the community at large, and increase capacity to address the needs of their patients. The flexibilities and changes contained within this IFC are responsive to this developing pandemic emergency and to recent legislation that gives us additional authority. Given the potentially catastrophic impact to public health, it is difficult to estimate the economic impact of the spread of COVID-19 under current payment rules compared to the rules issued in this IFC.

We believe that the needs of Medicare and Medicaid beneficiaries suffering from COVID-19 will likely test the capacity of the health care system over the coming months. Our policies implemented in this IFC will provide flexibilities, during the PHE for COVID-19, to physicians and other practitioners, home health and hospice providers, FQHCs, RHCs, hospitals, critical access hospitals, CMHCs, IRFs, IPFs LTCHs, skilled clinical laboratories, providers of the laboratory testing benefit in Medicaid, Opioid Treatment Programs (OTPs), Shared Savings Program ACOs, and DMEPOS suppliers. These policies will likely minimize exposure risks to patients, clinicians and the general public.

The flexibilities available to hospitals and CMHCs to furnish certain outpatient services

remotely will allow more of these services to be furnished in a manner that reduces the exposure risk to patients, hospital staff, and physicians. To the extent that hospitals use these flexibilities to care for patients who would have otherwise received care in more traditional hospital settings, they likely would not result in any significant change in aggregate Medicare payments for hospital services.

The policy to exclude temporarily added surge capacity beds when determining a teaching hospital's IME payments, may increase costs relative to those that would otherwise been incurred under current policies during the PHE for COVID-19; however, we estimate that there will not be a significant change in aggregate Medicare IME payments relative to current policies absent the PHE for COVID-19. A similar policy will also allow RHCs that are provider-based to a hospital to maintain their payment amounts levels if the hospital temporarily adds additional beds, which would otherwise disqualify them. Likewise, we are adopting a policy to maintain IRF and IPF average daily census numbers so that IRF and IPF teaching status adjustment payments do not decrease during the pandemic.

The changes to Medicare and Medicaid regulations to expand the scope of the practitioners who may order home health services are anticipated to eliminate some burdens on practitioners and beneficiaries. Similarly, the changes to Medicaid's regulations to expand the circumstances under which certain laboratory tests can be covered during a PHE and subsequent periods of active surveillance are anticipated to eliminate some burdens on providers and beneficiaries. The changes to the BHP regulations to allow states to submit a revised Blueprint retroactive to the start of the PHE for the COVID-19 pandemic will eliminate some burdens on states and will help ensure enrollees' increased access to coverage during the PHE for the COVID-19 pandemic.

The temporary increase to certain DME payment rates, as required by section 3712 of the CARES Act, will increase Medicare expenditures as well as beneficiary cost-sharing. Moreover,

it is possible that the other flexibilities and changes contained within this IFC would increase aggregate Medicare or Medicaid services. Improvements in both provider and/or patient health are intended benefits of this IFC. For example, if the protections against exposure risk, such as teaching physicians remotely reviewing visits furnished by residents, are effective, providers may maintain their own health and thus be available to furnish more services overall.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set

forth in the Executive Order.

Executive Order 12866 and other laws and Executive Orders require economic analysis of the effects of proposed and final (including interim final) rules.[64] The Office of Management and Budget has designated this rulemaking as "economically significant" under E.O. 12866 and also major under the Congressional Review Act.

This IFC's designation under Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs (82 FR 9339), which was issued on January 30, 2017, will be informed by public comments received.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $8.0 million to $41.5 million in any 1 year). Individuals and states are not included in the definition of a small entity. As its measure of significant economic impact on a substantial number of small entities, HHS uses an adverse change in revenue of more than 3 to 5 percent. We do not believe that this threshold will be reached by the provisions in this IFC.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This IFC will not have a significant impact on the operations of a substantial number of small rural hospitals.

[64] Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-04, enacted on March 22, 1995) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2020, that amount is approximately $156 million. This IFC does not mandate, on an unfunded basis, any requirements for State, local, or tribal governments, or for the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This IFC does not have a substantial direct cost impact on state or local governments, preempt state law, or otherwise have federalism implications.

C. Detailed Economic Analysis of the Provisions of the IFC

1. Reporting Under the Home Health Value-Based Purchasing Model for CY 2020 during the COVID-19 Public Health Emergency

Section II.A. of this IFC implements a policy to align HHVBP Model data submission requirements with any exceptions or extensions granted for purposes of the HH QRP during the PHE for the COVID-19 pandemic, as well as a policy for granting exceptions to the New Measures data reporting requirements under the HHVBP Model during the PHE for the COVID-19 pandemic. We do not anticipate a change to Medicare expenditures as a result of this policy. However, we expect reduced burden on providers.

2. Scope of Practice

Section II.B. of this IFC implements several policies to temporarily add flexibility for certain nonphysician healthcare professionals in supervision, documentation and other requirements of the Medicare program that could impact the availability and efficiency of care. As discussed in section II.B. of this IFC, several states have sought to increase pharmacist capacity by relaxing supervision requirements during the PHE for COVID-19We expect that, especially when coupled with policies adopted by states, the temporary flexibility and clarification we provide in this IFC will increase capacity for pharmacists and other healthcare practitioners. We anticipate that these changes could possibly result in higher Medicare expenditures because, although the changes primarily modify supervision requirements, without a corresponding change in payment rate, the added flexibility could result in a higher volume of

services. We anticipate that the changes will allow the same services that were occurring before the PHE to continue during the PHE; however, expenditures could increase if additional services are furnished. To the extent that expenditures increased due to increases in service volume, this would represent a cost to the Federal Government.

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

Section II.C. of this IFC implements a policy to allow Medicare beneficiaries to get COVID-19 and other related testing during the COVID-19 PHE without requiring the order of the treating physician or practitioner, and instead allowing the testing to be ordered by any healthcare professional who is authorized to do so under applicable state law. We do not anticipate that this change will affect overall Medicare expenditures over time because we expect that the change would accelerate the timing of COVID-19 testing that would otherwise have occurred over a longer timeframe.

4. Opioid Treatment Programs – Furnishing Periodic Assessments via Communication Technology

Section II.D. of this IFC implements a change to allow periodic assessments furnished by OTPs to be furnished via two-way interactive audio-video communication technology, and in cases where beneficiaries do not have access to two-way audio/video communications technology, to allow periodic assessments to be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology, provided all other applicable requirements are met. This change will not result in an increase in Medicare expenditures because the add-on payment for these services was available prior to the PHE for COVID-19 and because this change only provides OTPs additional flexibilities regarding the manner in which they furnish these services during the pandemic.

5. Treatment of Certain Relocating Provider-Based Departments during the PHE

Section II.E. of this IFC adopts a temporary extraordinary circumstances relocation

exception policy for on-campus and excepted off-campus PBDs that relocate off-campus in response to the PHE that permits the PBDs that relocate to continue to be paid under the OPPS. This policy could drive slightly higher spending during the PHE than would otherwise occur, but generally it would maintain current payment rates to on-campus and excepted off-campus PBDs in the event of a temporary relocation due to the PHE for COVID-19. These policies would be time limited and we do not believe they would result in higher use of services; rather they would allow services furnished by these relocated departments to continue to be paid at the higher rate under the OPPS, rather than at the lower PFS-equivalent rate if these excepted PBDs relocated off-campus outside of the PHE and were not granted an extraordinary circumstances relocation exception.

Overall there would be minimal change in the types of patients treated under these policies compared to the absence of these policy changes. To the extent that Medicare expenditures increased, it would represent a transfer from the Federal Government to hospitals paid under the OPPS.

6. Furnishing Hospital Outpatient Services Remotely

Section II.F. of this IFC discusses flexibilities under which certain outpatient services, including PHP services furnished by a hospital or CMHC in the beneficiary's home, can be furnished remotely during the PHE for COVID-19. These changes will not result in higher costs because they only provide flexibility for providers to continue to furnish these services during the pandemic.

7. Medical Education

Section II.G. of this IFC implements a policy that excludes temporarily added surge capacity beds when determining a teaching hospital's IME payments. This policy could increase costs relative to the baseline IME payments that would be established under current payment rules if teaching hospitals temporarily add beds given the COVID-19 PHE, but will mitigate

changes in IME payments relative to their levels before the COVID-19 PHE. To the extent that IME payments do change, the changes in payments would represent a transfer between teaching hospitals and the Federal Government (that is, an increase in payments would be a transfer from the Federal Government to teaching hospitals, and vice versa).

This section also implements a policy to hold, for the duration of the COVID-19 PHE, IRF and IPF teaching status adjustment payments at their values prior to the COVID-19 PHE. This will mitigate changes in teaching adjustment payments relative to their levels before the COVID-19 PHE. To the extent that teaching adjustment payments did change, the changes would represent a transfer between IPFs or IRFs and the Federal Government (with an increase in payments being a transfer from the Federal Government to IPFs or IRFs, and vice versa).

This section also implements a policy to allow, for the duration of the COVID-19 PHE, teaching hospitals to claim, towards their resident FTE counts, residents that teaching hospitals send to other hospitals to respond to the PHE associated with COVID. To the extent that hospitals are not sending or accepting residents because of our current regulations, and those residents continue to train at the home teaching hospitals, allowing the residents to train elsewhere is budget neutral. The hospitals would continue to get paid the same GME payments that they would have received if the residents had continued to train at the home hospitals. No other hospitals would receive additional GME payments for that resident training.

8. Rural Health Clinics

Section II.H. of this IFC implements a policy that excludes temporarily added surge capacity beds from a hospital's bed count for the purposes of determining whether a RHC that is provider-based to that hospital is subject to a per-visit national payment limit. We do not anticipate that this policy would increase the number of RHCs that would not be subject to the payment limit; rather, it would ensure those RHCs who were not subject to the limit prior to the PHE maintain that status. This policy could increase costs relative to the baseline of current

payment rules and the PHE, but will mitigate changes in costs relative to their levels before the COVID-19 PHE. To the extent payments to RHCs increased, it would represent a transfer from the Federal Government to RHCs.

9. DME Interim Pricing in the CARES Act

Section II.I. of this IFC implements the temporary increase to certain DME payment rates, as required by section 3712 of the CARES Act. Section 3712 of the CARES Act increases Medicare expenditures, as well as beneficiary cost-sharing by increasing Medicare payment rates for certain DMEPOS items furnished in non-rural and contiguous non-competitively bid areas. The increase is a result of paying a blend of 75 percent of the fully adjusted payment rates and 25 percent of the unadjusted payment rates and is estimated to increase affected rates on average 33%. However, the estimated Medicare gross benefit cost against the FY 2021 President's Budget baseline is $140 million dollars. It would represent a transfer from the Federal Government to DMEPOS suppliers and a transfer from beneficiaries to the Federal Government. This change may also affect the federal financial participation limit for DMEPOS items and services furnished to Medicaid beneficiaries, but we are unable to quantify the effect.

10. Care Planning for Medicare Home Health Services

Section II.J. of this IFC implements conforming regulations text changes required by section 3708 of the CARES Act. We believe that section 3708 of the CARES Act will have a negligible impact on Medicare expenditures. NPPs generally work in collaboration with or under the supervision of a physician; therefore, utilization is unlikely to change substantially as a result of the CARES Act. In areas where NPPs are able to act independently under their state scopes of practice and where physicians are scarce, there may be a slight increase in utilization; however, we are unable to quantify the impact. Although the majority of states require physician collaboration for these NPPs, we note that even in states that allow independent practice authority, many of these practitioners continue to work in a practice environment (inpatient

facility or outpatient or physician's office) that includes a physician.

11. CARES Act Waiver of the "3-Hour Rule" and Modification of IRF Coverage and Classification Requirements for Freestanding IRF Hospitals for the PHE During the COVID-19 Pandemic

Section II.K. of this IFC amends section § 412.622(a)(3)(ii) (commonly referred to as the "3-hour rule") to address the waiver required by section 3711(a) of the CARES Act during the emergency period described in section 1135(g)(1)(B) of the Act and amends§ 412.29(d), (e), (h), and (i) and § 412.622(a)(3), (4), and (5) to add an exception for patients admitted solely for care furnished to patients in an IRF solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge during the PHE. We expect that the waiver required by the CARES Act will increase Medicare expenditures because it will increase the volume of patients admitted to IRFs and paid for under the IRF PPS. However, we do not expect that the other changes to § 412.29(d), (e), (h), and (i) and § 412.622(a)(3), (4), and (5) for freestanding IRF hospitals will increase the IRF volume of cases beyond the increases that will already be expected to occur as a result of the CARES Act. Moreover, these changes are likely to minimize exposure risks to patients, clinicians, and the general public. To the extent that Medicare expenditures increase, it would represent a transfer from the Federal Government to IRFs.

12. Shared Savings Program

Changes to the Shared Savings Program as described in section II.L. of this IFC are estimated to reduce program spending relative to a status quo baseline by preventing COVID-19-related treatment costs from causing highly variable and uncertain distortions in the calculation of shared savings and shared losses for individual ACOs and by offering flexibilities that are expected to help retain ACO participation in the face of broader uncertainties from the historic disruption caused by the COVID-19 pandemic. In modeling the impacts of these changes, we used ACO performance data from performance year 2018 to simulate 2020 performance, and

included assumptions for variation in COVID-19 spending and a decline in elective services and the deferral of other services. In modeling the impact of these changes, we considered the following:

- Based on a typical year, we assumed up to a 20 percent reduction in expenditures for 2020 because of a decline in elective services and the deferral of other services, and we assumed increases in expenditures due to COVID-19 inpatient treatment and related spending. We estimate that this variation in COVID-19 related spending would roughly double the standard deviation in gross measured savings and losses (expressed as a percentage of benchmark) that would have been determined across all ACOs participating in PY 2020.

- Absent flexibilities to encourage continued participation (by allowing a voluntary 1-year extension for ACOs whose agreement periods expire on December 31, 2020, and allowing ACOs to maintain participation at the same level of the BASIC track's glide path for performance year 2021) and an adjustment to certain program calculations to remove payment amounts for episodes of care for treatment of COVID-19, we project that up to 30 percent of all ACOs would elect to discontinue their participation. This would represent a significant increase in the program's attrition rate, which was 16 percent in 2019 and has been 11 percent on average.[65] Further, based on a recent National Association of ACOs (NAACOS) survey, 56 percent of risk-based ACOs may leave the program due to concerns about having to pay shared losses in 2020 because of costs incurred in treating COVID-19.[66]

A key new flexibility is the allowance for ACOs in the last performance year of their current agreement period (mainly Track 1 ACOs and Track 1+ Model ACOs) to elect to extend their agreement period by an additional performance year in 2021. The anticipated resulting

[65] Verma S. Number of ACOs Taking Downside Risk Doubles Under 'Pathways To Success'. *Health Affairs*. January 10, 2020. Available at https://www.healthaffairs.org/do/10.1377/hblog20200110.9101/full/
[66] NAACOS, Survey Shows ACOs' Concerns About the Effect of COVID-19. Available at https://www.naacos.com/assets/docs/pdf/2020/SurveyReportACO-EffectsCOVID19-04132020.pdf.

increase in retention of existing ACOs that would have otherwise been unlikely to renew in the face of pandemic uncertainty is estimated to lower net program spending (that is, increase federal savings) by $100 million (ranging from $90 to $120 million) despite potential increases in shared savings payments to certain ACOs that will benefit from the additional year under their existing agreement period for which the ACO's historical benchmark is established, adjusted, updated, and reset (as applicable) according to the methodologies specified in §§ 425.602 and 425.603.

Another important new flexibility allows certain ACOs to temporarily freeze their position along the BASIC track's glide path, which will allow some ACOs to avoid transitioning to a higher level of performance-based risk for performance year 2021. This flexibility is also estimated to decrease program spending (increase federal savings) mainly by reducing the chance that risk-averse ACOs would drop out of the Shared Savings Program rather than transition to a higher level of performance-based risk for performance year 2021. For example, ACOs opting to remain in Level B instead of transitioning to Level C or higher risk and reward (such as Level E, which qualifies as an Advanced APM) for performance year 2021 would in effect accept a lower savings sharing rate (and their participating ACO providers/suppliers would forgo potential incentive payments from qualifying as participating in an Advanced APM) in exchange for elimination of performance-based risk in the face of elevated uncertainty. The net effect of offering this flexibility is estimated to be a $60 million reduction in federal spending, with the reduction ranging from $0 to $170 million.

In modeling the impact of forgoing the application cycle for a January 1, 2021 agreement start date, we considered a combination of factors. Not offering an application cycle for a 2021 start date helps to mitigate any complexity arising from the use of 2020 as a benchmark year, when expenditures for 2020 could be extremely unusual given the COVID-19 pandemic and the related disruption to normal health care utilization. In particular, forgoing a January 1, 2021 agreement start date prevents 2020 serving as benchmark year 3, which is most heavily weighted

in the case of ACOs entering a first agreement period (§ 425.601(a)(7)).

In addition, maintaining an application cycle for a January 1, 2021 start date could result in a scenario where only a small number of organizations are able to devote resources to applying to participate (or renew their participation) in the Shared Savings Program given the impact of the COVID-19 pandemic on their operations and the challenges facing providers and suppliers. There is a particular risk that the unusual circumstances surrounding the COVID-19 pandemic could result in selective participation by only those ACOs that find their historical benchmark, for whatever reason, would provide for large windfall shared savings payments over a 5-year agreement period. Therefore, forgoing the application cycle for a January 1, 2021 start date is estimated to mitigate such selective participation and therefore reduce program spending by $150 million (with the reduction estimate ranging from $0 to $410 million).

The most significant impact is estimated to result from the new policy to adjust certain Shared Savings Program calculations to remove Parts A and B expenditures for episodes of care for treatment of COVID-19. Failing to remove this spending would likely create highly variable shared savings and shared losses results for individual ACOs that happen to have over-representation or under-representation of COVID-19-related hospitalizations in their assigned beneficiary population. At baseline, such variability would likely produce windfall payments to certain ACOs while causing other ACOs with significant exposure to COVID-19 in their assigned beneficiary populations to potentially leave the Shared Savings Program. Excluding expenditures for these episodes of care for treatment of COVID-19 from the specified financial calculations under the Shared Savings Program is anticipated to reduce program spending by $1,110 million (reduction estimate ranging from $560 to $1,710 million) mainly by preventing windfall payments of shared savings to ACOs favored by such extreme variation.

By reducing program spending (even at the low-magnitude end of the range of uncertainty), this change to exclude payment amounts for episodes of care for treatment of

COVID-19 necessarily satisfies the requirement under section 1899(i)(3)(B) of the Act that program spending not exceed spending that would have occurred under a hypothetical version of the program that would not have utilized flexibilities allowed under section 1899(i)(3) of the Act. The adjustments to expenditure and revenue calculations to mitigate the impact of COVID-19 that require the use of our authority under section 1899(i)(3) of the Act will only lower anticipated program spending further below the hypothetical baseline compared to what we have determined in previous rulemaking to meet the requirements of section 1899(i)(3)(B) of the Act.[67] Therefore, we believe that the adjustments to remove payment amounts for episodes of care for treatment of COVID-19 from the calculation of performance year expenditures, updates to the historical benchmark, and ACO participants' Medicare FFS revenue used to determine the loss sharing limit in the two-sided models of the BASIC track, meet the requirements for use of our authority under section 1899(i)(3) of the Act.

In total, the changes to the Shared Savings Program described in this IFC are estimated to reduce program spending by $1.43 billion over the 2020 to 2025 period (ranging from a reduction of $790 million to $2.12 billion), with most of the reduction ($1.11 billion) attributable to performance year 2020.

Table 2 provides our best estimate, net of shared savings payments to ACOs, of the change in resource use and transfers between the Federal Government and ACOs and ACO providers/suppliers as a result of the changes to the Shared Savings Program included in this IFC. The change in expenditures is classified as a net change in expenditures because it is a mix of transfers between the Federal Government and ACOs and other Medicare-enrolled providers, suppliers, and practitioners as well as real changes in resource use. At this time, we are unable to separately estimate transfers and real changes in resource use.

[67] See for example, 81 FR 38011 and 38012, and 83 FR 68060.

As shown Table 2, the net change in expenditures to the Federal Government associated with the Shared Savings Program policies in this IFC is estimated at -$1.1 billion for performance year 2020, -$0.13 billion for performance year 2021, -$0.05 billion for performance years 2022 and 2023, and -$0.04 billion for performance years 2024 and 2025. We present the estimates as undiscounted streams over 6 performance years rather than annualized streams because we estimate that more than 75 percent of the total change will accrue to performance year 2020.

TABLE 2: Estimated Net Savings to Medicare Program from Shared Savings Program Policies

Performance Year	Net Change in Expenditures
2020	-$1.11 billion
2021	-$0.13 billion
2022	-$0.05 billion
2023	-$0.05 billion
2024	-$0.04 billion
2025	-$0.04 billion

Note: Performance years co-occur with calendar years. Negative values reflect a reduction in federal net cost. Net change in expenditures includes both changes in real resource use and transfers between the Federal Government and ACOs and Medicare-enrolled suppliers, providers, and practitioners.

13. Additional Flexibility under the Teaching Physician Regulations

Section II.M. of this IFC discusses changes to allow teaching physicians to review the services furnished by residents, as required under the primary care exception rules, remotely through virtual means via interactive telecommunications technology during the PHE for COVID-19. This change will give teaching physicians additional flexibilities to direct the care furnished by residents remotely to minimize exposure risks to patients, clinicians, and the general public; and there would be no change in Medicare payment rates or change in the types of patients treated under this policy compared to the absence of this policy change. Aggregate Medicare expenditures could increase if the changes allow residents to furnish more services with remote supervision from teaching physicians. To the extent that Medicare expenditures

increase because residents furnish more services, this change will represent a cost to the Federal Government.

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

Section II.N. of this IFC increases payment rates, for the duration of the PHE for COVID-19, for telephone E/M visits to match payment rates under the PFS for office/outpatient visits with established patients. We expect that these increases in payment rates will not result in higher aggregate Medicare expenditures as long as these telephone E/M visits fully substitute during the pandemic for in-person or telehealth E/M visits that otherwise would have occurred. Absent the increase in payment rates, it is unlikely that telephone E/M visits would have served as an alternative for in-person or telehealth E/M visits to the same extent as could occur with the increase in payment rates. However, it is also possible that this provision would increase aggregate Medicare payments. For example, if the protections against exposure risk are effective, physicians may maintain their own health and thus be available to furnish more services overall. Improvements in the health of patients and physicians are intended benefits of this provision. If additional services are furnished, Medicare expenditures will increase, resulting in a cost to the Federal Government.

15. Flexibility for Medicaid Laboratory Services

Section II.O. of this IFC implements revisions to the Medicaid laboratory benefit at § 440.30 to provide states with flexibility to provide Medicaid coverage for laboratory tests and X-ray services that may not meet certain requirements in § 440.30(a) or (b) (such as the requirement that tests be furnished in an office or similar facility) during periods of a PHE resulting from an outbreak of communicable disease and during any subsequent periods of active surveillance. The purpose of such laboratory and X-ray services must be to diagnose or detect SARS-CoV-2, antibodies to SARS-CoV-2, COVID-19, or the communicable disease named in the PHE or its causes, and the deviation from the requirements in § 440.30 (a) or (b) must be

intended to avoid transmission of the communicable disease. This change is not estimated to have a significant impact on federal expenditures for the Medicaid program.

16. Improving Care Planning for Medicaid Home Health Services

Section II.P. of this IFC implements revisions to the Medicaid home health benefit at § 440.70 to expand the scope of practitioners who may order home health services. This change is not estimated to have a significant impact on federal expenditures for the Medicaid program.

17. Basic Health Program (BHP) Blueprint Revisions

Section II.Q. of this IFC provides flexibility to states that operate a BHP to seek certification of temporary revisions that make significant changes to their respective Blueprint that are directly tied to the PHE for the COVID-19 pandemic and increase access to coverage. A state operating a BHP can seek to apply these revisions retroactively to the start of the PHE for the COVID-19 pandemic. Such revisions would expire at the end of the PHE, or a reasonable later date as certified by HHS. This change is not estimated to have a significant impact on federal expenditures for the BHP.

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

Section II.R. of this IFC amends § 414.1400(b)(3)(v)(C) and (D) to delay the implementation of these policies by 1 year. Both QCDR measure approval criteria necessitate QCDRs collecting data from clinicians in order to assess the measure, and we anticipate that QCDRs may be unable to collect, and clinicians unable to submit, data on QCDR measures due to prioritizing the care of COVID-19 patients. This delay will not affect reporting burden for QDCRs or clinicians; therefore, there is no expected impact.

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

Section II.S.2. of this IFC exercises enforcement discretion for LCDs related to clinical

indications for therapeutic continuous glucose monitors. This policy may temporarily allow additional beneficiaries to be covered by Medicare for home use of therapeutic continuous glucose monitors during the PHE for the COVID-19 pandemic including diabetic patients with COVID-19 infections. While this should be a small and temporary increase in the use of therapeutic continuous glucose monitors it is possible that this increase will be offset by a reduction in hospitalizations. Additionally, patients using therapeutic continuous glucose monitors may be able to reduce their use of other diabetic testing supplies which could also contribute to offsetting costs.

20. Delay in the Compliance Date of Policies Adopted for the IRF QRP, LTCH QRP, HH QRP and SNF QRP

Section II.T. of this IFC delays certain reporting requirements for policies adopted for the IRF QRP, LTCH QRP, HH QRP, and SNF QRP. We do not anticipate any economic impact as a result of the delay.

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

Section II.U. of this IFC updates the Hospital VBP Program's ECE policy to more closely align that policy with the ECE policies of CMS' other hospital QRP and VBP program, and to also provide more flexibility to hospitals confronted with unforeseen extraordinary circumstances beyond their control. Under the current policy, a hospital must submit the Hospital VBP Program ECE request form, including any available evidence of the impact of the extraordinary circumstances on the hospital's quality measure performance, within 90 calendar days of the date on which the natural disaster or other extraordinary circumstance occurred (78 FR 50706). We are retaining this policy as well as introducing a new policy that allows us to grant an ECE to hospitals affected by an extraordinary circumstance, such as the COVID-19 PHE, within an entire region or locale without requiring that each affected hospital individually

submit an ECE request form.

The existing individual ECE request form policy is accounted for in the currently approved Hospital Inpatient Reporting PRA package, OMB control #0938-1022. There are no changes to the individual ECE request form policy and therefore no changes to the burden associated with the HVBP program.

The updated policy that allows CMS to grant exceptions for entire regions, including the entire United States, during an extraordinary circumstance, does not require hospitals to submit any documentation: therefore, we do not anticipate any change in burden or costs for the Hospital VBP Program based on the changes to the ECE policy set forth in this IFC.

22. COVID-19 Serology Testing

Section II.V. of this IFC provides for national coverage of COVID-19 FDA-authorized serology tests for certain Medicare beneficiaries during the PHE for the COVID-19 pandemic. It is unclear to what extent this test will increase Medicare expenditures. The cost to Medicare will be primarily dependent on the availability of testing, the price of the test and the length of the PHE. While the tests are new and have not previously been covered by Medicare it is possible that some of the cost of furnishing the test will be offset. As a result of serology testing there may be patients identified as not having had an immune response to COVID-19. If these patients take preventive measures to reduce their risk of infection as a result of this information then they may avoid COVID-19 infections, related hospitalizations and additional costs to Medicare.

23. Certification of Home Health Services – Revision to § 424.507

In section II.W. of this IFC, we discuss the provision to allow certain NPPs the ability to certify a patient's need for home health services. Previously only physicians were eligible to certify the need for home health under Medicare. The majority of NPPs are likely already enrolled in the Medicare program and will not need to take any additional enrollment actions. However, we estimate that approximately 5,000 currently unenrolled or non-opted out

NPs, CNSs, and PAs will elect to enroll in or opt-out of Medicare solely for the purpose of certifying home health services. We believe they will do so in the first year following the effective date of this IFC; moreover, 1,000 new NPs, CNSs, and PAs each year will enroll in or opt-out of Medicare for the same purpose.

24. Separate Billing and Segregation of Funds for Abortion Services

In light of the immediate need for QHP issuers and Exchanges to divert resources to responding to COVID-19, we are delaying implementation of the separate billing policy for 60 days as discussed in section II.X. of this IFC. Under this 60-day extension, QHP issuers must comply with the separate billing policies finalized at § 156.280(e)(2)(ii) beginning on or before their first billing cycle following August 26, 2020. We estimate that delaying the implementation deadline for the separate billing policies by 60 days will not result in substantial changes to the one-time implementation costs as estimated in the 2019 Program Integrity final rule. Some issuers and State Exchanges may have already sent notices to enrollees informing them of the separate billing and payment requirements and may now have to send additional notices to inform them of the change. In such cases, the reduction in ongoing costs will be lower. We request comment that would allow for refinement of the upfront and ongoing cost savings estimates. Reduction in costs directly related to printing and sending of separate bills for issuers and State Exchanges that perform premium billing and payment processing have been discussed previously in the "Collection of Requirements" section of this IFC.

In the 2019 Program Integrity final rule, we estimated that issuers and State Exchanges that perform premium billing and payment processing will each incur ongoing annual costs of approximately $1 million associated with activities such as processing and reconciling separate payments, support for enrollees who enter grace period for non-payments, customer service, outreach and compliance. Delaying the implementation by 60 days will reduce these ongoing costs by approximately $16.2 million for all 94 issuers and 3 State Exchanges that perform

premium billing and payment processing. We also estimated that each of the 12 State Exchanges will incur ongoing annual costs associated with increased customer service, outreach, and compliance, estimated to be approximately $200,000 for the 6 months in 2020. The 60-day delay in implementation will reduce these ongoing costs in 2020 by approximately $0.8 million for all 12 Exchanges. In addition, we estimated that the FFEs will incur ongoing costs of approximately $400,000 for the 6 months in 2020. The delay in implementation will reduce the ongoing costs in 2020 by approximately $133,333.

Consumers will also experience a reduction in burden. In the 2019 Program Integrity final rule, we estimated that issuers and State Exchanges performing premium billing and payment processing will be required to send a separate bill to approximately 2 million policy holders and that consumers will incur a burden of 5 minutes per month after the initial month to read and understand the separate bill. Delaying the implementation by 60 days will result in a burden reduction of 10 minutes (at a cost of $12.37 per hour) in 2020 for each consumer. For approximately 2 million policyholders, the total reduction in burden in 2020 will be approximately 337,793 hours with an equivalent cost savings of approximately $4.2 million.

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

Section II.Y. of this IFC revises the infection prevention and control requirements for LTC facilities to more effectively respond to the specific challenges posed by the COVID-19 pandemic. Specifically, we are adding provisions to require facilities to electronically report information related to confirmed or suspected COVID-19 cases in a standardized format and frequency specified by the Secretary and requiring facilities to inform residents and their representatives of confirmed or suspected COVID-19 cases in the facility among residents and staff. As discussed in the Collection of Information section, we expect a burden increase of $16,402,763 attributed to the CDC's NHSN collection (OMB Control #0920-1290).

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

Section II.Z. of this IFC implements a policy that for the duration of the PHE for the COVID-19 pandemic, the typical times for purposes of level selection for an office/outpatient E/M service furnished via telehealth are the times listed in the CPT code descriptor. We do not anticipate a change to Medicare expenditures as a result of this policy.

27. Updating the Medicare Telehealth List

Section II.AA. of this IFC revises the process during the PHE for COVID-19 by which CMS could add services to the Medicare telehealth list and that services added through the process would remain on the Medicare telehealth list during the PHE for COVID-19. This section does not add any services to the Medicare telehealth list. Therefore, we do not anticipate a change to Medicare expenditures.

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

Section II.BB. of this IFC describes a policy to make assessment and specimen collection for COVID-19 testing payable under the Medicare PFS and conditionally packaged under the OPPS for the duration of the PHE for COVID-19. Because these services were not previously payable under the Medicare PFS or conditionally packaged under the OPPS, Medicare expenditures will increase, representing a cost to the Federal Government. However, on net we estimate that greater testing combined with proper public health practices of physical distancing and isolation for exposed or infected individuals would result in fewer COVID-19 infections and consequently, this policy would reduce expenditures for the treatment of Medicare beneficiaries with COVID-19, which would be a benefit to the Federal Government.

29. Payment for Remote Physiologic Monitoring (RPM) Services furnished during the COVID-19 PHE

Section II.CC. of this IFC describes a policy, for the duration of the PHE for COVID-19, to allow the RPM monitoring service to be reported to Medicare for periods of time that are fewer than 16 days of 30 days, as long as the other requirements for billing the code are met. To the extent that this increases volume of the RPM monitoring service, this policy would increase Medicare expenditures, resulting in a cost to the Federal Government.

D. Accounting Statement

1. Medicare Program

As required by OMB Circular A–4 (available at https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf), in the following Table 3, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this IFC as they relate to the Medicare program.

TABLE 3: Accounting Statement: Classification of Estimated Transfers

Category	**Estimates**	**Units**		
		Year Dollar	**Discount Rate**	**Period Covered (CY)**
Transfers				
Annualized Monetized ($million/year)	-269.6	2019	7%	2020 - 2025
	-250.8	2019	3%	2020 - 2025
From Whom to Whom	Reduced transfer from Federal Government to ACOs and Medicare-enrolled suppliers, providers, and practitioners			

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 415

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 440

Grant programs-health, Medicaid.

42 CFR part 483

Grant programs-health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 484

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 600

Administration practice and procedure, Health care, Health insurance, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Brokers, Conflict of interests, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs-health, Medicaid, Organization and functions (Government agencies), Prescription drugs, Public assistance programs, Reporting and recordkeeping requirements, Sunshine Act, Technical assistance, Women, Youth.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 409—HOSPITAL INSURANCE BENEFITS

1. The authority citation for part 409 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

§ 409.41 [Amended]

2. Section 409.41 is amended in paragraph (b) by removing the phrase "the physician certification" and adding in its place the phrase "the certification".

§ 409.42 [Amended]

3. Section 409.42 is amended—

a. In the heading of paragraph (b) and in paragraphs (b) and (c) introductory text by removing the phrase “a physician” and adding in its place the phrase “a physician or allowed practitioner, as defined at § 484.2 of this chapter”.

b. In paragraph (c) introductory text by removing the phrase “the physician certification” and adding in its place the phrase “the certification”.

4. Section 409.43 is amended--

a. By revising paragraph (a) introductory text and (a)(1);

b. In paragraph (b), by removing the phrases "physician's orders" and "physician order" and adding in its place the phrases "physician or allowed practitioner’s orders" and "physician or allowed practitioner order", respectively;

c. In the heading of paragraph (c) and in paragraph (c)(1) introductory text by removing the term "physician" and adding in its place the phrase "physician or allowed practitioner";

d. In paragraph (c)(1)(i) introductory text by removing the phrase “physician’s order” and adding in its place the phrase "physician or allowed practitioner’s orders"; and

e. In paragraphs (d), (e)(1) introductory text, (e)(2) and (f) by removing the term

"physician" and adding in its place the phrase "physician or allowed practitioner".

The revision reads as follows:

§ 409.43 Plan of care requirements.

(a) *Contents.* An individualized plan of care must be established and periodically reviewed by the certifying physician or allowed practitioner, as defined at § 484.2 of this chapter.

(1) The HHA must be acting upon a plan of care that meets the requirements of this section for HHA services to be covered.

* * * * *

5. Section 409.44 is amended--

a. By revising paragraph (c)(1) introductory text;

b. In paragraphs (c)(2)(i)(D)(*1*), (c)(2)(i)(F)(*3*), and (c)(2)(iii)(A), by removing the term "physician" and adding in its place the term "physician or allowed practitioner";

c. In paragraph (c)(2)(iv) introductory text by—

i. Removing the phrase “physician’s assessment” and adding in its place the phrases "physician or allowed practitioner’s assessment"; and

ii. Removing the term "physician" and adding in its place the term "physician or allowed practitioner".

The revision reads as follows:

§ 409.44 Skilled services requirements.

* * * * *

(c) * * *

(1) Speech-language pathology services and physical or occupational therapy services must relate directly and specifically to a treatment regimen (established by the physician or allowed practitioner) after any needed consultation with the qualified therapist, that is designed to treat the beneficiary's illness or injury. Services related to activities for the general physical

welfare of beneficiaries (for example, exercises to promote overall fitness) do not constitute physical therapy, occupational therapy, or speech-language pathology services for Medicare purposes. To be covered by Medicare, all of the requirements apply as follows:

* * * * *

§ 409.45 [Amended]

6. Section 409.45 is amended—

a. In paragraph (a) by removing the term “physician” and adding in its place the phrase “physician or allowed practitioner”.

b. In paragraph (b)(1) introductory text by removing the phrase “physician’s order” and adding in its place the phrases "physician or allowed practitioner’s orders"; and

c. In paragraphs (b)(2)(i), (c)(1), and (g) by removing the term “physician” and add in its place the phrase “physician or allowed practitioner”.

§ 409.46 [Amended]

7. Section 409.46 is amended in paragraph (a) by removing the term “physician” and adding in its place the phrase “physician or allowed practitioner”.

§ 409.48 [Amended]

8. Section 409.48 is amended in paragraph (c)(1) by removing the term “physician” and adding in its place the phrase “physician or allowed practitioner”.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

9. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

10. Section 410.32 is amended--

a. In paragraph (a) introductory text by removing the phrase “All diagnostic x-ray tests, diagnostic laboratory tests” and adding in its place the phrase “Except as otherwise provided in this section, all diagnostic x-ray tests, diagnostic laboratory tests”;

b. By adding paragraph (a)(3);

c. By revising paragraphs (b)(1) and (b)(2)(iii)(B);

d. By adding paragraph (b)(2)(viii);

e. By revising paragraph (b)(3) introductory text;

f. By revising paragraphs (d)(2)(i) and (ii) introductory text; and

g. By revising paragraph (d)(3)(i) introductory text.

The revisions and additions read as follows:

§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

(a) * * *

(3) *Public Health Emergency exception.* During the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID-19 pandemic, the order of a physician or NPP is not required for otherwise covered diagnostic laboratory tests for COVID-19 and for otherwise covered diagnostic laboratory tests for influenza virus or similar respiratory condition needed to obtain a final COVID-19 diagnosis when performed in conjunction with COVID-19 diagnostic laboratory test in order to discount influenza virus or related diagnosis. FDA-authorized COVID-19 serology tests are included as covered tests during the Public Health Emergency, as defined in § 400.20 of this chapter, for the COVID-19 pandemic, as they are reasonable and necessary under section 1862(a)(1)(A) of the Act for beneficiaries with known current or known prior COVID-19 infection or suspected current or suspected prior COVID-19 infection.

(b) * * *

(1) *Basic rule*. Except as indicated in paragraph (b)(2) of this section, all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the Act or, during the Public Health Emergency as

defined in § 400.200 of this chapter, for the COVID-19 pandemic, by a nurse practitioner, clinical nurse specialist, physician assistant or a certified nurse-midwife to the extent that they are authorized to do so under applicable state law. Services furnished without the required level of supervision are not reasonable and necessary (see § 411.15(k)(1) of this chapter).

(2) * * *

(iii) * * *

(B) Furnished under the general supervision of a physician, clinical psychologist, or during the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID-19 pandemic, by a nurse practitioner, clinical nurse specialist, physician assistant or a certified nurse-midwife, to the extent that they are authorized to perform the tests under applicable State law.

* * * * *

(viii) During the COVID-19 Public Health Emergency as defined in § 400.200 of this chapter, diagnostic tests performed by a physician assistant authorized to perform the tests under applicable State law.

* * * * *

(3) *Levels of supervision.* Except where otherwise indicated, all diagnostic x-ray and other diagnostic tests subject to this provision and payable under the physician fee schedule must be furnished under at least a general level of supervision as defined in paragraph (b)(3)(i) of this section. In addition, some of these tests also require either direct or personal supervision as defined in paragraph (b)(3)(ii) or (iii) of this section, respectively. When direct or personal supervision is required, supervision at the specified level is required throughout the performance of the test.

* * * * *

(d) * * *

(2) * * *

(i) *Ordering the service.* Except for tests described in paragraph (a)(3) of this section, the physician (or qualified nonphysician practitioner, as defined in paragraph (a)(2) of this section), who orders the service must maintain documentation of medical necessity in the beneficiary's medical record.

(ii) *Submitting the claim.* Except for tests described in paragraph (a)(3) of this section, the entity submitting the claim must maintain the following documentation:

* * * * *

(3) * * *

(i) *Documentation requirements.* Except for tests described in paragraph (a)(3) introductory text, upon request by CMS, the entity submitting the claim must provide the following information:

* * * * *

11. Section 410.67 is amended in paragraph (b)(7) by adding a sentence at the end of the paragraph to read as follows:

§ 410.67 Medicare coverage and payment of Opioid use disorder treatment services furnished by Opioid treatment programs.

* * * * *

(b) * * *

(7) * * * During the Public Health Emergency for the COVID-19 pandemic, as defined in § 400.200 of this chapter, these periodic assessments can be furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all other applicable requirements. In cases where a beneficiary does not have access to two-way audio-video communications technology, periodic assessments can be furnished using audio-only telephone calls rather than via two-way interactive audio-video

communication technology if all other applicable requirements are met.

* * * * *

12. Section 410.78 is amended by revising paragraph (f) to read as follows:

§ 410.78 Telehealth services.

* * * * * *

(f) *Process for adding or deleting services.* Except as otherwise provided in this paragraph, changes to the list of Medicare telehealth services are made through the annual physician fee schedule rulemaking process. During the Public Health Emergency for the COVID-19 pandemic, as defined in § 400.200 of this chapter, we will use a subregulatory process to modify the services included on the Medicare telehealth list during the Public Health Emergency taking into consideration infection control, patient safety, and other public health concerns resulting from the emergency. A list of the services covered as telehealth services under this section is available on the CMS Web site.

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

13. The authority citation for part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

14. Section 412.29 is amended by revising paragraphs (d), (e), (h), and (i) to read as follows:

§ 412.29 Classification criteria for payment under the inpatient rehabilitation facility prospective payment system.

* * * * *

(d) Except for 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, as defined in § 412.622 of this chapter, during the Public Health Emergency, as defined in §

400.200 of this chapter, have in effect a preadmission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient hospital program. This procedure must ensure that the preadmission screening for each Medicare Part A fee-for-Service patient is reviewed and approved by a rehabilitation physician prior to the patient's admission to the IRF.

(e) Except for 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, as defined in § 412.622 of this chapter, during the Public Health Emergency, as defined in § 400.200 of this chapter, have in effect a procedure to ensure that patients receive close medical supervision, as evidenced by at least 3 face-to-face visits per week by a licensed physician with specialized training and experience in inpatient rehabilitation to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process except that during the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID-19 pandemic such visits may be conducted using telehealth services (as defined in section 1834(m)(4)(F) of the Act).

* * * * *

(h) Except for 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, as defined in § 412.622 of this chapter, during the Public Health Emergency, as defined in § 400.200 of this chapter, have a plan of treatment for each inpatient that is established, reviewed, and revised as needed by a physician in consultation with other professional personnel who provide services to the patient.

(i) Except for 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, as defined in § 412.622 of this chapter, during the Public Health Emergency, as defined in §

400.200 of this chapter, use a coordinated interdisciplinary team approach in the rehabilitation of each inpatient, as documented by the periodic clinical entries made in the patient's medical record to note the patient's status in relationship to goal attainment and discharge plans, and that team conferences are held at least once per week to determine the appropriateness of treatment.

* * * * *

15. Section 412.105 is amended by revising paragraphs (d)(1) and (f)(1)(iii)(A) to read as follows:

§ 412.105 Special treatment: Hospitals that incur indirect costs for graduate medical education programs.

* * * * *

(d) * * *

(1) *Step one*. A factor representing the sum of 1.00 plus the hospital's ratio of full-time equivalent residents to beds, as determined under paragraph (a)(1) of this section, excluding beds temporarily added during the time frame that the Public Health Emergency as defined in § 400.200 of this chapter is in effect, is raised to an exponential power equal to the factor set forth in paragraph (c) of this section.

* * * * *

(f) * * *

(1) * * *

(iii)(A) Full-time equivalent status is based on the total time necessary to fill a residency slot. No individual may be counted as more than one full-time equivalent. If a resident is assigned to more than one hospital, the resident counts as a partial full-time equivalent based on the proportion of time worked in any areas of the hospital listed in paragraph (f)(1)(ii) of this section to the total time worked by the resident. A hospital cannot claim the time spent by residents training at another hospital, unless the exception provided at § 413.78(i) of this chapter

applies. A part-time resident or one working in an area of the hospital other than those listed under paragraph (f)(1)(ii) of this section (such as a freestanding family practice center or an excluded hospital unit) would be counted as a partial full-time equivalent based on the proportion of time assigned to an area of the hospital listed in paragraph (f)(1)(ii) of this section, compared to the total time necessary to fill a full-time residency slot.

* * * * *

16. Section 412.165 is amended by adding paragraph (c) to read as follows —

§ 412.165 Performance scoring under the Hospital Value-Based Purchasing (VBP) Program.

* * * * *

(c) *Extraordinary circumstances exception*. (1) A hospital may request and CMS may grant exceptions to the Hospital VBP Program's requirements under this section when there are certain extraordinary circumstances beyond the control of the hospital.

(2) A hospital may request an exception within 90 calendar days of the date that the extraordinary circumstances occurred by submitting a completed Extraordinary Circumstances Request Form (available on the Hospital Value-Based Purchasing (HVBP) Program section of the QualityNet website (QualityNet.org)), and any available evidence of the impact of the extraordinary circumstances on the hospital's quality measure performance. The form must be sent via secure file transfer via the *QualityNet Secure portal*, secure fax, email, or conventional mail.

(3) Following receipt of the request form, CMS will provide a written acknowledgement using the contact information provided in the request, to the CEO and any additional designated personnel, notifying them that the hospital's request has been received, and provide a written response to the CEO and any additional designated personnel using the contact information provided in the request.

(4) CMS may grant an exception to one or more hospitals that have not requested an exception if CMS determines that an extraordinary circumstance has affected an entire region or locale, which may include the entire United States. CMS will notify hospitals that it has granted an exception under this paragraph via multiple methods, which may include memos, emails, and notices posted on the public QualityNet website (see https://www.qualitynet.org).

17. Section 412.622 is amended–

a. By revising paragraphs (a)(3)(i) through (iv), (a)(4) introductory text, and (a)(5) introductory text; and

b. In paragraph (c) by adding the definition of "State (or region, as applicable) that is experiencing a surge" in alphabetical order.

The revisions and addition read as follows:

§ 412.622 Basis of payment.

(a) * * *

(3) * * *

(i) Except for 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 Public Health Emergency, as defined in § 400.200 of this chapter, requires the active and ongoing therapeutic intervention of multiple therapy disciplines (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics therapy), one of which must be physical or occupational therapy.

(ii) Except during the emergency period described in section 1135(g)(1)(B) of the Act, generally requires and can reasonably be expected to actively participate in, and benefit from, an intensive rehabilitation therapy program. Under current industry standards, this intensive rehabilitation therapy program generally consists of at least 3 hours of therapy (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics therapy) per day at

least 5 days per week. In certain well-documented cases, this intensive rehabilitation therapy program might instead consist of at least 15 hours of intensive rehabilitation therapy within a 7-consecutive-day period, beginning with the date of admission to the IRF. Benefit from this intensive rehabilitation therapy program is demonstrated by measurable improvement that will be of practical value to the patient in improving the patient patient's functional capacity or adaptation to impairments. The required therapy treatments must begin within 36 hours from midnight of the day of admission to the IRF.

(iii) Except for 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 Public Health Emergency, as defined in § 400.200 of this chapter, is sufficiently stable at the time of admission to the IRF to be able to actively participate in the intensive rehabilitation therapy program that is described in paragraph (a)(3)(ii) of this section.

(iv) Except for 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 Public Health Emergency, as defined in § 400.200 of this chapter, requires physician supervision by a rehabilitation physician. The requirement for medical supervision means that the rehabilitation physician must conduct face-to-face visits with the patient at least 3 days per week throughout the patient 's stay in the IRF to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient’s capacity to benefit from the rehabilitation process except that during the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID-19 pandemic such visits may be conducted using telehealth services (as defined in section 1834(m)(4)(F) of the Act).The post-admission physician evaluation described in paragraph (a)(4)(ii) of this section may count as one of the face-to-face visits.

(4) *Documentation***.** Except for 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 Public Health Emergency, as defined in § 400.200 of this chapter, to document that each patient for whom the IRF seeks payment is reasonably expected to meet all of the requirements in paragraph (a)(3) of this section at the time of admission, the patient's medical record at the IRF must contain the following documentation –

* * * * *

(5) *Interdisciplinary team approach to care.* Except for 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 Public Health Emergency, as defined in § 400.200 of this chapter, in order for an IRF claim to be considered reasonable and necessary under section 1862(a)(1) of the Act, the patient must require an interdisciplinary team approach to care, as evidenced by documentation in the patients' medical record of weekly interdisciplinary team meetings that meet all of the following requirements –

* * * * *

(c) * * *

State (or region, as applicable) that is experiencing a surge means a state (or region, as applicable) that is in phase 1 of the President's Guidelines for Opening Up America Again (https://www.whitehouse.gov/openingamerica/), specifically, a state (or region, as applicable) that satisfies all of the following, as determined by applicable state and local officials:

(i) All vulnerable individuals continue to shelter in place.

(ii) Individuals continue social distancing.

(iii) Individuals avoid socializing in groups of more than 10.

(iv) Non-essential travel is minimized.

(v) Visits to senior living facilities and hospitals are prohibited.

(vi) Schools and organized youth activities remain closed.

PART 413— PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

18. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww.

19. Section 413.78 is amended by revising paragraph (b) and adding new paragraph (i) to read as follows:

§ 413.78 Direct GME payments: Determination of the total number of FTE residents.

* * * * *

(b) No individual may be counted as more than one FTE. A hospital cannot claim the time spent by residents training at another hospital, except as provided in paragraph (i) of this section. Except as provided in paragraphs (c), (d), and (e) of this section, if a resident spends time in more than one hospital or in a nonprovider setting, the resident counts as partial FTE based on the proportion of time worked at the hospital to the total time worked. A part-time resident counts as a partial FTE based on the proportion of allowable time worked compared to the total time necessary to fill a full-time internship or residency slot.

* * * * *

(i) For the time frame that the Public Health Emergency (as defined in § 400.200 of this chapter) associated with COVID-19 was in effect, a sending hospital can include FTE residents training at another hospital in its FTE count if all of the following conditions are met.

(1) The sending hospital sends the resident to the other hospital in response to the COVID-19 pandemic.

(2) The time spent by the resident training at the other hospital is in lieu of time that would have been spent in approved training at the sending hospital.

(3) The time that the resident spent training immediately prior to and/or subsequent to the time frame that the Public Health Emergency (as defined in § 400.200 of this chapter) associated with COVID-19 was in effect is included in the FTE count for the sending hospital.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

20. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

21. Section 414.210 is amended by--

a. Revising paragraph (g)(9)(iii) and (iv); and

b. Adding paragraph (g)(9)(v).

The revisions and addition read as follows:

§ 414.210 General payment rules.

* * * * *

(g) * * *

(9) * * *

(iii) For items and services furnished in rural areas and non-contiguous areas (Alaska, Hawaii, and U.S. territories) with dates of service from June 1, 2018 through December 31, 2020 or through the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later, based on the fee schedule amount for the area is equal to 50 percent of the adjusted payment amount established under this section and 50 percent of the unadjusted fee schedule amount.

(iv) For items and services furnished in areas other than rural or noncontiguous areas with dates of service from June 1, 2018 through March 5, 2020, based on the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section.

(v) For items and services furnished in areas other than rural or noncontiguous areas with dates of service from March 6, 2020, through the remainder of the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), based on the fee schedule amount for the area is equal to 75 percent of the adjusted payment amount established under this section and 25 percent of the unadjusted fee schedule amount. For items and services furnished in areas other than rural or noncontiguous areas with dates of service from the expiration date of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), through December 31, 2020, based on the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section.

* * * * *

§ 414.1400 [Amended]

22. Section 414.1400 is amended in paragraphs (b)(3)(v)(C) and (D) by removing the phrase that reads "Beginning with the 2021 performance period" and adding in its place the phrase "Beginning with the 2022 performance period".

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

23. The authority citation for part 415 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

24. Section 415.172 is amended by revising paragraphs (a) introductory text, (a)(2), and (b) to read as follows:

§ 415.172 Physician fee schedule payment for services of teaching physicians.

(a) *General rule.* If a resident participates in a service furnished in a teaching setting, physician fee schedule payment is made only if a teaching physician is present during the key portion of any service or procedure for which payment is sought. During the Public Health

Emergency, as defined in § 400.200 of this chapter, for the COVID-19 pandemic, if a resident participates in a service furnished in a teaching setting, physician fee schedule payment is made if a teaching physician is present during the key portion of the service using audio/video real-time communications technology for any service or procedure for which payment is sought.

* * * * *

(2) In the case of evaluation and management services, the teaching physician must be present during the portion of the service that determines the level of service billed. (However, in the case of evaluation and management services furnished in hospital outpatient departments and certain other ambulatory settings, the requirements of § 415.174 apply.) During the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID-19 pandemic, the teaching physician may be present during the portion of the service that determines the level of service billed using audio/video real-time communications technology. (However, in the case of evaluation and management services furnished in hospital outpatient departments and certain other ambulatory settings, the requirements of § 415.174 apply.)

(b) *Documentation*. Except for services furnished as set forth in §§ 415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), 415.176 (concerning renal dialysis services), and 415.184 (concerning psychiatric services), the medical records must document the teaching physician was present at the time the service is furnished. The presence of the teaching physician during procedures and evaluation and management services may be demonstrated by the notes in the medical records made by the physician or as provided in § 410.20(e) of this chapter. During the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID-19 pandemic, except for services furnished as set forth in §§ 415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), 415.176 (concerning renal dialysis services), and 415.184 (concerning psychiatric services), the medical records must document if the teaching physician

was physically present or if the teaching physician was present through audio/video real-time communications technology at the time the service is furnished. The presence of the teaching physician during procedures and evaluation and management services may be demonstrated by the notes in the medical records made by the physician or as provided in § 410.20(e) of this chapter.

* * * * *

25. Section 415.174 is amended by revising paragraph (b) and adding paragraph (c) to read as follows:

§ 415.174 Exception: Evaluation and management services furnished in certain centers.

* * * * *

(b) Nothing in paragraph (a) of this section may be construed as providing a basis for the coverage of services not determined to be covered under Medicare, such as routine physical check-ups.

(c) During the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID-19 pandemic, the requirements in paragraph (a)(3) of this section for a teaching physician to direct the care and then to review the services furnished by each resident during or immediately after each visit may be met using audio/video real-time communications technology.

26. Section 415.180 is revised to read as follows:

§ 415.180 Teaching setting requirements for the interpretation of diagnostic radiology and other diagnostic tests.

(a) *General rule*. Physician fee schedule payment is made for the interpretation of diagnostic radiology and other diagnostic tests if the interpretation is performed or reviewed by a physician other than a resident. During the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID-19 pandemic, physician fee schedule payment may also be made for

the interpretation of diagnostic radiology and other diagnostic tests if the interpretation is performed by a resident when the teaching physician is present through audio/video real-time communications technology.

(b) [Reserved]

27. Section 415.184 is revised to read as follows:

§ 415.184 Psychiatric services.

To qualify for physician fee schedule payment for psychiatric services furnished under an approved GME program, the physician must meet the requirements of §§ 415.170 and 415.172, including documentation, except that the requirement for the presence of the teaching physician during the service in which a resident is involved may be met by observation of the service by use of a one-way mirror, video equipment, or similar device. During the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID-19 pandemic, the requirement for the presence of the teaching physician during the service in which a resident is involved may be met by direct supervision by audio/video real-time communications technology.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

28. The authority citation for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

29. Section 424.22 is amended—

a. By revising the introductory text;

b. In paragraphs (a)(1) introductory text and (a)(1)(i), by removing the term “physician” each time it appears and adding in its place the phrase “physician or allowed practitioner”;

c. In paragraph (a)(1)(i) by removing the phrase “physician’s signature” each time it appears and adding in its place the phrase "physician or allowed practitioner’s signature";

d. By revising paragraph (a)(1)(iii), (iv), (v) introductory text and (a)(1)(v)(A)(*1*);

e. By removing paragraph (a)(1)(v)(A)(*2*);

f. By redesignating paragraphs (a)(1)(v)(A)(*3*) through (*5*) as paragraphs (a)(1)(v)(A)(*2*) through (*4*), respectively;

g. By revising newly redesignated paragraphs (a)(1)(v)(A)(*2*) through (*4*).

h. By adding paragraph (a)(1)(v)(C);

i. In paragraphs (a)(2), (b)(1) introductory text, (b)(2) introductory text, and (b)(2)(ii) introductory text, by removing the term “physician” and adding in its place the phrase “physician or allowed practitioner”;

j. In paragraph (b)(2)(ii)(A) by removing the phrase “physician’s signature” and adding in its place the phrase "physician or allowed practitioner’s signature";

k. By revising paragraph (b)(2)(ii)(B);

l. In paragraphs (c)(1) introductory text by removing the phrase “physician’s medical records” and adding in its place the phrase "physician or allowed practitioner’s medical record";

m. In paragraph (c)(1)(i) by removing the phrase “physician’s medical record” and adding in its place the phrase “physician or allowed practitioner’s medical record”;

n. In paragraph (c)(1)(ii)(A) by removing the term “physician” and adding in its place the phrase “physician or allowed practitioner”;

o. In the heading of paragraph (d) by removing the term "physician" and adding in its place the phrase “physician or allowed practitioner’s”;

p. In paragraphs (d) introductory text by removing the term "physician" and adding in its place the phrase “physician or allowed practitioner”; and by removing the term “physician’s” adding in its place the phrase “physician or allowed practitioner’s”; and

q. In paragraph (d)(1) by removing the term "physician" each time it appears and adding in its place the phrase “physician or allowed practitioner”.

The revisions and addition read as follows:

§ 424.22 Requirements for home health services.

Medicare Part A or Part B pays for home health services only if a physician or allowed practitioner as defined at § 484.2 of this chapter certifies and recertifies the content specified in paragraphs (a)(1) and (b)(2) of this section, as appropriate.

(a) * * *

(1) * * *

(iii) A plan for furnishing the services has been established and will be or was periodically reviewed by a physician or allowed practitioner and who is not precluded from performing this function under paragraph (d) of this section.

(iv) The services will be or were furnished while the individual was under the care of a physician or allowed practitioner.

(v) A face-to-face patient encounter, which is related to the primary reason the patient requires home health services, occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care and was performed by physician or non-physician practitioner defined in paragraph (a)(1)(v)(A) of this section. The certifying physician or certifying allowed practitioner must also document the date of the encounter as part of the certification.

(A) * * *

(*1*) The certifying physician (as defined at § 484.2 of this chapter) or a physician, with privileges, who cared for the patient in an acute or post-acute care facility from which the patient was directly admitted to home health.

(*2*) The certifying nurse practitioner (as defined at § 484.2 of this chapter), certifying clinical nurse specialist (as defined at § 484.2 of this chapter), or a nurse practitioner or a clinical nurse specialist who is working in accordance with State law and in collaboration with a physician or in collaboration with an acute or post-acute care physician with privileges who cared for the patient in the acute or post-acute care facility from which the patient was directly

admitted to home health.

(*3*) A certified nurse midwife (as defined in section 1861(gg) of the Act) as authorized by State law, under the supervision of a physician or under the supervision of an acute or post-acute care physician with privileges who cared for the patient in the acute or post-acute care facility from which the patient was directly admitted to home health.

(*4*) A certifying physician assistant (as defined at § 484.2 of this chapter) or a physician assistant under the supervision of a physician or under the supervision of an acute or post-acute care physician with privileges who cared for the patient in the acute or post-acute care facility from which the patient was directly admitted to home health.

* * * * *

(C) The face-to-face patient encounter must be performed by the certifying physician or allowed practitioner unless the encounter is performed by:

(*1*) A certified nurse midwife as described in paragraph (a)(1)(v)(A)(4) of this section.

(*2*) A physician, physician assistant, nurse practitioner, or clinical nurse specialist with privileges who cared for the patient in the acute or post-acute facility from which the patient was directly admitted to home health and who is different from the certifying practitioner.

* * * * *

(b) * * *

(2) * * *

(ii) * * *

(B) Exists as an addendum to the recertification form, in addition to the physician or allowed practitioner's signature on the recertification form, the physician or allowed practitioner must sign immediately following the narrative in the addendum.

* * * * *

30. Section 424.507 is amended by revising paragraph (b)(1) introductory text to read as

follows:

§ 424.507 Ordering covered items and services for Medicare beneficiaries.

* * * * *

(b) * * *

(1) The ordering/certifying physician, or the ordering/certifying physician assistant, nurse practitioner, or clinical nurse specialist working in accordance with State law, must meet all of the following requirements:

* * * * *

PART 425—MEDICARE SHARED SAVINGS PROGRAM

31. The authority citation for part 425 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

32. Section 425.200 is amended by revising paragraph (b)(3)(ii) to read as follows:

§ 425.200 Participation agreement with CMS.

* * * * *

(b) * * *

(3) * * *

(ii) The term of the participation agreement is 3 years, except as follows:

(A) For an ACO whose first agreement period in Track 1 began in 2014 or 2015, in which case the term of the ACO's initial agreement period under Track 1 (as described under § 425.604) may be extended, at the ACO's option, for an additional year for a total of 4 performance years if the conditions specified in paragraph (e) of this section are met.

(B) For an ACO whose agreement period started on January 1, 2018, the term of the participation agreement is extended by 12 months if both of the following conditions are met:

(*1*) The ACO elects to extend the participation agreement for a fourth performance year until December 31, 2021.

(*2*) The ACO's election to extend its agreement period is made in the form and manner and by a deadline established by CMS.

* * * * *

33. Section 425.400 is amended by adding paragraph (c)(2) to read as follows:

§ 425.400 General.

* * * * *

(c) * * *

(2) For the performance year starting on January 1, 2020, and for any subsequent performance year that starts during the COVID-19 Public Health Emergency defined in § 400.200, in determining beneficiary assignment, we use the primary care service codes identified in paragraph (c)(1) of this section, and additional primary care service codes as follows:

(i) CPT codes:

(A) 99421, 99422, and 99423 (codes for online digital evaluation and management services).

(B) 99441, 99442, and 99443 (codes for telephone evaluation and management services).

(ii) HCPCS codes:

(A) G2010 (code for remote evaluation of patient video/images).

(B) G2012 (code for virtual check-in).

34. Section 425.600 is amended by--

a. Redesignating paragraph (a)(4)(i)(B)(*2*)(*iii*) as paragraph (a)(4)(i)(B)(*2*)(*iv)*; and

b. Adding new paragraph (a)(4)(i)(B)(*2*)(*iii*).

The addition reads as follows:

§ 425.600 Selection of risk model.

(a) * * *

(4) * * *

(i) * * *

(B) * * *

(*2*) * * *

(*iii*) Exception for ACOs participating in the BASIC track's glide path that elect to maintain their participation level for performance year 2021. Prior to the automatic advancement for performance year 2021, an ACO that is participating in the BASIC track's glide path for performance year 2020 may elect to remain in the same level of the BASIC track's glide path that it entered for the 2020 performance year, for performance year 2021. For performance year 2022, the ACO is automatically advanced to the level of the BASIC track's glide path to which the ACO would have automatically advanced absent the election to maintain its participation level for performance year 2021, unless the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i). A voluntary election by an ACO under this paragraph must be made in the form and manner and by a deadline established by CMS.

* * * * *

35. Section 425.611 is added to read as follows:

§ 425.611 Adjustments to Shared Savings Program calculations to address the COVID-19 pandemic.

(a) *General.* This section describes adjustments CMS makes to Shared Savings Program calculations to address the impact of the COVID-19 pandemic.

(b) *Episodes of care for treatment of COVID-19.* (1) CMS identifies an episode of care for treatment of COVID-19 based on either of the following:

(i) Discharges for inpatient services eligible for the 20 percent adjustment under section 1886(d)(4)(C) of the Act.

(ii) Discharges for acute care inpatient services for treatment of COVID-19 from facilities that are not paid under the inpatient prospective payment system, such as CAHs, when the date of admission occurs within the Public Health Emergency as defined in § 400.200 of this chapter.

(2) CMS defines the episode of care as starting in the month in which the inpatient stay begins as identified by the admission date, all months during the inpatient stay, and the month following the end of the inpatient stay as indicated by the discharge date.

(c) *Applicability of adjustments.* Notwithstanding any other provision in this part, CMS adjusts the following Shared Savings Program calculations to exclude all Parts A and B fee-for-service payment amounts for a beneficiary's episode of care for treatment of COVID-19 as described in paragraph (b) of this section:

(1) Calculation of Medicare Parts A and B fee-for-service expenditures for an ACO's assigned beneficiaries for all purposes including the following: establishing, adjusting, updating, and resetting the ACO's historical benchmark and determining performance year expenditures.

(2) Calculation of fee-for-service expenditures for assignable beneficiaries as used in determining county-level fee-for-service expenditures and national Medicare fee-for-service expenditures, including the following calculations:

(i) Determining average county fee-for-service expenditures based on expenditures for the assignable population of beneficiaries in each county in the ACO's regional service area according to §§ 425.601(c) and 425.603(e) for purposes of calculating the ACO's regional fee-for-service expenditures.

(ii) Determining the 99th percentile of national Medicare fee-for-service expenditures for assignable beneficiaries for purposes of the following:

(A) Truncating assigned beneficiary expenditures used in calculating benchmark expenditures under §§ 425.601(a)(4), 425.602(a)(4), 425.603(c)(4), and performance year expenditures under §§ 425.604(a)(4), 425.605(a)(3), 425.606(a)(4), 425.610(a)(4).

(B) Truncating expenditures for assignable beneficiaries in each county for purposes of determining county fee-for-service expenditures according to §§ 425.601(c)(3) and 425.603(e)(3).

(iii) Determining 5 percent of national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program for assignable beneficiaries for purposes of capping the regional adjustment to the ACO's historical benchmark according to § 425.601(a)(8)(ii)(C).

(iv) Determining the flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program for assignable beneficiaries, for purposes of updating the ACO's historical benchmark according to § 425.602(b)(2).

(v) Determining national growth rates that are used as part of the blended growth rates used to trend forward BY1 and BY2 expenditures to BY3 according to § 425.601(a)(5)(ii) and as part of the blended growth rates used to trend the benchmark and update the benchmark according to § 425.601(b)(2).

(3) Calculation of Medicare Parts A and B fee-for-service revenue of ACO participants for purposes of calculating the ACO's loss recoupment limit under the BASIC track as specified in § 425.605(d).

(4) Calculation of total Medicare Parts A and B fee-for-service revenue of ACO participants and total Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries for purposes of identifying whether an ACO is a high revenue ACO or low revenue ACO, as defined under § 425.20, and determining an ACO's eligibility for participation options according to § 425.600(d).

(5) Calculation or recalculation of the amount of the ACO's repayment mechanism arrangement according to § 425.204(f)(4).

PART 440—SERVICES: GENERAL PROVISIONS

36. The authority citation for part 440 continues to read as follows:

Authority: 42 U.S.C. 1302.

37. Section 440.30 is amended by adding paragraph (d) to read as follows:

§ 440.30 Other laboratory and X-ray services.

* * * * *

(d) During the Public Health Emergency defined in 42 CFR 400.200 or any future Public Health Emergency resulting from an outbreak of communicable disease, and during any subsequent period of active surveillance (as defined in this paragraph), Medicaid coverage is available for laboratory tests and X-ray services that do not meet conditions specified in paragraphs (a) or (b) of this section, if the purpose of such laboratory and X-ray services is to diagnose or detect SARS-CoV-2, antibodies to SARS-CoV-2, COVID-19, or the communicable disease named in the Public Health Emergency or its causes, and if the deviation from the conditions specified in paragraphs (a) or (b) of this section is intended to avoid transmission of the communicable disease. For purposes of this paragraph, a period of active surveillance is defined 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. Additionally, during the Public Health Emergency defined in 42 CFR 400.200 or any future Public Health Emergency resulting from an outbreak of communicable disease, and during any subsequent period of active surveillance (as defined in this paragraph), Medicaid coverage is available for laboratory processing of self-collected laboratory test systems that are authorized by the FDA for home use, if available to diagnose or detect SARS-CoV-2, antibodies to SARS-CoV-2, COVID-19, or the communicable disease named in the Public Health Emergency or its causes, even if those self-collected tests would not otherwise meet the requirements of

paragraphs (a) or (b) of this section, provided that the self-collection of the test is intended to avoid transmission of the communicable disease. If, pursuant to this paragraph, a laboratory processes a self-collected test system that is authorized by the FDA for home use, and the test system does not meet the conditions in paragraph (a) of this section, the laboratory must notify the patient and the patient's physician or other licensed non-physician practitioner (if known by the laboratory), of the results.

38. Section 440.70 is amended—

a. By revising paragraph (a)(2);

b. By adding paragraph (a)(3);

c. By revising paragraph (b)(1)(ii);

d. In paragraph (b)(3)(iii), by removing the phrase "for the period of the Public Health Emergency";

e. In paragraph (b)(3)(iv), by removing the phrase "for the period of the Public Health Emergency";

f. By revising paragraphs (f) introductory text and (f)(3)(i);

g. In paragraph (f)(3)(ii) and (iv), by removing the phrase "under the supervision of the physician referenced in paragraph (a) of this section" and adding in its place the phrase "in accordance with State law";

h. By adding paragraph (f)(3)(vi);

i. By revising paragraphs (f)(4);

j. In paragraph (f)(5) introductory text, by removing the phrase "the physician responsible" and adding in its place the phrase "the practitioner responsible"; and

k. By revising paragraph (g)(1).

The revisions and addition read as follows:

§ 440.70 Home health services.

* * * * *

(a) * * *

(2) On orders written by a physician, nurse practitioner, clinical nurse specialist or physician assistant, working in accordance with State law, as part of a written plan of care that the ordering practitioner reviews every 60 days for services described in (b)(1), (2) and (4) of this section; and

(3) On his or her physician's orders or orders written by a licensed practitioner of the healing arts acting within the scope of practice authorized under State law, as part of a written plan of care for services described in paragraph (b)(3) of this section. The plan of care must be reviewed by the ordering practitioner as specified in paragraph (b)(3)(iii) of this section.

(b) * * *

(1) * * *

(ii) Receives written orders from the patient's practitioner as defined in (a)(2) of this section;

* * * * *

(f) No payment may be made for services referenced in paragraphs (b)(1) through (4) of this section, unless a practitioner referenced in paragraph (a)(2) of this section or for medical equipment, a practitioner described in paragraph (a)(3) of this section documents that there was a face-to-face encounter with the beneficiary that meets the following requirements

* * * * *

(3) * * *

(i) A physician;

* * * * *

(vi) For medical equipment, supplies, or appliances, a licensed practitioner of the healing

arts acting within the scope of practice authorized under state law.

* * * * *

(4) If State law does not allow the non-physician practitioner, as described in paragraphs (f)(3)(ii) through (vi) of this section, to perform the face-to-face encounter independently, the non-physician practitioner must communicate the clinical findings of that face-to-face encounter to the ordering physician. Those clinical findings must be incorporated into a written or electronic document included in the beneficiary's medical record.

* * * * *

(g)(1) No payment may be made for medical equipment, supplies, or appliances referenced in paragraph (b)(3) of this section to the extent that a face-to-face encounter requirement would apply as durable medical equipment (DME) under the Medicare program, unless a practitioner referenced in paragraph (a)(3) of this section documents a face-to-face encounter with the beneficiary consistent with the requirements of paragraph (f) of this section except as indicated in paragraph (g)(2) of this section.

* * * * *

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

39. The authority citation continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a-7, 1395i, 1395hh and 1396r.

40. Section 483.80 is amended by adding paragraph (g) to read as follows:

§ 483.80 Infection control.

* * * * *

(g) *COVID-19 reporting*. The facility must--

(1) Electronically report information about COVID-19 in a standardized format specified by the Secretary. This report must include but is not limited to—

(i) Suspected and confirmed COVID-19 infections among residents and staff, including

residents previously treated for COVID-19;

(ii) Total deaths and COVID-19 deaths among residents and staff;

(iii) Personal protective equipment and hand hygiene supplies in the facility;

(iv) Ventilator capacity and supplies in the facility;

(v) Resident beds and census;

(vi) Access to COVID-19 testing while the resident is in the facility;

(vii) Staffing shortages; and

(viii) Other information specified by the Secretary.

(2) Provide the information specified in paragraph (g)(1) of this section at a frequency specified by the Secretary, but no less than weekly to the Centers for Disease Control and Prevention's National Healthcare Safety Network. This information will be posted publicly by CMS to support protecting the health and safety of residents, personnel, and the general public.

(3) Inform residents, their representatives, and families of those residing in facilities by 5 p.m. the next calendar day following the occurrence of either a single confirmed infection of COVID-19, or three or more residents or staff with new-onset of respiratory symptoms occurring within 72 hours of each other. This information must—

(i) Not include personally identifiable information;

(ii) Include information on mitigating actions implemented to prevent or reduce the risk of transmission, including if normal operations of the facility will be altered; and

(iii) Include any cumulative updates for residents, their representatives, and families at least weekly or by 5 p.m. the next calendar day following the subsequent occurrence of either: each time a confirmed infection of COVID-19 is identified, or whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other.

* * * * *

PART 484—HOME HEALTH SERVICES

41. The authority citation for part 484 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

42. Section 484.2 is amended by—

a. Adding the definitions of "Allowed practitioner", "Clinical nurse specialist", "Nurse practitioner", "Physician", and "Physician assistant" in alphabetical order; and

b. Revising the definitions of "Summary report" and "Verbal order".

The additions and revisions read as follows:

§ 484.2 Definitions.

* * * * *

Allowed practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as defined at this part.

* * * * *

Clinical nurse specialist means an individual as defined at § 410.76(a) and (b) of this chapter, and who is working in collaboration with the physician as defined at § 410.76(c)(3) of this chapter.

* * * * *

Nurse practitioner means an individual as defined at § 410.75(a) and (b) of this chapter, and who is working in collaboration with the physician as defined at § 410.75(c)(3) of this chapter.

* * * * *

Physician is a doctor of medicine, osteopathy, or podiatric medicine, and who is not precluded from performing this function under paragraph (d) of this section. (A doctor of podiatric medicine may perform only plan of treatment functions that are consistent with the functions he or she is authorized to perform under State law.)

Physician assistant means an individual as defined at § 410.74(a) and (c) of this chapter.

* * * * *

Summary report means the compilation of the pertinent factors of a patient's clinical notes that is submitted to the patient's physician, physician assistant, nurse practitioner, or clinical nurse specialist.

* * * * *

Verbal order means a physician, physician assistant, nurse practitioner, or clinical nurse specialist order that is spoken to appropriate personnel and later put in writing for the purposes of documenting as well as establishing or revising the patient's plan of care.

§ 484.50 [Amended]

43. Section 484.50 is amended in paragraphs (d)(1) and (3) by removing the term "physician" and adding in its place the phrase "physician or allowed practitioner".

§ 484.55 [Amended]

44. Section 484.55 is amended in paragraphs (a)(1), (b)(3) and (d)(2) by removing the term "physician" and add in its place the phrase "physician or allowed practitioner".

45. Section 484.60 is amended—

a. By revising paragraphs (a)(1), (a)(2)(xvi), (b) and (c)(1); and

b. In paragraphs (c)(3)(i), (c)(3)(ii), (d)(1), and (d)(2), by removing the term "physicians" and adding in its place the phrase "physicians or allowed practitioners".

The revisions read as follows:

§ 484.60 Condition of participation: Care planning, coordination of services, and quality of care.

* * * * *

(a) * * *

(1) Each patient must receive the home health services that are written in an individualized plan of care that identifies patient-specific measurable outcomes and goals, and

which is established, periodically reviewed, and signed by a doctor of medicine, osteopathy, or podiatry or allowed practitioner acting within the scope of his or her state license, certification, or registration. If a physician or allowed practitioner refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician or allowed practitioner is consulted to approve additions or modifications to the original plan.

(2) * * *

(xvi) Any additional items the HHA or physician or allowed practitioner may choose to include.

(b) *Standard: Conformance with physician or allowed practitioner orders.* (1) Drugs, services, and treatments are administered only as ordered by a physician or allowed practitioner.

(2) Influenza and pneumococcal vaccines may be administered per agency policy developed in consultation with a physician, physician assistant, nurse practitioner, or clinical nurse specialist, and after an assessment of the patient to determine for contraindications.

(3) Verbal orders must be accepted only by personnel authorized to do so by applicable state laws and regulations and by the HHA's internal policies.

(4) When services are provided on the basis of a physician or allowed practitioner's verbal orders, a nurse acting in accordance with state licensure requirements, or other qualified practitioner responsible for furnishing or supervising the ordered services, in accordance with state law and the HHA's policies, must document the orders in the patient's clinical record, and sign, date, and time the orders. Verbal orders must be authenticated and dated by the physician or allowed practitioner in accordance with applicable state laws and regulations, as well as the HHA's internal policies.

(c) * * *

(1) The individualized plan of care must be reviewed and revised by the physician or allowed practitioner who is responsible for the home health plan of care and the HHA as

frequently as the patient's condition or needs require, but no less frequently than once every 60 days, beginning with the start of care date. The HHA must promptly alert the relevant physician(s) or allowed practitioner(s) to any changes in the patient's condition or needs that suggest that outcomes are not being achieved and/or that the plan of care should be altered.

* * * * *

§ 484.75 [Amended]

46. Section 484.75 is amended in the introductory text and paragraph (b)(3), by removing the term “physician” and adding in its place the phrase “physician or allowed practitioner”.

§ 484.80 [Amended]

47. Section 484.80 is amended in paragraph (g)(2)(i) by removing the term “physician;” and adding in its place the phrase “physician or allowed practitioner;”.

§ 484.205 [Amended]

48. Section 484.205 is amended--

a. In paragraphs (h)(1)(ii) by removing the term “physician’s” and adding in its place the phrase “physician or allowed practitioner’s”;

b. In paragraphs (h)(1)(iii) and (h)(2) introductory text, by removing the term “physician” and adding in its place the phrase “physician or allowed practitioner”; and

c. In paragraphs (i)(2)(i), and (j)(2)(i) by removing the term “physician’s” and adding in its place the phrase “physician or allowed practitioner’s”.

§ 484.235 [Amended]

49. Section 484.235 is amended--

a. In paragraphs (a)(1) and (3) by removing the term “physician” and adding in its place the phrase “physician or allowed practitioner”;

b. In paragraphs (b)(1) and (b)(3) by removing the phrase “assessment and physician

certification" and adding in its place the phrase "assessment and certification"; and

c. In paragraph (b)(3) by removing the term "physician" and adding in its place the phrase "physician or allowed practitioner".

50. Section 484.315 is amended by revising paragraph (b) to read as follows:

§ 484.315 Data reporting for measures and evaluation and the public reporting of model data under the Home Health Value-Based Purchasing (HHVBP) Model

* * * * *

(b) Competing home health agencies in selected states will be required to report information on New Measures, as determined appropriate by the Secretary, to CMS in the form, manner, and at a time specified by the Secretary, and subject to any exceptions or extensions CMS may grant to home health agencies for the Public Health Emergency as defined in § 400.200 of this chapter.

* * * * *

PART 600 - ADMINISTRATION, ELIGIBILITY, ESSENTIAL HEALTH BENEFITS, PERFORMANCE STANDARDS, SERVICE DELIVERY REQUIREMENTS, PREMIUM AND COST SHARING, ALLOTMENTS, AND RECONCILIATION

51. The authority citation for part 600 continues to read as follows:

Authority: Section 1331 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148, 124 Stat. 119), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111 – 152, 124 State. 1029).

52. Section 600.125 is amended by revising paragraph (b) and adding paragraph (c) to read as follows:

§ 600.125 Revisions to a certified BHP Blueprint.

* * * * *

(b) *Continued operations*. The state is responsible for continuing to operate under the terms of the existing certified Blueprint until and unless a revised Blueprint that seeks to make significant change(s) is certified, except as specified in paragraph (c) of this section.

(c) *Public health emergency.* For the Public Health Emergency, as defined in § 400.200 of this chapter, the State may submit to the Secretary for review and certification a revised Blueprint, in the form and manner specified by HHS, that makes temporary significant changes to its BHP that are directly related to the Public Health Emergency and would increase enrollee access to coverage. Such revised Blueprints may have an effective date retroactive to the first day of the Public Health Emergency and through the last day of the Public Health Emergency, or a later date if requested by the state and certified by HHS. Such revised Blueprints are not subject to the public comment requirements under § 600.115(c).

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR as set forth below:

PART 156 – HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

53. The authority citation for part 156 continues to read as follows:

Authority: 42 U.S.C. 18021-18024, 18031-18032, 18041-18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701.

54. Section 156.280 is amended by revising paragraph (e)(2)(ii) introductory text to read as follows:

§ 156.280 Separate billing and segregation of funds for abortion services.

* * * * *

(e) * * *

(2) * * *

(ii) Beginning on or before the first billing cycle following August 26, 2020, to satisfy the obligation in paragraph (e)(2)(i) of this section—

* * * * *

Dated: April 24, 2020.

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Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: April 28, 2020.

_____

Alex M. Azar II,

Secretary,

Department of Health and Human Services.