

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services**

42 CFR Parts 410, 413, 414, 422, 423, 482, 483, 485, 488 and 493

[CMS-3401-IFC]

RIN 0938-AU33

Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

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

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period (IFC) revises regulations to strengthen CMS' ability to enforce compliance with Medicare and Medicaid long-term care (LTC) facility requirements for reporting information related to coronavirus disease 2019 (COVID-19), establishes a new requirement for LTC facilities for COVID-19 testing of facility residents and staff, establishes new requirements in the hospital and critical access hospital (CAH) Conditions of Participation (CoPs) for tracking the incidence and impact of COVID-19 to assist public health officials in detecting outbreaks and saving lives, and establishes requirements for all CLIA laboratories to report COVID-19 test results to the Secretary of Health and Human Services (Secretary) in such form and manner, and at such timing and frequency, as the Secretary may prescribe during the Public Health Emergency (PHE).

DATES: *Effective date:* These regulations are effective on September 2, 2020.

Applicability date: These regulations are applicable for the duration of the PHE for COVID-19. Section 488.447 is applicable 1 year beyond the expiration of the PHE for COVID-19. The amendment to § 414.1305 and the expansion of telehealth codes used in beneficiary assignment for the CMS Web Interface and CAHPS for MIPS survey (found in section II.I. of the preamble) are applicable beginning January 1, 2020.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 2, 2020.

ADDRESSES: In commenting, please refer to file code CMS-3401-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-3401-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-3401-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:

Debra Lyons, (410) 786-6780, for information on the LTC enforcement regulation at 42 CFR part 488.

CAPT Scott Cooper, USPHS, (410) 786-9465, for the hospital and CAH COVID-19 reporting requirements.

Sarah Bennett, (410) 786-3354, for laboratory reporting information.

Julia Venanzi, (410) 786-1471, for provisions related to the Hospital Value-Based Purchasing Program.

Erin Patton, (410) 786-2437, for provisions related to the Hospital Readmissions Reduction Program.

Lang Le, (410) 786-5693, for provisions related to the Skilled-Nursing Facility Value-Based Purchasing Program and the Hospital-Acquired Condition Reduction Program.

Delia Houseal, (410) 786-2724, for provisions related to the End-Stage Renal Disease Quality Incentive Program.

Kimberly Long, (410) 786-5702, or NCDsPublicHealthEmergency@cms.hhs.gov, for provisions related to NCD Procedural Volumes for Facilities and Practitioners to Maintain Medicare Coverage.

Jennifer Dupee, (410) 786-6537, for provisions related to order requirements for COVID-19 and related testing.

Jaya Ghildiyal, (301) 492-5149, for PPACA risk adjustment requirements.

Christina Whitefield, (301) 492-4172, for PPACA medical loss ratio requirements.

Elizabeth Goldstein, (410) 786-6665, or PartCandDStarRatings@cms.hhs.gov, for the modifications to the calculation of the 2022 Part C and D Star Ratings.

Molly MacHarris, (410) 786-4461, for issues related to the Merit-based Incentive Payment System (MIPS).

Kianna Banks, (410) 786-3498, for the LTC resident and staff COVID-19 testing requirements.

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://www.regulations.gov>. Follow the search instructions on that website to view public comments.

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Executive Summary

This interim final rule with comment period (IFC) revises regulations to strengthen CMS' ability to enforce compliance with Medicare and

Medicaid long-term care (LTC) facility requirements for reporting information related to coronavirus disease 2019 (COVID-19), establishes a new requirement for LTC facilities for COVID-19 testing of facility residents and staff, establishes new requirements in the hospital and critical access hospital (CAH) Conditions of Participation (CoPs) for tracking the incidence and impact of COVID-19 to assist public health officials in detecting outbreaks and saving lives, and establishes requirements for all CLIA laboratories to report COVID-19 test results to the Secretary of Health and Human Services (Secretary) in such form and manner, and at such timing and frequency, as the Secretary may prescribe during the Public Health Emergency (PHE). This IFC updates the extraordinary circumstances exceptions granted for the ESRD Quality Incentive Program (QIP), Hospital Acquired Condition (HAC) Reduction Program, Hospital Readmissions Reduction Program (HRRP), and Hospital VBP Program for the PHE for COVID-19, and revises the FY 2022 performance period under the Skilled Nursing Facility (SNF) VBP as a result of the PHE for COVID-19. This IFC also announces that with respect to the Hospital VBP Program, HRRP, HAC Reduction Program, SNF VBP Program and the ESRD QIP, if, as a result of a decision to grant a new nationwide ECE without request or a decision to grant a substantial number of individual ECE requests, we do not have enough data to reliably compare national performance on measures, we may propose to not score facilities, hospitals, or SNFs based on such limited data or make the associated payment adjustments for the affected program year. In addition, this IFC announces that CMS will not enforce certain procedural volume requirements for four national coverage determinations, revises the previous policy outlined in the May 8th COVID-19 IFC by establishing that one single COVID-19 diagnostic test and one of each other applicable related tests without an order from a treating physician or other practitioner is reasonable and necessary, establishes a policy whereby the orders of pharmacists and other practitioners that are allowed to order laboratory tests in accordance with state scope of practice and other pertinent laws can fulfill the requirements related to orders for covered COVID-19 and related tests for Medicare patients, specifies how temporary premium credits for individual and small group health insurance coverage are treated for

purposes of the risk adjustment and medical loss ratio programs, modifies the application of the extreme and uncontrollable circumstances policy for calculation of the 2022 Part C and D Star Ratings to address the effects of the PHE for COVID-19, includes in the Merit-Based Incentive Payment System (MIPS) beneficiary assignment methodology for the CMS Web Interface and Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS survey for performance year 2020 and any subsequent performance year that starts during the PHE for COVID-19 certain Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) code additions, and modifies IA_ERP_3.

I. Background

The United States is responding to an outbreak of respiratory disease caused by coronavirus disease that was first detected in China and which has now been detected in more than 190 countries internationally, and all 50 States, the District of Columbia, and the U.S. territories. 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, pursuant to section 319 of the Public Health Service Act (PHSA) (42 U.S.C. 247d), the Health and Human Services Secretary (the Secretary) 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 COVID-19). On March 11, 2020, the WHO publicly declared COVID-19 a pandemic. On March 13, 2020, President Donald J. Trump (the President) declared the COVID-19 pandemic a national emergency. Effective July 25, 2020, the Secretary renewed the January 31, 2020 determination that was previously renewed on April 21, 2020, that a PHE for COVID-19 exists and has existed since January 27, 2020.

The Centers for Disease Control and Prevention (CDC) has reported that some people are at higher risk of severe illness from COVID-19.¹ These higher-risk categories include:

- Older adults, with risk increasing by age.
- People of any age who have certain underlying medical conditions such as:
 - ++ Cancer.
 - ++ Chronic kidney disease.
 - ++ Obesity.
 - ++ Serious heart conditions (for example, heart failure, coronary artery disease, or cardiomyopathies).
 - ++ Sickle cell disease.
 - ++ Diabetes mellitus.
 - ++ Hypertension.
 - ++ Chronic obstructive pulmonary disease (COPD).
 - ++ Neurologic/Neurodevelopmental disability.²
 - ++ Immunocompromised state from solid organ transplant.
- Residents of LTC facilities, including nursing homes, Intermediate Care Facilities for Individuals with Intellectual and Developmental Disabilities (ICF/IIDs), inpatient psychiatric and substance abuse treatment facilities including institutions for mental disorders (IMD) and Psychiatric Residential Treatment Facilities (PRTF), assisted living facilities, group homes for individuals with developmental disabilities and board-and-care facilities.

The CDC has developed guidance to help in the risk assessment and management of people with potential exposures to COVID-19, including recommending that healthcare professionals make every effort to interview a person under investigation for infection by telephone, text monitoring system, or video conference.³

As the healthcare community establishes and implements recommended infection prevention and control practices, regulatory agencies operating under appropriate waiver authority granted by the PHE for COVID-19 are also working to revise and implement regulations that support these healthcare community infection prevention and treatment practices. Based on the current and projected increases in the COVID-19 incidence rates in the US, observed fatalities in the older adult population, and the impact on health workers who are at increased risk due to treating special populations, it is CMS’ belief that certain regulations should be reviewed and revised as appropriate to offer additional flexibilities in furnishing and providing services to combat the PHE for COVID-19 and to address and minimize the

² https://www.cdc.gov/mmwr/volumes/69/wr/mm6924e2.htm?s_cid=mm6924e2_w.

³ <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/summary.html>.

¹ <https://www.cdc.gov/mmwr/volumes/69/wr/mm6915e3.htm>.

unique impact of the PHE for COVID-19 on other regulatory provisions. We addressed some of these regulations in two previous interim final rules with comment period (IFCs). The “Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency” IFC 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”), and the “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” IFC appeared in the May 8, 2020 **Federal Register** (85 FR 27550) with an effective date of May 8, 2020 (hereafter referred to as the “May 8th COVID-19 IFC”).

In this IFC, we are revising regulations to strengthen CMS’ ability to enforce new LTC requirements added to 42 CFR part 483 published in the May 8th COVID-19 IFC to report facility data related to COVID-19 and infection control at least weekly. Specifically, we are adding a regulation to specify the civil money penalty (CMP) amounts that may be imposed for the failure to electronically report COVID-19 data each week, which includes, among other things, suspected and confirmed COVID-19 infections among residents and staff, including residents previously treated for COVID-19, total deaths of COVID-19 deaths among residents and staff, and personal protective equipment and hand hygiene supplies in the facility.

We are also requiring hospitals and CAHs to report information in accordance with a frequency, and in a standardized format, as specified by the Secretary during the PHE for COVID-19. We believe that universal reporting by all hospitals and CAHs is and will be an important tool for supporting surveillance of COVID-19 and for future planning to prevent the spread of the virus, especially to those most vulnerable and at risk to its effects.

In this IFC, we also address condition-level noncompliance related to SARS-CoV-2 laboratory reporting and strengthen CMS’ ability to enforce new requirements to electronically report SARS-CoV-2 test results in such form and manner, and at such timing and frequency, as the Secretary may prescribe during the PHE for COVID-19.

On October 31, 1988, Congress enacted the Clinical Laboratory Improvement Amendments of 1988

(CLIA) (Pub. L. 100-578) (codified as amended at 42 U.S.C. 263a), requiring any laboratory that examines human specimens for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of health, of human beings to be certified by the Secretary for the categories of examinations or procedures performed by the laboratory. The implementing regulations at 42 CFR part 493 specify the conditions and standards that must be met to achieve and maintain CLIA certification. These conditions and standards strengthen federal oversight of clinical laboratories and help ensure the accuracy and reliability of patient test results.

On March 27, 2020, the President signed the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116-136) into law. The CARES Act includes section 18115, which requires every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 to report the results for such test to the Secretary until the conclusion of the PHE for COVID-19.

Subsequently, on June 4, 2020, the Department of Health and Human Services (HHS) published the COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115 Guidance,⁴ implementing the requirement under section 18115 of the CARES Act for laboratories to report COVID-related information to the Secretary.

With regard to laboratory oversight, HHS endeavors to improve consistency in application of laboratory standards, to improve coordination, collaboration, and communication in both routine and emergent situations, and thereby further improve the level of laboratory oversight and ultimately patient care. In order for CMS to ensure laboratories are properly reporting SARS-CoV-2 test results, CMS has determined that modifications to the CLIA regulations must be made. We are requiring all laboratories performing testing related to SARS-CoV-2, to report SARS-CoV-2 test results in such form and manner, and at such timing and frequency, as the Secretary may prescribe during the PHE for COVID-19.

In addition, this IFC clarifies the data reporting requirements for issuers of risk adjustment covered plans⁵ to specify that, for the purposes of 2020

benefit year risk adjustment data submissions, issuers of risk adjustment covered plans that provide temporary premium credits must report to their distributed data environments (EDGE servers) the adjusted plan premiums that reflect actual premiums billed to enrollees, taking the premium credits into account as a reduction in premiums. In addition, we clarify that, consistent with the reporting of the actual premium amounts billed to enrollees for 2020 benefit year risk adjustment data submissions, HHS’s calculation of risk adjustment payment and charges for the 2020 benefit year under the state payment transfer formula will be calculated using the statewide average premium that reflects actual premiums billed, taking into account any temporary premium credits provided as a reduction in premium for the applicable months of 2020 coverage. In this IFC, we similarly clarify the Medical Loss Ratio (MLR) reporting and rebate calculation requirements in 45 CFR part 158 for issuers that elect to provide temporary premium credits in 2020 such that these issuers must report as earned premium the actual premium paid, taking into account any temporary premium credits provided for the applicable months of 2020 coverage.

This IFC also announces that we will not enforce certain procedural volume requirements in order for facilities and practitioners to maintain Medicare coverage under specific national coverage determinations (NCDs). This applies to facilities and practitioners that, prior to the PHE for COVID-19, met the volume requirements for these NCDs.

In this IFC, we are also revising the previous policy outlined in the May 8th COVID-19 IFC, which allowed for broad COVID-19 testing for a single beneficiary without a physician or other practitioner order, by establishing that one single COVID-19 diagnostic test and one of each other related tests (as listed in the May 8th COVID-19 IFC) without a treating physician or other practitioner order is reasonable and necessary. We are also establishing a policy whereby the orders of pharmacists and other practitioners that are allowed to order laboratory tests in accordance with state scope of practice and other pertinent laws can fulfill the requirements related to orders for covered COVID-19 tests for Medicare patients. In addition, this IFC updates the extraordinary circumstances exceptions (ECEs) we granted on March 22, 2020, for the ESRD Quality Incentive Program (QIP), Hospital Acquired Condition (HAC) Reduction Program, HRRP, and Hospital Value-Based

⁴ <https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf>.

⁵ See 45 CFR 153.20 for a definition of “risk adjustment covered plan”.

Purchasing (VBP) Program in response to the PHE for COVID-19, revises the FY 2022 performance period under the SNF VBP as a result of the PHE for COVID-19, implements a COVID-19 reporting requirement for hospitals and critical access hospitals (CAHs), and modifies the application of the extreme and uncontrollable circumstances policy for calculation of the 2022 Part C and D Star Ratings to address the effects of the PHE for COVID-19.

This IFC also announces that with respect to the Hospital VBP Program, HRRP, HAC Reduction Program, SNF VBP Program and the ESRD QIP, if, as a result of a decision to grant a new nationwide ECE without request or a decision to grant a substantial number of individual ECEs, we do not have enough data to reliably compare national performance on measures, we may propose to not score facilities based on such limited data or make the associated payment adjustments for the affected program year.

In this IFC, for the 2020 performance year and any subsequent performance year that starts during the PHE for COVID-19, we are including in the MIPS beneficiary assignment methodology for the CMS Web Interface and Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS survey the following additions due to the PHE for COVID-19: (1) CPT codes: 99421, 99422, and 99423 (codes for online digital evaluation and management (E/M) service (e-visit)), and 99441, 99442, and 99443 (codes for telephone E/M services); and (2) HCPCS codes: G2010 (code for remote evaluation of patient video/images) and G2012 (code for virtual check-in). In addition, we are: (1) Expanding the improvement activity IA_ERP_3 titled "COVID-19 Clinical Trial" to also allow credit for clinicians who participate in the care of patients diagnosed with COVID-19 and simultaneously submit relevant clinical data to a clinical data registry for ongoing or future COVID-19 research; (2) updating the title; and (3) extending it through the CY 2021 performance period.

In an effort to support national efforts to control the spread of COVID-19, we are also revising the LTC facility infection control regulations at § 483.80 to establish a new requirement for LTC facilities to test their facility residents and staff, including individuals providing services under arrangement and volunteers. We are requiring that resident and staff testing in LTC facilities for COVID-19 be conducted based on parameters set forth by the Secretary. We believe these requirements will positively and

substantially impact efforts to control the spread of COVID-19 in LTC facilities.

All provisions included in this IFC are effective only for the duration of the PHE for COVID-19, unless otherwise indicated. The provision at § 488.447 is intended to be in effect beyond the expiration of the PHE for COVID-19.

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 under section 319 of the PHSA on January 31, 2020, and renewed effective July 25, 2020,⁶ as a result of confirmed cases of COVID-19.

A. New Enforcement Requirement for LTC Facilities

Under sections 1866 and 1902 of the Social Security Act (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. 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 nursing facilities (NFs) for Medicaid. The federal participation requirements for these facilities are specified in sections 1819 and 1919 of the Act and in implementing regulations at 42 CFR part 483, subpart B.

Under sections 1819(f)(1) and 1919(f)(1) of the Act, the Secretary must assure that the enforcement of compliance with the participation requirements are adequate to protect the health, safety, welfare, and rights of residents and to promote the effective use of public moneys. The federal requirements related to enforcement of the requirements for SNFs, NFs, or dually-certified facilities, are set forth in sections 1819(h) and 1919(h) of the Act and codified in the regulations at 42 CFR part 488, subpart F. Among the remedies available to be imposed for noncompliance with the requirements is a civil money penalty (CMP), as authorized in sections 1819(h)(2)(B)(ii) and 1919(h)(3)(C)(ii) of the Act, and §§ 488.430 through 488.444.

We are using our authority under this IFC to immediately implement a new enforcement regulation identified below in order to effectively enhance enforcement of the new infection

prevention and control reporting requirements at § 483.80(g)(1) and (2) that became effective on May 8, 2020 as discussed in the May 8th COVID-19 IFC.

Prior to the PHE for COVID-19, regulations at § 483.80(a)(2)(ii) required facilities to have written standards, policies and procedures regarding infection control, which must include when and to whom possible incidents of communicable disease or infections should be reported. This includes reporting to local/state health authorities.

In an effort to support ongoing surveillance of COVID-19 cases, we added to the infection control requirements provisions to establish weekly facility reporting of suspected and/or confirmed COVID-19 cases, among other information, at new § 483.80(g) in the May 8th COVID-19 IFC (85 FR 27550, 27601 through 27602). This new regulation requires nursing homes to report COVID-19 related facility data to the CDC National Healthcare Safety Network (NHSN). These new CMS reporting requirements do not preclude a facility from following all state and local public health reporting laws and regulations.

Specifically, we revised our requirements by adding new provisions at §§ 483.80(g)(1) and (2), to require facilities to electronically report information about COVID-19 in a standardized format and at a frequency specified by the Secretary, but not less than weekly to the CDC NHSN. This critical information will provide real-time information on COVID-19 in nursing homes, and will be used to monitor trends in infection rates, and inform public health policies. To coincide with this new reporting requirement, we developed an automated process within the existing ASPEN (Automated Survey Process Environment) survey software application, which uses information received weekly from the CDC to determine whether a provider reported the data as required. We will determine if noncompliance exists through a retrospective review each week to identify the facilities that failed to take the necessary and timely actions to report to CDC. Noncompliance with this requirement for each weekly reporting cycle will be cited at a scope of widespread, and a severity of no actual harm with potential for more than minimal harm that is not immediate jeopardy, which constitutes a level "F" deficiency. This is consistent with guidance that was issued in QSO 20-

⁶ <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

29–NH⁷ which also included enforcement policies for the imposition of a CMP for the failure to report to the CDC NHSN.

With this IFC, we are furthering enforcement efforts of the recently issued requirements at § 483.80(g)(1) and (2) that facilities report COVID–19 related information to the CDC’s NHSN by making revisions to part 488. These revisions codify enforcement policies that are specifically tailored to reviewing compliance with and imposing CMPs for the failure to report. We are enforcing the new reporting requirements through the imposition of CMPs for each time a facility fails to report the required data to the CDC NHSN system. We believe that CMPs are an appropriate enforcement remedy that will facilitate a swift return to compliance with the new reporting requirement. Sections 1819(h)(2)(B)(ii)(I) and 1919(h)(3)(C)(ii)(I) of the Act limit the amount of a CMP to \$10,000⁸ for each day of noncompliance. We have determined that a minimum \$1,000 initial CMP, with a \$500 incremental increase, is within the authorized CMP range and an appropriate amount to deter noncompliance with this requirement. Specifically, we are noting that a minimum \$1,000 CMP will be imposed for the first occurrence of noncompliance, that is, the first time the facility fails to submit a timely report as required under § 483.80(g)(1) and (2). For each subsequent time the facility fails to report the requisite COVID–19 related data, the amount of the CMP imposed will be increased by \$500, which is consistent with sections 1819(h)(2)(B) and 1919(h)(3)(C) of the Act providing for the imposition of incrementally more severe fines for repeated deficiencies. For example, if a facility fails to report in 1 week, a minimum \$1,000 CMP will be imposed for that occurrence of noncompliance. If it fails to report again in the subsequent week that new noncompliance determination will lead to the imposition of another CMP but in the increased amount of \$1,500 for that failure to report. In this example, if the facility complies with the reporting

requirements by submitting the required report in a 3rd week, but then subsequently fails to report again in a following week, a CMP in the amount of \$2,000 for failing to report a third time will be imposed for that missed weekly report (which is \$500 more than the last imposed amount). After each CMP is imposed, CMS will place the facility back into compliance, without requiring a Plan of Correction (POC) in accordance with § 488.408(f). A facility may still submit a POC if it chooses to do so; however, because compliance will be imposed each week and facilities will be assessed an increased CMP amount for each subsequent failure to report, a POC will not be necessary. Facilities are offered an opportunity for Independent Informal Dispute Resolution under § 488.431. This may be requested for reasons, such as technical difficulties that should be adequately documented, that may have prevented the facility from submitting its report in a timely manner.

Currently, under § 488.408(d), Category 2 CMP remedies for noncompliance that is not immediate jeopardy, but is widespread deficient practice that does not constitute actual harm with a potential for more than minimal harm, or that constitutes actual harm, are imposed at a daily amount not to exceed \$6,695.⁹ Similarly, because noncompliance with § 483.80(g)(1) and (2) will be cited at a scope and severity of an “F”, which would trigger a Category 2 remedy, we will not continue incrementally increasing the CMP amount after 12 occurrences of noncompliance, so that the maximum CMP amount imposed would not exceed \$6,500 for each subsequent occurrence of noncompliance. This specific maximum amount imposed for the failure to report was established to be consistent with the existing CMPs within Category 2 noncompliance. We believe imposing CMPs in this manner is a fair and effective penalty for the failure to report, as assessed each week.

To support and further codify these enhanced enforcement efforts, we are adding § 488.447 to impose a minimum CMP amount of \$1,000 for the first occurrence of noncompliance with the reporting requirements at § 483.80(g)(1) and (2), and will increase the CMP by \$500 for each subsequent time the facility fails to report COVID–19 related data as required. Compliance with the

requirements at § 483.80(g)(1) and (2) will be assessed weekly. Facilities found out of compliance with § 483.80(g)(1) and (2) are not required to submit a plan of correction as indicated in § 488.408(f)(1). These CMP amounts are subject to annual adjustments for inflation at 45 CFR 102.3. Under this rule, we will increase the CMP amounts for up to 12 subsequent noncompliance occurrences to the amount specified in § 488.408(d)(1)(iii), which would be \$6,500 per occurrence of noncompliance. CMPs imposed in accordance with this rule are subject to the same procedures as all other CMPs imposed under sections 1819(h) and 1919(h) of the Act, including notice, escrow, independent informal dispute resolution, and collections. Also, facilities may appeal the determination leading to a CMP imposed under this rule in accordance with 42 CFR part 498.

As discussed in section III. of this IFC, “Waiver of Proposed Rulemaking,” we believe the urgency of this PHE for COVID–19 constitutes good cause to waive the normal notice-and-comment process under Administrative Procedure Act (APA), 5 U.S.C. 533, and section 1871(b)(2)(C) of the Act. Waiving notice and comment is in the public interest because the heightened threat to resident health and safety for, widespread infection control noncompliance necessitates the expedited imposition of enforcement remedies. Additionally, because it is imperative to track the incidence and impact of COVID–19 in nursing homes, it is crucial that a financial penalty be imposed for failure to report. The CMP amounts we codify in this IFC will help deter noncompliance and encourage facilities to establish procedures that result in prompt weekly COVID–19 related data reports for the duration of the PHE for COVID–19. Proper enforcement mechanisms designed to deter noncompliant behavior and prompt corrective actions will help to ensure that residents, staff, and the public are safe, and will help provide critical COVID–19 related data to assist CMS and public health authorities in detecting and expeditiously responding to outbreaks. Furthermore, requiring prior notice and comment is impracticable because the PHE for COVID–19 that the CMP amounts are tailored to address may expire or be nearly over before a proposed rule can be finalized. Finally, we think prior notice and comment is unnecessary because we have broad discretion under the statute and existing CMP regulations to establish a CMP amount, but we are

⁷ “Interim Final Rule Updating Requirements for Notification of Confirmed and Suspected COVID–19 Cases Among Residents and Staff in Nursing Homes.” QSO–20–29–NH (May 6, 2020) <https://www.cms.gov/files/document/qso-20-29-nh.pdf>.

⁸ This amount is adjusted annually under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, and listed in 42 CFR 102.3. The 2020 adjusted amount is \$22,320 (85 FR 2870, January 17, 2020): <https://www.federalregister.gov/documents/2020/01/17/2020-00738/annual-civil-monetary-penalties-inflation-adjustment>.

⁹ Reflects the 2020 annual inflation adjusted amount under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, listed in 42 CFR 102.3 (85 FR 2870, January 17, 2020): <https://www.federalregister.gov/documents/2020/01/17/2020-00738/annual-civil-monetary-penalties-inflation-adjustment>.

choosing to make our policies more transparent. We believe that a completely transparent CMP structure will help deter noncompliance, encourage timely reporting, and eliminate possible gaps in reporting that could hinder the government's response to the PHE for COVID-19 in specific geographic areas. For example, depending on the circumstances, the failure of one facility to report COVID-19 cases on a timely basis could delay our ability to detect and respond to an emerging COVID-19 hot spot.

For similar reasons, we are also waiving the 30-day delay in effective date for these provisions. The effective date for § 488.447 is the date of the publication of this rule (that is, the effective date as noted in the **DATES** section of this IFC). Furthermore, while we would generally expect that the new § 488.447 would no longer be in effect as of the end of the PHE for COVID-19 as defined in § 400.200, enhanced enforcement to ensure facilities continue to comply with infection control reporting requirements to avoid possible spread of COVID-19 will need to temporarily be in effect for a longer period of time. In conjunction with the PHE for COVID-19, these enforcement policies will continue to be in effect for up to one year beyond the end of the PHE.

B. Condition of Participation (CoP) Requirements for Hospitals and CAHs To Report COVID-19 Data As Specified by the Secretary During the PHE for 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. Hospitals (all hospitals to which the requirements of 42 CFR part 482 apply, including short-term acute care hospitals, LTC hospitals, rehabilitation hospitals, psychiatric hospitals, cancer hospitals, and children's hospitals) and CAHs seeking to be Medicare and Medicaid providers of services must be certified as meeting federal participation requirements. Our conditions of participation (CoPs), conditions for coverage (CfCs), and requirements set out the patient health and safety protections established by the Secretary for various types of providers and suppliers. The specific statutory authority for hospital CoPs is set forth in section 1861(e) of the Act; section 1820(e) of the Act provides similar authority for CAHs. The hospital provision authorizes the Secretary to issue any regulations he or she deems

necessary to protect the health and safety of patients receiving services in those facilities; the CAH provision authorizes the Secretary to issue such other criteria as he or she may require. The CoPs are codified in the implementing regulations at part 482 for hospitals, and at 42 CFR part 485, subpart F, for CAHs.

Our CoPs at § 482.42 for hospitals and § 485.640 for CAHs, respectively, have active facility-wide programs, for the surveillance, prevention, and control of healthcare-associated infections (HAIs) and other infectious diseases and for the optimization of antibiotic use through stewardship. Additionally, the programs must demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as to best practices for improving antibiotic use where applicable, and for reducing the development and transmission of HAIs and antibiotic-resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the required hospital and CAH programs must also be addressed in coordination with facility-wide quality assessment and performance improvement (QAPI) programs.

Infection prevention and control is a primary goal of hospitals and CAHs in their normal day-to-day operations, and these programs have been at the center of initiatives taking place in hospitals and CAHs during the PHE for COVID-19. Our regulations at §§ 482.42(a)(3) and 485.640(a)(3) require infection prevention and control program policies to address any infection control issues identified by public health authorities. On March 4, 2020, we issued guidance¹⁰ stating that hospitals should inform infection prevention and control services, local and state public health authorities, and other healthcare facility staff as appropriate about the presence of a person under investigation for COVID-19.

In this IFC, we are now requiring hospitals and CAHs to report information in accordance with a frequency, and in a standardized format, as specified by the Secretary during the PHE for COVID-19. Examples of data elements that may be required to be reported include things such as the number of staffed beds in a hospital and the number of those that are occupied, information about its supplies, and a count of patients currently hospitalized who have laboratory-confirmed COVID-19. This list is not exhaustive of those

data items that we may require hospitals and CAHs to submit, as specified by the Secretary (see <https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf> for the current list of data items specified.).

We believe that universal reporting by all hospitals and CAHs is and will be an important tool for supporting surveillance of COVID-19 and for future planning to prevent the spread of the virus, especially to those most vulnerable and at risk to its effects, and we thank the thousands of hospitals and CAHs that have voluntarily reported this data in support of our efforts. However, while we recognize the important and immeasurable role that the timely and continued delivery of COVID-19 information plays in protecting both individual patients, as well as the overall health of the general public, we also recognize the crucial need for data reporting options that will help eliminate the duplicative and sometimes competing reporting requests that continue to place a significant burden on hospitals and CAHs whose resources are already stressed during this PHE for COVID-19.

We expect that the new reporting requirements that will be specified by the Secretary, would include reporting channel options to make submission of data as user-friendly as possible to reduce the strain and burden hospitals and CAHs are currently experiencing as they face data requests from a multitude of federal, state, local, and private entities. The new standards will require hospitals and CAHs to report information on COVID-19 in a standardized format specified by the Secretary. Also, the information must be reported at a frequency and manner specified by the Secretary.

We believe that a streamlined approach to reporting data will greatly assist the White House Coronavirus Task Force (COVID-19 Task Force) in tracking the movement of the virus and identifying potential problems in the healthcare delivery system. The completeness, accuracy, and timeliness of the data will inform the COVID-19 Task Force decisions on capacity and resource needs to ensure a fully coordinated effort across the nation. Furthermore, we believe that consistent processes and streamlined methods for the reporting of COVID-19 information will possibly reduce future, and urgent, requests for such data.

We note here that the new reporting requirements at §§ 482.42(e) and 485.640(d) do not relieve a hospital or a CAH, respectively, of its obligation to continue to comply with §§ 482.42(a)(3)

¹⁰ <https://www.cms.gov/files/document/qso-20-13-hospitalspdf.pdf-2>.

or 485.640(a)(3), each of which requires a facility to address any infection prevention and control issues identified by public health authorities. We believe that the requirements, as specified in this rule, to collect and transmit these data, will also encourage greater awareness and promotion of best practices in infection prevention and control within these facilities.

This reporting requirement supports our responsibility to protect and ensure the health and safety of hospital and CAH patients by, among other things, ensuring that these facilities follow infection prevention and control protocols based on recognized standards of practice. We believe that these reporting requirements are necessary for CMS to monitor whether individual hospitals and CAHs are appropriately tracking, responding to, and mitigating the spread and impact of COVID-19 on patients, the staff who care for them, and the general public. We believe that this action reaffirms our commitment to protecting the health and safety of all patients who receive care at the approximately 6,200 Medicare- and Medicaid-participating hospitals and CAHs nationwide.

As discussed in section III. of this IFC, “Waiver of Proposed Rulemaking,” we believe the urgency of this PHE for COVID-19 constitutes good cause to waive the normal notice-and-comment process under the APA 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 tracking the incidence and impact of COVID-19 in hospitals and CAHs; such information will assist public health officials in detecting outbreaks and saving lives.

The applicability date for § 482.42(e) for hospitals and § 485.640(d) for CAHs is the date of the publication of this rule as noted in the **DATES** section of this IFC.

2. Enforcement of Requirements for Hospitals and Critical Access Hospitals (CAHs) To Report COVID-19 Data

We believe reporting by hospitals and CAHs is an important tool for supporting surveillance of COVID-19 and we will enforce violations of reporting requirements to the extent authorized by the Secretary. Should a hospital or CAH fail to consistently report test results throughout the duration of the PHE for COVID-19, it will be non-compliant with the hospital and the CAH CoPs set forth at §§ 482.42(e) and 485.640(d), respectively, and subject to termination as defined at 42 CFR 489.53(a)(3). We have taken a position on the importance of COVID-19 test results reporting in

other provider areas, including use of CMPs for nursing homes that fail to report, and find it prudent to enact penalties for hospitals and CAHs that similarly fail to report COVID-19 test results. CMS currently lacks the statutory authority to impose CMPs against hospitals and CAHs; however, intermediate penalties such as CMPs have been an extremely useful tool in the enforcement of reporting requirements for nursing homes, helping to achieve 98 percent compliance. Therefore, we will continue to utilize all enforcement and payment authorities available to incentivize and promote compliance with all health and safety requirements, as allowed by statute and regulation.

C. Requirements for Laboratories To Report SARS-CoV-2 Test Results During the PHE for COVID-19

Assuring a rapid and thorough public health response to the COVID-19 pandemic relies on having complete and comprehensive laboratory testing data, including standardized test results, relevant demographic details, and additional information that can improve both the response to SARS-CoV-2 and treatment of COVID-19. These data can contribute to understanding disease incidence and trends: Initiating epidemiologic case investigations, assisting with contact tracing, assessing availability and use of testing resources, and identifying supply chain issues for reagents and other material. Laboratory testing data, in conjunction with case reports and other data, also provide vital guidance for mitigation and control activities.

Section 18115(a) of the CARES Act requires every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a “SARS-CoV-2 test” or “COVID-19 diagnostic test”) to report the results from each such test to the Secretary until the end of the PHE for COVID-19. In addition, the statute authorizes the Secretary to prescribe the form and manner, and timing and frequency, of such reporting. As indicated in HHS guidance issued on June 4, 2020,¹¹ in an effort to receive these data in the most efficient and effective manner, the Secretary has required that all data be reported through existing public health data reporting methods. The June 4, 2020 guidance states that “as a guiding

principle, data should be sent to state or local public health departments using existing reporting channels (in accordance with state law or policies) to ensure rapid initiation of case investigations by those departments, concurrent to laboratory results being shared with an ordering provider, or patient as applicable.”¹²

The June 4, 2020 guidance further explains that “all laboratories—including laboratories, testing locations operating as temporary overflow or remote locations for a laboratory, and other facilities or locations performing testing at point of care or with at-home specimen collection related to SARS-CoV-2—shall report data for all testing completed, for each individual tested, within 24 hours of results being known or determined, on a daily basis to the appropriate state or local public health department based on the individual’s residence.”

On October 31, 1988, Congress enacted the CLIA (Pub. L. 100-578) (codified as amended at 42 U.S.C. 263a) requiring any laboratory that examines human specimens for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of health, of human beings to be certified by the Secretary for the categories of examinations or procedures performed by the laboratory. The implementing regulations at 42 CFR part 493 specify the conditions and standards that must be met to achieve and maintain CLIA certification. These conditions and standards strengthen federal oversight of clinical laboratories and help ensure the accuracy and reliability of patient test results.

Currently, the CLIA program only collects non-waived testing specialty and subspecialty information from laboratories issued a Certificate of Compliance (CoC), Certificate of Accreditation (CoA), or Certificate of Registration (CoR). Such information is collected for certain specialties, subspecialties, and analytes for proficiency testing purposes and during surveys to ensure that the laboratory is meeting CLIA requirements for the level and specialty/subspecialty of testing performed. CMS does not know the complete universe of laboratories performing SARS-CoV-2 testing, or which tests are being performed as information related to specific test systems is not captured in our database.

While we collect this information when laboratories initially apply for all certificate types, subsequently it is only

¹¹ COVID-19 Pandemic Response, Laboratory Data Reporting: Section 18115 of the CARES Act, <https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf>.

¹² <https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf>.

collected for CoC and CoA laboratories during an initial, recertification, validation, or complaint survey, as described above. This data is collected to ensure that such labs are meeting the applicable CLIA test complexity testing quality requirements. Certificate of Waiver (CoW) and Certificate for Provider-Performed Microscopy (PPM) laboratories are not required to submit information related to updating their test menu as long as the new testing falls under their current certificate. During this PHE for COVID-19, the Food and Drug Administration (FDA) is issuing Emergency Use Authorizations for in vitro diagnostics that are categorized to be run by certain CLIA-certified laboratories (which may include laboratories with a CoW or Certificate for PPM), depending on the scope and FDA's categorization of the authorized test. SARS-CoV-2 testing includes molecular, antibody, and antigen methods. Molecular (RT-PCR) tests detect the virus's genetic material and antigen tests detect specific proteins on the surface of the virus. Both types of tests are used to detect active or acute infection with SARS-CoV-2. Serology (antibody) testing is used to look for the presence of antibodies which are proteins produced by the body in response to infections. Due to the variety of COVID-19 testing available, our current informational limitations present a gap in understanding the universe of laboratories performing SARS-CoV-2 testing.

We believe that, by collecting testing information, the CLIA program will be able to identify quality and accuracy issues with laboratories performing SARS-CoV-2 testing during this PHE for COVID-19. Currently we do not have a specific reporting requirement that allows for collection of SARS-CoV-2 testing information. Once we have accurate information on which laboratories are performing SARS-CoV-2 testing, our oversight authority will allow us to survey these laboratories to determine if they are performing testing within their appropriate CLIA certificate and that they are meeting applicable CLIA requirements to perform accurate and reliable testing. For CMS to ensure laboratories are reporting SARS-CoV-2 test results, the CLIA regulations need to be modified to require SARS-CoV-2 test result reporting. In the interest of ensuring quality laboratory testing during the PHE for COVID-19, we are finalizing the requirement for submission of SARS-CoV-2 test results to the Secretary. Specifically, we are finalizing that during the PHE for COVID-19, as defined in § 400.200, each

laboratory that performs a SARS-CoV-2 test must report SARS-CoV-2 test results in such form and manner, and at such timing and frequency, as the Secretary may prescribe. We are also finalizing that failure to submit SARS-CoV-2 test results to the Secretary will be considered a violation of the new CLIA reporting requirements, resulting in condition level deficiencies for which CMPs or other penalties may apply.

These regulatory amendments at §§ 493.41 and 493.1100(a) will require all laboratories, including, those holding a CoW, to report SARS-CoV-2 test results to the Secretary for the duration of the PHE for COVID-19, and specify that failure to do so will result in a condition level violation of the CLIA regulations. Should a laboratory not report required SARS-CoV-2 test results, we will impose a CMP under §§ 493.1804 and 493.1834.

We are adding or amending the following regulations:

- At § 493.2, Definitions, we are amending the definition of "Condition level requirements" to include the requirements in § 493.41. This change is necessary to allow for the imposition of CMPs on CoW laboratories that fail to comply with § 493.41 during the Secretary's PHE declaration for COVID-19 or any extension of such declaration.
- At § 493.41, we are adding a that, for the duration of the PHE for COVID-19, CoW laboratories report SARS-CoV-2 test results to the Secretary.
- At § 493.555, we are amending the provision by adding paragraph (c)(6) requiring that, for the duration of the PHE for COVID-19, CMS-deemed Accreditation Organizations (AO) and State Licensure Programs, Exempt States (ES), notify CMS within 10 days after identifying a laboratory that fails to report SARS-CoV-2 test results as required at §§ 493.41 and 493.1100(a).
- At § 493.1100, we are adding paragraph (a) which requires that, for the duration of the PHE for COVID-19, all laboratories performing non-waived SARS-CoV-2 testing report SARS-CoV-2 test results to the Secretary.
- At § 493.1804, we are revising paragraph (c)(1) to allow us to impose alternative sanctions (including CMPs) on CoW laboratories for failure to comply with §§ 493.41 and 493.1100(a) during the PHE for COVID-19.
- At § 493.1834, we are amending the provision by adding paragraph (d)(2)(iii) to define the per day CMP amounts that may be imposed as a result of SARS-CoV-2 reporting violations. Such CMPs will be \$1000 for the first day of noncompliance with the new reporting requirements, and \$500 for each subsequent day the laboratory fails to

report SARS-CoV-2 test results. The statute allows for the imposition of CMPs in an amount not to exceed \$10,000 for each violation (for example, per sample not reported) or for each day of substantial noncompliance. We believe imposing CMPs based on a per day basis is a fairer and more effective penalty for failure to report than a per violation basis. The latter could lead to large CMPs for brief lapses in reporting.

The CLIA regulations at § 493.551(a)(1) require both the AOs and ESs to have requirements that are equal to, or more stringent than, the CLIA condition-level requirements, so we would expect the AOs and ESs to have equivalent reporting requirements to CMS. AOs do not impose CMPs; however, ESs do have the ability to impose CMPs, so we would expect ESs to have an equivalent penalty structure to CMS. The ESs are generally approved by CMS to operate their own oversight programs so we would expect that the two ESs would report these laboratories to CMS, but would then impose the penalties based on their updated CMS-approved standards. In the case of the accredited laboratories, the laboratories identified as not reporting SARS-CoV-2 results as required would result in CMS taking a subsequent enforcement action as described in this section.

D. Quality Reporting: Updates to the Extraordinary Circumstances Exceptions (ECE) Granted for Four Value-Based Purchasing Programs in Response to the PHE for COVID-19, and Update to the Performance Period for the FY 2022 SNF VBP Program

As part of our response to the COVID-19 pandemic, on March 22, 2020, we granted ECEs to ESRD facilities, hospitals, and SNFs to reduce the data collection and reporting burden on these facilities and providers so they could direct their full resources to patient care during the early months of the pandemic. Each of these ECEs relieved these providers and facilities of their obligation to report data for the fourth quarter calendar year (CY) 2019, first quarter CY 2020 and second quarter CY 2020, but we stated that we would score such data if optionally reported.

We continue to believe that the data we have excepted from mandatory reporting under these ECEs serves multiple purposes, including allowing us to understand the impact of the PHE for COVID-19 on quality of care. However, we are concerned about the national comparability of these data due to the geographic differences of COVID-19 incidence rates and hospitalizations, along with different impacts resulting from different state and local laws and

policy changes implemented in response to COVID–19.

As a result, we believe it is necessary in this IFC to update the ECEs that we have granted for the following value-based purchasing programs:

- The End-Stage Renal Disease Quality Incentive Program (ESRD QIP);
- The Hospital-Acquired Condition (HAC) Reduction Program;
- The Hospital Readmissions Reduction Program (HRRP); and
- The Hospital Value-Based Purchasing (HVBP) Program.

Under these updated ECEs, we will only score data that was optionally reported for fourth quarter CY 2019. We will also exclude all data that was optionally reported for the first or second quarter of CY 2020 from our calculation of performance. We note that all of the ECEs that have been granted for the time periods discussed above have now ended.

In this IFC, we are also updating the performance period for the FY 2022 SNF VBP Program because we are concerned that using qualifying claims from the two quarters that are not excepted under the ECE for COVID–19 (October 1, 2019 through December 31, 2019 (Q4 2019), and July 1, 2020 through September 30, 2020 (Q3 2020)) for all SNFs nationwide to calculate the SNF Readmission Measure (SNFRM) for the FY 2022 Program will not yield measure scores that reliably reflect SNF quality of care as determined by hospital readmission rates. As explained more fully below, the new performance period will be April 1, 2019 through December 31, 2019 and July 1, 2020 through September 30, 2020.

1. Updates to ESRD QIP: Utilization of Fourth Quarter CY 2019 ESRD QIP Data and the Removal of the Option for Facilities to Opt-Out of the Extraordinary Circumstances Exception (ECE) Granted With Respect to First and Second Quarter (CY) 2020 ESRD QIP Data

a. Background of the ESRD QIP ECE Policy

The ESRD QIP is authorized under section 1881(h) of the Act, and it aims to promote high-quality care in dialysis facilities by linking a portion of their payment under the ESRD prospective payment system (PPS) directly to their performance on quality of care measures. The ESRD QIP assesses facility performance on clinical and reporting measures adopted through the rulemaking process and scores dialysis facilities based on that performance. A facility that does not meet or exceed the minimum total performance score (TPS)

set by CMS for the applicable payment year receives up to a 2 percent reduction to its ESRD PPS payment for that year.

In the CY 2015 ESRD PPS final rule (79 FR 66189 through 66190), we adopted an ECE policy for the ESRD QIP, which recognized that there are times when facilities are unable to submit required quality data due to extraordinary circumstances that are not within their control, and that facilities should not be penalized for such circumstances or have their burden unduly increase during these times. This policy was implemented under the authority of section 1881(h)(3)(A)(i) of the Act, which requires the Secretary to develop a methodology for assessing the total performance of each provider of services and renal dialysis facility based on performance standards for the measures selected under section 1881(h)(2) of the Act for a performance period established under section 1881(h)(4)(D) of the Act. We interpreted section 1881(h)(3)(A)(i) of the Act to enable us to configure the methodology for assessing facilities' total performance such that we would not require a facility to submit, nor penalize a facility for failing to submit, data on any ESRD QIP quality measure data from any month in which a facility is granted an ECE.

In the CY 2018 ESRD PPS final rule (82 FR 50761 through 50763), we modified the requirements for the ESRD QIP's ECE policy to further align that policy with the ECE policy adopted by other quality reporting and VBP programs. In the CY 2020 ESRD PPS final rule (84 FR 60714), we codified requirements for the ECE policy at 42 CFR 413.178(d)(3) through (7), including a new option for facilities to reject an ECE granted by CMS under certain circumstances. We stated that this option would provide facilities with flexibility under the ECE policy. We also adopted this provision to provide further guidance to the public on the scope of our ECE policy.

b. Background of the ESRD QIP ECE Granted in Response to the PHE for COVID–19

On March 22, 2020, in response to COVID–19, we announced relief for clinicians, providers, hospitals and facilities participating in Medicare quality reporting programs (QRPs) and VBP programs.¹³ On March 27, 2020, we published a supplemental guidance memorandum that described in more detail the scope and duration of the ECE

we were granting under each Medicare QRP and VBP program.¹⁴

Under the ECE for the PHE for COVID–19 that we granted to all facilities participating in the ESRD QIP, such facilities are currently excepted from the following reporting requirements and submission deadlines:

- For the National Healthcare Safety Network (NHSN) blood stream infection (BSI) clinical measure and NHSN Dialysis Event reporting measure:
 - ++ March 31, 2020, June 30, 2020, September 30, 2020 reporting deadlines for encounters during the following periods:

—October 1, 2019 to December 31, 2019 (Q4 2019)—We noted that data from the 4th quarter 2019 would be utilized if submitted.

—January 1, 2020 to March 30, 2020 (Q1 2020).

—April 1, 2020 to June 30, 2020 (Q2 2020).

- For ESRD QIP CROWNWeb reporting deadlines and applicable clinical months:

++ March 31, 2020 (January 2020 clinical month).

++ April 30, 2020 (February 2020 clinical month).

++ June 1, 2020 (March 2020 clinical month).

++ June 30, 2020 (April 2020 clinical month).

++ August 3, 2020 (May 2020 clinical month).

++ August 31, 2020 (June 2020 clinical month).

- For the Consumer Assessment of Healthcare Providers and Systems In-Center Hemodialysis (ICH–CAHPS) Survey:

++ The data collected to fulfill the July 2020 data submission deadline for the Spring 2020 Survey.

++ Data collected May 1, 2020–July 10, 2020.

- For ESRD QIP claims-based measures, claims data during the following times would be excluded from measure calculations:

++ March 1, 2020–June 30, 2020.

With respect to the requirement that facilities selected for validation under one or both ESRD QIP data validation studies (CROWNWeb and NHSN) submit medical records within 60 days of the date identified on the written request letter, we excepted facilities from that requirement as follows:

- NHSN and CROWNWeb record requests for discharge periods:

++ January 1, 2019–March 31, 2019 (Q1 2019).

¹³ CMS press release available at <https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting>.

¹⁴ CMS memorandum available at <https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf>.

++ April 1, 2019–June 30, 2019 (Q2 2019).

In the March 27, 2020 guidance, we also advised that facilities should be aware of the potential subsequent impact to a facility's TPS when data are excluded from score calculations, and noted that facilities impacted by COVID-19 could elect to opt out of this ECE by emailing their request to the ESRD QIP at esrdqip@cms.hhs.gov by June 19, 2020.

c. Update to the ESRD QIP ECE Policy for the PHE for COVID-19

We continue to believe that the ESRD QIP data we have excepted serves multiple purposes, including allowing us to understand the impact of the PHE for COVID-19 on the quality of ESRD care provided to Medicare beneficiaries and supporting the continued analysis and evaluation of ESRD quality data submitted to CROWNWeb. However, we are concerned about the national comparability of these data due to the geographic differences of COVID-19 incidence rates and hospitalizations, along with different impacts resulting from different state and local law and policy changes implemented in response to COVID-19. For these reasons, we are adopting in this IFC two updates to our current ECE policy for the ESRD QIP. First, we are updating our regulations at 42 CFR 413.178(d)(7) to state that a facility has opted out of the ECE for COVID-19 with respect to the reporting of fourth quarter 2019 NHSN data if the facility actually reported the data by the March 31, 2020 deadline but did not notify CMS that it would do so. Additionally, we are removing the ability of facilities to opt-out of the ECE we granted with respect to Q1 and Q2 2020 ESRD QIP data.

i. CY 2019 Fourth Quarter NHSN ESRD QIP Measure Data

As described previously, we excepted facilities from the requirement to report fourth quarter CY 2019 data for the NHSN BSI clinical measure and NHSN Dialysis Event reporting measure to alleviate the reporting burden on facilities responding to the PHE for COVID-19 that would otherwise be required to report these data by the March 31, 2020 submission deadline. However, in both the March 22nd and March 27th guidance we also stated that we would utilize these data if submitted. At the time we announced the ECE for COVID-19, there were approximately 9 days (time period between March 22, 2020 to March 31, 2020) remaining for facilities to submit their fourth quarter 2019 NHSN data, and nearly all facilities (97.6 percent)

timely reported fourth quarter 2019 ESRD QIP data on these measures. These data also assess facility performance prior to the start of the PHE for COVID-19. Unlike the first and second quarter 2020 data, we do not have concerns about the national comparability or representativeness of the fourth quarter 2019 NHSN data because those data reflect facility performance prior to the start of the PHE for COVID-19. In addition, nearly all facilities reported these data prior to the announcement of the ECE with the expectation that they would be used for scoring. Accordingly, we are updating our regulations at § 413.178(d)(7) to state that a facility has opted out of the ECE for COVID-19 with respect to the reporting of fourth quarter 2019 NHSN data if the facility actually reported the data by the March 31, 2020 submission deadline but did not notify CMS that it would do so, and we will include these data when we calculate facility TPSs for PY 2021 and performance standards for PY 2023. This change will enable us to use the data which, as we explain above, are reflective of facility performance and were reported with the expectation that they would be used for scoring. This change is also consistent with our statement in the ECE announcement that we would score these data if they were submitted. A facility that did not timely report its fourth quarter 2019 NHSN BSI clinical measure and NHSN Dialysis Event reporting measure data will not be eligible to receive scores on those measures for PY 2021.

ii. CY 2020 First and Second Quarter ESRD QIP Data

Under our current policy, facilities may opt out of the ECE we proactively granted in response to the PHE for COVID-19, and continue to report ESRD QIP data. We implemented this policy to give facilities flexibility to continue to report, in particular where a facility does not believe it has been impacted by the extraordinary circumstance(s). We do not believe that is the case here, as the PHE for COVID-19 is a nationwide PHE and an overwhelming majority of facilities continue to be impacted by COVID-19. For example, regardless of protocols in place at facilities, dialysis patients concerned about being exposed to COVID-19 at a facility may decide to skip their treatment sessions.¹⁵ This could be reflected in quality metrics captured for the facility when the patients return to treatment. Furthermore, due to the national nature

of this PHE for COVID-19, we believe performance scores for certain measures could be biased and not reflective of nationally comparable performance. Similarly, we are concerned that there may be indirect and unintended consequences of calculating scores using potentially biased data that may not reflect the facility's overall quality. Due to facilities having the option to submit or not submit data for this period, the data may not provide a nationally comparable assessment of performance. Thus, reporting bias is possible due to the voluntary submission of data; that is, a bias could be potentially introduced because only high performers and/or facilities not impacted or better resourced would choose to submit data, while impacted facilities and/or facilities with fewer resources would choose not to submit data. This would affect comparisons between facilities with different circumstances, and would not be in keeping with the program goal of national comparison. Therefore, we believe that it would be inappropriate to include data submitted regarding care provided during first and second quarter CY 2020 in our calculation of a facility's TPS, which is used to determine each facility's payment adjustment. Therefore, we are revising the opt out policy currently codified at § 413.178(d)(7) to provide that the opt out policy does not apply to data excepted due to the PHE for COVID-19 with—that is, the first quarter and second quarters of CY 2020 ESRD QIP data.

Finally, although the ECE we granted for the ESRD QIP has ended, with data collection and reporting requirements having resumed July 1, 2020, we understand that geographic differences in COVID-19 incidence continue to change during the PHE for COVID-19. To maintain flexibility for addressing the impact of COVID-19 on the ESRD QIP and determine how best to implement the program equitably, we are announcing in this IFC that if, as a result of an extension of the ECE for the whole country that we grant without a request or the submission of individual ECE requests, we do not have enough data to reliably measure national performance under the ESRD QIP, we may propose to not score facilities based on such limited data or make the associated payment adjustments to facilities under the ESRD PPS for the affected program year. For example, if we granted an ECE that excepted facilities from the requirement to report data for 11 of the 12 months of a given performance period, we would consider

¹⁵ See <https://www.kidney.org/coronavirus/dialysis-covid-19>.

not scoring or applying payment adjustments for the associated ESRD QIP payment year because data from the one non-exception month may not be large enough to calculate reliable measure results for scoring purposes. Although the data themselves may be accurate, the measure(s) might not meet the reliability standards because of the small sample of the remaining non-exception part of the performance period.¹⁶ In addition, in the scenario we describe above, it is plausible that only larger facilities would be able to meet the required case minimums to be scored in the non-exception part of the performance period. We may conclude that only scoring remaining facilities would not produce an accurate national comparison of dialysis facilities. Alternatively, if we do not extend the ECE to cover Q3 and Q4 2020, it is possible that a majority of facilities might still submit individual ECE requests for those quarters and it is possible that so many facilities will submit individual ECE requests that we will not be able to produce a reliable national comparison. In both cases, we are concerned about using the measures calculated based on these data to score facilities under the ESRD QIP and base payment adjustments on those scores. If circumstances warrant, we may propose to suspend prospective application of program penalties or payment adjustments through the annual ESRD PPS proposed rule. However, in the interest of time and transparency, we may provide subregulatory advance notice of our intentions to suspend such penalties and adjustments through routine communication channels to facilities, vendors, and Quality Improvement Organizations (QIOs). The communications could include memos, emails, and notices on the public QualityNet website (<https://www.qualitynet.org/>). We welcome public comments on the update to our regulations at § 413.178(d)(7) to consider a facility as having opted out of the ECE with respect to NHSN data reported for Q4 2019 if the facility actually reported the data by the submission deadline, without notifying CMS, and we will include these data when we calculate facility TPSs for PY 2021 and performance standards for PY 2023. We also welcome public comments on the exception we are finalizing to the ECE opt out policy for the ESRD QIP, and we will exclude any ESRD QIP data that facilities optionally reported during Q1 and Q2 2020 from

¹⁶ See <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdIdentifier=id&ItemID=86453> and choose the "Evaluation Guidance" link.

our calculation of Payment Year 2022 TPSs and from the baseline for PY 2023.

2. Updates to the Application of the HAC Reduction Program ECE Policy in Response to the PHE for COVID-19

a. Background of the HAC Reduction Program ECE Policy

The Hospital-Acquired Condition Reduction Program ("HAC Reduction Program") is authorized under section 1886(p) of the Act and it aims to heighten awareness of HACs and reduce the number of incidences that occur through implementing the payment adjustments authorized under such statute. The HAC Reduction Program began affecting hospitals' Medicare payments with FY 2015 discharges (that is, October 1, 2014). In the FY 2016 Inpatient Prospective Payment System (IPPS)/Long-term Care Hospitals (LTCH) PPS final rule (80 FR 49579 through 49581), we adopted an ECE policy for the HAC Reduction Program, which recognized that there may be periods of time during which a hospital is affected by an extraordinary circumstance beyond its control. We noted that we considered the feasibility and implications of excluding data for certain measures for a limited period of time from the calculations of the hospital's measure results or Total HAC Score for the applicable performance period. We expressed our aim to minimize data excluded from the program to allow affected hospitals to continue to participate in the HAC Reduction Program for a given year if these hospitals continue to meet applicable measure minimum threshold requirements. We further observed that section 1886(p)(4) of the Act permits the Secretary to determine the applicable period for HAC data collection, and we interpreted the statute to allow us to determine that the period not include times when hospitals may encounter extraordinary circumstances. This policy was similar to the ECE policy for the Hospital Inpatient QRP, as initially adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651), and modified in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277).

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49580 through 49581), we also stated that this policy would not preclude CMS from granting ECEs to hospitals that do not request them if we determine at our discretion that a disaster or other extraordinary circumstance has affected an entire region or locale. We noted that if CMS makes such a determination to grant an

ECE to hospitals in an affected region or locale, we will convey this decision through routine communication channels to hospitals, vendors, and QIOs, including, but not limited to, issuing memos, emails, and notices on the QualityNet website. When time permits we will also communicate such decisions through the annual IPPS/LTCH PPS proposed rule.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38276 through 38277), we modified the requirements for the HAC Reduction Program ECE policy to further align with the process used by other QRP and VBP programs for requesting an exception from program reporting due to an extraordinary circumstance not within a provider's control.

b. Background of the HAC Reduction Program ECE Granted for the PHE for COVID-19

On March 22, 2020, in response to COVID-19, we announced relief for clinicians, providers, hospitals, and facilities participating in Medicare QRPs and VBP programs.¹⁷ On March 27, 2020, we published a supplemental guidance memorandum that described in more detail the scope and duration of the ECEs we were granting under each Medicare QRP and VBP program.¹⁸

Under the ECE granted to all eligible hospitals under the HAC Reduction Program, we stated that qualifying claims would be excluded from the measure calculations for the CMS Patient Safety Indicators (PSI) 90 during the periods January 1, 2020–March 31, 2020 (Q1 2020) and April 1, 2020–June 30, 2020 (Q2 2020). We also provided an exception to reporting for all chart-abstracted HAC Reduction Program measures for the May, August, and November 2020 submission deadlines (for reporting Q4 2019, Q1 2020, and Q2 2020 data, respectively). This exception includes the following NHSN HAI Measures:

++ NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure, National Quality Forum (NQF) #0138.

++ NHSN Central Line-Associated Blood Stream Infection (CLABSI) Outcome Measure, NQF #0139.

++ NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile*

¹⁷ CMS press release available at <https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting>.

¹⁸ CMS memorandum available at <https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf>.

Infection (CDI) Outcome Measure, NQF #1717.

++ NHSN Facility-wide Inpatient Hospital-onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure, NQF #1716.

++ American College of Surgeons—Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure, NQF #0753.

We also advised that hospitals should be aware of the potential subsequent impact to the HAC Reduction Program minimum case threshold counts for inclusion in these programs.

c. Update to the HAC Reduction Program ECE Granted in Response to the PHE for COVID-19

We continue to believe that the HAC Reduction Program data we have excepted serves multiple purposes, including allowing us to understand the impact of the PHE for COVID-19 on quality of care. Furthermore, the chart-abstracted measures in the HAC Reduction Program are calculated based on data submitted to the CDC's NHSN. We recognize that because the CDC uses the same data for epidemiological surveillance, hospitals may have reporting requirements which are not affected by our ECE (for example, state requirements). We are also concerned with the national comparability of these data due to the geographic differences of COVID-19 incidence rates and hospitalizations along with different impacts resulting from different state and local law and policy changes implemented in response to COVID-19.

For data which hospitals optionally report, we believe that the exception granted for those programs with data submission deadlines in April and May 2020 (that is, data from the fourth quarter of CY 2019) is distinct from the exceptions granted because data collected may be greatly impacted by the response to COVID-19 (that is, data from the first and second quarters of CY 2020).

i. CY 2019 Fourth Quarter Data

As described previously, we excepted hospitals from the requirement to report fourth quarter CY 2019 data for the HAC Reduction Program to alleviate the reporting burden on hospitals that were responding to the PHE for COVID-19 during the May 18, 2020 data submission deadline. However, nearly all hospitals (95.3 percent) reported these data by the submission deadline, which reflects care provided prior to January 27, 2020, which is the start of the PHE for COVID-19 under the

Secretary's declaration of a PHE under section 319 of the PHSA. Therefore, we determined that it would be appropriate to include data that were optionally reported by hospitals for the fourth quarter of CY 2019 in calculating hospitals' Total HAC Scores, which are used to determine the worst-performing 25 percent of hospitals on HAC performance for assessing the 1 percent HAC Reduction Program penalty. This determination is consistent with the policy stated in the March 27, 2020 guidance memo.¹⁹

ii. CY 2020 First and Second Quarter Data

In our application of the ECE policy for the PHE for COVID-19, we excepted hospitals from the requirement to report first and second quarter of CY 2020 HAC Reduction Program chart-abstracted measures and stated we would exclude qualifying claims both because we hoped to alleviate the reporting burden on hospitals that were responding to the PHE for COVID-19 and because of our concern that the representativeness of the data collected during this period may be greatly impacted by the response to COVID-19.

We also noted that if hospitals optionally chose to report data, we would use that data for program calculations. While we continue to encourage optional submission of data, we also aim to have the most representative comparison of hospital performance as possible and do not wish to unfairly penalize hospitals that were responding to COVID-19. We believe that using CY 2020 optionally reported data may not provide a nationally comparable assessment of hospital performance for multiple reasons. First, allowing hospitals the option to voluntarily submit for this period may introduce reporting bias; that is, a bias introduced because, for example, only high performers and/or hospitals not impacted or better resourced would choose to submit data, which would render comparisons between hospitals with different circumstances not in keeping with the program goal of national comparison. In addition, a number of other factors could also contribute to our ability to accurately calculate a national comparison. For example, geographic differences in COVID-19 incidence rates and COVID-19 related hospitalizations and differences resulting from changes in referral and hospitalization patterns

could both impact the national comparability of optionally submitted data. Because the HAC Reduction Program relies on a relative scoring methodology, we believe that it would be inappropriate and could disparately impact hospitals to include data from quarters excepted under CMS guidance for the PHE for COVID-19 in our calculation of hospitals' performance for the program.

Finally, although the ECE we granted for the HAC Reduction Program has ended, with data collection and reporting requirements resuming July 1, 2020, we understand that geographic differences in COVID-19 incidence continue to change during the PHE for COVID-19. To maintain flexibility for addressing the impact of COVID-19 on the HAC Reduction Program and determine how best to implement the program equitably, we are announcing that if, as a result of the extension of the ECE for the whole country that we grant without a request or the submission of individual ECE requests, we do not have enough HAC Reduction Program data to reliably measure national performance, we may propose to not score hospitals based on such limited data or make the associated payment adjustments to hospitals under the IPPS for the affected program year. If we grant another ECE in the future, we would not require that hospitals report the excepted data for the duration of the ECE. Although a hospital may voluntarily report data during the ECE, we may determine that such data will not be used for scoring purposes. We would still require that hospitals report the non-excepted data. However, we may determine that it would be inappropriate to score such data or base payment adjustments on it because of reliability concerns. For illustrative purposes only, if a PHE excepted enough quarters from the HAC Reduction Program's 24-month performance period to lead to unreliable measure calculations, we might consider not scoring for the fiscal year because the sample may not be large enough to calculate reliable measure results for scoring purposes. Although the data itself may be accurate, the measure(s) may not meet the reliability standards because of the small sample of the remaining non-excepted part of the performance period. In addition, in the scenario we describe above, it is likely that only larger hospitals would be able to meet the required case minimums to be scored in the non-excepted part of the performance period. We may conclude that only scoring those remaining large hospitals will not produce an accurate national

¹⁹ CMS memorandum available at <https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf>.

comparison of hospitals. Alternatively, if we do not extend the ECE to cover Q3 and Q4 2020, it is possible that a majority of providers may still submit individual ECE requests for those quarters and it is possible that so many hospitals will submit individual ECE requests that we will not be able to produce a reliable national comparison. In both cases, we are concerned about using the measure calculated based on these data to score hospitals under the HAC Reduction Program and base payment adjustments on those scores. If circumstances warrant, we may propose to suspend prospective application of program penalties or payment adjustments through the annual IPPS/LTCH PPS proposed rule. However, in the interest of time and transparency, we may provide subregulatory advance notice of our intentions to suspend such penalties and adjustments through routine communication channels to hospitals, vendors, and Quality Improvement Organizations (QIOs). The communications could include memos, emails, and notices on the public QualityNet website (<https://www.qualitynet.org/>). We welcome public comments on our policy to exclude any data submitted regarding care provided during the first and second quarter of CY 2020 from our calculation of performance for the FY 2022 and FY 2023 program years.

3. Update to the HRRP ECE Granted in Response to the PHE for COVID-19

a. Background of the Hospital Readmissions Reduction Program ECE Policy

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49542 through 49543), we adopted an ECE policy for the Hospital Readmissions Reduction Program, which recognized that there may be periods of time during which a hospital is not able to submit all claims (from which readmission measures data are derived) in an accurate or timely fashion due to an extraordinary circumstance beyond its control. We noted that we considered the feasibility and implications of excluding data for certain measures for a limited period of time from the calculations for a hospital's excess readmissions ratios for the applicable performance period. We expressed that we hoped to minimize data excluded from the program to allow affected hospitals to continue to participate in the HRRP for a given year if these hospitals otherwise continue to meet applicable measure minimum threshold requirements. We further observed that section 1886(q)(5)(D) of the Act permits the Secretary to

determine the applicable period for readmissions data collection, and we interpreted the statute to allow us to determine that the period not include times when hospitals may encounter extraordinary circumstances. This policy was similar to the ECE policy for the Hospital Inpatient Quality Reporting (IQR) Program, as initially adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651), and modified in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277).

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49542), we also stated that this policy would not preclude CMS from granting ECEs to hospitals that do not request them if we determined at our discretion that a disaster or other extraordinary circumstance has affected an entire region or locale. We noted that if CMS made such a determination to grant an ECE to hospitals in an affected region or locale, we would convey this decision through routine communication channels to hospitals, vendors, and QIOs, including, but not limited to, issuing memos, emails, and notices on the QualityNet website.

In the 2018 IPPS/LTCH PPS final rule (82 FR 38239), we modified the requirements for the HRRP ECE policy to further align with the processes used by other QRP and VBP programs for requesting an exception from program reporting due to an extraordinary circumstance not within a provider's control.

b. Background of the HRRP ECE Granted for the PHE for COVID-19

On March 22, 2020, in response to COVID-19, CMS announced relief for clinicians, providers, hospitals and facilities participating in Medicare QRPs and VBP programs.²⁰ Specifically, we announced that we were granting ECEs for certain data reporting requirements and submission deadlines for the first and second quarters of CY 2020. On March 27, 2020, we published a supplemental guidance memorandum that described the scope and duration of the ECEs we were granting under each Medicare QRP and VBP program.²¹

Under the ECE for the PHE for COVID-19 that we granted to all hospitals subject to the HRRP, qualifying claims from January 1, 2020 through March 31, 2020 (Q1 2020) and

April 1, 2020 through June 30, 2020 (Q2 2020) will be excluded from the measure calculations for the readmission measures used in the program. We also advised that hospitals should be aware of the potential subsequent impact to the HRRP minimum case threshold counts for inclusion in this program.

c. Update to the HRRP ECE Granted in Response to the PHE for COVID-19

We continue to believe that the readmissions claims data we have excepted serve multiple purposes, including allowing us to understand the impact of the PHE for COVID-19 on the quality of care provided to Medicare beneficiaries. However, we are concerned that excess readmission ratios calculated using excepted claims data could affect the national comparability of these data due to the geographic differences of COVID-19 incidence rates and hospitalizations along with different impacts resulting from different state and local law and policy changes implemented in response to COVID-19. Thus, the excess readmission ratios and payment adjustments calculated from excepted data during the PHE for COVID-19 may not provide a nationally comparable assessment of performance in keeping with the program goal of national comparison.

i. CY 2019 Fourth Quarter Data

Data were not excepted from the fourth quarter of CY 2019 from the HRRP. The readmissions measures used to evaluate performance are claims-based measures and do not require hospitals to report data to CMS. Additionally, we believe that the quality measure data regarding care provided prior to the PHE would not be affected by the PHE for COVID-19.

ii. CY 2020 First and Second Quarter Data

In our application of the ECE policy for the PHE for COVID-19, we excepted the use of claims data from the first and second quarters of CY 2020 from the HRRP because of our concern that the data collected during this period may be greatly impacted by the response to COVID-19, and therefore, may not be reflective of a hospital's performance during this time due to concerns with national comparability, as described above. Therefore, we believe that it would be inappropriate to include claims data submitted regarding care provided during first and second quarter CY 2020 in our calculation of a hospital's performance that assesses their performance as compared to other

²⁰ CMS press release available at <https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting>.

²¹ CMS memorandum available at <https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf>.

hospitals in the nation to determine penalties for excess readmissions.

Finally, although the ECE we granted for HRRP has ended, with data collection and reporting requirements having resumed July 1, 2020, we understand that geographic differences in COVID-19 incidence continue to change during the PHE for COVID-19. To maintain flexibility for addressing the impact of COVID-19 on HRRP and determine how best to implement the program equitably, we are announcing in this IFC that if, as a result of the extension of the ECE for the whole country that we grant without a request or the submission of individual ECE requests, we do not have enough data to reliably measure national performance, we may propose to not score hospitals based on such limited data or make the associated payment adjustments to hospitals under the IPPS for the affected program year. If we grant another ECE in the future, we would not require that hospitals report the excepted data for the duration of the ECE. Although a hospital may report data during the ECE, we may determine that such data will not be used for scoring purposes. We would still require that hospitals report the non-excepted data. However, we may determine that it would be inappropriate to score such data or base payment adjustments on it because of reliability concerns. For illustrative purposes only, if a PHE excepted enough quarters from the HRRP 36-month performance period to lead to unreliable measure calculations, we might consider not scoring for the entire year because the sample may not be large enough to calculate reliable measure results for scoring purposes. Although the data itself may be accurate, the measure(s) may not meet the reliability standards because of the small sample of the remaining non-excepted part of the performance period. In addition, in the scenario we describe above, it is likely that only larger hospitals would be able to meet the required case minimums to be scored in the non-excepted part of the performance period. We may conclude that only scoring those remaining large hospitals will produce an accurate national comparison of hospitals. Alternatively, if we do not extend the ECE to cover Q3 and Q4 2020, it is possible that a majority of providers may still submit individual ECE requests for those quarters and it is possible that so many hospitals will submit individual ECE requests that we will not be able to produce a reliable national comparison. In both cases, we are concerned about using the measures

calculated based on these data to score hospitals under the HRRP and base payment adjustments on those scores. If circumstances warrant, we may propose to suspend prospective application of program penalties or payment adjustments through the annual IPPS/LTCH PPS proposed rule. However, in the interest of time and transparency, we may provide subregulatory advance notice of our intentions to suspend such penalties and adjustments through routine communication channels to facilities, vendors, and QIOs. The communications could include memo, emails, and notices on the public QualityNet website (<https://www.qualitynet.org/>).

We welcome public comments on our policy to exclude any data submitted regarding care provided during first and second quarter of CY 2020 from our calculation of performance for FY 2022, FY 2023, and FY 2024.

4. Update to the Hospital VBP Program ECE Granted in Response to the PHE for COVID-19

a. Background of the Hospital VBP ECE Policy

In the FY 2014 IPPS/LTCH final rule (78 FR 50704 through 50707), we finalized a disaster/ECE policy for the Hospital VBP Program. We stated that, 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, 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.

In the May 8th COVID-19 IFC (85 FR 27550), we modified 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 (85 FR 27597 through 27598). We stated that 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 also stated that 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 diagnosis-related group (DRG) payment amount for each discharge in the applicable program year, and will also not be eligible to receive any value-based incentive payments for the applicable program year. We referred 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 in order to receive a TPS for a program year under the Hospital VBP Program.

b. Background of the Hospital VBP Program ECE Granted in Response to the PHE for COVID-19

On March 22, 2020, in response to COVID-19, CMS announced relief for clinicians, providers, hospitals, and facilities participating in Medicare QRPs and VBP programs.²² On March 27, 2020, CMS published a supplemental guidance memorandum that described in more detail the scope and duration of the ECEs we were granting under each Medicare QRP and VBP program.²³

Specifically, we granted an ECE for the PHE for COVID-19 to all hospitals participating in the Hospital VBP Program for the following reporting requirements:

- Hospitals will not be required to report data for the NHSN HAI measures and Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey for the following quarters: October 1, 2019 through December 31, 2019 (Q4 2019), January 1, 2020 through March 31, 2020 (Q1 2020), and April 1, 2020 through June 30, 2020 (Q2 2020). However, hospitals can optionally submit part or all of these data by the posted submission deadlines on the Hospital VBP Program QualityNet site (available at <https://www.qualitynet.org/inpatient/iqr/participation>). This includes the following specific measures:
++ HCAHPS, NQF #0166.

²² CMS press release available at <https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting>.

²³ CMS memorandum available at <https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf>.

++ NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure, NQF #0138.

++ NHSN CLABSI Outcome Measure, NQF #0139.

++ NHSN Facility-wide Inpatient Hospital-onset CDI Outcome Measure, NQF #1717.

++ NHSN Facility-wide Inpatient Hospital-onset MRSA Bacteremia Outcome Measure, NQF #1716.

++ American College of Surgeons—Centers for Disease Control and Prevention Harmonized Procedure SSI Outcome Measure, NQF #0753.

In the March 27, 2020 guidance, we also advised that hospitals should be aware of the potential subsequent impact to its Hospital VBP Program minimum case threshold counts for inclusion in that program, and that data from the impacted quarters for the HCAHPS survey and HAI measures would be used if submitted voluntarily.

- The ECE also stated that we would exclude qualifying claims data from measure calculations for the following quarters: January 1, 2020 through March 31, 2020 (Q1 2020) and April 1, 2020 through June 30, 2020 (Q2 2020). This exception applies to the following measures:

++ Medicare Spending Per Beneficiary (MSPB)-Hospital, NQF #2158.

++ Hospital 30-Day, All Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) 30-Day Mortality Rate, NQF #0230.

++ Hospital 30-Day, All Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) 30-Day Mortality Rate, NQF #0229.

++ Hospital 30-Day, All Cause, Risk-Standardized Mortality Rate Following Pneumonia (PN) 30-Day Mortality Rate, NQF #0468.

++ Hospital-Level Risk-Standardized Complication Rate Following Total Hip Arthroplasty (THA)/Total Knee Arthroplasty Complication Rate (TKA), NQF #1550.

++ Hospital 30-Day, All Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) 30-Day Mortality Rate, NQF #1893.

++ Hospital 30-Day, All Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Grafting (CABG) 30-Day Mortality Rate, NQF #2558.

c. Update to the Hospital VBP ECE Granted in Response to the PHE for COVID-19

We continue to believe that the Hospital VBP Program data we have excepted serves multiple purposes,

including allowing us to understand the impact of COVID-19 on quality of care. Furthermore, the HAI measures in the Hospital VBP Program are not abstracted from claims and are calculated based on data submitted to the CDC through the NHSN. We recognize that the CDC separately collects the same data for epidemiological surveillance and that hospitals may have other reporting requirements which are not affected by our ECE (for example, state requirements). We are concerned with the national comparability of these data due to the geographic differences of COVID-19 incidence rates and hospitalizations along with different impacts resulting from different state and local law and policy changes implemented in response to COVID-19. For these reasons, and as discussed more fully below, we are revising the current ECE we granted for the Hospital VBP Program with respect to first and second quarter CY 2020 excepted data. Under the revised ECE, we will not use any first or second quarter CY 2020 excepted Hospital VBP data that hospitals optionally reported to calculate total performance scores for the FY 2022 through FY 2025 program years or baseline scores for the FY 2024 through FY 2030 program years. We will still use optionally reported fourth quarter CY 2019 Hospital VBP Program data to calculate TPSs for those hospitals for the FY 2021 through FY 2024 program years and baseline scores for the FY 2026 through FY 2029 program years because, as explained below, we believe that the exception granted for those programs with data submission deadlines in April and May 2020 (that is, data from the fourth quarter of CY 2019) is distinct from the exceptions granted because data collected may be greatly impacted by the response to COVID-19 (that is, data from the first and second quarters of CY 2020).

i. CY 2019 Fourth Quarter Hospital VBP Program HAI and HCAHPS Data

We excepted hospitals from the requirement to report fourth quarter CY 2019 HAI and HCAHPS data for the HVB Program to alleviate the reporting burden on hospitals that were responding to the PHE for COVID-19 that would otherwise be required to report these data by the May 18, 2020 and April 1, 2020 submission deadlines, respectively. However, we believe that the quality measure data regarding care provided prior to the PHE for COVID-19 would not be affected. Additionally, as of April 2020, 92.6 percent of hospitals submitted fourth quarter CY 2019 HAI data. Therefore, we are not

making changes to the Hospital VBP Program ECE that we granted with respect to these data for the PHE for COVID-19 and will include all voluntarily reported measure data for the HCAHPS survey and the five NHSN HAI measures when we calculate hospital TPSs for the FY 2021 program year, as well as when we calculate baseline data for the FY 2023 program year. Because we did not except fourth quarter CY 2019 claims-based data for the Hospital VBP Program, we will also include those data when we calculate hospital TPSs for the FY 2021 through FY 2024 program years and baseline data for the FY 2026 through FY 2029 program years.

ii. CY 2020 First and Second Quarter Hospital VBP Program Data

We excepted hospitals from the requirement to report all first and second quarter CY 2020 Hospital VBP Program data to alleviate the reporting burden on hospitals that were responding to the PHE for COVID-19 and because we were concerned that the data collected during this period could be greatly impacted by the response to COVID-19. Although we permitted hospitals to voluntarily report these data, we aim to have the most representative comparison of hospital performance as possible and do not wish to unfairly penalize hospitals that were responding to COVID-19. We believe that using first and second quarter CY 2020 optionally reported data may not provide an accurate national assessment of hospital performance for multiple reasons. First, if only the optionally submitted data is used, it may not provide an accurate national comparison as it is possible that there may be reporting bias introduced by voluntary submission. Reporting bias could be introduced if, for example, only high performers and/or hospitals not impacted or better resourced would choose to submit data, hindering comparisons between hospitals with different circumstances and preventing the program from keeping with its goal of national comparison. A number of other factors could also contribute to CMS' ability to generate an accurate national comparison. For example, geographic differences in COVID-19 incidence rates and COVID-19 related hospitalizations and differences resulting from changes in referral and hospitalization patterns could both impact the national comparability of optionally submitted data. We believe that it would be inappropriate to include optionally submitted data regarding care provided

during first and second quarter CY 2020 in our calculation of a hospital's TPS.

Accordingly, for these reasons, we will not use any first or second quarter CY 2020 excepted Hospital VBP data to calculate total performance scores for the FY 2022 through FY 2025 program years or baseline scores for the FY 2024 through FY 2030 program years to avoid unfairly penalizing hospitals.

Finally, although the ECE we granted for the Hospital VBP Program has ended, with data collection and reporting requirements having resumed July 1, 2020, we understand that geographic differences in COVID-19 incidence continue to change during the PHE for COVID-19. To maintain flexibility for addressing the impact of COVID-19 on the Hospital VBP Program and determine how best to implement the program equitably, we are announcing in this IFC that if, as a result of the extension of the ECE for the whole country that we grant without a request or the submission of individual ECE requests, we do not have enough data to reliably measure national performance, we may propose to not score hospitals based on such limited data or make the associated payment adjustments to facilities under the Hospital VBP Program for the affected program year. If we grant another ECE in the future, we would not require that hospitals report the excepted data for the duration of the ECE. Although a hospital may voluntarily report data during the ECE, we may determine that it would be inappropriate to use such data for scoring purposes. We would still require that hospitals report the non-excepted data. However, we may determine that it would be inappropriate to score such data or base payment adjustments on it because of reliability concerns. For example, if we granted an ECE that excepted hospitals from the requirement to report data for 11 of the 12 months of a given performance period, we would consider not scoring or applying payment adjustments for the associated program year because data from the one non-excepted month may not be large enough to calculate reliable measure results. Although the data itself may be accurate, the measure(s) may not meet the reliability standards because of the small sample of the remaining non-excepted part of the performance period. In addition, in the scenario we describe above, it is plausible that only larger hospitals would be able to meet the required case minimums to be scored in the non-excepted part of the performance period. We may conclude that only scoring those remaining large hospitals will produce an accurate

national comparison of hospitals. Alternatively, if we do not extend the ECE to cover Q3 and Q4 2020, it is possible that a majority of hospitals may still submit individual ECE requests for those quarters and it is possible that so many hospitals will submit individual ECE requests that we will not be able to produce a reliable national comparison. In both cases, we are concerned about using the measures calculated based on these data to score facilities under the Hospital VBP Program and base payment adjustments on those scores. At this time, we are not applying this updated ECE policy to the Hospital VBP Program. If circumstances warrant, we may propose to suspend prospective application of program penalties or payment adjustments through the annual IPPS/LTCH PPS proposed rule. However, in the interest of time and transparency, we may provide subregulatory advance notice of our intentions to suspend such penalties and adjustments through routine communication channels to facilities, vendors, and QIOs. The communications could include memos, emails, and notices on the public QualityNet website (<https://www.qualitynet.org/>). We welcome public comments on our updated Hospital VBP Program ECE policy to exclude any data submitted regarding care provided during the first and second quarter of CY 2020 from our calculation of performance.

5. Revised Performance Period for the FY 2022 SNF VBP Program as a Result of the ECE Granted for the PHE for COVID-19

In this IFC, we are revising the performance period for the FY 2022 SNF VBP Program because, as explained more fully below, we are concerned that using qualifying claims from the two quarters that are not excepted under the ECE for COVID-19 (October 1, 2019 through December 31, 2019 (Q4 2019), and July 1, 2020 through September 30, 2020 (Q3 2020)) for all SNFs nationwide to calculate the SNFRM for the FY 2022 Program will not yield measure scores that reliably reflect quality of care as determined by hospital readmission rates. We are also announcing that we may propose to update the SNF VBP ECE policy for future ECEs that may be granted during the PHE for COVID-19.

a. Background of the SNF VBP ECE Policy

In the FY 2019 SNF PPS final rule (83 FR 39280 through 39281), we finalized an ECE policy for the SNF VBP Program. We stated that a SNF requesting an ECE would indicate the dates and duration

of the extraordinary circumstance in its request, along with any available evidence of the extraordinary circumstance, and if approved, we would exclude the corresponding calendar months from that SNF's measure rate for the applicable measurement period and by extension, its SNF performance score for applicable fiscal years. We noted that this policy does not preclude us from granting exceptions to SNFs that have not requested them when we determine that an extraordinary circumstance, such as an act of nature or PHE, affects an entire region or locale.

We also finalized under the SNF VBP Program ECE policy that we would score any SNFs receiving ECEs on achievement and improvement for any remaining months during the performance period, provided the SNF had at least 25 eligible stays during both of those periods. As an example, we stated that if a SNF received an approved ECE for 6 months of the performance period, we would score the SNF on its achievement during the remaining 6 months on the Program's measure as long as the SNF met the 25 eligible stay threshold during the performance period. We also stated that under this example, we would score the SNF on improvement as long as it met the proposed 25 eligible stay threshold during the applicable baseline period.

b. Background of the SNF VBP Program ECE Granted for the PHE for COVID-19

On March 22, 2020, in response to the PHE for COVID-19,²⁴ we announced relief for clinicians, providers, hospitals and facilities participating in Medicare QRPs and VBP programs. On March 27, 2020, we published a supplemental guidance memorandum that described in more detail the scope and duration of the ECEs we were granting under each Medicare QRP and VBP program.²⁵

Under the ECE, SNFs qualifying claims are excepted from the calculation of the SNF 30-Day All-Cause Readmission Measure (SNFRM; NQF #2510) for the following periods:

- January 1, 2020–March 31, 2020 (Q1 2020).
- April 1, 2020–June 30, 2020 (Q2 2020).

We refer readers to the March 22 and March 27, 2020 guidance memos for additional information regarding

²⁴ CMS press release available at <https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting>.

²⁵ CMS memorandum available at <https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf>.

exceptions related to the PHE for COVID-19.

We continue to believe that the claims data we have excepted serves multiple purposes, including allowing us to understand the impact of the PHE for COVID-19 on the quality of care provided to Medicare beneficiaries. However, we excepted claims data from the first and second quarters of CY 2020 from the SNF VBP Program because of our concern that the data reliability during this period may be greatly impacted by the response to COVID-19. We are also concerned with the national comparability of these data due to the geographic differences of COVID-19 incidence rates and hospitalizations along with different impacts resulting from different state and local law and policy changes implemented in response to COVID-19. Therefore, we believe that it would be inappropriate to include data submitted regarding care provided during first and second quarter CY 2020 in our calculation of a SNF's performance score. However, by excluding 6 months of qualifying claims in CY 2020 (January 1, 2020 through June 30, 2020) for all SNFs nationally, this policy will impact the performance period (October 1, 2019 through September 30, 2020) for the FY 2022 SNF VBP Program Year by reducing the total amount of data available to evaluate SNF performance. Accordingly, as discussed below, we are finalizing in this IFC a new performance period for the FY 2022 SNF VBP that we believe will more reliably reflect SNF performance and quality of care provided to Medicare beneficiaries.

In addition, although the ECE we granted for the SNF VBP Program has ended, and data collection resumed July 1, 2020, we understand that geographic differences in COVID-19 incidence continue to change during the PHE for COVID-19. To maintain flexibility for addressing the impact of COVID-19 on the SNF VBP Program and determine how best to implement the program equitably, we are announcing in this IFC that if, as a result a ECE that we grant for the whole country without a request or the submission of individual ECE requests, we do not have enough SNF VBP Program data to reliably measure national performance, we may propose to not score facilities based on such limited data or make the associated payment adjustments to facilities under the SNF PPS for the affected program year. If we grant another ECE in the future, we would not use claims data submitted to CMS during the ECE for scoring purposes under the SNF VBP program. We may determine that it would be inappropriate to score

remaining non-excepted data or base payment adjustments on it because of reliability concerns. For example, if we granted an ECE that excepted, for all facilities nationwide, the use of claims data for 11 of the 12 months of a given performance period, we would consider not scoring or applying payment adjustments for the associated program year because data from the one non-excepted month may not be large enough to calculate reliable measure results for scoring purposes. Although the data itself may be accurate, the measure(s) may not meet the reliability standards because of the small sample of the remaining non-excepted part of the performance period. In addition, in the scenario we describe above, it is likely that only larger facilities would be able to meet the required minimum number of eligible SNF stays to be scored in the non-excepted part of the performance period. We may conclude that only scoring those remaining large facilities will not produce an accurate national comparison of SNFs. Alternatively, if we do not extend the ECE to cover Q3 and Q4 2020, it is possible that a majority of SNFs may still submit individual ECE requests for those quarters and it is possible that so many SNFs will submit individual ECE requests that we will not be able to produce a reliable national comparison. In both cases, we are concerned about using the measures calculated based on these data to score facilities under the SNF VBP Program and base payment adjustments on those scores. At this time, we are not applying this updated ECE policy to the SNF VBP Program. Rather, as described in detail in the next section, we are revising the performance period of the FY 2022 SNF VBP Program to include data from: April 1, 2019 through December 31, 2019 and July 1, 2020 through September 30, 2020. However, if at a future date if circumstances warrant, we may propose to suspend prospective application of program penalties or payment adjustments through the annual SNF PPS proposed rule. However, in the interest of time and transparency, we may provide subregulatory advance notice of our intentions to suspend such penalties and adjustments through routine communication channels to facilities, vendors, and QIOs. The communications could include memos, emails, and notices on the public CMS website (<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/SNF-VBP/SNF-VBP-Page>) or, if time allows, through the annual SNF PPS proposed rule.

d. Revised Performance Period for the FY 2022 SNF VBP Program

The performance period for the FY 2022 SNF VBP Program is FY 2020 (84 FR 38822). The ECE for the PHE for COVID-19 excepts 6 months of claims data from the calculation of the SNFRM during the performance period of the FY 2022 SNF VBP Program.

We are concerned that using qualifying claims during only the remaining 6 months of FY 2020 (October 1, 2019 through December 31, 2019 (Q4 2019), and July 1, 2020 through September 30, 2020 (Q3 2020)) for all SNFs nationwide to calculate the SNFRM for the FY 2022 Program will not yield measure scores that reliably reflect quality of care as determined by hospital readmission rates because the reliability of the SNFRM rate is related to sample size. We distinguish between ECEs that grant exceptions for a limited number of SNFs on a case-by-case basis (that is, if a SNF submits an ECE form with appropriate supporting evidence), which would yield an acceptable reflection of those SNFs' performance, and blanket ECEs that grant exceptions for all SNFs nationwide, which may decrease the likelihood that measure performance would reflect the quality of care across a large number of SNFs. Furthermore, the NQF endorsed the SNFRM as a one-year measure.²⁶ In line with NQF endorsement, the performance period and baseline period SNFRM rate for a program year has been calculated based on one year of data since the Program's inception. Our internal analysis indicates that calculating the SNFRM based on 6 months data for all SNFs nationwide would decrease the SNFRM's reliability by approximately one-third compared to calculating the SNFRM based on one year of data, resulting in unacceptably low measure reliability. This situation differs from, for example, calculating the SNFRM based on 6-months of data for only several SNFs, which would not meaningfully impact the SNFRM's reliability and would not impact the vast majority of SNFs whose SNFRM rate would still be calculated based on one year of data. We do not believe it is appropriate to calculate the SNFRM in such a way that does not align with NQF endorsement and may decrease the likelihood that the SNFRM reliably reflects the quality of care provided by those SNFs. Therefore, we are revising the performance period for the FY 2022 SNF VBP Program. The revised

²⁶ From https://www.qualityforum.org/Measures_Reports_Tools.aspx, click "NQF-Endorsed Measures (QPS)" under "Find Measures" then search "2510" to view the SNFRM.

performance period for the FY 2022 SNF VBP program will include data from: April 1, 2019 through December 31, 2019 and July 1, 2020 through September 30, 2020. We note that this 12-month period includes 6 months of FY 2019 data and 6 months FY 2020 data, but does not include the 6 months of data that we excepted for the SNF VBP Program under the ECE for the PHE for COVID-19. Eligible SNF stays with admissions during this revised 12-month period, April 1, 2019 through December 31, 2019 and July 1, 2020 through September 30, 2020, will be included in performance period SNFRM calculations for the FY 2022 SNF VBP Program. We believe using data from these two periods, which combines 9 months of data prior to the start of the PHE for COVID-19 and 3 months of data after the end of the ECE we granted for this program, will provide sufficiently reliable data for evaluating SNF performance that can be used for FY 2022 scoring. We selected this performance period data as it was the most operationally feasible, did not use data from FY 2018 (the baseline period for the SNF VBP FY 2022 program year), and provided the least overlap with performance periods for other program years.

We are aware that the revised performance period for the FY 2022 Program overlaps with the performance period of the FY 2021 Program (FY 2019) by 6 months. However, in order to ensure that 12 months of claims data are used to calculate the SNFRM, we believe that this is the most feasible option. We also note that although April 1, 2019 through September 30, 2019 data would be used for two different program years (FY 2021 and FY 2022), October 1, 2019 through December 31, 2019 and July 1, 2020 through September 30, 2020 data would only be used for the FY 2022 program year. Beginning with the FY 2023 program year, the performance period will be FY 2021, consistent with our previously finalized policy. Furthermore, we note that historically there has been an instance of overlapping data during performance periods of the SNF VBP Program; when the SNF VBP Program transitioned from using CY to FY data for calculating the performance period, the performance period of the FY 2019 SNF VBP Program (CY 2017) overlapped with the performance period of the FY 2020 SNF VBP Program (FY 2018) by 3 months (October 1, 2017 through December 31, 2017). We refer readers to the FY 2018 SNF PPS final rule (82 FR 36613 through 36614) for additional

information on those performance periods.

The baseline period of the FY 2022 Program has not been impacted by the PHE for COVID-19 and will remain as FY 2018 (October 1, 2017 through September 30, 2018), and the FY 2022 Program performance standards included in the FY 2020 final rule (84 FR 38822 through 38823) will remain as finalized.

We welcome public comments regarding our policy to revise the FY 2022 SNF VBP Program performance period to April 1, 2019 through December 31, 2019 and July 1, 2020 through September 30, 2020.

E. NCD Procedural Volumes for Facilities and Practitioners To Maintain Medicare Coverage

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 of the Act. Some NCDs include procedural volume requirements that facilities and/or practitioners must meet as conditions of coverage for specific items and services. If those volume requirements are not satisfied, Medicare payment would not be permitted. On March 18, 2020, CMS encouraged hospitals and practitioners to delay certain non-essential procedures due to the COVID-19 pandemic.²⁷ On June 9, 2020, as coronavirus disease-related healthcare demand decreased, CMS found it was important to safely resume care to treat ongoing health needs that had been postponed and issued guidance that hospitals could resume providing these services.²⁸ Even so, as a result of the PHE for COVID-19, hospitals and practitioners have performed fewer non-essential procedures for several months and as a result may not be able to meet certain procedural volume requirements that are set forth in these NCDs.

Four NCDs set forth such procedural volume requirements. These NCDs are:

- NCD 20.34 Percutaneous Left Atrial Appendage Closure (LAAC).
- NCD 20.32 Transcatheter Aortic Valve Replacement (TAVR).
- NCD 20.33 Transcatheter Mitral Valve Repair (TMVR).
- NCD 20.9.1 Ventricular Assist Devices (VADs).

Because of the disruption in the healthcare delivery system, including

²⁷ <https://www.cms.gov/newsroom/press-releases/cms-releases-recommendations-adult-elective-surgeries-non-essential-medical-surgical-and-dental>.

²⁸ <https://www.cms.gov/files/document/covid-recommendations-reopening-facilities-provide-non-emergent-care.pdf>.

the delay in non-essential procedures as noted above, we are not enforcing the procedural volume requirements contained in the four NCDs noted above for facilities and practitioners that, prior to the PHE for COVID-19, met the volume requirements. This enforcement discretion applies only during the period of the PHE for COVID-19 and ensures that beneficiaries will continue to have access to the services that are covered under the NCD.

Please note that all other coverage requirements under these NCDs remain in effect.

F. Limits on COVID-19 and Related Testing Without an Order and Expansion of Testing Order Authority

In this IFC, we are establishing that one COVID-19 diagnostic test and one of each other related test (as listed in the May 8th COVID-19 IFC) without an order from a physician or other practitioner is reasonable and necessary for Medicare payment purposes. For the COVID-19 and other related diagnostic tests for which an order is required, we are also establishing a policy whereby tests can be covered when ordered by a pharmacist or other healthcare professional who is authorized to order diagnostic laboratory tests in accordance with state scope of practice and other pertinent laws.

In the May 8th COVID-19 IFC, CMS stated that, given the critical importance of expanding COVID-19 testing to combat the pandemic and the heightened risk that the disease presents to Medicare beneficiaries during the PHE for COVID-19, Medicare would not require an order from a physician or other applicable practitioner for COVID-19 testing. We amended our regulation at 42 CFR 410.32(a) to remove the requirement that otherwise covered COVID-19 diagnostic laboratory tests are covered only based on the order of a treating physician or other practitioner.²⁹ In addition, we removed the ordering requirement for coverage of a diagnostic laboratory test for influenza virus and respiratory syncytial virus, a type of common respiratory virus, but only when these tests 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. We also noted that FDA-authorized COVID-19 serology tests are included as covered tests during the PHE for COVID-19, as they are

²⁹ The list of COVID-19, Influenza, and RSV clinical diagnostic laboratory tests is available at <https://www.cms.gov/files/document/covid-ifc-2-flu-rsv-codes.pdf>.

reasonable and necessary under section 1862(a)(1)(A) of the Act for beneficiaries with a known current or known prior COVID-19 infection or a suspected current or suspected prior COVID-19 infection.

In this IFC, we are revising the previous policy adopted in the May 8th COVID-19 IFC, which allowed for broad coverage of multiple instances of COVID-19 testing for a single beneficiary without a physician or other practitioner order, by establishing that one single COVID-19 diagnostic test and one of each other related test (as listed in the May 8th COVID-19 IFC) without an order from a physician or other practitioner is reasonable and necessary. This limitation on tests without a physician/other practitioner order will apply beginning on the effective date of this rule, and any tests furnished prior to the effective date will not be considered for purposes of this limit on tests without a physician or other practitioner order. In other words, if a beneficiary received a test or multiple tests without an order before the effective date of this rule, these tests would not count toward the limit of one test without a physician or other practitioner order under this rule. We believe that this approach will provide sufficient notice for laboratories to set up the systems and processes necessary to require an order beyond one test. For the COVID-19 and other related diagnostic tests for which an order is required, we are also establishing a policy whereby the tests can be covered when ordered by a pharmacist or other healthcare professional who is authorized to order diagnostic laboratory tests in accordance with state scope of practice and other pertinent laws.

Just as the previous policy was developed based on what was known about COVID-19 at the time, as additional information has become available, policies require modification. This approach is consistent with the CDC's introductory statement in its July 2, 2020 testing guidance that "recommendations for SARS-CoV-2 testing have been developed based on what is currently known about COVID-19 and are subject to change as additional information becomes available."³⁰ Whereas we are committed to reducing impediments to access to COVID-19 testing and the other related tests identified in the May 8th COVID-19 IFC, we believe that it is contrary to the public interest to allow open-ended coverage of COVID-19

testing without an order from a physician, practitioner, or other healthcare professional. Our determination to revise the May 8th IFC policy is due both to the significant potential for fraud, waste, and abuse, as well as public health and safety issues that would arise from beneficiaries being subjected to repeated testing without proper medical attention or oversight, including public health issues with the ongoing spread of COVID-19, as outlined by CDC guidance on specific patient categories³¹ that has been published in the May 8th COVID-19 IFC.

First, laboratory testing has been a significant source of fraud and abuse in the Medicare program. In one recent example from September 2019, CMS, along with our law enforcement partners, undertook a landmark investigation and prosecution of fraudulent genetic cancer testing, resulting in charges against 35 defendants associated with dozens of telemedicine companies and cancer genetic testing laboratories for their alleged participation in one of the largest healthcare fraud schemes ever charged. According to the charges, the defendants fraudulently billed Medicare for genetic testing, using telemarketers to make phone calls and other unsolicited contacts with Medicare beneficiaries to fraudulently bill more than \$2.1 billion to the Medicare program.³²

We have already found that similar schemes are occurring whereby fraudulent laboratories and telemarketing companies are directly contacting beneficiaries, oftentimes using stolen identifying information, to solicit items and services payable by Medicare under the guise of COVID-19 treatment or prevention. An HHS Office of Inspector General (HHS-OIG) fraud alert³³ describes situations in which scammers are offering unapproved and illegitimate COVID-19 tests and other services to Medicare beneficiaries in exchange for personal details, including Medicare information. However, the services are unapproved and illegitimate. Fraudsters are targeting beneficiaries in a number of ways, including telemarketing calls, text messages, social media platforms, and door-to-door visits. The personal information collected can be used to fraudulently bill federal healthcare programs and commit medical identity

theft. In addition, if Medicare denies the claim for an unapproved test, the beneficiary could be responsible for the cost. The availability of broad COVID-19 and related testing without an order significantly increases the risk and scope of these fraud schemes, leading not only to considerable risk to taxpayer dollars, but also potential physical and financial harm to Medicare beneficiaries.

In addition to our concerns about previous laboratory schemes being applied to COVID-19 testing itself, the risk is exacerbated by the ability of the laboratory to perform add-on tests, such as to confirm or rule-out diagnoses other than COVID-19. The HHS-OIG has recognized that "[r]elaxation of the [ordering] rules could allow unscrupulous actors more leeway for fraudulent billing of unnecessary add-on testing," and announced in June 2020 that it was undertaking a trend analysis for potential fraud and abuse with COVID-19 add-on testing.³⁴

In addition to our concerns about potential fraud, we believe that broad COVID-19 testing without the order of any healthcare professional—including testing for the related conditions identified in the May 8th COVID-19 IFC—may result in a beneficiary not receiving the medical attention and oversight required to ensure that diagnosis and treatment is applied consistent with CDC guidelines and other medical standards. Allowing testing to occur without proper medical attention or oversight can lead to direct or indirect harm to beneficiaries, their families and their contacts, from a variety of perspectives, including the fact that the beneficiary may not receive complete and accurate information on how the test results should be interpreted and acted upon (for example, contact tracing and public health precautions) and how the beneficiary should be monitored in the case of a positive test.

Of the nearly 1.9 million beneficiaries who have been tested, approximately 83 percent have had only one test performed. However, claims data from the past 8 months have shown that the number of beneficiaries receiving more than one COVID-19 test has been increasing. While we do not have data to examine whether these tests are being performed without a physician or other practitioner order, we expect the proportion of beneficiaries who are tested more than once to increase over time until a vaccine or other containment strategy is available to

³¹ <https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html>.

³² <https://oig.hhs.gov/newsroom/media-materials/2019/geneticscam/index.asp>.

³³ <https://oig.hhs.gov/coronavirus/fraud-alert-covid19.asp>.

³⁴ <https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000489.asp>.

³⁰ <https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html>.

meaningfully reduce the risk of COVID-19. We believe that allowing Medicare payment for one test without an order will allow beneficiaries access to urgent testing, as we outlined in the May 8th COVID-19 IFC, yet also provide sufficient opportunity for beneficiaries to seek out the medical care needed to ensure that the test results are interpreted and acted upon appropriately, both from the perspective of the individual beneficiary and also in the context of the area of the country in which the beneficiary is located.

While some areas of the country continue to have minimal impact from the disease or are seeing the COVID-19 infection curve flattening, other areas are seeing a resurgence. Executing an effective, regional response to COVID-19 disease requires coordinated effort and guidance by qualified medical professionals who know how to interpret and react to testing results. Recent experience with this disease has also demonstrated that substantial COVID-19 transmission occurs from infectious individuals both with and without symptoms, and that isolation of infected persons has been identified as a key strategy for preventing further spread of COVID-19. Testing without healthcare oversight can lead to a bypassing of risk-stratified protocols for management of negative COVID-19 test results. A negative test does not rule out the disease; if a physician or other appropriate healthcare professional suspects a patient may have COVID-19 based on symptoms or other factors, infection control measures should be implemented regardless of test results. For example, isolation of persons infected with SARS-CoV-2, the virus that causes COVID-19, is a key strategy for preventing further spread of COVID-19. In fact, when infected individuals are separated from others while awaiting their test results, transmission is reduced much more than when individuals are not separated. By having patients isolated one to two days earlier, spread of COVID-19 can be reduced significantly.³⁵ When a physician or other health care provider is able to counsel patients who are being tested for COVID-19, beneficiaries may be more likely to isolate or quarantine themselves more quickly, which may reduce transmission in the community. Self-quarantine for those who may be infectious is also a key element to ensuring that health care providers and suppliers are able to continue to safely provide COVID-19-related and non-COVID-19 essential care, patients can

resume elective procedures, and that the nation can continue steps to reopen the economy.

We remain committed to ensuring beneficiaries have access to needed testing services, and to the medical oversight required to address this complex pandemic. First, we note that our numerous provisions enhancing access to and use of telehealth and other communications technology-based services (CTBS) have enabled beneficiaries to overcome some of the obstacles associated with seeking care in physician offices and other medical facilities during the PHE for COVID-19. The telehealth and CTBS flexibilities have provided a modernized framework for care delivery, including the ability for clinicians to remotely assess the medical condition of patients and determine the need for COVID-19 testing and perform related clinical oversight, which takes advantage of modern technology while addressing the health needs of the Medicare beneficiary population.

In addition, in our March 31st COVID-19 IFC, we established payment policies to provide specimen collection fees for independent laboratories collecting specimens from beneficiaries who are homebound or non-hospital inpatients for COVID-19 testing during the PHE for COVID-19. In our May 8th COVID-19 IFC, we also established payment mechanisms for specimen collection for COVID-19 testing under the Physician Fee Schedule (PFS) and OPFS during the PHE for COVID-19. To help ensure that laboratories located in the United States wishing to perform COVID-19 testing that are applying for a CLIA certificate are able to begin testing as quickly as possible during the PHE for COVID-19, we have also reviewed our regulations (42 CFR part 493) and our procedures to expedite review of applications for a CLIA certificate. We are committed to taking critical steps to ensure Medicare beneficiaries are able to access safe and reliable COVID-19 and related testing.

CMS and CDC are also taking steps to ensure that physicians and other practitioners who counsel patients on COVID-19 testing are paid for these services. On July 30, 2020, CMS and CDC announced that payment is available to practitioners and suppliers to counsel patients, at the time of COVID-19 testing, about the importance of self-isolation after they are tested and prior to the onset of symptoms.³⁶

³⁶ <https://www.cms.gov/newsroom/press-releases/cms-and-cdc-announce-provider-reimbursement-available-counseling-patients-self-isolate-time-covid-19>.

Through counseling, health care providers can discuss with patients: (1) The signs and symptoms of COVID-19; (2) the immediate need to separate from others by isolation, particularly while awaiting test results; (3) the importance of informing close contacts of the person being tested (for example, family members) to separate from the patient awaiting test results; (4) the fact that if the patient tests positive, the patient will be contacted by the public health department to learn the names of the patient's close contacts; and (5) the services that may be available to assist the patient in successfully isolating at home.

We also believe that pharmacists and other healthcare professionals play an important role in the response to the PHE for COVID-19, and we explicitly clarified in the May 8th COVID-19 IFC that pharmacists fall within the regulatory definition of auxiliary personnel under our regulation at § 410.26. As such, pharmacists may provide services incident-to the professional services, and under the appropriate level of supervision, of the billing physician or practitioner, 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 practitioner and in accordance with the pharmacist's state scope of practice and applicable state law. We believe this clarification may encourage pharmacists to work with physicians and other applicable practitioners in new ways that expand the availability of health care services during the PHE for COVID-19. One service that may be rendered in accordance with these authorities is an assessment and specimen collection for COVID-19 testing. Specifically, we stated in the May 8th COVID-19 IFC that CPT code 99211 can be billed for both new and established patients for the duration of the PHE for COVID-19, when the services described by that code for a level 1 E/M visit are furnished for the purpose of a COVID-19 assessment and specimen collection. These services can be billed as services provided by auxiliary clinical staff, including pharmacists, if those staff meet all of the requirements to furnish services as "incident to," as described in § 410.26 of our regulations and in our frequently asked questions document discussing virtual supervision.³⁷

To further ensure that beneficiaries continue to have access to appropriate COVID-19 testing even when some

³⁷ <https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf>.

³⁵ <https://www.cms.gov/files/document/se20011.pdf>.

professional care is not separately billable under Medicare, we are establishing a policy whereby otherwise covered COVID-19 and specified related tests ordered by pharmacists and other healthcare professionals who are authorized to order diagnostic laboratory tests in accordance with state scope of practice and other pertinent laws are covered for the duration of the PHE for COVID-19. Under this policy, an otherwise covered COVID-19 test (and other related tests, as specified on the CMS website) is considered reasonable and necessary during the PHE for COVID-19 if ordered by a pharmacist or other healthcare professional who is practicing in accordance with applicable state scope of practice laws. Because pharmacists and certain other healthcare professionals are not considered to be physicians or practitioners under the Medicare statute, they cannot be paid directly under the Medicare program; therefore, pharmacists and other auxiliary personnel still need to be functioning in an incident-to arrangement with a physician or non-physician practitioner for the services they provide to be paid by Medicare under Part B for the front-end assessment and specimen collection associated with the order, as described above. However, we believe this interim ordering policy is appropriate during the duration of the PHE for COVID-19 to ensure adequate access to testing as permitted under state scope of practice and other applicable laws.

With this IFC, we are amending our regulation at § 410.32(a)(3) to state that, starting with the effective date of the revision and carrying forward for the remaining duration of the PHE for COVID-19, the order of a physician or other practitioner is not required for one otherwise covered diagnostic laboratory test for COVID-19 and for one otherwise covered diagnostic laboratory test each for influenza virus or similar respiratory condition needed to obtain a final COVID-19 diagnosis, when performed in conjunction with a COVID-19 diagnostic laboratory test in order to discount influenza virus or related diagnosis.³⁸ This includes FDA-authorized COVID-19 serology tests, as they are reasonable and necessary under section 1862(a)(1)(A) of the Act for beneficiaries with known current or known prior COVID-19 infection or suspected current or suspected prior COVID-19 infection. We are also

³⁸ The list of COVID-19, Influenza, and RSV clinical diagnostic laboratory tests is available at <https://www.cms.gov/files/document/covid-ifc-2-flu-rsv-codes.pdf>.

amending the regulation so the orders of pharmacists and other practitioners that are allowed to order laboratory tests in accordance with state scope of practice and other pertinent laws can fulfill the requirements related to orders for covered COVID-19 tests for Medicare patients. We note that Medicare continues to cover other medically necessary clinical diagnostic laboratory tests when a treating physician or other practitioner orders them, and that other Medicare conditions of coverage and payment continue to apply, including any applicable local coverage determinations.

The policies described in this section apply to the Medicare program only. Coverage policies for COVID-19 testing for group health plans and health insurance issuers offering group and individual health insurance coverage are generally governed by other rules of other federal agencies and/or HHS and states. States administer the Medicaid program and the Children's Health Insurance Program (CHIP) subject to federal requirements, and therefore, have significant responsibility for establishing coverage and payment policies for those programs, within federal parameters.

G. Recognizing Temporary Premium Credits as Premium Reductions

1. Background

Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104-191, enacted on August 21, 1996) added a new title XXVII to the PHS Act to establish various reforms to the group and individual health insurance markets. These provisions of the PHS Act have also been augmented by later laws, including the Patient Protection and Affordable Care Act (PPACA).³⁹ Subtitles A and C of title I of the PPACA reorganized, amended, and added to the provisions of part A of title XXVII of the PHS Act relating to group health plans and health insurance issuers in the group and individual markets.

Section 1321(a) of the PPACA provides broad authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges,⁴⁰

³⁹ 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" or "PPACA".

⁴⁰ American Health Benefit Exchanges, or "Exchanges," are entities established under the

qualified health plans (QHPs), and other components of title I of the PPACA. Section 1321(a)(1) of the PPACA directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the PPACA for, among other things, the establishment and operation of Exchanges.

Section 1321(d) of the PPACA provides that nothing in title I of the PPACA must be construed to preempt any state law that does not prevent the application of title I of the PPACA. Section 1311(k) of the PPACA specifies that Exchanges may not establish rules that conflict with or prevent the application of regulations issued by the Secretary.

Section 1343 of the PPACA establishes an annual permanent risk adjustment program to provide payments to health insurance issuers that attract higher-than-average risk populations, such as those with chronic conditions, funded by payments from those that attract lower-than-average risk populations, thereby reducing incentives for issuers to avoid higher-risk enrollees. Consistent with section 1321(c)(1) of the PPACA, the Secretary is responsible for operating the risk adjustment program on behalf of any state that does not elect to do so. We established the framework for the risk adjustment program in a final rule, published in the March 23, 2012 **Federal Register** (77 FR 17219) (Premium Stabilization Rule), and first established the federally-certified risk adjustment methodologies and other parameters related to the risk adjustment program applicable to the 2014 benefit year in the 2014 Payment Notice final rule in the March 11, 2013 **Federal Register** (78 FR 15409). In the October 30, 2013 **Federal Register** (78 FR 65046), we finalized the proposed modification to the HHS methodology related to community rating states. We published a correcting amendment to the 2014 Payment Notice final rule in the November 6, 2013 (78 FR 66653) to address how an enrollee's age for the risk score calculation would be determined under the HHS methodology. We have generally published the parameters and methodology for the applicable risk adjustment benefit year in each subsequent HHS annual notice of benefit and payment parameters.⁴¹ In

PPACA through which qualified individuals and qualified employers can purchase health insurance coverage in qualified health plans (QHPs).

⁴¹ See the 2015 Payment Notice final rule published in the March 11, 2014 **Federal Register** (79 FR 13743); the 2016 Payment Notice final rule published in the February 27, 2015 **Federal Register** (80 FR 10749); the 2017 Payment Notice final rule

the July 30, 2018 **Federal Register** (83 FR 36456), we published a final rule that adopted the 2017 benefit year risk adjustment methodology as established in the final rules published in the March 23, 2012 (77 FR 17220 through 17252) and in the March 8, 2016 editions of the **Federal Register** (81 FR 12204 through 12352). The final rule sets forth additional explanation of the rationale supporting the use of the statewide average premium in the HHS-operated risk adjustment state payment transfer formula for the 2017 benefit year, including the reasons why the program is operated in a budget-neutral manner. The final rule permitted HHS to resume 2017 benefit year risk adjustment payments and charges. HHS also provided guidance as to the operation of the HHS-operated risk adjustment program for the 2017 benefit year in light of publication of this IFC.⁴²

In the August 10, 2018 **Federal Register** (83 FR 39644), we published a proposed rule seeking comment on adopting the 2018 benefit year risk adjustment methodology in the final rules published in the March 23, 2012 (77 FR 17219) and in the December 22, 2016 editions of the **Federal Register** (81 FR 94058). The proposed rule set forth additional explanation of the rationale supporting use of statewide average premium in the HHS-operated risk adjustment state payment transfer formula for the 2018 benefit year, including the reasons why the program is operated in a budget-neutral manner. In the December 10, 2018 **Federal Register** (83 FR 63419), we issued a final rule adopting the 2018 benefit year HHS-operated risk adjustment methodology as established in the final rules published in the March 23, 2012 (77 FR 17219) and the December 22, 2016 (81 FR 94058) editions of the **Federal Register**. That final rule sets forth additional explanation of the rationale supporting use of statewide average premium in the HHS-operated risk adjustment state payment transfer formula for the 2018 benefit year, including the reasons why the program is operated in a budget-neutral manner. We adopted the risk adjustment methodology and parameters for the

2020 benefit year in the 2020 Payment Notice final rule in the April 25, 2019, **Federal Register** (84 FR 17454). On May 14, 2020, we adopted the risk adjustment methodology and parameters for the 2021 benefit year in the 2021 Payment Notice final rule in the **Federal Register** (85 FR 29164).

Section 2718 of the PHSA, as added by the PPACA, generally requires health insurance issuers to submit an annual report to the Secretary that details the percentage of premium revenue (after certain adjustments) expended on reimbursement for clinical services provided to enrollees under health insurance coverage and on activities that improve healthcare quality. The ratio of premium revenue spent on clinical services and quality improvement activities is called the medical loss ratio (MLR). Section 2718(b) of the PHSA requires an issuer to provide rebates to enrollees if its MLR falls below specified MLR standards (generally 80 percent for the individual and small group markets, and 85 percent for the large group market). We published an interim final rule in the December 1, 2010 **Federal Register** (75 FR 74863). A final rule was published in the December 7, 2011 **Federal Register** (76 FR 76573). The MLR program requirements were amended in final rules published in the December 7, 2011 **Federal Register** (76 FR 76595), the May 16, 2012 **Federal Register** (77 FR 28790), the March 11, 2014 **Federal Register** (79 FR 13743), the May 27, 2014 **Federal Register** (79 FR 30339), the February 27, 2015 **Federal Register** (80 FR 10749), the March 8, 2016 **Federal Register** (81 FR 12203), the December 22, 2016 **Federal Register** (81 FR 94183), the April 17, 2018 **Federal Register** (83 FR 16930), and the April 25, 2019 **Federal Register** (84 FR 17454).

Due to the urgent need to help facilitate the nation's response to the COVID-19 pandemic, CMS announced the adoption of certain temporary policies of relaxed enforcement for all issuers offering health insurance coverage in the individual and small group markets to support continuity of coverage for individuals, families, and small employers who may struggle to pay premiums because of illness or loss of incomes or revenue resulting from the PHE for COVID-19. On August 4, 2020, CMS issued a memo, "Temporary Policy on 2020 Premium Credits Associated with the COVID-19 Public Health Emergency," wherein CMS adopted certain temporary policies of relaxed enforcement for the premium rules set forth at 45 CFR 147.102, 155.200(f)(4), 155.400(e) and (g), 155.706(b)(6)(1)(A),

156.80(d), 156.210(a), and 156.286(a)(2) through (4) to allow issuers in the individual and small group markets the flexibility, when consistent with state law, to temporarily offer premium credits for 2020 coverage.⁴³ The memo also advised of our intention to pursue future rulemaking to address risk adjustment data submissions and MLR reporting requirements for issuers that elect to provide these credits to ensure that issuers accurately report premium amounts actually billed for months in 2020 for which issuers are providing these credits.

This IFC clarifies the data reporting requirements for issuers of risk adjustment covered plans⁴⁴ to specify that, for the purposes of 2020 benefit year risk adjustment data submissions, issuers of risk adjustment-covered plans that provide temporary premium credits must report to their dedicated distributed data environment (EDGE server) adjusted plan premiums that reflect actual premiums billed to enrollees, taking the premium credits into account as a reduction in premiums. In addition, this IFC clarifies, consistent with the reporting of the actual premium amounts billed to enrollees for 2020 benefit year risk adjustment data submissions, HHS's calculation of risk adjustment payment and charges for the 2020 benefit year under the state payment transfer formula⁴⁵ will be calculated using the statewide average premium that reflects actual premiums billed, taking into account any temporary premium credits provided as a reduction in premium for the applicable months of 2020 coverage.

This IFC similarly clarifies the MLR reporting and rebate requirements in 45 CFR part 158 for issuers that elect to provide temporary premium credits such that these issuers must report as earned premium the actual premium paid, taking into account any temporary premium credits as a reduction in premium for the applicable months of 2020 coverage.

These interim final provisions are effective as of the date of finalization of this IFC and apply to temporary

published in the March 8, 2016 **Federal Register** (81 FR 12203); the 2018 Payment Notice final rule published in the December 22, 2016 **Federal Register** (81 FR 94058); the 2019 Payment Notice final rule published in the April 17, 2018 **Federal Register** (83 FR 16930); and the 2019 Payment Notice final rule correction published in the May 11, 2018 **Federal Register** (83 FR 21925).

⁴² "Update on the HHS-operated Risk Adjustment Program for the 2017 Benefit Year." July 27, 2018. Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2017-RA-Final-Rule-Resumption-RAOps.pdf>.

⁴³ See <https://www.cms.hhs.gov/CCIIO/Programs-and-Initiative/Health-Insurance-Marketplaces/Downloads/Premium-Credit-Guidance.pdf>.

⁴⁴ See 45 CFR 153.20 for a definition of "risk adjustment covered plan".

⁴⁵ The state payment transfer formula refers to the part of the HHS risk adjustment methodology established consistent with 45 CFR 153.320 that calculates payments and charges at the state market risk pool level. See, for example, the 2020 Payment Notice final rule, 84 FR at 17485. The state payment transfer calculations are performed prior to the calculation of the high-cost risk pool payment and charge terms.

premium credits provided for 2020 coverage.

2. Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment (45 CFR Part 153)

This IFC addresses changes necessary to align the 2020 benefit year data submission requirements and state payment transfer formula calculations under the HHS-operated risk adjustment program with guidance published by CMS allowing temporary premium credits due to the PHE for COVID-19.

a. Provisions and Parameters for the Risk Adjustment Program

In subparts A, B, D, G, and H of part 153, we established standards for the administration of the PPACA risk adjustment program. The risk adjustment program is a permanent program created by section 1343 of the PPACA that transfers funds from lower-than-average risk, risk adjustment covered plans to higher-than-average risk, risk adjustment covered plans in the individual and small group markets (including merged markets), inside and outside the Exchanges. HHS is responsible for operating risk adjustment in any state that does not elect to do so.⁴⁶ HHS did not receive any requests from states seeking to operate their own risk adjustment program for the 2020 benefit year.⁴⁷ Therefore, HHS is responsible for operating the risk adjustment program established under section 1343 of the PPACA in all 50 states and the District of Columbia for the 2020 benefit year.⁴⁸

i. Calculation of Plan Average Premium and State Average Premium Under the Federally-Certified Risk Adjustment Methodology (§ 153.320)

The HHS risk adjustment methodology applicable to the 2020 benefit year includes the state payment transfer formula and the high-cost risk pool parameters.⁴⁹ The state payment transfer formula includes a set of cost adjustment terms that require transfers to be calculated at the geographic rating area level for each plan (that is, we calculate separate transfer amounts for each rating area in which a risk adjustment covered plan operates). It also includes a 14 percent administrative cost reduction to the statewide average premium. The state payment transfer formula generally

calculates the difference between the revenues required by a plan, based on the health risk of the plan's enrollees, and the revenues that the plan can generate for those enrollees. These differences are then compared across plans in the state market risk pool⁵⁰ and converted to a dollar amount based on the statewide average premium. The difference between the two premium estimates determines whether a plan pays a risk adjustment charge or receives a risk adjustment payment.⁵¹

HHS chose to use statewide average premium and normalize the risk adjustment state payment transfer formula to reflect state average factors so that each plan's enrollment characteristics are compared to the state average and the calculated payment amounts equal calculated charges in each state market risk pool.⁵² Thus, the state payment transfer formula provides a per member per month (PMPM) transfer amount for a plan within a rating area. This resulting PMPM plan payment or charge is multiplied by the number of billable member months to determine the plan payment or charge based on plan liability risk scores for a plan's geographic rating area for the applicable state market risk pool. The payment or charge under the state payment transfer formula is thus calculated to balance the state market risk pool in question.

In prior rulemaking,⁵³ CMS finalized the calculation of plan average premium as equal to the actual premiums charged to plan enrollees, weighted by the number of months enrolled, and finalized the calculation of the state average premium as equal to the average of individual plan average premiums, weighted by each plan's share of statewide enrollment in the risk pool

market, based on billable member months.

This IFC sets forth how HHS will treat temporary premium credits provided for purposes of applying the state payment transfer formula for the 2020 benefit year.⁵⁴ For states where issuers of risk adjustment covered plans have provided temporary premium credits, the plan average premium and statewide average premium used in the state payment transfer formula will be calculated using issuers' adjusted premium amounts—that is, the actual premiums billed to plan enrollees will be the amounts used in the calculations under the state payment transfer formula. We clarify that HHS will use adjusted plan premiums for all enrollees whom the issuer has actually provided premium credits as a reduction to 2020 benefit year premiums, even if the credits were not provided in a manner consistent with the August 4, 2020 memo, when calculating transfers under the state payment transfer formula for the 2020 benefit year. As detailed further below, issuers providing these temporary premium credits must report the lower, actual premium amounts billed to plan enrollees to their respective EDGE servers. We believe that the applicable definitions of plan average premium and state average premium retain the meaning previously finalized by reflecting the actual monthly premium billed to enrollees. In addition, the recognition of temporary premium credits for 2020 coverage as a reduction in premium for purposes of the risk adjustment program is a necessary and appropriate step to align risk adjustment charges and payments under the state payment transfer formula with the flexibilities provided to issuers and states elsewhere in this rulemaking to respond to the PHE for COVID-19. This approach also provides necessary clarity to issuers as they evaluate whether and in what amount to offer premium relief to enrollees to assist those adversely affected financially by the PHE for COVID-19 to maintain continuous health insurance coverage. This IFC does not change any other aspect of the state payment transfer formula or the method for calculating payments and charges under the HHS risk adjustment methodology (inclusive of the state payment transfer formula and high-cost risk pool parameters).⁵⁵

In the 2019 Payment Notice, we provided states the flexibility to request

⁴⁶ See section 1321(c)(1) of the PPACA. Also see 45 CFR 153.310(a).

⁴⁷ See the 2020 Payment Notice final rule, 84 FR at 17463 (April 25, 2019).

⁴⁸ *Ibid.*

⁴⁹ See the 2020 Payment Notice final rule, 84 FR at 17466 through 17468 and 17480 through 17486.

⁵⁰ Risk adjustment transfer under the state payment transfer formula are calculated at the risk pool level, and catastrophic plans are treated as a separate risk pool for purpose of these calculations.

⁵¹ The value of the plan average risk score by itself does not determine whether a plan would be assessed a charge or receive a payment—even if the risk score is greater than 1.0, it is possible that the plan would be assessed a charge if the premium compensation that the plan may receive through its rating (as measured through the allowable rating factor) exceeds the plan's predicated liability associated with risk selection.

⁵² See the 2020 Payment Notice final rule for further details on other reasons why statewide average premium is the cost-scaling factor in the state payment transfer formula. See 84 FR at 17480 through 17484.

⁵³ See, for example, the 2014 Payment Notice final rule, 78 FR 15409, available at <https://www.govinfo.gov/content/pkg/FR-2013-03-11/pdf/2013-04902.pdf> (March 11, 2013). Also see the 2020 Payment Notice final rule, 84 FR 17454, available at <https://www.govinfo.gov/content/pkg/FR-2019-04-25/pdf/2019-08017.pdf>.

⁵⁴ CMS intends to consider adopting a similar approach for the 2021 benefit year, as may be appropriate (for example, if similar temporary premium credits are permitted for 2021 coverage).

⁵⁵ See the 2020 Payment Notice final rule, 84 FR at 17466 through 17468 and 17480 through 17486.

a reduction to the otherwise applicable risk adjustment transfers calculated under the HHS-operated risk adjustment methodology's state payment transfer formula, which is calibrated on a national dataset, for the state's individual, small group, or merged markets, by up to 50 percent to more precisely account for differences in actuarial risk in the applicable state's market(s).⁵⁶ For the 2020 benefit year, HHS approved a request from Alabama state insurance regulators to reduce risk adjustment transfers for the Alabama small group market by 50 percent.⁵⁷ Consistent with this IFC, the state payment transfer formula will incorporate calculations using issuers' adjusted premium amounts—that is, the lower actual premiums billed to plan enrollees will be the amounts used in the calculations under the state payment transfer formula to reflect these temporary premium credits. As such, if an issuer in the Alabama small group market chooses to provide temporary premium credits, the state average premium will decrease, and HHS will apply the 50 percent transfer reduction to the lower PMPM payment or charge transfer amount calculated under the state payment transfer formula for the Alabama small group market.

ii. Data Requirements for Risk Adjustment Covered Issuers (§ 153.610 and § 153.710)

Section 153.610 requires an issuer of a risk adjustment covered plan to submit or make accessible risk adjustment data for all risk adjustment covered plans in accordance with the risk adjustment data collection approach established by a state, or HHS on behalf of a state. The HHS-operated risk adjustment program uses a distributed data collection approach, and issuers of risk adjustment covered plans must provide HHS with access to plan enrollment data, enrollee claims data, and enrollee encounter data through their respective EDGE server, pursuant to the requirements of § 153.710 and applicable technical guidance.⁵⁸ Issuers are required to report to their EDGE server subscriber-level premium information that is used by HHS to calculate each plan's total

premium revenue for the state payment transfer formula. We clarify in this IFC that, for purposes of 2020 benefit year data submissions,⁵⁹ the subscriber-level premium information that issuers upload to their EDGE servers must reflect the adjusted (that is, lower) monthly premium reflecting the amounts actually billed to their enrollees, inclusive of any premium credits provided. We clarify in this IFC that CMS will require issuers to submit adjusted plan premiums to their EDGE servers for all enrollees whom the issuer has actually provided premium credits as a reduction to 2020 benefit year premiums, even if these premium credits were not provided in a manner consistent with the August 4, 2020 memo. Issuers should continue to submit the full, unadjusted premium amounts for any coverage for which they did not provide temporary premium credits. This IFC does not change any other aspect of the 2020 benefit year data submission requirements for the HHS-operated risk adjustment program. As such, any temporary premium credits that are reported as a reduction in premium for risk adjustment purposes are subject to the applicable regulations at part 153, the EDGE server business rules, and applicable CMS guidance.

3. Issuer Use of Premium Revenue: Reporting Requirements (45 CFR Part 158)

In this IFC, we also address changes necessary to align the reporting and data submission requirements under the PPACA MLR program with the temporary premium credits that issuers may provide to enrollees in 2020.⁶⁰

a. Premium Revenue (§ 158.130)

Section 2718(a) of the PHSA requires health insurance issuers to report to the Secretary the percentage of premium revenue (after certain adjustments) expended on reimbursement for clinical services provided to enrollees under health insurance coverage and on activities that improve healthcare quality. Section 158.130 specifies the reporting requirements with regard to earned premium, which must include all monies paid by a policyholder or subscriber as a condition of receiving

coverage from the issuer, with certain adjustments.

This IFC sets forth how CMS will treat temporary premium credits for purposes of MLR reporting and rebate requirements of these amounts for 2020 coverage.⁶¹ During 2020, a number of issuers are expected to provide premium relief to enrollees, which will result in policyholders and subscribers paying a reduced amount of premium for coverage in 2020 in the months for which the credits are provided. The recognition of temporary premium credits as a reduction in premium for purposes of the MLR program is a necessary and appropriate step to align MLR calculations with the flexibilities provided to issuers and states elsewhere in this rulemaking to respond to the PHE for COVID-19. This approach also provides necessary clarity to issuers as they evaluate whether and in what amount to offer temporary premium credits to assist enrollees in maintaining continuous health insurance coverage during the PHE for COVID-19.

To ensure that an issuer's MLR accurately reflects the amounts actually paid by their enrollees as the issuer's premium revenue, we clarify that for purposes of § 158.130, issuers must account for temporary premium credits as reductions in earned premium in the individual and small group (or merged) markets,⁶² consistent with any technical guidance set forth in the applicable MLR Annual Reporting Form Instructions.⁶³ Specifically, we clarify that the amount of temporary premium credits⁶⁴ constitutes neither collected premium nor due and unpaid premium described in the MLR Annual Reporting Form Instructions for purposes of reporting written premium (which is a component of earned premium). As a result of this flexibility, issuers who offer temporary premium credits should

⁶¹ CMS intends to consider adopting a similar approach if temporary premium credits are permitted for 2021 coverage, if appropriate.

⁶² While this IFC and the August 4, 2020 memo focus on the individual and small group markets, to remove the barriers in support of issuers offering these premium credits to enrollees impacted by PHE for COVID-19, we note that issuers in the large group market may also, when consistent with state law, offer premium credits and should similarly report the lower, adjusted amount that accounts for the premium credits for MLR purposes.

⁶³ Available from https://www.cms.gov/ccio/Resources/Forms-Reports-and-Other-Resources/index#Medical_Loss_Ratio.

⁶⁴ MLR rebates provided in the form of premium credits are different than the temporary premium credits such as those outlined in the August 4, 2020 guidance issued by CMS. When MLR rebates are provided in the form of premium credits, issuers must continue to report the full amount of earned premium and may not reduce it by the amount of MLR rebates provided in form of premium credits, as required by § 158.130(b)(3).

⁵⁶ See the 2019 Payment Notice final rule, 83 FR at 6955 to 16960. Also see 45 CFR 153.320(d).

⁵⁷ See the 2020 Payment Notice final rule, 84 FR at 17484 through 17485. HHS approved a similar request to reduce 2021 benefit year Alabama small group market transfers by 50 percent. See the 2021 Payment Notice final rule, 85 FR at 29193 through 29194.

⁵⁸ See EDGE Server Business Rules (ESBR) v16.0 Section 5.8 Premium Amounts, at https://www.regtap.info/uploads/library/DDC_ESBR_V16.0_052920_5CR_052920.pdf.

⁵⁹ As noted above, CMS intends to consider adopting a similar approach for the 2021 benefit year, as may be appropriate.

⁶⁰ The MLR reporting year means a calendar year during which group or individual health insurance coverage is provided by an issuer. See 45 CFR 158.103. The 2020 MLR reporting year refers to the MLR reports that issuers must submit for the 2020 benefit year by July 31, 2021. See 45 CFR 158.110(b).

report as earned premium for MLR and rebate calculation purposes the actual, reduced premium paid. We clarify that issuers must report the actual, reduced premium amount for all enrollees whom the issuer has actually provided premium credits for 2020 coverage, even if these premium credits were not provided in a manner consistent with the August 4, 2020 memo. This IFC does not change any other aspect of the MLR reporting or rebate calculation requirements.

H. Addressing the Impact of COVID-19 on Part C and Part D Quality Rating Systems

1. Background

CMS develops and publicly posts a 5-star rating system for Medicare Advantage (MA) and Part D plans based on its authority to disseminate comparative information, including about quality, to beneficiaries under sections 1851(d) and 1860D-1(c) of the Act and authority to collect various types of quality data under section 1852(e) of the Act. The Star Rating system for MA and Part D plans is also the basis for determining quality bonus payment (QBP) status for MA plans under section 1853(o) of the Act and the amount of beneficiary rebates under section 1854(b) of the Act. As background, approximately \$12 billion for 2020 will be paid as part of QBPs in the form of higher benchmarks for both Individual and Employer Group Waiver Plans, which represent about 4.35 percent of the total MA benchmarks. Cost plans under section 1876 of the Act are also included in the MA and Part D Star Rating system, as codified at 42 CFR 417.472(k).

The Star Ratings are generally based on measures of performance during a period that is 2 calendar years before the year for which the Star Ratings are issued; for example, 2022 Star Ratings will generally be based on performance during 2020. We use a variety of data sources to measure quality and performance of contracts, such as CMS administrative data, surveys of enrollees, information from health and drug plans, and data collected by CMS contractors. Various regulations require plans to report on quality improvement and quality assurance and to provide data which we can use to help beneficiaries compare plans (for example, §§ 417.472(j) and (k), 422.152(b), 423.153(c), and 423.156). In addition, we can require plans to report statistics and other information in specific categories (§§ 422.516 and 423.514). Data from these sources and other sources are used to calculate

measures of plan sponsor performance each year, as provided in §§ 422.162 and 423.182. The Star Ratings are central in providing comparative information to enrollees and are also used to determine whether an MA plan is eligible for a QBP and the amount of beneficiary rebates.

Sections 1853(o) and 1854(b)(1)(c) of the Act provide for quality ratings, based on a 5-star rating system and the information collected under section 1852(e) of the Act, to be used in calculating payment to MA organizations beginning in 2012. Specifically, these provisions provide, respectively, for an increase in the benchmark against which MA organizations bid and in the portion of the savings between the bid and the benchmark available to the MA organization to use as a rebate. In addition, CMS assigns both low and high performing icons, which are displayed on <https://www.medicare.gov/plan-compare/>, to help Medicare beneficiaries make plan decisions, based on either consistently low performance (2.5 or fewer stars at the summary rating level) for 3 or more years or receipt of 5 stars for the highest rating in any given year.

There are other regulations, regarding marketing authority, special enrollment periods, and contract terminations, that are tied to the Star Ratings, demonstrating how the Star Ratings are important to the MA and Part D programs as a whole. Because the Star Ratings serve a variety of purposes for CMS, cost plans, and MA and Part D plans, we assume plans engage in multiple activities during the measurement period to improve their Star Ratings. Therefore, it is necessary to adopt rules for, and provide information about how performance in 2020—during the PHE for COVID-19—will be used in the Star Ratings program as quickly as possible. Without adopting these rules immediately, plans will believe that, based on current rules, CMS will be unable to assign Star Ratings for Contract Year 2022 and be unable to pay QBPs for Contract Year 2023. Given the significant impact of QBPs on overall plan payments, described above, without immediate action, plans would not have a clear incentive to focus on providing high quality care for enrollees impacted by COVID-19, and instead either spend time and effort trying to ensure that future Star Ratings and QBP ratings are not impacted by the PHE for COVID-19, or shift focus from providing quality care to cost containment. Delaying these changes would limit (or eliminate) the time left in the 2020 measurement period for plans to

manage their performance based on these changes.

In the March 31st COVID-19 IFC, we adopted a series of changes to the 2021 and 2022 Star Ratings to accommodate the disruption to data collection and impact on performance posed by the PHE for COVID-19. The Star Ratings changes adopted in that rule addressed the need of health and drug plans and their providers to curtail certain data collections and to adapt their current practices in light of the PHE for COVID-19 and the need to care for the most vulnerable patients, such as the elderly and those with chronic health conditions. As explained in the March 31st COVID-19 IFC, we believe that there will be changes in measure-level scores because of increased healthcare utilization due to COVID-19, reduced or delayed non-COVID-19 care due to advice to patients to delay routine and/or elective care, and changes in non-COVID-19 inpatient utilization. We realize that this will impact the data collected during the 2020 measurement year which will impact the 2022 Part C and D Star Ratings. Thus, as part of the March 31st COVID-19 IFC, we made some adjustments to account for the potential decreases in measure-level scores so health and drug plans can have some degree of certainty knowing that the Star Ratings will be adjusted and can continue their focus on patients who are most in need right now.

Specifically, the March 31st COVID-19 IFC:

- Eliminates the requirement to collect and submit Healthcare Effectiveness Data and Information Set (HEDIS) and Medicare CAHPS data otherwise collected in 2020, and replaces the 2021 Star Ratings measures calculated based on those HEDIS and CAHPS data collections with earlier values from the 2020 Star Ratings (which are not affected by the public health threats posed by COVID-19);
- Establishes how we will calculate or assign the 2021 Star Ratings in the event that CMS' functions become focused on only continued performance of essential agency operations and the agency and/or its contractors do not have the ability to calculate the 2021 Star Ratings;
- Modifies the current rules for the 2021 Star Ratings to replace any measure that has a systemic data quality issue for all plans due to the COVID-19 outbreak with the measure-level Star Ratings and scores from the 2020 Star Ratings;
- Replaces the measures calculated based on Health Outcomes Survey (HOS) data collections with earlier values that are not affected by the public

health threats posed by COVID-19 for the 2022 Star Ratings in the event that we are unable to complete HOS data collection in 2020 (for the 2022 Star Ratings) due to the PHE for COVID-19;

- Removes guardrails for the 2022 Star Ratings by delaying their application to the 2023 Star Ratings;
- Expands the existing hold harmless provision for the Part C and D Improvement measures to include all contracts for the 2022 Star Ratings; and
- Revises the definition of “new MA plan” so that, for purposes of 2022 QBPs based on 2021 Star Ratings only, new MA plan means an MA contract offered by a parent organization that has not had another MA contract in the previous 4 years, in order to address how the 2021 Star Ratings will be based in part on data for the 2018 performance period.

Please see the March 31st COVID-19 IFC for further information on these changes for the 2021 and 2022 Star Ratings.

2. Impact of COVID-19 on the Extreme and Uncontrollable Circumstance Policy for the 2022 Star Ratings

The March 31st COVID-19 IFC amended, as necessary, certain calculations for the 2021 and 2022 Part C and D Star Ratings to incorporate changes to address the expected impact of the PHE for COVID-19 on data collection and performance in 2020 that were immediately apparent. As the PHE for COVID-19 has progressed and various federal and state agencies have taken steps to address the PHE, we have become aware that application of the current Star Ratings disaster policy for extreme and uncontrollable circumstances (§§ 422.166(i) and 423.186(i)) will cause unintended and unworkable consequences for the 2022 Star Ratings, which will be based on the 2020 measurement period for cost, MA, and Part D plans. The Star Ratings disaster policy for extreme and uncontrollable circumstances was developed with natural disasters such as hurricanes and wildfires in mind. Those types of emergencies typically impact well-defined geographic areas. The policy uses declarations by the Federal Emergency Management Agency (FEMA) of counties or county-equivalents as Individual Assistance areas that make up all or part of a contract’s service area, as well as whether the contract’s service area is within an “emergency area” during an “emergency period” as defined in section 1135(g) of the Act, as a condition for applying an adjustment to how the Star Ratings are calculated for the contract. Contracts with a certain

minimum percentage of enrollees residing in an area declared as an Individual Assistance area are eligible for Star Ratings adjustments for extreme and uncontrollable circumstances. The disaster policy was not designed to address global pandemics. In the past several years that we have used the extreme and uncontrollable circumstance adjustment for the Part C and D Star Ratings, the FEMA declarations have only been to county/county-equivalents and the declarations have only resulted in adjustments for a limited number of contracts.

At the time of writing the March 31st COVID-19 IFC to adopt a series of changes for the 2021 and 2022 Star Ratings as a result of the PHE for COVID-19, no counties or county-equivalents had been declared Individual Assistance areas as a result of COVID-19. As of July 28, 2020, 51 out of 55 states/territories⁶⁵ covering all counties or county-equivalents within these states and territories have been designated as Individual Assistance areas due to COVID-19 with an incident period starting in 2020 (thus affecting the 2020 measurement year), and this number could continue to grow throughout 2020 as the PHE for COVID-19 evolves. This means that the PHE for COVID-19 now meets the Star Ratings criteria for an extreme and uncontrollable circumstance in nearly all states/territories (and service areas), and most contracts would be eligible for the extreme and uncontrollable circumstance adjustments to their 2022 Star Ratings as a result of the PHE for COVID-19.

Under the current disaster policy, for all non-CAHPS measures, the numeric scores for contracts with 60 percent or more of their enrollees living in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance are excluded from: (1) The measure-level cut point calculations for non-CAHPS measures; and (2) the performance summary and variance thresholds for the Reward Factor as described at §§ 422.166(i)(9)(i) and (i)(10)(i), and 423.186(i)(7)(i) and (i)(8)(i). When only a small number of counties are designated as Individual Assistance areas, application of these exclusions means that the performance from other contracts serving larger or other service areas are used to establish the necessary thresholds for Star Ratings. Up until now, disasters have been localized, and the 60 percent rule has removed only a

small fraction of contracts (that is, less than 5 percent of contracts on average).

The unprecedented impact of COVID-19 creates a new methodological issue where, without a revision to our current disaster policy rules for calculating the measure-level cut points for the 2022 Star Ratings, we will not have enough contracts to reliably calculate the non-CAHPS measure-level cut points. Consequently, CMS will not be able to assign Star Ratings for all non-CAHPS measures. Similarly, we will not have enough contracts to reliably calculate the performance summary and variance thresholds for the Reward Factor. Applying the 60 percent rule for extreme and uncontrollable circumstances to the 2022 Star Ratings would result in removal of a large proportion of contracts (close to 98 percent) from threshold calculations, resulting in too few contracts to reliably calculate cut points using the clustering methodology for the non-CAHPS measures and too few contracts to reliably calculate the weighted means and variance used to calculate the Reward Factor. Due to the unprecedented way the PHE for COVID-19 has affected all contracts in 2020, and the fact that a majority of the country has been designated as Individual Assistance areas, we are creating special rules for the 2022 Star Ratings to remove the 60 percent rule to avoid having to exclude the vast majority of contracts from the methodology used to assign Star Ratings which would result in unreliable ratings or missing data for all contracts in the 2022 Star Ratings.

Under our current regulation, the 60 percent rule would remove nearly all values from the calculation of cut points and the Reward Factor for the 2022 Star Ratings and, if we are unable to calculate non-CAHPS measure-level cut points for the 2022 Star Ratings (such as because of the application of the 60 percent rule), all contracts will have missing measure-level Star Ratings for all non-CAHPS measures. In that circumstance, we will not have enough measures with Star Ratings to calculate either the 2022 overall or summary Star Ratings or 2023 QBPs. In addition to the 60 percent rule, for contracts that have 25 percent or more of their enrollees living in FEMA-designated Individual Assistance areas, our current regulations at §§ 422.166(i) and 423.186(i) apply various rules including permitting use of the previous year’s measure-level rating and corresponding measure score if it is higher on most Star Rating measures. However, §§ 422.166(i)(8) and 423.186(i)(6) state that if the measure-level rating is missing for most measures

⁶⁵ This includes the 50 states, Washington, DC, Guam, Northern Mariana Islands, Puerto Rico and Virgin Islands.

in the current or prior year and a comparison cannot be done, the contract gets the current year's measure-level rating. Therefore, under our current regulations, without a change to the 60 percent rule to ensure that contracts receive measure-level ratings for the 2022 Star Ratings, we would not be able to apply the 25 percent rule to compare the 2022 measure-level Star Ratings to the 2021 measure-level Star Ratings, and nearly all contracts would have missing 2022 overall and summary Star Ratings and 2023 QBP.

The change adopted by this IFC will remove application of the 60 percent rule and avoid the exclusion of contracts with 60 percent or more of their enrollees living in FEMA-designated Individual Assistance areas from calculation of the non-CAHPS measure-level cut points and calculation of the Reward Factor for the 2022 Star Ratings. By removing application of this particular exclusion, the performance of contracts in 2020 in these service areas will be used to calculate the cut points for all non-CAHPS measures and to calculate the Reward Factor; subject to these changes, all other Star Ratings rules (as revised in the March 31st COVID-19 IFC) will apply. This change will ensure that CMS can: calculate measure-level cut points for the 2022 Star Ratings; calculate measure-level ratings for the 2022 Star Ratings; apply the "higher of" policy for non-CAHPS measures, as described at §§ 422.166(i)(3)(iv), 422.166(i)(4)(v) and 423.186(i)(4)(i); calculate the Reward Factor; and ultimately calculate overall and summary ratings for 2022 Star Ratings and 2023 QBPs. It is critical to adopt the change in this IFC to avoid an unworkable result from the current policy in these extraordinary circumstances and so that CMS can measure actual performance for the 2020 measurement period so plans have an opportunity to demonstrate how they are tailoring care in innovative ways to meet the needs of their enrollees during the PHE for COVID-19. Given the unprecedented impacts of the PHE for COVID-19, it is important to be able to calculate the 2022 Star Ratings to help to continue to drive quality improvement for plans and providers.

3. Provisions of IFC

In this IFC, we are adopting a change to tailor the existing disaster policy described at §§ 422.166(i) and 423.186(i) to address the impact of the PHE for COVID-19 and in calculating the 2022 Part C and D Star Ratings. As the current rules are written, we will not be able to calculate the 2022 overall or summary Star Ratings or 2023 QBP ratings, and

the change adopted in this IFC will avoid that outcome and preserve the ability to calculate and issue 2022 Star Ratings.

Furthermore, plans need to know this change so they have certainty about how their ratings will be calculated which will allow them to focus on providing the best care possible to beneficiaries during the remainder of the 2020 measurement period. Without knowing the changes made by this IFC to the methodology for calculating the 2022 Star Ratings, plans could have conflicting priorities between continued focus on caring for enrollees impacted by COVID-19 and keeping Medicare beneficiaries safe, while at the same time wanting to ensure that future Star Ratings and QBP ratings are not impacted by the PHE for COVID-19 which could negatively impact future benefits offered by MA organizations. The changes to the calculations for 2022 Star Ratings are designed to avoid inadvertently creating incentives for plans to place cost considerations above efforts to address the care of patients during the PHE for COVID-19, which they may do if they believe that quality performance in 2020 would not factor into their 2022 Star Rating or potential 2023 QBP.

This IFC modifies the calculation of the 2022 Part C and D Star Ratings to address the application of the extreme and uncontrollable circumstances policy for the PHE for COVID-19. Specifically, for the 2022 Star Ratings, CMS will not exclude the numeric values (that is, the performance data) for affected contracts with 60 percent or more of their enrollees in FEMA-designated Individual Assistance areas during the 2020 performance and measurement period: (1) From the clustering algorithms; or (2) from the determination of the performance summary and variance thresholds for the Reward Factor. This means that CMS will use the performance scores for contracts for the 2020 performance and measurement period to establish cut points for non-CAHPS measures and the Reward Factor for the 2022 Star Ratings, subject to the other rules in the Star Ratings methodology, including the specific rules adopted in the March 31st COVID-19 IFC. We are not modifying the 25 percent rules, even though it is clear that the 25 percent rules will result in nearly all contracts being "affected contracts" and eligible for adjustment to their measure-level ratings for the 2022 Star Ratings because the PHE for COVID-19 was an extreme and uncontrollable circumstance that may have negatively impacted contracts' performance on Star Ratings measures.

Under the 25 percent rules at §§ 422.166(i)(2) through (6) and 423.186(i)(2) through (5), contracts with at least 25 percent of their service area in a FEMA-designated Individual Assistance area in 2020 will receive the higher of their measure-level rating from the current and prior Star Ratings years for purposes of calculating the 2022 Star Ratings (thus, for 2022 Star Ratings, contracts will receive the higher of their measure-level rating from 2021 or 2022).

For the 2022 Star Ratings, we expect data collection and submission of HEDIS and CAHPS data to continue as usual; those data will be collected during spring and summer 2021. The majority of measures for the 2022 Star Ratings are based on the 2020 measurement year, during which the PHE for COVID-19 continues. The March 31st COVID-19 IFC made some changes to the methodology for the 2022 Star Ratings so as not to inappropriately incentivize actions by plans and healthcare providers that are not directly related to the PHE for COVID-19 and to provide assurances to Medicare health and drug plans about how performance changes driven or caused by the PHE for COVID-19 will be addressed in the 2022 Star Ratings. The significant number of declarations of Individual Assistance areas makes it impossible to calculate the cut points of non-CAHPS measures for the 2022 Star Ratings since almost all contracts will be excluded from the calculations as a result of the 60 percent exclusion rule. In this IFC, at §§ 422.166(i)(11) and 423.186(i)(9), we are revising, for 2022 Star Ratings only, the current disaster policy codified at §§ 422.166(i) and 423.186(i) to: (1) Remove the 60 percent exclusion rule for cut point calculations for non-CAHPS measures; and (2) remove the 60 percent exclusion rule for the determination of the performance summary and variance thresholds for the Reward Factor. The new regulation for MA Star Ratings specifically provides that CMS will not apply the provisions §§ 422.166(i)(9) or (i)(10) in calculating the 2022 Star Ratings, and the new regulation for the Part D Star Ratings provides that CMS will not apply the provisions of §§ 423.186(i)(7) or (i)(8) in calculating the 2022 Star Ratings. This change will ensure that CMS can: (1) Calculate measure-level cut points for the 2022 Star Ratings; (2) calculate measure-level Star Ratings for the 2022 Star Ratings; (3) apply the "higher of" policy for non-CAHPS measures, as described at §§ 422.166(i)(3)(iv), 422.166(i)(4)(v), and 423.186(i)(4)(i) for all contracts with 25 percent or more of their enrollees living

in FEMA-designated Individual Assistance areas which will include almost all Part C and D contracts for the 2020 measurement period; and (4) ultimately calculate overall and summary ratings for 2022 Star Ratings and 2023 QBPs.

I. Merit-Based Incentive Payment System (MIPS) Updates

1. Quality Performance Category: Expansion of Telehealth Codes Used in Beneficiary Assignment for the CMS Web Interface and CAHPS for MIPS Survey

a. Background

On March 17, 2020, we announced (<https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet>) 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 (Pub. L. 116–123, enacted March 6, 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 COVID–19, we recognize that physicians and other healthcare professionals are faced with new challenges regarding potential exposure risks, including for Medicare beneficiaries, for healthcare providers, and for members of the community at large. For example, the CDC has urged healthcare professionals to make every effort to interview persons under investigation for infection by telephone, text messaging system, or video conference instead of in-person (85 FR 27582). In the March 31st COVID–19 IFC, to facilitate the use of telecommunications technology as a safe substitute for in-person services, CMS added on an interim basis many services to the list of eligible Medicare telehealth services, eliminating frequency limitations and other requirements associated with particular services furnished via telehealth, and clarifying 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, these specified Medicare telehealth services are reported using the same codes used for the “face-to-face” services, but are furnished using audio/video, real-time, interactive communications 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 for purposes of the PHE for COVID–19 are already included in the definition of primary care services for purposes of the MIPS beneficiary assignment methodology for the CMS Web Interface and CAHPS for MIPS survey (81 FR 77168 through 77169; and 82 FR 53646 through 53647).

In the March 31st COVID–19 IFC, we also established flexibilities and separate payment for certain services that are furnished virtually using communication technologies, but that are not considered Medicare telehealth services such as virtual check-ins and e-visits. Additionally, we established separate payment for telephone E/M and other services codes during the PHE for COVID–19. The communications technology-based services (CTBS) and the telephone E/M services are not currently included in the definition of primary care services that is used for purposes of the MIPS beneficiary assignment methodology for the CMS Web Interface and CAHPS for MIPS survey.

We believe it is critical to include the codes for CTBS and telephone E/M services, as identified and discussed later in this section, 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. Including these codes will ensure that the assignment methodology appropriately reflects the expanded use of technology that is helping people who need routine care during the PHE for COVID–19 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 or other uses of communications technology, we ensure that this care is appropriately reflected in our consideration of where beneficiaries receive the plurality of their primary care, for purposes of assigning beneficiaries to groups and virtual groups.

b. Use of Codes for Virtual Check-ins, Remote Evaluations, E-Visits, and Telephone E/M Services in MIPS Beneficiary Assignment for the CMS Web Interface and CAHPS for MIPS Survey

We have added new services to the separately billable CTBS under the PFS over the past several years and as a result of the PHE for COVID–19, we expect that the utilization of CTBS will substantially increase during the PHE for COVID–19 and thereafter. We believe that clinicians are increasingly using such services as a key component of their ongoing primary care. At § 414.1305, we are codifying the definition of primary care services for purposes of MIPS beneficiary assignment methodology for the CMS Web Interface and CAHPS for MIPS survey. The included codes consist of previously finalized codes that are already considered primary care services and additional codes that CMS will be treating as primary care services for the duration of the PHE for COVID–19. The previously finalized codes are as follows:

- *CPT codes*: 99201 through 99215 (codes for office or other outpatient visit for the E/M of a patient); 99304 through 99318 (codes for professional services furnished in a nursing facility, excluding professional services furnished in a SNF for claims identified by place of service (POS) modifier 31) (81 FR 77168); 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit); 99341 through 99350 (codes for E/M services furnished in a patients' home for claims identified by POS modifier 12); 99487, 99489, and 99490 (codes for chronic care management); and 99495 and 99496 (codes for transitional care management services); and
- *HCPCS codes*: G0402 (code for the Welcome to Medicare visit); and G0438 and G0439 (codes for the annual wellness visits).

The additional codes we are adding through this IFC are as follows: (1) CPT codes: 99421, 99422, and 99423 (codes for online digital E/M service (e-visit)), and 99441, 99442, and 99443 (codes for telephone E/M services); and (2) HCPCS codes: G2010 (code for remote evaluation of patient video/images) and G2012 (code for virtual check-in).

We note that including these codes in the MIPS beneficiary assignment methodology for the CMS Web Interface and CAHPS for MIPS survey aligns with the revision that was made in the May 8th COVID–19 IFC (85 FR 27583) to the definition of primary care services used for purposes of beneficiary assignment

under the Medicare Shared Savings Program to include the same codes in determining beneficiary assignment for performance year 2020 and any subsequent performance year that starts during the PHE for COVID-19.

The services listed above are an important component of primary care and as a result, we believe it is appropriate to include these codes in the definition of primary care services used for assignment for the CMS Web Interface and CAHPS for MIPS survey because the services represented by these codes are being used during the PHE for COVID-19 in place of similar E/M services, the codes for which are already included in the list of codes used for assignment. It should be noted that the remote evaluation of patient video/images and virtual check-in codes, and the online digital E/M service (e-visit) codes are not separately billable by a clinician if they are related to a visit within the past 7 days or lead to a visit within the following 24 hours or next available appointment. The only codes that are newly billable during the PHE for COVID-19 pertain to the telephone E/M services.

We are including these codes in the definition of primary care services for the 2020 MIPS performance year and any subsequent performance year that starts during the PHE for COVID-19. We recognize that the application of this policy for the 2020 MIPS performance period is retroactive. Section 1871(e)(1)(A)(ii) of the Act provides for retroactive application of a substantive change to an existing policy when the Secretary determines that failure to apply the policy change retroactively would be contrary to the public interest. Without the inclusion of these codes in the MIPS beneficiary assignment methodology for the CMS Web Interface and CAHPS for MIPS survey for the 2020 MIPS performance year during the PHE for COVID-19, we would not be able to adequately account for the ways in which beneficiaries are receiving primary care services during the PHE for COVID-19 and as a result, the process to derive assignment and sampling of beneficiaries for the CMS Web Interface and CAHPS for MIPS survey would not be able to comprehensively capture how primary care services are being furnished to beneficiaries, which may cause many groups and virtual groups to have insufficient sample sizes to be able to administer the 2020 CAHPS for MIPS survey or report data for the quality performance category using the CMS Web Interface measures.

In regard to the CMS Web Interface, such groups and virtual groups may not have sufficient time to select an

alternate collection type and prepare their systems to report on measures from a different collection type before the submission period begins for the 2020 MIPS performance period and as a result, they would not be able to meet the quality performance category reporting requirements, which could negatively impact their MIPS final score and MIPS payment adjustment. We believe it is important to include these codes in our assignment methodology because we determine assignment based upon where beneficiaries receive the plurality of their primary care services and whether beneficiaries have designated a MIPS eligible clinician as their primary clinician, responsible for their overall care, and hold groups and virtual groups accountable for the resulting assigned beneficiary population. Including these codes in the definition of primary care services used in MIPS beneficiary assignment during the PHE for COVID-19 will result in a more accurate identification of where beneficiaries have received the plurality of their primary care services.

2. Improvement Activities Performance Category: Improvement Activities Inventory Update

a. Background

The CY 2018 Quality Payment Program final rule (82 FR 53660) finalized that we would add new improvement activities or make modifications to existing improvement activities in the Improvement Activities Inventory through notice-and-comment rulemaking. An improvement activity means an activity that relevant MIPS eligible clinician, organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes. We refer readers to Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199), Tables F and G in the Appendix of the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229), Tables A and B in the Appendix 2 of the CY 2019 PFS final rule (83 FR 60286 through 60303), and Tables A, B, and C in the Appendix 2 of the CY 2020 PFS final rule (84 FR 63514 through 63538) for our previously finalized Improvement Activities Inventory. We also refer readers to the Quality Payment Program website at <https://qpp.cms.gov/> for a complete list of the most current list of improvement activities.

The COVID-19 pandemic has been deemed a PHE⁶⁶ by the Secretary of the Department of HHS. In response, in the March 31st IFC for COVID-19 (85 FR 19276 through 19277), we added one new improvement activity to the Improvement Activities Inventory for the CY 2020 performance period in response to the PHE titled "COVID-19 Clinical Trials." As described in the March 31st IFC for COVID-19, this improvement activity promotes clinician participation in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection.⁶⁷ We stated that to receive credit for this improvement activity, a clinician must attest to participation in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry (85 FR 19276). In that IFC, we also stated that we believe that participation in this activity would likely result in improved outcomes by improving the collection of data clinicians use for the care of their patients as they monitor and manage COVID-19 and drive care improvements (85 FR 19277). We stated that we believe that encouraging clinicians to utilize an open source clinical data repository or clinical data registry for data reporting will bring the results of their research to the forefront of healthcare far quicker than if it goes through the cycle of peer review and publishing (85 FR 19277). In addition, we stated that we believe that centralized data could improve clinical practice and care delivery (85 FR 19277).

b. Modification

Following the publication of the March 31st IFC for COVID-19, we received several inquiries through meetings, email correspondence, and Quality Payment Program help desk requesting further information on whether a clinician working with COVID-19 patients who provides their data to a clinical data registry, without participating in a clinical trial, may get credit for this activity. The Quality Payment Program help desk tracks, documents, and resolves inquiries submitted by MIPS eligible clinicians and groups. Stakeholders may submit inquiries to the help desk via 1-866-288-8292 (Monday-Friday 8 a.m.-8

⁶⁶ Information regarding the PHE for COVID-19 is available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

⁶⁷ For more information on the COVID-19 clinical trials, we refer readers to the U.S. National Library of Medicine website at <https://clinicaltrials.gov/ct2/results?cond=COVID-19>.

p.m. ET) or email QPP@cms.hhs.gov or email QPP@cms.hhs.gov. Some stakeholders believed that clinicians providing care to patients with COVID-19 outside of a clinical trial that report that data through a clinical data registry should receive credit for this activity. It has come to our attention that clinical data registries not only collect data as part of clinical trials, but also collect data from clinicians not participating in clinical trials. The improvement activity as written was causing confusion for clinicians and groups attempting to meet the needs of patients and address gaps in research. Since IA_ERP_3 titled "COVID-19 Clinical Trials" was established, this improvement activity has been the subject of approximately 30 percent of the inquiries to the Quality Payment Program help desk, demonstrating the desire for clinicians to improve clinical care and overall outcomes for patients diagnosed with COVID-19 by conducting this improvement activity, but also indicating the need for further clarity in its activity description.

As a result, we are expanding the improvement activity to include clinicians participating in the care of a patient diagnosed with COVID-19 who simultaneously submit their clinical patient data to a clinical data registry for research. Thus, in order to receive credit for this improvement activity, a MIPS eligible clinician or group must: (1) Participate in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study; or (2) participate in the care of patients diagnosed with COVID-19 and simultaneously submit relevant clinical data⁶⁸ to a clinical data registry for ongoing or future COVID-19 research.⁶⁹ Data would be submitted to the extent permitted by applicable privacy and security laws. We are also modifying the improvement activity title to reflect this change.

For purposes of this improvement activity, clinical data registries must meet the following requirements: (1) The receiving entity must declare that they are ready to accept data as a clinical registry; and (2) be using the

data to improve population health outcomes. Most public health agencies and clinical data registries declare readiness to accept data from clinicians via a public online posting. Clinical data registries should make publicly available specific information on what data the registry gathers, technical requirements or specifications for how the registry can receive the data, and how the registry may use, re-use, or disclose individually identifiable data it receives. For purposes of credit toward this improvement activity, any data should be sent to the clinical data registry in a structured format, which the registry is capable of receiving. A MIPS-eligible clinician may submit the data using any standard or format that is supported by the clinician's health IT systems, including but not limited to, certified functions within those systems. Such methods may include, but are not limited to, a secure upload function on a web portal, or submission via an intermediary, such as a health information exchange. To ensure interoperability and versatility of the data submitted, any electronic data should be submitted to the clinical data registry using appropriate vocabulary standards for the specific data elements, such as those identified in the United States Core Data for Interoperability (USCDI) standard adopted in 45 CFR 170.213.

As stated in the March 31st COVID-19 IFC, we continue to believe that participation in this activity is likely to result in improved outcomes by improving the collection of data clinicians use for the care of their patients. We believe that all clinical data gathered in the treatment of patients diagnosed with COVID-19 may be helpful in finding a solution to end this pandemic. We believe encouraging clinicians collectively to utilize a clinical data registry for data reporting could facilitate sharing of data for use in additional clinical studies with larger sample sizes. These additional and larger clinical studies are likely to identify efficacy of certain treatments, which in turn could result in wider improvements in health outcomes, including reduced severity and mortality due to COVID-19 across the nation. This could benefit patients nationwide as well as improve clinical practice and care delivery for the patients of the clinician attesting to this improvement activity. We would like to encourage all clinicians to provide data through an open source clinical data repository or clinical data registry, meaning that the results of research are made public, including via publications

and scientific data sources, which enables reuse, increases transparency, and facilitates reproducibility of research results. Furthermore, a clinical data registry may allow such data to be publicly available which may be used for research.

We believe that this improvement activity would incentivize clinicians to submit COVID-19 data to clinical data registries, which is imperative to help combat the PHE for COVID-19 because the data could be used to inform research and treatment options and potentially save lives. We recognize that under the Promoting Interoperability performance category there is the required Public Health and Clinical Data Exchange Objective that includes the reporting of data to two different public health agencies or clinical data registries.

We note that under the Promoting Interoperability performance category there are five specific types of public health agencies and clinical data registries that clinicians may submit data to, including an immunization registry or public health registry. The submission requirements for the Promoting Interoperability performance category would not be changed by this improvement activity. Thus a clinician could report COVID-19 data to a public health agency or clinical data registry as part of fulfilling one of the required Public Health and Clinical Data Exchange Objective reporting options under the Promoting Interoperability performance category and include it in their Promoting Interoperability performance category data submission. They could also receive credit for this improvement activity if they fulfill the requirements of the improvement activity and include it in their improvement activity performance category data submission.

We refer readers to section IV.H.3.h.(4)(d)(i)(C) of CY 2019 PFS final rule (83 FR 59776 through 59777) where we discussed that high-weighting should be used for activities that directly address areas with the greatest impact on beneficiary care, safety, health, and well-being and/or is of high intensity, requiring significant investment of time and resources. We believe this modified improvement activity should still be high-weighted because it directly addresses an area with the greatest impact on beneficiary care, safety, health, and well-being particularly under this PHE for COVID-19 and participation in a clinical trial and/or collection and submission of patient data to a clinical data registry or repository requires a significant investment of time and resources.

⁶⁸ We refer readers to the U.S. National Library of Medicine website at <https://clinicaltrials.gov/ct2/results?cond=COVID-19> for more information on the COVID-19 clinical trials.

⁶⁹ We also refer readers to the National Institute of Health website at <https://search.nih.gov/search?utf8=%E2%9C%93&affiliate=nih&query=COVID-19+registries&commit=Search> for more information on COVID-19 clinical data registries.

In the CY 2019 PFS final rule (83 FR 59778 through 59782), we provided details regarding the Annual Call for Activities and how stakeholders submit potential improvement activities. In general, to nominate a new activity or request a modification to an existing improvement activity, a stakeholder must submit a nomination form available at www.gpp.cms.gov during the Annual Call for Activities. For this improvement activity, we made a one-time exception from our established Annual Call for Activities timeframe and processes due to the PHE for COVID-19 (85 FR 19277). In this IFC, we are again making an exception from our established Annual Call for Activities timeframe and processes due to the ongoing PHE for COVID-19. We believe the modifications to the improvement activity should be

established as soon as possible because the PHE for COVID-19 continues to require considerable effort by clinicians and researchers. As discussed above, we want to allow clinicians treating patients with COVID-19 and providing that data to a clinical data registry receive credit for this improvement activity.

c. Continuation Through CY 2021 Performance Period

As stated above, we previously added the improvement activity to the Inventory for the CY 2020 performance period only in response to the PHE for COVID-19. In this IFC, we are extending the newly modified COVID-19 Clinical Data Reporting with or without Clinical Trial improvement activity through the CY 2021 performance period due to the increased rate of COVID-19 infection

we are experiencing nationwide. We anticipate the need for COVID-19 clinical trials and data collection/sharing through registries to continue through CY 2021 at which time we will reassess whether there remains a need for additional data sharing or if preventive measures and clinical treatments have advanced to the point where these type of data are not needed. We would like eligible clinicians to be able to attest to this improvement activity if it is still pertinent. We believe that participation in this improvement activity is likely to result in improved outcomes by improving the collection of data clinicians use for the care of their patients as they monitor and manage COVID-19.

Table 1 displays a full description of the modified improvement activity.

TABLE 1—CONTINUATION WITH MODIFICATION OF IMPROVEMENT ACTIVITY FOR THE MIPS CY 2020–2021 PERFORMANCE PERIODS

Improvement Activity	
<p>Current Activity ID:</p> <p>Current Subcategory:</p> <p>Current Activity Title:</p> <p>Current Activity Description:</p> <p>Current Weighting:</p> <p>Change and Rationale:</p> <p>New Activity Title:</p>	<p>IA_ERP_3.</p> <p>Emergency Response and Preparedness.</p> <p>COVID-19 Clinical Trials.</p> <p>To receive credit for this activity, a MIPS-eligible clinician must participate in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study. For more information on the COVID-19 clinical trials, we refer readers to the U.S. National Library of Medicine website at https://clinicaltrials.gov/ct2/results?cond=COVID-19.</p> <p>High.</p> <p>This improvement activity addresses the COVID-19 pandemic, which has been deemed a public health emergency (PHE) by the Secretary of the Department of Health and Human Services.* While this improvement activity was finalized in the interim final rule in response to the PHE for the CY 2020 performance period only (85 FR 19230), we believe it should be continued for the CY 2021 performance period because the COVID-19 pandemic may extend into CY 2021, and we would like eligible clinicians to be able to attest to this improvement activity if it is still pertinent.</p> <p>We believe that clinicians who treat patients diagnosed with COVID-19 and simultaneously submit relevant data regarding that patient to a clinical data registry for COVID-19 research should also receive credit. We believe that all clinical data gathered in the treatment of patients diagnosed with COVID-19 may be helpful in finding a solution to end this pandemic. Encouraging clinicians collectively to utilize a clinical data registry for data reporting could facilitate sharing of data for use in additional clinical studies with larger sample sizes. These additional and larger clinical studies are likely to identify efficacy of certain treatments, which in turn could result in wider improvements in health outcomes, including reduced severity and mortality due to COVID-19 across the nation. This could benefit patients nationwide as well as improve clinical practice and care delivery for the patients of the clinician attesting to this improvement activity.</p> <p>We refer readers to section IV.H.3.h.(4)(d)(i)(C) of CY 2019 PFS final rule (83 FR 59776 through 59777) where we discussed that high-weighting should be used for activities that directly address areas with the greatest impact on beneficiary care, safety, health, and well-being and/or is of high intensity, requiring significant investment of time and resources. We believe this modified improvement activity should still be high-weighted because it directly addresses an area with the greatest impact on beneficiary care, safety, health, and well-being particularly under this PHE and participation in a clinical trial and/or clinical data registry requires a significant investment of time and resources.</p> <p>COVID-19 Clinical Data Reporting with or without Clinical Trial.</p>

TABLE 1—CONTINUATION WITH MODIFICATION OF IMPROVEMENT ACTIVITY FOR THE MIPS CY 2020–2021 PERFORMANCE PERIODS—Continued

<p>New Activity Description:</p> <p>New Weighting:</p>	<p>In order to receive credit for this improvement activity, a MIPS eligible clinician or group must: (1) Participate in a COVID–19 clinical trial utilizing a drug or biological product to treat a patient with a COVID–19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study; or (2) participate in the care of patients diagnosed with COVID–19 and simultaneously submit relevant clinical data to a clinical data registry for ongoing or future COVID–19 research. Data would be submitted to the extent permitted by applicable privacy and security laws. Examples of COVID–19 clinical trials may be found on the U.S. National Library of Medicine website at https://clinicaltrials.gov/ct2/results?cond=COVID-19. In addition, examples of COVID–19 clinical data registries may be found on the National Institute of Health website at https://search.nih.gov/search?utf8=%E2%9C%93&affiliate=nih&query=COVID-19+registries&commit=Search.</p> <p>For purposes of this improvement activity, clinical data registries must meet the following requirements: (1) The receiving entity must declare that they are ready to accept data as a clinical registry; and (2) be using the data to improve population health outcomes. Most public health agencies and clinical data registries declare readiness to accept data from clinicians via a public online posting. Clinical data registries should make publically available specific information on what data the registry gathers, technical requirements or specifications for how the registry can receive the data, and how the registry may use, re-use, or disclose individually identifiable data it receives. For purposes of credit toward this improvement activity, any data should be sent to the clinical data registry in a structured format, which the registry is capable of receiving. A MIPS-eligible clinician may submit the data using any standard or format that is supported by the clinician’s health IT systems, including but not limited to, certified functions within those systems. Such methods may include, but are not limited to, a secure upload function on a web portal, or submission via an intermediary, such as a health information exchange. To ensure interoperability and versatility of the data submitted, any electronic data should be submitted to the clinical data registry using appropriate vocabulary standards for the specific data elements, such as those identified in the United States Core Data for Interoperability (USCDI) standard adopted in 45 CFR 170.213.</p> <p>High.</p>
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* For more information, see <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

J. Requirement for Long-Term Care (LTC) Facilities To Test Facility Residents and Staff for 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. LTC facilities seeking to be Medicare and Medicaid providers of services must be certified as meeting federal participation requirements. LTC facilities include skilled nursing facilities (SNFs) for Medicare and nursing facilities (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)(4)(B) and 1919(d)(4)(B) of the Act explicitly authorize the Secretary to issue any regulations deemed necessary to protect the health and safety of residents. Sections 1819(d)(3) and 1919(d)(3) of the Act authorize the Secretary to establish criteria for assessing a facility’s compliance with such regulations with respect to infection control. Under the explicit instructions of Congress, existing regulations at § 483.80 require facilities to establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment in which residents reside

and to help prevent the development and transmission of disease and infection.

After several months facing the effects of COVID–19, we believe there exists a need to strengthen the requirements for LTC facilities to better protect residents, members of a high-risk population. As demonstrated by the PHE for COVID–19, a strong infection control program is critical to protect the health and safety of both residents and healthcare personnel of LTC facilities. The CDC has developed guidance identifying those who are “. . . more likely than others to become severely ill . . .” if they become infected with COVID–19 titled, *People Who Are at Increased Risk for Severe Illness* (<https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-increased-risk.html>).⁷⁰ Based on this guidance, given the congregate nature of LTC facilities and the high-risk nature of the population served, LTC facilities are at greater risk of COVID–19 outbreaks as well as higher rates of incidence, morbidity, and mortality. To support national efforts to control the spread of COVID–19, we are revising the LTC facility infection control regulations at § 483.80 to establish a new requirement for LTC facilities to test their facility residents and staff, including

⁷⁰ The Centers for Disease Control and Prevention, (2020). *People Who Are at Increased Risk for Severe Illness*. Retrieved from: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-increased-risk.html>.

individuals providing services under arrangement and volunteers. We believe these requirements will positively and substantially impact efforts to control the spread of COVID–19 in LTC facilities.

1. LTC Facility Resident and Staff Testing

The CDC published guidelines titled, *Testing Guidelines for Nursing Homes*, which note that, “Nursing home residents are at high risk for infection, serious illness, and death from COVID–19. Testing for [COVID–19] . . . can detect current infections . . . among residents in nursing homes. Testing is an important addition to other infection prevention and control recommendations aimed at preventing [COVID–19] from entering nursing homes, detecting cases quickly, and stopping transmission.”⁷¹ CMS recognizes the need for facilities to protect LTC facility staff while preventing the spread of COVID–19 within the facility. As a result, we are amending the current infection control requirements for LTC facilities at § 483.80 by adding a paragraph (h) that requires a facility to test all of its residents and facility staff for COVID–19. Under this requirement, “staff” are considered any individuals employed

⁷¹ The Centers for Disease Control and Prevention, (2020). *Testing Guidelines for Nursing Homes*. Retrieved from: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html>.

by the facility, any individuals that have arrangements to provide services for the facility, and any individuals volunteering at the facility. An example of individuals providing services under arrangement include a hospice that may have an agreement in accordance with the requirements for the use of outside resources under § 483.70(g) and (o) to provide hospice care for residents in the facility. We expect that only those individuals that are physically working on-site at the facility be required to be tested for COVID-19. The facility may have staff, including individuals providing services under arrangement and volunteers, who provide services for the facility from an off-site location that is not physically located within the facility, and such staff would not be required to be tested for COVID-19.

Other individuals may require access to the facility, such as state surveyors and ombudsmen. Sections 1819(c)(3)(A) and 1919(c)(3)(A) of the Act, and implementing regulations at § 483.10(f)(4)(i)(C), require that LTC facilities provide representatives of the State LTC Ombudsman with immediate access to any resident. In accordance with the guidance published in a CMS Quality, Safety, and Oversight Memorandum on April 24, 2020 (and revised on July 9, 2020), during the PHE for COVID-19, in-person access to residents may be restricted. If in-person access is not advisable due to infection control concerns and transmission of COVID-19, facilities must facilitate resident communication (for example, by phone or through use of other technology) with the ombudsman (QSO-20-28-NH, <https://www.cms.gov/files/document/qso-20-28-nh-revised.pdf>). Regarding state surveyors, facilities have a statutory obligation to allow facility access to the surveyors. In accordance with the requirements at 42 CFR part 488, state agencies are responsible for ensuring that surveyors are following CDC guidance for infection prevention and refraining or returning to work.

At § 483.80(h)(1), we are requiring that resident and staff testing for COVID-19 be conducted based on parameters set forth by the Secretary. These parameters may include, but are not limited to:

- Testing frequency;
- The identification of any facility resident or staff diagnosed with COVID-19 in the facility;
- The identification of any facility resident or staff with symptoms consistent with COVID-19 or with known or suspected exposure to COVID-19;

- The criteria for conducting testing of asymptomatic individuals specified in this paragraph, such as the positivity rate of COVID-19 in a county;
- The response time for test results; and

Other factors specified by the Secretary that help identify and prevent the transmission of COVID-19.

We recognize that there may be additional factors that may be useful in developing parameters for COVID-19 testing. As a result, we are soliciting comments on other factors the Secretary should consider for LTC facility resident and staff testing for COVID-19. The testing guidelines that have been specified by the Secretary will be made available to LTC facilities via CMS memoranda, and CMS and CDC websites.

We are requiring at § 483.80(h)(2) that all resident and staff testing be conducted in a manner that is consistent with current professional standards of practice for conducting COVID-19 tests. Current “professional standards of practice” refers to those professional standards that apply at the time that the care or service is delivered. Given that COVID-19 is caused by a newly discovered coronavirus, the standards of practice for testing for the virus may continue to change or evolve as more is learned about the virus and as technological advances are developed. Testing residents and staff for COVID-19 in a manner that is consistent with current professional standards of practice is important to ensure accurate and effective testing. A key factor in the effectiveness of testing is the turnaround time for results of the tests that are being used. There are many different tests available and facilities have the flexibility and discretion to select the test that best suits their needs so long as the tests are conducted in accordance with nationally recognized standards and meet the response time for test results as specified by the Secretary. The CDC provides detailed recommendations for testing both residents and healthcare personnel for COVID-19 at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html>. These recommendations provide information about the use of specific testing methods and focus on how testing can be added to other infection prevention and control practices to keep COVID-19 out of facilities, detect cases quickly, and stop its transmission.

We are requiring at § 483.80(h)(3)(i) that for each instance of resident or staff COVID-19 testing, which includes testing of individuals providing services under arrangement and volunteers, the

facility document that testing was completed and the results of each staff test. We expect that this documentation would be located in the staff personnel record for all staff. In the case of individuals who are providing services under arrangement at the facility, we expect that this documentation be located in the record or file that the facility maintains for the individual. In the event that no such record or file is maintained, we expect that the agreement for the services that are being provided under arrangement include a process for documenting these results. Consistent with the documentation requirements we are adding for LTC facility staff, we are requiring at § 483.80(h)(3)(ii) that the facility document in the resident’s medical record that testing was offered, completed (as appropriate to the resident’s testing status), and the results of each test.

According to the CDC, “The virus that causes COVID-19 is spreading very easily and sustainably between people. Information from the ongoing COVID-19 pandemic suggests that this virus is spreading more efficiently than influenza. . . . In general, the more closely a person interacts with others and the longer that interaction, the higher the risk of COVID-19 spread.”⁷² The nature of LTC facilities make outbreaks of COVID-19 difficult to control. To address the transmissibility of COVID-19 in LTC facilities, we are requiring at § 483.80(h)(4) that the facility take actions to prevent the transmission of COVID-19 when a resident or staff member, including individuals providing services under arrangement and volunteers, present with symptoms consistent with COVID-19 or who test positive for COVID-19.

In accordance with the current regulatory requirements for LTC facilities at § 483.80(g), facilities are required to electronically report information about COVID-19 in a standardized format specified by the Secretary, which includes reporting suspected and confirmed COVID-19 infections among residents and staff.

For facility staff, we expect facilities to restrict the access to the facility for any staff member, including individuals providing services under arrangement and volunteers, who presents with symptoms consistent with COVID-19 or who tests positive for COVID-19 until he or she is deemed to be safe to return to work. The testing guidelines specified

⁷² The Centers for Disease Control and Prevention (2020). How COVID-19 Spreads. Retrieved from: <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html>.

by the Secretary include specified return to work criteria. Following the return to work criteria established by the Secretary will ensure that staff, including individuals providing services under arrangement and volunteers, who are still capable of spreading the virus do not have access to the facility, thus increasing resident safety by removing any potential threats of exposure. These proactive efforts support a facility's ability to prevent outbreaks, create opportunities for early intervention, and mitigate the transmission of the virus between healthcare personnel and facility residents.

For facility residents who present with symptoms consistent with COVID-19 or who test positive for COVID-19, we expect the facility to take measures to mitigate the transmission of the virus within the facility that may include resident cohorting, consistent with CDC's guidance, *Responding to Coronavirus (COVID-19) in Nursing Homes*.⁷³ Cohorting involves preventing the spread of COVID-19 in the facility by confining residents who are known or suspected to have COVID-19 to a specified area to prevent contact with other residents who do not have (or suspected to have) COVID-19. The CDC's current recommendations include avoiding the sharing of staff between residents that are COVID-19 positive and residents that have not tested positive.

We acknowledge that not all residents and staff will consent to COVID-19 testing. In accordance with the requirements at § 483.10(c)(6), residents have the right to refuse and/or discontinue treatment. In addition, staff retain the right to refuse COVID-19 testing. There may also be instances in which facility residents or staff are not able to be tested, such as the presence of anatomical or other medical contraindications. At § 483.80(h)(5), we are requiring that the facility have procedures for addressing residents and staff, including individuals providing services under arrangement and volunteers, who refuse or are unable to be tested. In these instance, we also expect facilities to take steps to maintain the health and safety of its staff and residents who have not been diagnosed with COVID-19 that may include limiting the staff's access to the facility and cohorting residents.

We are requiring at § 483.80(h)(6) that the LTC facility must coordinate with

state and local health departments on the availability of testing supplies, obtaining testing supplies, and processing test results when necessary. As appropriate, facilities should also coordinate with their tribal representatives and authorities for these resources as well. Facilities may also coordinate with their local certified laboratories covered under Clinical Laboratory Improvement Amendments (CLIA) on the availability of testing supplies, obtaining testing suppliers, and processing test results. Considerations such as access to adequate testing supplies and arrangements for acquiring testing supplies must be addressed by a facility's infection prevention and control plan. Additionally, the testing plan must include any arrangements that may be necessary to conduct, process, and receive test results prior to the administration of the required tests.

LTC facilities are currently required to have policies and procedures in place to address the use of volunteers in an emergency under the emergency preparedness requirements at § 483.73(b)(6). During this pandemic, the use of volunteers and other emergency staffing strategies, including the use of state and federal healthcare professionals, is important in addressing staff shortages. Facilities are expected to assess their ability to replace workers who can no longer work, either on a short term basis or permanently, with personnel trained for the vacant positions. The LTC facility should maintain an appropriate staffing level at all times to provide a safe work environment for healthcare personnel (HCP) and safe resident care. As the COVID-19 pandemic continues, staffing shortages will likely occur due to HCP exposures and illness. Due to the unique challenges in managing the mitigation of COVID-19, facilities should assess their staffing needs and the minimum number of staff needed to provide a safe work environment and care for residents. In addition, facilities should be prepared to make various adjustments such as using volunteers, and adjusting work and time-off schedules. Facilities should also be prepared to contact "The Emergency System for Advance Registration of Volunteer Health Professionals" (<https://www.phe.gov/esarvhp>), their local healthcare coalition, federal, state and local healthcare partners for assistance with staffing shortages. Further resources and guidelines, such as those provided by the CDC at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/mitigating-staff-shortages.html>, can

provide additional suggestions for managing staff shortages.

We believe that these new regulatory actions strengthen CMS' response to the PHE for COVID-19, and reaffirms our commitment to transparency and protecting the health and safety of LTC residents. As discussed in section III. of this IFC, "Waiver of Proposed Rulemaking", we believe the urgency of this PHE for COVID-19 constitutes good cause to waive the normal notice-and-comment process under the APA 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 controlling the spread of COVID-19, and universal resident and staff testing will assist public health officials in detecting outbreaks and saving lives.

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 are finalized, either as proposed or as amended in response to public comments, and take effect, in accordance with the Administrative Procedure Act (APA) (Pub. L. 79-404), 5 U.S.C. 553, and, where applicable, section 1871 of the Act. Specifically, 5 U.S.C. 553 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. Further, 5 U.S.C. 553 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 for rulemaking carrying out the administration of the insurance programs under title XVIII of the Act. Section 1871(b)(2)(C) of the Act and 5 U.S.C. 553 authorize the agency to waive these procedures, however, if the agency for good cause finds 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(b)(B) of title 5 of the U.S. Code 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

⁷³ The Centers for Disease Control and Prevention, (2020). *Responding to Coronavirus (COVID-19) in Nursing Homes*. Retrieved from: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-responding.html>.

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) (Pub. L. 104–121, Title II) 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 a “Public Health Emergency of international concern”. On January 31, 2020, pursuant to section 319 of the PHSA, the Secretary determined that a PHE exists for the United States to aid the nation’s healthcare community in responding to COVID–19. On March 11, 2020, the WHO publicly declared COVID–19 a pandemic. On March 13, 2020, the President declared the COVID–19 pandemic a national emergency. Effective July 25, 2020, the Secretary renewed the January 31, 2020 determination that was previously renewed on April 21, 2020, that a PHE exists and has existed since January 27, 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, 2020.⁷⁴

Ensuring the health and safety of all Americans, including Medicare

⁷⁴ <https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx>.

beneficiaries, Medicaid recipients, and healthcare workers is of primary importance. This IFC directly supports that goal by requiring COVID–19 reporting by hospitals, CAHs, and CLIA laboratories; by requiring testing of nursing home staff and residents; and by strengthening enforcement of important nursing home infection prevention and control requirements related to COVID–19 reporting. It is critically important that we implement the policies in this IFC as quickly as possible. As we are in the midst of the PHE for COVID–19, 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. 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 establish these policies in this IFC applicable as of the date this rule is published.

In this IFC, we are revising the previous policy outlined in the May 8th COVID–19 IFC, which allowed for broad COVID–19 testing for a single beneficiary without a physician order, by establishing that only a single COVID–19 test and one of each other related test (as listed in the May 8th COVID–19 IFC) without a treating physician or NPP order is reasonable and necessary. We are also establishing a policy whereby the orders of pharmacists and other practitioners that are allowed to order laboratory tests in accordance with state scope of practice and other pertinent laws can fulfill the requirements related to orders for covered COVID–19 tests for Medicare patients.

Just as the previous policy was developed based on what was known about COVID–19 at the time, as additional information has become available, policies require modification. Whereas we are committed to reducing impediments to access to COVID–19 testing and the other related tests identified in the May 8th COVID–19 IFC, we believe that it is contrary to the public interest to allow open-ended coverage of COVID–19 testing without an order from a physician, practitioner, or other healthcare professional. Our determination to revise the May 8th IFC policy is due both to the significant potential for fraud, waste, and abuse, as well as public health and safety issues that would arise from beneficiaries being subjected to repeated testing without proper medical attention or oversight, including public health issues with the ongoing spread of COVID–19.

Laboratory testing has been a significant source of fraud and abuse in the Medicare program. We have already found that schemes are occurring whereby fraudulent laboratories and telemarketing companies are directly contacting beneficiaries, oftentimes using stolen identifying information, to solicit items and services payable by Medicare under the guise of COVID–19 treatment or prevention. In fact, an HHS Office of Inspector General (HHS–OIG) fraud alert⁷⁵ describes situations in which scammers are offering unapproved and illegitimate COVID–19 tests and other services to Medicare beneficiaries in exchange for personal details, including Medicare information. The financial impact of this fraud risk is exacerbated by the ability of the laboratory to perform expensive add-on tests, such as to confirm or rule-out diagnoses other than COVID–19, that are not medically necessary.

We also believe that allowing Medicare payment for one test without an order will allow beneficiaries access to urgent testing, as we outlined in the May 8th COVID–19 IFC, yet also provide sufficient opportunity for beneficiaries to seek out the medical care needed to ensure that the test results are interpreted and acted upon appropriately, both from the perspective of the individual beneficiary and also in the context of the area of the country in which the beneficiary is located. Executing an effective, regional response to COVID–19 disease requires coordinated effort and guidance by qualified medical professionals who know how to interpret and react to testing results. When a physician or other healthcare provider is able to counsel patients who are being tested for COVID–19, beneficiaries may be more likely to isolate themselves more quickly, which may reduce transmission in the community. Consistent with this information, CMS and CDC recently announced that they are taking steps to ensure that physicians and other practitioners who counsel patients on COVID–19 testing are paid for these services.⁷⁶

We also believe that pharmacists and other healthcare professionals play an important role in the response to the PHE for COVID–19, and to further ensure that beneficiaries continue to have access to appropriate COVID–19 testing even when some professional care is not separately billable under

⁷⁵ <https://oig.hhs.gov/coronavirus/fraud-alert-covid19.asp>.

⁷⁶ <https://www.cms.gov/newsroom/press-releases/cms-and-cdc-announce-provider-reimbursement-available-counseling-patients-self-isolate-time-covid-19>.

Medicare, we are establishing a policy whereby otherwise covered COVID–19 and specified related tests ordered by pharmacists and other healthcare professionals who are authorized to order diagnostic laboratory tests in accordance with state scope of practice and other pertinent laws are covered for the duration of the PHE for COVID–19.

In this IFC, we are updating the extraordinary circumstances exceptions (ECEs) we granted on March 22, 2020, for the ESRD QIP, HAC Reduction Program, HRRP, and Hospital VBP Program in response to the PHE for COVID–19. We are also revising the FY 2022 performance period under the SNF VBP Program.

We believe that these policy updates are immediately necessary to provide clarification to hospitals, dialysis facilities, and SNFs on which reporting requirements under the ESRD QIP, HAC Reduction Program, HRRP, Hospital VBP Program, and SNF VBP Program are excepted and how the exceptions will impact program scoring. These updates will also clarify how optionally submitted data for excepted reporting periods will be used. Since existing Q1 and Q2 2020 deadlines are upcoming in August, October and November 2020, providing this clarification now will allow hospitals, facilities and SNFs to have the information they need and the flexibility to determine how best to direct their resources during the PHE for COVID–19. Therefore, we believe that it would be impracticable and contrary to the public interest to undertake full notice and comment rulemaking to implement these policies.

The IFC also modifies the calculation of the 2022 Part C and D Star Ratings to address the application of the extreme and uncontrollable circumstances policy for the PHE for COVID–19. Applying the 60 percent rule to 2022 Star Ratings would result in removal of a large fraction of contracts from threshold calculations, resulting in too few contracts to reliably calculate cut points for non-CAHPS measures using the clustering methodology and too few contracts to reliably calculate and apply Reward Factors for 2022 Star Ratings; failure to adopt the change would result in CMS' inability to calculate 2022 Star Ratings. This change to the calculation methodology for the 2022 Star Ratings is urgently necessary to ensure that MA organizations, cost plans, and Part D plan sponsors are aware during the 2020 measurement period how their performance in the 2020 measurement period will be used in calculating the Star Ratings.

We believe that the clarifications are immediately necessary to address both

program integrity and clinical issues that have arisen since the publication of the May 8th COVID–19 IFC. We believe that it is contrary to the public interest to allow open-ended coverage of COVID–19 testing without an order due to the significant potential for fraud, waste, and abuse, as well as public health and safety issues that would arise from beneficiaries being subjected to testing without proper medical necessity or oversight.

In this IFC, we clarify the data reporting requirements for issuers of risk adjustment covered plans to specify that, for the purposes of 2020 benefit year risk adjustment data submissions, issuers of risk adjustment-covered plans that provide temporary premium credits must report to their EDGE server the adjusted plan premiums that reflect actual premiums billed to enrollees, taking the premium credits into account as a reduction in premiums. In addition, we clarify that, consistent with the reporting of the actual premium amounts billed to enrollees for 2020 benefit year risk adjustment data submissions, HHS's calculation of risk adjustment payment and charges for the 2020 benefit year under the state payment transfer formula⁷⁷ will be calculated using the statewide average premium that reflects actual premiums billed, taking into account any temporary premium credits provided as a reduction in premium for the applicable months of 2020 coverage, including premium credits that were not provided in a manner consistent with the August 4, 2020 memo. We believe that, in light of the temporary premium credits authorized in CMS guidance during the PHE for COVID–19, immediate clarification on risk adjustment reporting requirements are necessary in order to maintain confidence in the risk adjustment program and stability in the individual and small group (or merged) insurance markets, as issuers have already begun to prepare for 2020 benefit year risk adjustment data submission. These clarifications are also immediately necessary to enable issuers to move quickly to evaluate the impact of these policies and, for those that elect to do so, to begin providing this premium relief to support continuity of coverage for those enrollees adversely affected

⁷⁷ The state payment transfer formula refers to the part of the HHS risk adjustment methodology established consistent with 45 CFR 153.320 that calculates payments and charges at the state market risk pool level. See, for example, the 2020 Payment Notice final rule, 84 FR at 17485. The state payment transfer calculations are performed prior to the calculation of the high-cost risk pool payment and charge terms.

financially by the PHE for COVID–19. We believe that it is contrary to the public interest to require full notice and comment because delayed clarification may prevent some issuers from offering temporary premium credits and may lead some enrollees who have been adversely affected financially by COVID–19 to lose health insurance coverage.

In this IFC, we similarly clarify the MLR reporting and rebate requirements in 45 CFR part 158 for issuers that elect to provide temporary premium credits in 2020 such that these issuers must report as earned premium the actual premium billed to enrollees, taking into account any temporary premium credits as a reduction in premium for the applicable months of 2020 coverage. These changes are necessary to align MLR calculations with the flexibilities provided to issuers and states elsewhere in this rulemaking to respond to the PHE for COVID–19. HHS believes that these clarifications are immediately necessary to enable issuers to quickly and accurately evaluate the financial impact of offering temporary premium credits to enrollees to support continuity of coverage during the PHE for COVID–19. We believe that it is contrary to the public interest to require full notice and comment because delayed clarification may prevent some issuers from offering temporary premium credits and may lead some enrollees who have been adversely affected financially by COVID–19 to lose health insurance coverage.

In this IFC, we are including CPT and HCPCS codes for CTBS and telephone E/M services to the definition of primary care services that is used for purposes of the MIPS beneficiary assignment methodology for the CMS Web Interface and the CAHPS for MIPS survey in order to ensure these services are included in determining where beneficiaries receive the plurality of their primary care for purposes of beneficiary assignment. Without the inclusion of these codes in the MIPS beneficiary assignment methodology for the CMS Web Interface and CAHPS for MIPS survey for the 2020 MIPS performance year and any subsequent performance year that starts during the PHE for COVID–19, we would not be able to adequately account for the ways in which beneficiaries are receiving primary care services during the PHE for COVID–19 and as a result, the process to derive assignment and sampling of beneficiaries for the CMS Web Interface and CAHPS for MIPS survey would not be able to comprehensively capture how primary care services are being furnished to beneficiaries, which may

cause many groups and virtual groups to have insufficient sample sizes to be able to administer the 2020 CAHPS for MIPS survey or report data for the quality performance category using the CMS Web Interface measures. Therefore, these codes are necessary to ensure a comprehensive assessment of MIPS quality performance and avoid imposing undue burden on clinicians during the PHE for COVID-19.

Lastly, under the MIPS Program in this IFC, we are also: (1) Expanding IA_ERP_3 to include clinicians participating in the care of a patient diagnosed with COVID-19 who simultaneously submit their clinical patient data to a clinical data registry for research; (2) updating the title; and (3) extending the activity through the CY 2021 performance period. For this improvement activity, we are making a one-time exception from our established Annual Call for Activities timeframe and processes due to the ongoing PHE for COVID-19. The modifications to the improvement activity should be established as soon as possible because the PHE for COVID-19 continues to require considerable effort by clinicians and researchers and this modified improvement activity would allow clinicians who treat patients with COVID-19 and provide data to a clinical data registry to receive credit under MIPS. We believe that this improvement activity as modified would incentive clinicians to submit COVID-19 data to clinical data registries, which is imperative to help combat the PHE for COVID-19 as the data could be used to inform research and treatment options and potentially save lives. We believe that all clinical data gathered in the treatment of patients diagnosed with COVID-19 may be helpful in finding a solution to end this pandemic, and the earlier the data is collected and shared, the sooner clinical treatment can evolve and a solution may be found. In this IFC, we are also extending the newly modified COVID-19 Clinical Data Reporting with or without Clinical Trial improvement activity through the CY 2021 performance period due to the increased rate of COVID-19 infection we are experiencing nationwide. We believe that the continued and increasing need for a solution to the PHE for COVID-19 indicates that we should encourage both participation in clinical trials, as well as data collection and sharing through clinical data registries as soon as practicable and at least through CY 2021.

For this IFC, 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 the CRA, 5 U.S.C. 808(2), we find it is impracticable and contrary to the public interest not to waive the delay in effective date of this IFC under the CRA, 5 U.S.C. 801(a)(3). Therefore, we find there is good cause to waive the CRA's delay in effective date pursuant to the CRA, 5 U.S.C. 808(2).

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.

Collection of Information for Clinical Laboratories

We are soliciting public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements (ICRs). The requirements and burden related to laboratory test result reporting is covered under OMB Control Number 0920-1299. CDC will be collecting the test results and other information related to SARS-CoV-2 testing. CDC will then provide the information to CMS to ensure that CLIA-certified laboratories are reporting as required under the CLIA regulations.

A. Laboratory Costs To Develop a Mechanism to Track SARS-CoV-2 Test Results

As discussed in section II. of this IFC, we are adding §§ 493.41 and 493.1100(a) to require that, during the PHE for COVID-19, each CLIA-certified laboratory that performs a test that is intended to detect SARS-CoV-2 or to

diagnose a possible case of COVID-19 must report SARS-CoV-2 test results in such form and manner, and at such timing and frequency, as the Secretary may prescribe. We estimate that approximately 30 percent (n (number) =77,024) of the total CLIA-certified laboratories⁷⁸ could potentially be performing SARS-CoV-2 testing. We are soliciting public comments related to the number of laboratories performing SARS-CoV-2 testing. Each of these laboratories would incur a one-time cost for the time needed to develop a mechanism to track and collect SARS-CoV-2 test results to be in compliance with this new requirement. We estimate it would take each laboratory 5 to 7 hours to develop such a mechanism. The burden hours range from 385,120 to 539,168 (77,024 laboratories × 5 or 7 hours). A management level employee (11-9111) would perform this task at an hourly wage of \$55.37 per hour as published by the Bureau of Labor Statistics (BLS) in 2019.⁷⁹ The wage rate would be doubled to \$110.74 to include overhead and fringe benefits. In addition, a database administrator/architect (15-1245) would be needed to perform this task at an hourly wage of \$46.21 per hour as published by the BLS in 2019.⁸⁰ The wage rate would be doubled to \$92.42 to include overhead and fringe benefits. The total hourly wage would be \$203.16 (\$110.74+ \$92.42). The total cost would range from \$78,240,979 to \$109,537,371 (385,120 to 539,168 × \$203.16).

B. Laboratory Costs To Collect SARS-CoV-2 Test Results for Reporting

As discussed in section II. of this IFC, we are adding §§ 493.41 and 493.1100(a) to require that, during the PHE for COVID-19, each laboratory that performs a SARS-CoV-2 test must report SARS-CoV-2 test results in such form and manner, and at such timing and frequency, as the Secretary may prescribe. We estimate that the approximately 30 percent (n=77,024) of the total CLIA-certified laboratories could potentially be performing SARS-CoV-2 and need to collect and report test results in accordance with §§ 493.41 and 493.1100(a). For purposes of this IFC, we are estimating a wide range of

⁷⁸ Includes Certificate of Waiver (CoW), Certificate of Provider-Performed Microscopy (PPM), Certificate of Compliance (CoC) and Certificate of Accreditation (CoA). Based on the CLIA web page the total number of laboratories as of March 2020 are as follows: CoW, n=193,474; PPM n=30,120; CoC n=17,432; CoA n=15,721; total =256,747.

⁷⁹ https://www.bls.gov/oes/current/oes_nat.htm. (11-9111).

⁸⁰ https://www.bls.gov/oes/current/oes_nat.htm. (15-1245).

test volumes to approximate a range from low volume laboratory to a laboratory using high throughput technology. We estimate that a low volume laboratory may report out 20 test results in a 24-hour period and a high throughput laboratory may report out 500 test results during the same period. We estimate it would take each laboratory approximately 0.5 hours for low volume laboratories and approximately 3 hours per day for a high throughput laboratory to collect this information to be in compliance with this new requirement. The burden hours range from 38,512 to 231,072 (77,024 laboratories \times 0.5 or 3 hours). A clinical laboratory technician would perform this task at an hourly wage of \$26.34 per hour as published by the BLS in 2019.⁸¹ The wage rate would be doubled to \$52.68 to include overhead and fringe benefits. The total cost would range from \$2,028,812 to \$12,172,873 (38,512 to 231,072 \times \$52.68) *per day* to collect the required information. Collection of test results would be an ongoing burden for each laboratory performing this type of testing.

C. Laboratory Costs To Report SARS-CoV-2 Test Results

As discussed in section II. of this IFC, we are adding §§ 493.41 and 493.1100(a) to require that, during the PHE for COVID-19, each laboratory that performs a SARS-CoV-2 test must report SARS-CoV-2 test results in such form and manner, and at such timing and frequency, as the Secretary may prescribe. We estimated the number of laboratories as outlined in section IV.A. of this IFC. We estimate that the approximately 30 percent (n=77,024) of the total CLIA-certified laboratories could potentially be performing SARS-CoV-2 and need to report test results in accordance with §§ 493.41 and 493.1100(a).

For purposes of this IFC, we are estimating a wide range of test volumes to approximate a range from low volume laboratory to a laboratory using high throughput technology. We estimate that a low volume laboratory may report out 20 test results in a 24-hour period and a high throughput laboratory may report out 500 test results during the same period. We estimate it would take each laboratory approximately 0.5 hours for low volume laboratories and approximately 3 hours for a high throughput laboratory to report this information to be in compliance with this new requirement. The burden hours range from 38,512 to 231,072 (77,024

laboratories \times 0.5 or 3 hours). A healthcare support worker (31-9099) would perform this task at an hourly wage of \$19.24 per hour as published by the BLS in 2019.⁸² The wage rate would be doubled to \$38.48 to include overhead and fringe benefits. The total cost would range from \$1,481,942 to \$8,891,651 (38,512 to 231,072 \times \$38.48) *per day* to collect the required information. Reporting of test results would be an ongoing burden for each laboratory performing this type of testing.

D. Laboratory Costs to Update Policies and Procedures

We expect that the approximately 77,024 laboratories performing SARS-CoV-2 testing would incur costs for the time needed to review the revised reporting regulations and update their policies and procedures to be in compliance. We estimate the total one-time burden per laboratory to review and update affected policies and procedures is 5 hours. The burden hours are 385,120 (77,024 laboratories \times 5 hours). A management level employee would perform this task at an hourly wage of \$55.37 per hour as published by the BLS in 2019.⁸³ The wage rate would be \$110.74 to include overhead and fringe benefits. The total estimated cost would be \$42,648,189 (385,120 hours \times \$110.74).

E. Accreditation Organization (AO) and Exempt State (ES) Costs To Update Standards for Reporting SARS-CoV-2 Test Results

We would expect the seven approved AOs and two ESs would have to review their standards, provide updates and submit the changes to CMS related to SARS-CoV-2 test reporting for approval (9 organizations/exempt states \times 25 or 30 hours). The CLIA regulations require both the AOs and ESs to have requirements that are equal to, or more stringent than the CLIA condition-level requirements, and the laboratory would meet the condition-level requirements if it were inspected against these requirements.⁸⁴ We assume a one-time cost of 25 to 30 hours to identify the applicable legal obligations and to develop the updated standards needed to reflect the new requirements for SARS-CoV-2 testing. The burden hours range from 225 to 270 (9 AO/ESs \times 25

or 30 hours). A management level employee (11-9111) would perform this task at an hourly wage of \$55.37 per hour as published by the BLS in 2019.⁸⁵ The wage rate would be doubled to \$110.74 to include overhead and fringe benefits. The total cost would range from \$24,917 to \$29,900 (225 to 270 hours \times \$110.74).

F. Accreditation Organization (AO) and Exempt State (ES) Costs To Update Policies and Procedures Related to Reporting Laboratories Performing SARS-CoV-2 Testing That Do Not Report Results as Required

We would expect the seven approved AOs and two ESs would have to develop policies and procedures related to identifying laboratories that do not report SARS-CoV-2 test results in order to report these laboratories to CMS. In the case of the accredited laboratories, the laboratories identified as not reporting SARS-CoV-2 results as required would result in CMS taking an enforcement action as described in section II. of this IFC. As stated in section IV.G. of this IFC, the CLIA regulations require both the AOs and ESs to have requirements that are equal to, or more stringent, the CLIA condition-level requirements, so we would expect the AOs and ESs to have equivalent reporting requirements to CMS. AOs do not impose CMPs; however, ESs do have the ability to impose CMPs so we would expect ESs to have an equivalent penalty structure to CMS. The ES are generally approved by CMS to operate their own oversight programs so we would expect that the two ESs would report these laboratories to CMS, but would then impose the penalties based on their CMS-approved updated standards. We are requiring the AOs/ESs to report this information to CMS no later than 10 days from identifying a laboratory that has failed to report SARS-CoV-2 test results as required. We assume a one-time cost of 10 to 15 hours to develop the policy and procedures needed to reflect the new requirements for reporting of SARS-CoV-2 test results. The burden hours range from 90 to 135 (9 AO/ESs \times 10 or 15 hours). A management level employee (11-9111) would perform this task at an hourly wage of \$55.37 per hour as published by the BLS in 2019. The wage rate would be doubled to \$110.74 to include overhead and fringe benefits. The total cost would range from \$9,967 to \$14,950 (90 to 135 hours \times \$110.74). In addition, the AOs and ESs would be required to report to CMS

⁸² [https://www.bls.gov/oes/current/oes_nat.htm.\(31-9099\)](https://www.bls.gov/oes/current/oes_nat.htm.(31-9099)).

⁸³ [https://www.bls.gov/oes/current/oes_nat.htm.\(11-9111\)](https://www.bls.gov/oes/current/oes_nat.htm.(11-9111)).

⁸⁴ CLIA Requirements at 42 CFR 493.551 (https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5%23se42.5.493_1551).

⁸¹ [https://www.bls.gov/oes/current/oes_nat.htm.\(29-2010\)](https://www.bls.gov/oes/current/oes_nat.htm.(29-2010)).

⁸⁵ [https://www.bls.gov/oes/current/oes_nat.htm.\(11-9111\)](https://www.bls.gov/oes/current/oes_nat.htm.(11-9111)).

every 10 days those laboratories that have not reported test results as required. The annual total number of times each AO and ES is required to report to CMS is 36.5. We assume a weekly cost of 2 to 4 hours to identify the laboratories and submit the information to CMS. The total burden hours range from 18 to 36 (9 AO/ESs × 2 or 4 hours). A computer network support specialist (15–1231) would perform this task at an hourly wage of \$33.10 per hour as published by the BLS in 2019.⁸⁶ The wage rate would be

doubled to \$66.20 to include overhead and fringe benefits. The total cost would range from would range from \$1,192 to \$2,383 (18 to 36 hours × \$66.20) per 10 days for an annual total of \$43,508 to \$86,980 (\$1,192 to \$2,383 × 36.5).

G. Condition of Participation (CoP) Requirements for Hospitals and Critical Access Hospitals (CAHs) To Report COVID-19 Data as Specified by the Secretary During the PHE for COVID-19

We are revising the regulations by adding provisions to the CoPs (§ 482.42

for hospitals and \$ 485,640 for CAHs), requiring hospitals and CAHs to electronically report information related to confirmed or suspected COVID-19 cases in a standardized format, and at a frequency, specified by the Secretary. Our preliminary estimates for these reporting activities can be found in Tables 2 and 3.

TABLE 2—ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Hospitals and CAHs	HHS Teletracking COVID-19 Portal	5500	365	1.5	3,011,250
Total	3,011,250

TABLE 3—ESTIMATED ANNUALIZED RESPONDENT BURDEN COSTS

Type of respondent	Total burden hours	Hourly wage rate	Total respondent costs
Hospital Staff—Registered Nurses	3,011,250	* \$70.48	\$212,232,900
Total	212,232,900

* The wage rate includes overhead and fringe benefits.

The burden associated with these reporting activities will be submitted under OMB Control Number 0990–NEW.

H. Requirements for Long-Term Care (LTC) Facilities To Test Facility Residents and Staff for COVID-19

As discussed in section II.J. of this IFC, we are revising the regulations at § 483.80(h) to require LTC facilities to test residents and facility staff, including individuals providing services under arrangement and volunteers, for COVID-19. We are also requiring at § 483.80(h)(3)(i) that for each instance of resident and staff COVID-19 testing (which includes testing of individuals providing services under arrangement and volunteers), the facility document that testing was completed and the results of each test. We expect that this documentation would be located in the staff personnel record for all staff. In the case of individuals who are providing services under arrangement at the facility, we expect that this documentation be located in the record or file that the facility maintains for such individuals.

In the event that no such record or file is maintained, we expect that the agreement for the services that are being provided under arrangement include a process for documenting these results. Consistent with the documentation requirements we are adding for LTC facility staff, we are requiring at § 483.80(h)(3)(ii) that the facility document in the resident’s medical record that testing was offered, completed (as appropriate to the resident’s testing status), and the results of each test.

Based on data from the Kaiser Family Foundation’s report on coronavirus statistics (<https://www.kff.org/report-section/covid-19-and-workers-at-risk-examining-the-long-term-care-workforce-tables>), we estimate that 1.8 million LTC facility staff would be tested for COVID-19 initially for each facility. We also estimate that 1.3 million residents would be tested. We have estimated that it will take approximately 2 minutes to locate a staff’s file and document the result of a COVID-19 test. Furthermore, we estimate that, based on the guidelines given regarding testing frequency, the

criteria for conducting a test, and the response time for test result, not all staff will be tested on the same frequency. For example, a third of the staff population could be tested weekly and two thirds of the staff population could receive a test every ten days or monthly. However, with variables that are not knowable at this time, we have provided an estimate based on an average schedule of all staff receiving a test every 14 days and residents to be tested monthly during the PHE for COVID-19. We estimate that it would take 2 minutes to provide documentation in 1.8 million records of staff members for 30 weeks (from September 2020 to March 2021) to record the test was administered and to record the test results. We also estimate that it would take 2 minutes to provide the same documentation in 1.3 million medical records of residents for the same period of time. The annual and ongoing cost to comply with this requirement can be further assessed based on guidelines established by the Secretary. The ongoing burden associated with these reporting activities will, if necessary, be

⁸⁶ https://www.bls.gov/oes/current/oes_nat.htm. (15-1231).

submitted under OMB Control Number 0938–New. For the purpose of this analysis, we estimate that it would take 2 minutes to document the initial test and that a healthcare support worker (31–9099)

would perform this task at an hourly wage of \$19.24 per hour as published by the BLS in 2019.⁸⁷ The wage rate would be doubled to \$38.48 to include overhead and fringe benefits. Based on

our assumptions, we estimate that the total cost to document the testing results for staff and LTC residents over the estimated course of the PHE for COVID–19 would be \$48,158,193. See Table 4.

TABLE 4—TOTAL COST TO DOCUMENT THE TESTING RESULTS FOR STAFF AND LTC RESIDENTS OVER THE ESTIMATED COURSE OF THE PHE FOR COVID–19

	Time to document	Staff	Resident	Testing frequency	Testing duration	Wage for health staff worker	Total
Staff	2 minutes	⁸⁸ 1,899,000	14 days	30 weeks	* \$38.48	\$36,344,360
Resident	2 minutes	1,315,757	30 days	7 months	\$38.48	11,813,833
							48,158,193

* The wage rate includes overhead and fringe benefits.

I. Quality Reporting: Updates to the Extraordinary Circumstances Exceptions (ECE) Granted for Four Value-Based Purchasing Programs in Response to the PHE for COVID–19, and Update to the Performance Period for the FY 2022 SNF VBP Program

1. Updates to ESRD QIP: Utilization of Fourth Quarter CY 2019 ESRD QIP Data and the Removal of the Option for Facilities To Opt-Out of the Extraordinary Circumstances Exception (ECE) Granted With Respect to First and Second Quarter (CY) 2020 ESRD QIP Data

In section II.D.1. of this IFC, we are updating our regulations at § 413.178(d)(7) to state that a facility has opted out of the ECE for COVID–19 with respect to the reporting of fourth quarter 2019 NHSN data if the facility actually reported the data by the March 31, 2020 deadline but did not notify CMS that it would do so. Additionally, we are removing the ability of facilities to opt-out of the ECE we granted with respect to Q1 and Q2 2020 ESRD QIP data. These updates do does not require facilities to complete any forms or submit any additional information to receive an ECE, and therefore, the program does not anticipate any change in burden associated with this IFC.

2. Updates to the Application of the HAC Reduction Program ECE Policy in Response to the PHE for COVID–19

In section II.D.2. of this IFC, we are updating the ECE granted for the HAC Reduction Program to not use Q1 and Q2 2020 data that were made optional under the Guidance memo for scoring in the HAC Reduction Program for scoring calculations in future program years (that is, the FY 2022 and FY 2023 program years). This policy does not

require hospitals to complete any forms or submit any additional information to receive an ECE, and therefore, the program does not anticipate any change in burden associated with this IFC.

3. Update to the HRRP ECE Granted in Response to the PHE for COVID–19

In section II.D.3. of this IFC, we excepted the use of claims data from the first and second quarters of CY 2020 from the HRRP because of our concern that the data collected during this period may be greatly impacted by the response to COVID–19, and therefore, may not be reflective of a hospital’s performance during this time due to concerns with national comparability of the data. This update does not require hospitals to complete any forms or submit any additional information, and therefore, the program does not anticipate any change in burden associated with this IFC.

4. Update to the Hospital VBP Program ECE Granted in Response to the PHE for COVID–19

In section II.D.4. of this IFC, we are updating the ECE granted for the Hospital VBP Program to not use Q1 and Q2 2020 data that was made optional under the Guidance memo for scoring in the Hospital VBP Program for the FY 2022 payment year. This change to the ECE policy does not require hospitals to complete any forms or submit any additional information, and therefore, the program does not anticipate any change in burden associated with this IFC.

5. Revised Performance Period for the FY 2022 SNF VBP Program as a Result of the ECE Granted for the PHE for COVID–19

As described in section II.D.5. of this IFC, we granted an ECE for the PHE for COVID–19 to exclude qualifying claims from the claims-based SNF 30-Day All-Cause Readmission Measure (SNFRM; NQF #2510) calculation for the following periods: January 1, 2020 through March 31, 2020 (Q1 2020); and April 1, 2020 through June 30, 2020 (Q2 2020).

Because we are excluding qualifying claims from January 1, 2020 through June 30, 2020, we are adopting a revised performance period for the FY 2022 SNF VBP Program Year in section II.D.5. of this IFC. The revised performance period for the FY 2022 SNF VBP program will be from: April 1, 2019 through December 31, 2019, and July 1, 2020 through September 30, 2020.

Changing the performance period for a SNF VBP Program Year does not require SNFs to complete any forms or submit any additional information. Accordingly, the SNF VBP Program does not anticipate any change in burden associated with this IFC.

J. Submission of Adjusted Premium Amounts for PPACA Risk Adjustment

Sections 153.610 and 153.710 provide that issuers of a risk adjustment covered plan must provide HHS with access to risk adjustment data through a dedicated distributed data environment, in a manner and timeframe specified by HHS. In section II.G.2. of this IFC, we clarify that, for purposes of 2020 benefit year risk adjustment data submissions, issuers that choose to provide temporary premium credits must submit the adjusted (that is, lower) plan premiums for those months, instead of the

⁸⁷ https://www.bls.gov/oes/current/oes_nat.htm. (31–9099).

⁸⁸ <https://www.kff.org/report-section/covid-19-and-workers-at-risk-examining-the-long-term-care-workforce-tables/>.

unadjusted plan premiums. We also clarify that CMS will require issuers to submit adjusted plan premiums to their EDGE servers for all enrollees whom the issuer has actually provided premium credits as a reduction to 2020 benefit year premiums, even if these premium credits were not provided in a manner consistent with the August 4, 2020 memo. This IFC does not change any other aspect of the 2020 benefit year data submission requirements for the HHS-operated risk adjustment program.

We do not believe that issuers who elect to provide these temporary premium credits will incur additional operational burden associated with EDGE server data submissions as a result of these requirements because we expect issuers' premium reporting systems will already be configured to enable issuers to upload the billable premiums actually charged to enrollees for the applicable benefit year to the EDGE server. Additionally, the current EDGE server operational guidance for the risk adjustment program allows issuers to submit billable premium changes so there will be no changes to the data submission rules.⁸⁹ Therefore, the burden related to this information collection is currently approved under OMB control number 0938-1155 (Standards Related to Reinsurance, Risk Corridors, Risk Adjustment, and Payment Appeals). The information collection request expires on February 23, 2021.

K. Medical Loss Ratio Premium Reporting Requirements

In section II.G.3. of this IFC, we are clarifying that issuers that elect to provide temporary premium credits to consumers in 2020 must account for these credits as reductions to premium for the applicable months during 2020 when reporting earned premium for the applicable MLR reporting year.⁹⁰ We do not anticipate that this clarification will require changes to the MLR Annual Reporting Form or change the associated burden for issuers. As noted above, we expect issuers' premium reporting systems will already be configured to enable issuers to track the premiums actually charged to enrollees for the applicable benefit year, enabling issuers that offer temporary premium credits to accurately report the adjusted (that is, lower) amounts actually billed to their enrollees on their respective MLR Annual Reporting Forms. The burden related to this information collection is currently approved under OMB control number 0938-1164 (Medical Loss Ratio Annual Reports, MLR Notices, and Recordkeeping Requirements (CMS-10418)). The information collection request expires on October 31, 2020.

L. Merit-Based Incentive Payment System (MIPS) Updates

In section II.I. of this IFC, for the 2020 performance year, we are proposing to include in the MIPS assignment methodology for the CMS Web Interface and CAHPS for MIPS survey the following additions due to the PHE for COVID-19: (1) CPT codes: 99421, 99422, and 99423 (codes for online

digital E/M service (e-visit)), and 99441, 99442, and 99443 (codes for telephone E/M services); and (2) HCPCS codes: G2010 (code for remote evaluation of patient video/images) and G2012 (code for virtual check-in). We do not believe this proposal will impact the number of beneficiaries selected for sampling, which will be used to complete quality reporting via the CMS Web Interface or administer the CAHPS for MIPS survey; however, this proposal could impact the number of beneficiaries eligible to be sampled. Therefore, we do not anticipate any change in burden or impact on clinicians.

In addition, we are: (1) Expanding the improvement activity IA_ERP_3 titled "COVID-19 Clinical Trial" to also allow credit for clinicians who participate in the care of patients diagnosed with COVID-19 and simultaneously submit relevant clinical data to a clinical data registry for ongoing or future COVID-19 research; (2) updating the title; and (3) extending it through the CY 2021 performance period. Because MIPS eligible clinicians are still required to submit the same number of activities and the per response time for each activity is uniform, we do not expect this proposal to affect our currently approved information collection burden estimates in terms of neither the number of estimated respondents nor the burden per response.

M. Summary of Burden in This IFC

Table 5 shows the burden and associated costs for sections IV.A. through F. in this IFC.

TABLE 5—BURDEN AND ASSOCIATED COSTS FOR THE PROVISIONS INCLUDED IN THIS IFC

Information collection requests	Burden hours increase/decrease (+/-)*	Cost (+/-)*
A. Laboratory Costs to Develop Mechanism to Track Results (<i>one time cost</i>)	+539,168	+109,537,371
B. Laboratory Costs to Collect Results for Reporting (<i>per day cost</i> *)	+231,072	+12,172,873
C. Laboratory Costs to Report Results (<i>per day cost</i> *)	+231,072	+8,891,651
D. Laboratory Costs to Update Policies/Procedures (<i>one time cost</i>)	+385,120	+42,648,189
E. AO/ES Costs to Update Standards (<i>one time cost</i>)	+270	+29,900
F. (a) AO/ES Costs to Update Policies/Procedures (<i>one time cost</i>)	+135	+15,971
F. (b) AO/ES Costs to Report Laboratories to CMS for not Reporting Results	+36	+86,980
Total	+1,386,873	+173,382,935

* Note that these are per day costs. For annual costs, see Table 9.

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

⁸⁹ See EDGE Server Business Rules (ESBR) v16.0 Section 5.8 Premium Amounts, at https://www.regtap.info/uploads/library/DDC_ESBR_V16.0_052920_5CR_052920.pdf.

⁹⁰ Because the MLR and rebate calculations are based on 3 years of data, reporting earned premium for the 2020 benefit year will impact the MLR and rebate calculations for the 2020 through 2022

reporting years. See section 2718(b)(1)(B)(ii) of the PHS Act. Also see 45 CFR 158.220(b).

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 healthcare providers and health insurance issuers maximum flexibility to minimize the spread of COVID-19 among Medicare and Medicaid beneficiaries, consumers of health insurance coverage in the individual and small group insurance markets, healthcare 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 and consumers of health insurance coverage in the individual and small group insurance markets suffering from COVID-19 will likely test the capacity of the healthcare 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, and clinical laboratories. Additionally, the policies and regulatory updates implemented in this IFC will increase the affordability and support continuity of health insurance coverage for consumers in the individual and small group (or merged) market during the PHE for COVID-19.

B. Overall Impact

We have examined the potential 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 Social Security 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. For CLIA purposes, no regulatory alternatives were considered as the CARES Act requires all laboratories to report SARS-CoV-2 test results. Only CLIA regulations requiring laboratories to report SARS-CoV-2 test results were added/revise.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). As described in section IV. of this IFC (Collection of Information Requirements) and this section, this IFC would be economically significant within the meaning of section 3(f)(1) of the Executive Order. We are adding §§ 493.41 and 493.1100(a) to require that, during the PHE for COVID-19, as defined in § 400.200, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 must report SARS-CoV-2 test results in such form and manner, and at such timing and frequency, as the Secretary may prescribe. These anticipated costs would result from laboratories needing to develop a mechanism to collect and report SARS-CoV-2 test results, update policies and procedures, update software, and train personnel. In addition, AOs and Exempt States (ESs) will also need to update their laboratory standards and policies and procedures

to comply with the new federal regulatory changes. We have provided an assessment of the impact of estimated costs of these changes in Tables 6 and 7.

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” 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. For purposes of the RFA, we estimate that the great majority of laboratories are small entities, either by being nonprofit organizations or by meeting the Small Business Administration definition of a small business (having revenues of less than \$8.0 million to \$41.5 million in any 1 year). For purposes of the RFA, approximately 75 percent of laboratories performing SARS-CoV-2 testing qualify as small entities. For purposes of this IFC, we expect that approximately 30 percent (n=77,024) of the total CLIA certified laboratories (n=256,747) could potentially be performing SARS-CoV-2 tests. Further, based on data from the CLIA website, we are estimating that 75 percent of the laboratories have a CoW (n=57,768) and 25 percent have a Certificate of PPM, CoC, CoA, or CoR (n=19,256). Each individual EUA test system authorized by the FDA specifies the settings in which the tests are authorized to be used during the PHE for COVID-19. Generally, CoW and PPM laboratories include, but are not limited to, the following types of facilities: Physician office laboratories; pharmacies; skilled nursing/nursing facilities; and other types of point-of-care facilities. Generally, we would consider these types of laboratories to be small entities. Individuals and states are not included in the definition of a small entity. All laboratories performing SARS-CoV-2 testing are affected by this IFC, and the impact is economically significant. Therefore, the Secretary has determined that this IFC will have a significant economic impact on a substantial number of small entities.

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. There are approximately 905 small rural hospitals in the U.S. Of the 905 small rural hospitals, approximately 500 are subsection (d) hospitals paid under IPPS and are subject to the HAC Reduction Program and HRRP. In section II.D. of IFC, we are updating the ECE policy for the two programs to allow the exclusion of data submitted for quarters impacted by the PHE for COVID-19. We estimate that the impact of the exclusion of data on scoring for small rural hospitals for the programs will be dependent upon hospitals' individual performance and experience, but that the exclusion of data will make small hospitals less likely to receive measure scores or meet minimum eligible discharge requirements for participation in the HAC Reduction Program and HRRP. All small rural hospitals, that is, both subsection (d) and critical access hospitals, often provide very limited laboratory services or may refer all their testing to larger facilities. We are unable to estimate the number of laboratories that support small rural hospitals, but do expect that the rule will have a significant impact on small rural hospitals. Therefore, the Secretary has determined that this rule will have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any proposed rule, or any final rule preceded by a proposed rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately \$156 million. This IFC was not preceded by a general notice of proposed rulemaking, and thus the requirements of UMRA do not apply.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Two states have exempt status, which means we have determined that the state has enacted laws relating to the laboratory requirements that are equal to or more stringent than CLIA

requirements and the state licensure program has been approved by us. These two states, New York and Washington, would need to update their standards, policies and procedures to maintain their exempt status to require reporting to CMS those accredited/exempt laboratories that have not reported SARS-CoV-2 test results as required. In addition, these two states would need to develop a CMP structure to impose CMPs that is equivalent to CMS and is based on their updated standards. In order to determine compliance with the reporting requirements, the State Agencies would be required to perform additional surveys on 5 percent of CoW and 5 percent of PPM laboratories. As previously stated, these two type of laboratories are not routinely surveyed. The total number of CoW laboratories as of March 2020 is 193,474. Five percent of 193,474 is 9,674 so for the duration of the IFC (3 years), a total of 3,225 CoW surveys would need to be performed annually across all State Agencies. The total number of PPM laboratories as of March 2020 is 30,120. Five percent of 30,120 is 1,506 so for the 3 years that this IFC would be in place, a total of 502 PPM surveys would need to be performed annually across all State Agencies. The combined number of these surveys that will need to be performed annually over the 3 years of the timeframe of the IFC is 3,727 across all State Agencies. Over the 3 years that this IFC is in place, one-third of the total number CoW and PPM laboratories would be surveyed each year. This would ensure that a total of 5 percent of each of these types of laboratories are surveyed during the duration of the PHE for COVID-19 to determine if SARS-CoV-2 requirements are met. Currently, there are no resources available to the State Agencies to perform these additional surveys. Therefore, this IFC would have a substantial direct effect on state or local governments. This IFC would also have a direct effect on preempting state laboratory requirements as they must change their current laboratory standards to remain equal to or more stringent than Federal laws when finalized.

C. Detailed Economic Analysis of the Provisions of the IFC

1. Revised Enforcement Requirements for LTC Facilities

Section II.A. of this IFC which implements a policy for specifying the CMP amounts tailored to noncompliance related to § 483.80(g)(1) and (2) (electronic reporting COVID-19 related data) will not result in any

additional financial burden for LTC providers if they remain compliant in reporting. Following the May 8th effective date of this reporting requirement, we began assessing the compliance for all 15,674 (data from Quality, Certification and Oversight Reports (QCOR) as of August 11, 2020) Medicare and Medicaid certified nursing homes each week and have found compliance has consistently increased week after week. Based on data provided to CMS by the CDC, compliance with this requirement has been greater than 98 percent since the reporting week ending June 28, 2020. Although there has been unprecedented compliance with the requirement to report, CMS has issued 2,507 citations for noncompliance as of August 10, 2020, with corresponding CMPs imposed. Financial impact will occur for facilities who are not compliant with the new reporting requirement. We do not expect these requirements to have a substantial economic impact or pose a financial burden to nursing homes beyond that which has already been established by CMS's existing enforcement regulations. This rule does not add new requirements, but clarifies our process to impose penalties for a failure to report for which compliance is assessed on a weekly basis, which is different from how all other LTC requirements are reviewed. CMS' enforcement authority remains unchanged under this IFC. Instead, it clarifies the specific CMP penalty range for noncompliance with the new COVID-19 related reporting requirements at § 483.80(g)(1) and (2). Furthermore, the penalty amounts are consistent with the lower level penalty range available at § 488.438(a)(1)(ii) in order to encourage compliance and to discourage similar conduct in the future without causing undue hardship that could impair a facility's ability to minimize COVID-19 infections among its residents and staff. In addition, the penalty is not aggregated but is increased only if future compliance assessments reveal repeated violations. In the event that a facility is unable to meet reporting requirements and/or experiences financial hardship, a facility may utilize the Independent Informal Dispute Resolution process under § 488.431 to dispute the findings and may submit a financial hardship request to CMS.

2. CoP Requirements for Hospitals and CAHs, and Requirements for LTC Facilities

a. CoP Requirements for Hospitals and CAHs To Report COVID-19 Data as Specified by the Secretary During the PHE for COVID-19

Section II.B. of this IFC revises the infection prevention and control requirements for hospitals and CAHs 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 specified by the Secretary. Many hospitals are already reporting data in a standardized format voluntarily. As detailed in section IV.G. of this IFC, we currently estimate the cost of these reporting requirements to total \$212,232,900. This estimate is likely an overestimate of the costs associated with reporting because it assumes that all hospitals will report manually. Efforts are underway to automate hospital and CAH reporting that have the potential to significantly decrease reporting burden and improve reliability. We anticipate that the need for reporting will be temporary in direct relationship to the duration of the PHE. Existing guidance on reporting, which may be revised in the future, can be found at <https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf>, and these guidance documents will be in CMS' 13891 portal. Data reported to the Secretary is used by Federal agencies and states, to provide data for the unified hospital picture, as well as guidance on the distribution of resources.

b. Requirement for Long-Term Care Facilities To Test Facility Staff and Residents for COVID-19

Section II.J. of this IFC revises the infection control requirements for LTC facilities at § 483.80 to require facilities to test their staff and residents for COVID-19 based on parameters set forth by the Secretary. Based on data from CDC and states where similar policies have already been implemented, we anticipate that this will result in widespread testing and significant resource use, but catch many cases that might otherwise go undetected. For example, implementing universal testing in 11 LTC facilities in Maryland increased the total number of detected cases in those facilities from 153 to

507.⁹¹ Costs incurred by facilities have potential to vary drastically depending on the extent of outbreaks in their respective communities, whether the facility has point-of-care testing, and the size of each facility; however, for some of these facilities the cost of testing may be less than the costs associated with lost productivity and revenue due to unmitigated outbreaks. We solicit comments on our cost estimates, as well as any additional costs associated with acquiring reagents, test kits, or anything else we may not have considered.

Best practices for catching and eliminating these outbreaks, as well as availability of the tools necessary to do so, is a quickly changing landscape. As of late July, over 600 point-of-care antigen testing devices had already been shipped to LTC facilities nationwide, with plans to provide every facility with their own instrument(s) and tests within 14 weeks.⁹² This method of testing effectively reduces the cost-per-test from approximately \$100 to only \$20. These efforts to provide every facility with these devices continue, but for the purposes of our estimates below, we assume a cost of \$60 per test; this accounts for the potential cost of replacing the antigen testing device, as well as the possibility that some facilities will choose to verify negative results with lab testing. The cost of these testing activities will ultimately depend on the extent of future outbreaks, and how the best practices, and thus our parameters for universal testing, evolve. We recognize that testing alone is not enough to control, treat, and eliminate outbreaks of COVID-19. Providing safe care is the inherent duty of all long term care facilities. Implementing highly effective infection prevention and control procedures, such as proper hand washing techniques and techniques for donning and removing PPE, are expected to be part of everyday facility procedures and do not impose an additional burden upon facilities. CDC provides, and continually updates, their infection control guidance for LTC facilities.⁹³ This guidance recommends, among other things, expanded viral testing of all residents if there is an outbreak in a facility; cohorting

residents in a COVID-19 care unit; assigning dedicated staff to the aforementioned care unit; and additional cleaning procedures. Although we do not have data to support exactly how many facilities are fully prepared for intervention at this scale, we assume that most facilities have made basic preparations in line with current best practices. Acknowledging this uncertainty, we are assuming the average facility requires intervention costing between 5 and 40 hours of the hourly wage of a registered nurse for each additional round of testing, doubled to account for the cost of overhead and fringe benefits. For facilities that are less prepared, a different mix of staffing could provide additional support for a similar cost.

In Tables 6 and 7, we provide sensitivity analyses showing the potential costs of universal testing in LTC facilities given these unknown variables described above. All costs below are assumed to be in addition to the current baseline testing activities; facilities that are already performing tests that would be in compliance with these testing requirements, or different parameters to trigger the testing requirements, would impact the number of facilities affected as detailed below. In the context of the Table 6, "rounds of testing" refers to the number of times each facility tests their entire staff and resident population on an annual basis. In light of uncertainty, this can be interpreted as the number of times the parameters set forth by the Secretary are triggered; additional tests that may be necessary to facilitate cohorting and identify new transmission events; or additional tests to verify negative results. We note that if baseline testing is not accounted for, benefits of this provision would be overstated in addition to (this category of) costs.

⁹¹ Bigelow BF, Tang O, Barshick B, et al. Outcomes of Universal COVID-19 Testing Following Detection of Incident Cases in 11 Long-term Care Facilities. *JAMA Intern Med.* Published online July 14, 2020. doi:10.1001/jamainternmed.2020.3738.

⁹² <https://www.cms.gov/files/document/covid-faqs-snf-testing.pdf>.

⁹³ <https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html>.

⁹⁴ For these estimates we assume the number of staff and residents are evenly distributed across facilities. This \$10 million estimate is equal to: (approximately 3.2 million staff and residents * 5 percent of facilities * \$60 per test * 1 round of testing) + ((\$37.24 cost for RN * 2 for fringe benefits and overhead) * 5 hours * 1 round of testing).

TABLE 6—SENSITIVITY ANALYSIS OF POTENTIAL COSTS OF LTC TESTING; LOW COSTS OF INTERVENTION
[In millions]

Rounds of testing	Facilities affected					
	5%	10%	25%	50%	75%	100%
	775	1,550	3,874	7,748	11,621	15,495
1	⁹⁴ \$10	\$20	\$50	\$99	\$149	\$198
2	20	40	99	198	297	396
3	30	59	149	297	446	594
4	40	79	198	396	594	792
5	50	99	248	495	743	990
6	59	119	297	594	891	1,188
7	69	139	347	693	1,040	1,386
8	79	158	396	792	1,188	1,584
9	89	178	446	891	1,337	1,783
10	99	198	495	990	1,485	1,981
11	109	218	545	1,089	1,634	2,179
12	119	238	594	1,188	1,783	2,377
13	129	257	644	1,287	1,931	2,575
14	139	277	693	1,386	2,080	2,773
15	149	297	743	1,485	2,228	2,971
16	158	317	792	1,584	2,377	3,169
17	168	337	842	1,683	2,525	3,367
18	178	357	891	1,783	2,674	3,565
19	188	376	941	1,882	2,822	3,763
20	198	396	990	1,981	2,971	3,961

TABLE 7—SENSITIVITY ANALYSIS OF POTENTIAL COSTS OF LTC TESTING; HIGH COSTS OF INTERVENTION
[In millions]

Rounds of testing	Facilities affected					
	5%	10%	25%	50%	75%	100%
	775	1,550	3,874	7,748	11,621	15,495
1	*\$12	\$24	\$60	\$119	\$179	\$238
2	24	48	119	238	358	477
3	36	72	179	358	537	715
4	48	95	238	477	715	954
5	60	119	298	596	894	1,192
6	72	143	358	715	1,073	1,431
7	83	167	417	835	1,252	1,669
8	95	191	477	954	1,431	1,908
9	107	215	537	1,073	1,610	2,146
10	119	238	596	1,192	1,788	2,384
11	131	262	656	1,311	1,967	2,623
12	143	286	715	1,431	2,146	2,861
13	155	310	775	1,550	2,325	3,100
14	167	334	835	1,669	2,504	3,338
15	179	358	894	1,788	2,683	3,577
16	191	382	954	1,908	2,861	3,815
17	203	405	1,013	2,027	3,040	4,054
18	215	429	1,073	2,146	3,219	4,292
19	227	453	1,133	2,265	3,398	4,531
20	238	477	1,192	2,385	3,577	4,769

* For these estimates we assume the number of staff and residents are evenly distributed across facilities. This \$12 million estimate is equal to: (Approximately 3.2 million staff and residents * 5 percent of facilities * \$60 per test * 1 round of testing) + ((\$37.24 cost for RN * 2 for fringe benefits and overhead) * 40 hours * 1 round of testing). This upper-bound scenario accounts for the possibility that each round of testing and intervention costs approximately \$2,607 more per facility than the lower-bound scenario.

While we currently have no reason to believe testing will be required anywhere near the extent demonstrated at the high end of this range, we are presenting our cost estimates in this format to underscore the unpredictable nature of this pandemic. Other potential administrative costs associated with this

provision are detailed in section IV.G.2. of this IFC. We note that almost half of the potential costs detailed above would be attributable to the testing of residents, the vast majority of which are enrolled in Medicare, Medicaid, or both, but Medicaid is the primary payer for approximately 62% of residents. The

Families First Coronavirus Response Act requires state Medicaid and CHIP programs to cover any COVID-19-related testing and diagnostic services; cost-sharing is not permitted for COVID-19 testing and testing-related services. For residents in a Medicare covered Part A skilled nursing facility

stay, testing is covered by the global PPS per diem rate that the long term care facility receives. In addition, HHS recently announced approximately \$5 billion in Provider Relief Fund distributions under the CARES Act for nursing homes. However, we would like to note that LTC facilities are responsible for the costs of testing in order to comply with the infection control requirements of this rule, regardless of whether specific reimbursement is available from Medicare, Medicaid, the Provider Relief Fund, or any other sources. Of this amount, approximately \$2.5 billion provides upfront funding to support increased testing, staffing, and Personal Protective Equipment (PPE), according to facilities' needs.⁹⁵

There is also potential for substantial benefits by catching and eliminating COVID-19 outbreaks early in these facilities. HHS' "Guidelines for Regulatory Impact Analysis" explain in some detail the concept of Quality Adjusted Life Years (QALYs).⁹⁶ QALYs, when multiplied by a monetary estimate such as the Value of a Statistical Life Year (VSLY), are estimates of the value

that people are willing to pay for life-prolonging and life-improving health care interventions of any kind (see sections 3.2 and 3.3 of the HHS Guidelines for a detailed explanation). The QALY and VSLY amounts used in any estimate of overall benefits is not meant to be precise, but instead are rough statistical measures that allow an overall estimate of benefits expressed in dollars.⁹⁷

Research surrounding changes in health-related quality of life due to the novel coronavirus, as well as the overall case fatality rate, is still ongoing. Due to these substantial uncertainties, as well as the unknown extent of future outbreaks, we have presented a threshold analysis of life-saving benefits below. The following estimates assume a the Value of a Statistical Life (VSL) of approximately \$10.1 million in 2020 as described in the aforementioned HHS Guidelines, inflated to 2019 dollars using the Implicit Price Deflators for Gross Domestic Product. We note, as detailed in the HHS Guidelines, that there is substantial uncertainty regarding how VSL varies with age,⁹⁸ making estimates of the VSL, which are

typically developed using wage data for working-age populations, potentially overstated in contexts such as this for a novel coronavirus that disproportionately affects the elderly; overstatement of the VSL would in turn lead to underestimation of the fatal illnesses that would need to be avoided in order for the regulatory provision to break even.

Consistent with the HHS Guidelines, we assume that the average individual in these underlying VSL studies is approximately 40 years of age, allowing us to calculate a VSLY of approximately \$469,000 to \$818,000 at 3 and 7 percent discount rates respectively. Table 8, when viewed alongside Table 7, demonstrates the number of years of life extension needed to break-even with the corresponding costs of testing and intervention. We reiterate, as discussed in our cost estimates, that the break-even points below are subject to any flaws in our assumptions of costs. Due to this uncertainty, these estimates are based on our high estimate of the costs of intervention.

TABLE 8—THRESHOLD ANALYSIS OF AVOIDED FATAL ILLNESSES, DUE TO LTC TESTING AND ASSOCIATED PROTECTIVE ACTIONS, REQUIRED FOR THE REGULATORY PROVISION TO BREAK EVEN

[In life years]

Rounds of testing	Facilities affected					
	5%	10%	25%	50%	75%	100%
	775	1,550	3,874	7,748	11,621	15,495
1	15–26	29–51	73–128	145–254	219–382	291–507
2	29–51	59–102	145–254	291–507	438–763	583–1017
3	44–77	88–153	219–382	438–763	657–1145	874–1524
4	59–102	116–203	291–507	583–1017	874–1524	1166–2034
5	73–128	145–254	364–635	729–1271	1093–1906	1457–2541
6	88–153	175–305	438–763	874–1524	1312–2287	1749–3051
7	101–177	204–356	510–889	1021–1780	1531–2669	2040–3558
8	116–203	234–407	583–1017	1166–2034	1749–3051	2333–4068
9	131–228	263–458	657–1145	1312–2287	1968–3432	2624–4575
10	145–254	291–507	729–1271	1457–2541	2186–3812	2915–5082
11	160–279	320–559	802–1398	1603–2795	2405–4193	3207–5592
12	175–305	350–610	874–1524	1749–3051	2624–4575	3498–6099
13	189–330	379–661	947–1652	1895–3304	2842–4957	3790–6609
14	204–356	408–712	1021–1780	2040–3558	3061–5338	4081–7116
15	219–382	438–763	1093–1906	2186–3812	3280–5720	4373–7626
16	234–407	467–814	1166–2034	2333–4068	3498–6099	4664–8133
17	248–433	495–863	1238–2160	2478–4321	3717–6481	4956–8643
18	263–458	524–915	1312–2287	2624–4575	3935–6862	5247–9150
19	278–484	554–966	1385–2415	2769–4829	4154–7244	5539–9659
20	291–507	583–1017	1457–2541	2916–5084	4373–7626	5830–10167

⁹⁵ <https://www.hhs.gov/about/news/2020/08/07/hhs-announces-allocations-of-cares-act-provider-relief-fund-for-nursing-homes.html>.

⁹⁶ <https://aspe.hhs.gov/pdf-report/guidelines-regulatory-impact-analysis>.

⁹⁷ We note that using such a measure to make coverage or reimbursement determinations is

prohibited by Section 1182(e) of the Act. That prohibition does not apply to the situation addressed in this IFC, where the purpose is not to determine medical coverage for individual patients, but to measure overall success in life-saving efforts to avert disease.

⁹⁸ There is somewhat more clarity about willingness-to-pay being positively correlated with length of life extension achieved by a rule or other policy intervention—an outcome that is related to age, but only somewhat loosely.

As described above, it is difficult to predict how many lives might be saved as a result of these testing requirements, but the benefits of catching, treating, and eliminating COVID-19 transmission and outbreaks among the over 3.2 million employees and residents of LTC facilities has potential to far exceed the costs. These benefits may be compounded by the possibility of LTC staff unknowingly infecting their families and respective communities, giving these testing requirements the potential for far-reaching benefits beyond the walls of LTC facilities.

3. Clinical Laboratories

As discussed in section II.C of this IFC, these provisions could impact all of the 256,747 CLIA-certified laboratories⁹⁹ to some extent. However, for purposes of this IFC, we estimate that approximately 30 percent (n=77,024) of the total CLIA-certified laboratories could potentially be performing SARS-CoV-2 testing. Although complete data are not available to calculate all estimated costs and benefits that would result from the changes in this IFC, we are providing an analysis of the potential impact based on available information and certain assumptions. Assuring a rapid and thorough public health response to the COVID-19 pandemic relies on having complete and comprehensive laboratory testing data, including standardized test results, relevant demographic details, and additional information that can improve both the public health response to SARS-CoV-2 and treatment of COVID-19. These data can contribute to understanding disease incidence and trends; Initiating epidemiologic case investigations, assisting with contact tracing, assessing availability and use of testing resources, and identifying supply chain issues for reagents and other material. Laboratory testing data, in conjunction with case reports and other data, also provide vital guidance for mitigation and control activities. Implementation of the requirements of this IFC will result in changes that are anticipated to have both quantifiable and non-quantifiable impacts on laboratories. In estimating the quantifiable impacts, we include costs to all laboratories that could result from the need to meet the new CLIA provisions.

⁹⁹ https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/cert_type.pdf.

a. Laboratory Costs To Develop a Mechanism To Track SARS-CoV-2 Test Results

As discussed in section II.C. of this IFC, we are adding §§ 493.41 and 493.1100(a) to require that, during the PHE for COVID-19, as defined in § 400.200, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 must report SARS-CoV-2 test results in such form and manner, and at such timing and frequency, as the Secretary may prescribe. We estimate that approximately 30 percent (n=77,024) of the total CLIA-certified laboratories¹⁰⁰ could potentially be performing SARS-CoV-2 testing. Each of these laboratories would incur a one-time cost for the time needed to develop a mechanism to track and report SARS-CoV-2 test results to be in compliance with this new requirement. As described in Table 10, we estimate the one-time costs for all laboratories to implement this requirement to be \$78,240,979 to \$109,537,371. (See section IV.A. of this IFC.)

b. Laboratory Costs To Collect Test Results for Reporting SARS-CoV-2 Test Results

As discussed in section II.C. of this IFC, we are adding §§ 493.41 and 493.1100(a) to require that, during the PHE for COVID-19, as defined in § 400.200, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 must report SARS-CoV-2 test results in such form and manner, and at such timing and frequency, as the Secretary may prescribe. We estimate that approximately 30 percent (n=77,024) of the total CLIA-certified laboratories could potentially be performing SARS-CoV-2, and by this rule would need to collect those test results to report them in accordance with §§ 493.41 and 493.1100(a). We estimate the total cost would range from \$2,028,812 to \$12,172,873 *per day* to collect and report the SARS-CoV-2 test results. Collection of test results, as well as reporting would be an ongoing burden (including, for example, the daily requirement to report, testing, volume, and personnel) for each laboratory performing this type of

¹⁰⁰ Includes Certificate of Waiver (CoW), Certificate of Provider-Performed Microscopy (PPM), Certificate of Compliance (CoC) and Certificate of Accreditation (CoA). Based on the CLIA web page (https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/cert_type.pdf), the total number of laboratories as of March 2020 are as follows: CoW, n=193,474; PPM n=30,120; CoC n=17,432; CoA n=15,721; total =256,747.

testing. See sections IV.B. and IV.D. of this IFC.

c. Laboratory Costs To Report SARS-CoV-2 Test Results

As discussed in section II.C. of this IFC, we are adding §§ 493.41 and 493.1100(a) to require that, during the PHE for COVID-19, as defined in § 400.200, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 must report SARS-CoV-2 test results in such form and manner, and at such timing and frequency, as the Secretary may prescribe. We expect that approximately 30 percent (n=77,024) of the total CLIA-certified laboratories could potentially be performing SARS-CoV-2 and need to report test results as required by the Secretary. Each of these laboratories would incur a *per day* cost that would range from \$1,481,942 to \$8,891,651. Reporting of test results would be an ongoing burden for each laboratory performing this type of testing. (See to section IV.C. of this IFC.)

d. Laboratory Costs To Update Policies and Procedures

We expect that the approximately 77,024 laboratories performing SARS-CoV-2 testing would incur costs for the time needed to review the revised reporting regulations and update their policies and procedures to be in compliance. The total one-time burden per laboratory to review and update affected policies and procedures is \$42,648,189. (See section IV.D. of this IFC.)

e. Accreditation Organization (AO) and Exempt State (ES) Costs To Update Standards for Reporting SARS-CoV-2 Test Results

We would expect the seven approved AOs and two ESs would have to review their standards, provide updates and submit the changes to CMS related to SARS-CoV-2 test reporting for approval (9 organizations/exempt states × 25 or 30 hours). We assume a one-time cost of from \$24,917 to \$29,900 to identify the applicable legal obligations and to develop the updated standards needed to reflect the new requirements for SARS-CoV-2 testing. (See section IV E. of this IFC.)

f. Accreditation Organization (AO) and Exempt State (ES) Costs To Update Policies and Procedures Related to Reporting Laboratories Performing SARS-CoV-2 Testing That Do Not Report Results as Required

We would expect the seven approved AOs and two ESs would have to develop policies and procedures related

to identifying laboratories that do not report SARS-CoV-2 test results in order to report these laboratories to CMS. We are requiring the AOs/ESs to report this information no later than 10 days after determining a laboratory is not reporting results, as required under §§ 493.41 and 493.1100(a). We assume a one-time cost would range from \$9,967 to \$14,950. In addition, the AOs and ESs would be required to report to CMS every 10 days those laboratories that have not reported test results as required. The annual total number of times each AO and ES is required to report to CMS is 36.5 (365 days/10 days). We estimate a cost of \$1,192 to 2,383 per 10 days which translates to an annual total cost range of \$43,508 to \$86,980 to identify the laboratories and submit the information to CMS. (See section IV.F. of this IFC.)

g. Enforcement, Imposition of Civil Money Penalties (CMPs)

CLIA/AO/ES surveyors typically perform approximately 16,577 surveys annually.¹⁰¹ In addition, the new requirements would also require 3,727 CoW and PPM laboratories to be surveyed annually for reporting requirements. This is a total of 20,304 laboratories that would be required to be surveyed annually and that may be impacted by the imposition of CMPs for failing to report SARS-CoV-2 as required. We estimate the fiscal impact of imposing CMPs on the estimated 20,304 laboratories performing this testing to be 20 percent of laboratories performing SARS-CoV-2 testing. That is, 4,061 laboratories may have a CMP imposed during the PHE for COVID-19 for not complying with the new CLIA reporting requirements. While we believe initially the number of laboratories having a CMP imposed would be significantly higher, we postulate that the number of laboratories that will require the imposition of a CMP for not reporting SARS-CoV-2 test results will decrease during the PHE for COVID-19. We believe this decrease will be a result of laboratories implementing the new requirements included in this IFC.

We have no data indicating how imposition of the alternative sanction of CMP would affect all laboratories. Prior to the changes included in this IFC, CMPs were not imposed on CoW laboratories. In 2016, CMS imposed 30 CMPs for an average of \$35,436 per laboratory; in 2017, 25 CMPs were

imposed for an average of \$72,237 per laboratory; and in 2018, 24 CMPs were imposed for an average of \$44,230 per laboratory. The average total CMP imposed per fined laboratory over the 3-year period was \$52,634. Based on our CMP requirements specific to SARS-CoV-2 at 493.1834(d)(2)(iii), we anticipate that would be a range of \$1,000 per violation and \$500 for each additional day of noncompliance that test results are not reported. For example, we are providing estimates for a minimum period of 3 days and a maximum period of 30 days. We estimate that the total cost of CMPs imposed across all laboratories collectively would range from \$8,122,000 to \$62,945,500 (4,061 laboratories × \$2000 (3 days) or 4,061 laboratories × \$15,500 (30 days)) for laboratories performing SARS-CoV-2 testing. (see Table 9).

h. Infrastructure

Several issues related to infrastructure have been identified (that is, reporting test results, personnel) that will have an increased burden on all laboratories. As stated above, for purposes of this IFC, we expect that the approximately 30 percent (n=77,024) of the total CLIA-certified laboratories could potentially be performing SARS-CoV-2 testing. Furthermore, based on data from the CLIA website¹⁰² we are estimating that 75 percent of the 77,024 laboratories have a CoW (n=57,768), and 25 percent have a Certificate of PPM, CoC, CoA, or CoR (n=19,256). Generally, the types of facilities that have a CoW include, but are not limited to: Physician office laboratories (45%); pharmacies (5%); skilled nursing/nursing facility (6%); and other types of point-of-care facilities.¹⁰³ The facilities with PPM generally are physician office laboratories (POL) or other types of point-of-care (POC) facilities.¹⁰⁴ We would also estimate that 45 percent of the CoC, CoA, and CoR laboratories would be POLs. For these POL and POC laboratories (n=66,433; 57,768 (CoWs) + 8,665 (other certificate types)), we believe there would be infrastructure issues related to implementing the new CLIA requirement that test results must be reported as required by the Secretary. While reporting of SARS-CoV-2 test results affects all laboratories performing this testing, we believe that meeting the new reporting requirements

will be more challenging for POL and POC laboratories given that this requirement creates the need for systemic changes to the ability to report results. If a laboratory does not currently have this capability to report in the form and manner specified by the Secretary, they would need to expeditiously ensure that the laboratory was able to submit the SARS-CoV-2 test results in such form and manner, and at such timing and frequency, as the Secretary may prescribe. Personnel would need to be trained to implement the new CLIA reporting requirements related to reporting of test results as prescribed by the Secretary. Further, given that CoW laboratories are not required to meet any personnel requirements, including laboratory director and testing personnel, this could contribute a significant challenge for these laboratories. In some cases, laboratory directors and testing personnel are not medical professionals. CoW laboratories may not have individuals in place that can train laboratory personnel to perform this task and may need to outsource this training.

While we do not have any data to be able estimate the fiscal burden that it would cost to update a laboratory's current software to ensure that the laboratory is able to report test results as required by the Secretary, we can estimate the time it would take each laboratory to implement the requirement. We are soliciting public comments related to cost and time it would take laboratories to update their software to ensure reporting of SARS-CoV-2 test results. It would take approximately 3 hours to implement or update to the form and manner prescribed by the Secretary and approximately 1 hour to train employees to be in compliance with this new requirement. We estimate the burden hours for updating and implementing the form would be 231,072 (77,024 laboratories × 3 hours). We estimate a database administrator/architect (15–1245) would be needed to implement or update the software to report the test results at an hourly wage of \$46.21 per hour as published by the BLS in 2019.¹⁰⁵ The wage rate would be doubled to \$92.42 to include overhead and fringe benefits. The total estimated cost to implement this requirement per laboratory would be \$21,355,674 (77,024 laboratories × 3 hours × \$92.42). We estimate a healthcare support worker (31–9099) would train employees to collect the additional required information at an hourly wage of \$19.24 per hour as published by the

¹⁰¹ As of March 2020, there were 17,432 Certificate of Compliance and 15,721 Certificate of Accreditation laboratories. CLIA surveys are performed biennially, so each year approximately half of the laboratories would be surveyed (33,154 × 0.50 = 16,577).

¹⁰² https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/cert_type.pdf.

¹⁰³ <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/factype.pdf>.

¹⁰⁴ <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/factype.pdf>.

¹⁰⁵ https://www.bls.gov/oes/current/oes_nat.htm.

BLS in 2019.¹⁰⁶ We estimate that at least one new or existing employee per laboratory (n=77,024) would need to be trained for the purpose of collecting this information. The wage rate would be doubled to \$38.48 to include overhead and fringe benefits. The total estimated cost would be \$2,963,884 (77,024 laboratories × 1 hour × \$38.48) *per day* to collect the required information. Reporting of test results would be an ongoing burden for each laboratory performing this type of testing since laboratories would need to train employees to perform this task as employees left and needed to be replaced. (See Table 9.)

TABLE 9—ESTIMATED COSTS, INCLUDING DAILY COSTS, TO LABORATORIES, ACCREDITATION ORGANIZATIONS (AO) AND EXEMPT STATES (ES) TO IMPLEMENT REPORTING REQUIREMENTS

Regulatory change	Affected group	Total number of affected entities	Hourly cost	Occupation	Hours		Range of cost estimate for implementing new CLIA requirements	
					Low	High	Low estimate	High estimate
Collect Laboratory Results ¹ .	All Laboratories Performing SARS-CoV-2 Testing.	77,024	\$52.68	29–2010	0.5	3	\$405,762,400	\$2,434,574,600
Reporting Costs ¹ ..	All Laboratories Performing SARS-CoV-2 Testing.	77,024	38.48	31–9099	0.5	3	296,388,400	1,778,330,200
AO/ES Reporting to CMS ² .	AO/ES	9	66.20	15–1231	2	4	43,508	86,980
Imposition of CMPs	All Laboratories Performing SARS-CoV-2 Testing.	4,061	n/a	n/a	n/a	n/a	8,122,000	62,945,500
Total Increased Cost.	710,316,308	4,275,937,280

¹ Please note that “Collect Laboratory Results” and “Reporting Costs” *per day* estimates are \$2,028,812 to \$12,172,873, and \$1,481,942 to \$8,891,651, respectively. For purposes of the annual cost, we estimated 200 days/year for testing/reporting (365 days/year – 104 weekend days – 10 federal holidays – approximately 50 days to account for laboratories who do not test 7 days/week.)

² Reporting requirement of once every 10 days. Calculation factor is 36.5 (365 days per year/10 days). The total cost would range from \$1,192 to \$2,383 (9 × 2 or 4 hours × \$66.20) per 10 days for an annual total cost of \$43,508 to \$86,980 (\$1,192 or \$2,383 × 36.5).

TABLE 10—ESTIMATED ONE-TIME COSTS TO LABORATORIES, ACCREDITATION ORGANIZATIONS (AO) AND EXEMPT STATES (ES) TO IMPLEMENT REPORTING REQUIREMENTS

Regulatory change	Affected group	Total number of affected entities	Hourly cost	Occupation	Hours		Range of cost estimate for implementing new CLIA requirements ¹ and Section 3202(b) of the CARES Act	
					Low	High	Low estimate	High estimate
Tracking Mechanism.	All Laboratories Performing SARS-CoV-2 Testing.	77,024	\$203.16 ¹	11–9111, 15–1245	5	7	\$78,240,979	\$109,537,371
Update Policies and Procedures.	All Laboratories Performing SARS-CoV-2 Testing.	77,024	110.74	11–9111	5	n/a	42,648,189	42,648,189
AO/ES Updating Standards.	AO/ES	9	110.74	11–9111	25	30	24,917	29,900
AO/ES Update Policies and Procedures.	AO/ES	9	110.74	11–9111	10	15	9,967	14,950
Infrastructure, Implementation of Test Reporting.	All Laboratories Performing SARS-CoV-2 Testing.	77,024	92.42	15–1245	3	n/a	21,355,674	21,355,674
Infrastructure, Personnel.	All Laboratories Performing SARS-CoV-2 Testing.	77,024	38.48	31–9099	1	n/a	2,963,884	2,963,884

¹⁰⁶ https://www.bls.gov/oes/current/oes_nat.htm. 31–9099.

TABLE 10—ESTIMATED ONE-TIME COSTS TO LABORATORIES, ACCREDITATION ORGANIZATIONS (AO) AND EXEMPT STATES (ES) TO IMPLEMENT REPORTING REQUIREMENTS—Continued

Regulatory change	Affected group	Total number of affected entities	Hourly cost	Occupation	Hours		Range of cost estimate for implementing new CLIA requirements ¹ and Section 3202(b) of the CARES Act	
					Low	High	Low estimate	High estimate
Total Increased Cost.	145,243,610	176,529,968

¹\$101.58 hourly rate includes \$55.37 (Management Level Employee) + \$46.21 (Database Administrative/Architect). The wage rate would be double to \$203.16 to include overhead and fringe benefits.

4. Quality Reporting: Updates to the Extraordinary Circumstances Exceptions (ECE) Granted for Four Value-Based Purchasing Programs in Response to the PHE for COVID-19, and Update to the Performance Period for the FY 2022 SNF VBP Program

a. Updates to ESRD QIP: Utilization of Fourth Quarter CY 2019 ESRD QIP Data and the Removal of the Option for Facilities To Opt-Out of the Extraordinary Circumstances Exception (ECE) Granted With Respect to First and Second Quarter (CY) 2020 ESRD QIP Data a

In section II.D.1. of this IFC, we are updating our regulations at 42 CFR 413.178(d)(7) to state that a facility has opted out of the ECE for COVID-19 with respect to the reporting of fourth quarter 2019 NHSN data if the facility actually reported the data by the March 31, 2020 deadline but did not notify CMS that it would do so.. Additionally, we are removing the ability of facilities to opt-out of the ECE we granted with respect to Q1 and Q2 2020 ESRD QIP data. These updates do not require facilities to complete any forms or submit any additional information to receive an ECE, and therefore, the program does not anticipate any change in burden associated with this IFC.

The existing individual ECE request form policy is accounted for in the currently approved Hospital Inpatient Reporting PRA package, OMB control #0938-1022 (expiration date December 31, 2022). There are no changes to the individual ECE request form policy and therefore no changes to the burden associated with the ESRD QIP.

b. Updates to the Application of the HAC Reduction Program ECE Policy in Response to the PHE for COVID-19

In section II.D.2. of this IFC, we are updating the ECE policy for the HAC Reduction Program to not use Q1 and Q2 2020 data that were made optional under the Guidance memo for scoring in the HAC Reduction Program for scoring

calculations in future program years (that is, the FY 2022 and FY 2023 program years). The existing individual ECE request form policy is accounted for in the currently approved Hospital Inpatient Reporting PRA package, OMB control #0938-1022 (expiration date December 31, 2022). There are no changes to the individual ECE request form policy.

This update does not require hospitals to complete any forms or submit any additional information to receive an ECE, and therefore, the program does not anticipate any change in burden associated with this IFC.

c. Update to the HRRP ECE Granted in Response to the PHE for COVID-19

In section II.D.3. of this IFC, we excepted the use of claims data from the first and second quarters of CY 2020 from the Hospital Readmissions Reduction Program because of our concern that the data collected during this period may be greatly impacted by the response to COVID-19, and therefore, may not be reflective of a hospital's performance during this time. The existing individual ECE request form policy is accounted for in the currently approved Hospital Inpatient Reporting PRA package, OMB control #0938-1022 (expiration date December 31, 2022). There are no changes to the individual ECE request form policy.

This update does not require hospitals to complete any forms or submit any additional information, and therefore, the program does not anticipate any change in burden associated with this IFC.

d. Update to the Hospital VBP Program ECE Granted in Response to the PHE for COVID-19

Section II.D.4. of this IFC updates the Hospital VBP Program ECE policy to allow CMS to exclude any data submitted regarding care provided during the first and second quarter of CY 2020 from our calculation of performance. This change does not

require hospitals to complete any forms or submit any additional information, and therefore, the program does not anticipate any change in burden associated with this IFC.

The existing individual ECE request form policy is accounted for in the currently approved Hospital Inpatient Reporting PRA package, OMB control #0938-1022 (expiration date December 31, 2022). There are no changes to the individual ECE request form policy, and therefore, no changes to the burden associated with the Hospital VBP Program.

e. Revised Performance Period for the FY 2022 SNF VBP Program as a Result of the ECE Granted for the PHE for COVID-19

In section II.D.5. of this IFC, we are revising the performance period for the FY 2022 SNF VBP Program Year.

In the FY 2021 SNF PPS final rule,¹⁰⁷ we set out estimated impacts of the FY 2021 SNF VBP Program. At this time, those estimates represent our best approximation of the financial impact of the FY 2022 SNF VBP Program. We anticipate that the revised performance period would not have a substantial impact on the estimated payback percentage, Medicare savings, and amount of value-based incentive payments redistributed to SNFs for the FY 2022 SNF VBP Program.

5. NCD Procedural Volumes for Facilities and Practitioners to Maintain Medicare Coverage

As discussed in section II.E. of this IFC, these provisions result in no impact to the Medicare program because they will enable facilities and practitioners to continue to be eligible for coverage under the impacted NCDs during the PHE for COVID-19 that would have been eligible for coverage if the COVID-

¹⁰⁷ The FY 2021 SNF PPS Final Rule can be accessed at <https://www.federalregister.gov/documents/2020/08/05/2020-16900/medicare-program-prospective-payment-system-and-consolidated-billing-for-skilled-nursing-facilities>.

19 pandemic had not occurred. Without the pandemic, facilities and practitioners would likely have continued to perform procedures necessary to meet the procedural volume requirements specified in the NCDs.

6. Limits on COVID-19 and Related Testing Without an Order

As discussed in section II.F. of this IFC, we are revising the previous policy outlined in the May 8th COVID-19 IFC, which allowed for broad COVID-19 testing for a single beneficiary without a physician or other practitioner order by establishing that only a single COVID-19 diagnostic test and one of each other related test (as listed in the May 8th COVID-19 IFC) without a treating physician or other practitioner order is reasonable and necessary for Medicare payment. This limitation on tests without a treating physician/practitioner order will apply beginning on the effective date of this rule, and any tests furnished prior to the effective date would not be considered for purposes of the limit on tests without a physician or eligible ordering practitioner order. We are also establishing a policy whereby the orders of pharmacists and other practitioners that are allowed to order laboratory tests in accordance with state scope of practice and other pertinent laws can fulfill the requirements related to orders for covered COVID-19 tests for Medicare patients. We do not anticipate that these changes will affect overall Medicare expenditures over time because they will better align the requirements for COVID-19 and related testing with other Medicare laboratory tests, which require the order of a physician or other practitioner based on the clinical needs of the beneficiary.

6. Premium Reductions

a. PPACA Risk Adjustment

In this IFC, we clarify that issuers that choose to provide temporary premium credits to consumers¹⁰⁸ must report the adjusted plan premium amount, taking into account the credits provided to consumers as a reduction to premiums for the applicable months during 2020, for risk adjustment data submissions for the 2020 benefit year. As stated in section IV. of this IFC, the Collection of Information section, we do not believe that the clarifications regarding risk adjustment reporting in this IFC would

impose additional administrative burden on health insurance issuers beyond the effort already required to submit data to HHS for the purposes of operating risk adjustment. Although we do not know how many states will permit issuers to provide temporary credits to reduce 2020 premiums or how many issuers will elect to do so, for purposes of this analysis, we estimate that approximately 40 percent of risk adjustment covered plans in each state market risk pool will provide these temporary premium credits to reduce the premiums charged to enrollees to support continuity of coverage during the PHE for COVID-19. We anticipate that reporting of the adjusted, lower subscriber level premiums for 2020 benefit year risk adjustment data submissions will lower the statewide average premium used to determine risk adjustment transfer amounts under the state payment transfer formula for the 2020 benefit year, thereby lowering aggregate risk adjustment payments, aggregate risk adjustment charges, and the overall magnitude of risk adjustment transfers, proportional to the amount of temporary premium credits provided by issuers of risk adjustment covered plans for the 2020 benefit year. Consistent with the assumptions used for the MLR program, as described below, we estimate that the aggregate impact of premium credits will result in an 8 percent reduction in annual premium, and a commensurate 8 percent reduction in transfers for the 2020 benefit year.¹⁰⁹ In the 2020 Payment Notice, HHS finalized the risk adjustment state payment transfer formula under the HHS risk adjustment methodology for the 2020 benefit year, and reaffirmed that HHS will continue to operate the risk adjustment program in a budget neutral manner. Therefore, there is no net aggregate financial impact on health insurance issuers or the federal government as a result of the risk adjustment provisions in this IFC. However, while risk adjustment transfers are net neutral in aggregate, we recognize that individual issuers may be financially impacted by reduced transfers (either lower risk adjustment payments or lower risk adjustment charges) if any issuer in the issuer's state market risk pool provides premium credits to enrollees. The extent of this impact will vary based on the number

¹⁰⁹ The effects of the risk adjustment program, including estimated outlays and receipts for the 2020 benefit year are provided in the 2020 Payment Notice final rule, published in the April 25, 2019, *Federal Register* (84 FR 17454 at 17551). We relied on those estimates for purposes of estimating the impacts of the temporary premium credit policies in this IFC.

of issuers in a state market risk pool that elect to provide the temporary premium credits, the amount of these premium credits provided, as well as the market share of the issuers that provide these premium credits. For example, issuers with larger market share that offer large premium credits will affect the statewide average premium more significantly. Although we recognize the potential for financial impacts for individual issuers as a result of the clarifications in this IFC, we believe that if HHS permitted issuers that provided premium credits to submit unadjusted premiums for the purposes of calculating risk adjustment, distortions could occur which could also financially impact individual issuers. For example, absent the requirement that issuers that offer premium credits report the adjusted, lower premium amount for risk adjustment purposes, an issuer with a large market share with higher-than-average risk enrollees that provides temporary premium credits would inflate the statewide average premium by submitting the higher, unadjusted premium amount, thereby increasing its risk adjustment payment. In such a scenario, a smaller issuer in the same state market risk pool that owes a risk adjustment charge, and also provides premium credits to enrollees, would pay a risk adjustment charge that is relatively higher than it would have been if it were calculated based on a statewide average that reflected the actual, reduced premium charged to enrollees by issuers in the state market risk pool. Therefore, we believe that requiring issuers that offer temporary premium credits for 2020 coverage to accurately report to the EDGE server the adjusted, lower premium amounts actually charged to enrollees is most consistent with existing risk adjustment program requirements and mitigates the distortions that would occur if issuers that offer these temporary premium credits did not report the actual amounts charged to enrollees, while not imposing additional financial burden on issuers, as compared to an approach that would permit issuers to report unadjusted premium amounts.

b. Medical Loss Ratio

In this IFC, we clarify that issuers that choose to provide temporary premium credits to consumers in 2020 must account for these credits as reductions to premium for the applicable months during 2020 when reporting earned premium for the applicable MLR reporting year.¹¹⁰ Although we do not

¹¹⁰ Because the MLR and rebate calculations are based on three years of data, reporting earned

¹⁰⁸ See the CMS Memo "Temporary Policy on 2020 Premium Credits Associated with the COVID-19 Public Health Emergency," (August 4, 2020), available at <https://www.cms.gov/GCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Premium-Credit-Guidance.pdf>.

know how many states will permit issuers to provide temporary credits to reduce premiums or how many issuers will elect to do so, for purposes of this analysis, we estimate that approximately 40 percent of issuers offering individual, small group or merged market health insurance coverage will provide these temporary premium credits to reduce the 2020 premiums charged to enrollees to support continuity of coverage during the PHE for COVID-19. If an issuer provides temporary premium credits and consequently reports a lower premium amount for MLR purposes, the lower reported premium will have the effect of increasing MLRs and reducing rebates. Although we do not know the number of issuers that will provide these credits or the amount of premium credits that issuers may elect to provide, for purposes of this estimate we assume that such premium credits would on average constitute approximately 8 percent of total annual premium (equivalent to one month of premium). Based on data for the 2018 MLR reporting year, we estimate that rebates for the 2020 MLR reporting year that will be paid in 2021 to enrollees by issuers that choose to provide temporary premium credits could decline by up to \$500 million, as a result of enrollees receiving a total of up to \$2 billion in premium relief up front in 2020. Because the MLR calculation uses three consecutive years of data, there may be additional rebate decreases in subsequent years, although the impact on rebates may be smaller as issuers would likely account for the premium relief provided to enrollees through these temporary premiums credits at the time they develop premium rates for the 2021 and 2022 benefit years.

7. Merit-Based Incentive Payment System (MIPS) Updates

In section II.I. of this IFC, for the 2020 MIPS performance period, we are proposing to include in the MIPS assignment methodology for the CMS Web Interface and CAHPS for MIPS survey the following additions due to the PHE for COVID-19: (1) CPT codes: 99421, 99422, and 99423 (codes for online digital E/M service (e-visit)), and 99441, 99442, and 99443 (codes for telephone E/M services); and (2) HCPCS codes: G2010 (code for remote evaluation of patient video/images) and G2012 (code for virtual check-in). We do not believe this proposal will impact the

premium for the 2020 benefit year will impact the MLR and rebate calculations for the 2020 through 2022 reporting years. See section 2718(b)(1)(B)(ii) of the PHSA. Also see 45 CFR 158.220(b).

number of beneficiaries selected for sampling, which will be used to complete quality reporting via the CMS Web Interface or administer the CAHPS for MIPS survey; however, this proposal could impact the number of beneficiaries eligible to be sampled. Therefore, we do not anticipate any change in burden or impact on clinicians. In addition, we are modifying the improvement activity IA_ERP_3 previously titled "COVID-19 Clinical Trial" and continuing it through CY 2021. Because MIPS eligible clinicians are still required to submit the same number of activities and the per response time for each activity is uniform, we do not expect this modification to affect our impact estimates in terms of the number of estimated respondents or the burden of compliance.

8. Addressing the Impact of COVID-19 on Part C and Part D Quality Rating Systems

As discussed in section II.H. of this IFC, this policy allows us to calculate the 2022 Star Ratings. We do not anticipate changes in the distribution of ratings from prior years. Therefore, these provisions result in no impact to the Medicare program since ratings will be similar to prior years.

List of Subjects

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologics, Drugs, Health facilities, Health professions, Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant program-health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

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 485

Grant programs-health, Health facilities, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 493

Administrative practice and procedure, Grant programs-health, Health facilities, Laboratories, Medicaid, Medicare, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 1. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 2. Section 410.32 is amended by revising paragraph (a)(3) to read as follows:

§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

(a) * * *

(3) *Public Health Emergency exceptions.* During the Public Health Emergency for COVID-19, as defined in § 400.200 of this chapter, the order of a physician or other applicable practitioner is not required for one otherwise covered diagnostic laboratory test for COVID-19 and for one otherwise covered diagnostic laboratory test each 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 rule-out influenza virus or related diagnosis. Subsequent otherwise covered COVID-19 and related tests described in the previous sentence are reasonable and necessary when ordered by a physician

or nonphysician practitioner in accordance with this paragraph (a), or when ordered by a pharmacist or other healthcare professional who is authorized under applicable state law to order diagnostic laboratory tests. FDA-authorized COVID-19 serology tests are included as covered tests subject to the same order requirements during the Public Health Emergency for COVID-19, as defined in § 400.20 of this chapter, 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.

* * * * *

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

■ 3. 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.

■ 4. Section 413.178 is amended by revising paragraph (d)(7) to read as follows:

§ 413.178 ESRD quality incentive program.

* * * * *

(d) * * *

(7) With the exception of first and second quarter 2020 ESRD QIP data for which CMS granted an exception under paragraph (d)(6) of this section, a facility that has been granted an exception to the data submission requirements under paragraph (d)(6) of this section may notify CMS that it will continue to submit data under paragraph (d)(1) of this section by sending an email signed by the CEO or another designated contact to the ESRD QIP mailbox at *ESRDQIP@cms.hhs.gov*. Upon receipt of an email under this clause, CMS will notify the facility in writing that CMS is withdrawing the exception it previously granted to the facility. With respect to fourth quarter 2019 ESRD QIP data for which CMS granted an exception under paragraph (d)(6) of this section, a facility is deemed to have met the requirements of this paragraph if the facility actually submitted the data by the March 31, 2020 submission deadline but did not notify CMS that it would do so.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 5. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 6. Section 414.1305 is amended by adding the definition of “Primary care services” in alphabetical order to read as follows:

§ 414.1305 Definitions.

* * * * *

Primary care services for purposes of CMS Web Interface and the CAHPS for MIPS survey beneficiary assignment means the set of services identified by any of the following:

(1) CPT codes:

(i) 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 nursing facility, excluding professional services furnished in a SNF for claims identified by place of service (POS) modifier 31); 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 POS modifier 12); 99490 (code for chronic care management); and 99495 and 99496 (codes for transitional care management services);

(ii) Beginning with the 2020 MIPS payment year, 99487 and 99489 (codes for chronic care management); and

(iii) For the CY 2020 MIPS performance period and any subsequent performance period that starts during the Public Health Emergency, as defined in § 400.200, 99421, 99422, and 99423 (codes for online digital evaluation and management services (e-visit)); and 99441, 99442, and 99443 (codes for telephone evaluation and management services).

(2) HCPCS codes:

(i) G0402 (code for the Welcome to Medicare visit); and G0438 and G0439 (codes for the annual wellness visits); and

(ii) For the CY 2020 MIPS performance period and any subsequent performance period that starts during the Public Health Emergency, as defined in § 400.200, G2010 (code for remote evaluation of patient video/images); and G2012 (code for virtual check-in).

* * * * *

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 7. The authority citation for part 422 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 8. Section 422.166 is amended by adding paragraph (i)(11) to read as follows:

§ 422.166 Calculation of Star Ratings.

* * * * *

(i) * * *

(11) *Special rules for the 2022 Star Ratings only.* For the 2022 Star Ratings only, CMS will not apply the provisions in paragraph (i)(9) or (10) of this section and CMS will not exclude the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms or from the determination of the performance summary and variance thresholds for the Reward Factor.

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 9. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w-101 through 1395w-152, and 1395hh.

■ 10. Section 423.186 is amended by adding paragraph (i)(9) to read as follows:

§ 423.186 Calculation of Star Ratings.

* * * * *

(i) * * *

(9) *Special rules for the 2022 Star Ratings only.* For the 2022 Star Ratings only, CMS will not apply the provisions in paragraphs (i)(7) or (8) of this section and CMS will not exclude the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms or from the determination of the performance summary and variance thresholds for the Reward Factor.

* * * * *

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 11. The authority citation for part 482 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr, unless otherwise noted.

■ 12. Section 482.42 is amended by adding paragraph (e) to read as follows:

§ 482.42 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

* * * * *

(e) *COVID-19 Reporting.* During the Public Health Emergency, as defined in § 400.200 of this chapter, the hospital must report information in accordance with a frequency as specified by the Secretary on COVID-19 in a standardized format specified by the Secretary.

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ 13. The authority citation continues to read as follows:

Authority: 42 U.S.C. 1302, 1320, 1320a-7, 1395i, 1395hh and 1396r.

■ 14. Section 483.80 is amended by adding paragraph (h) to read as follows:

§ 483.80 Infection control.

* * * * *

(h) *COVID-19 Testing.* The LTC facility must test residents and facility staff, including individuals providing services under arrangement and volunteers, for COVID-19. At a minimum, for all residents and facility staff, including individuals providing services under arrangement and volunteers, the LTC facility must:

- (1) Conduct testing based on parameters set forth by the Secretary, including but not limited to:
 - (i) Testing frequency;
 - (ii) The identification of any individual specified in this paragraph diagnosed with COVID-19 in the facility;
 - (iii) The identification of any individual specified in this paragraph with symptoms consistent with COVID-19 or with known or suspected exposure to COVID-19;
 - (iv) The criteria for conducting testing of asymptomatic individuals specified in this paragraph, such as the positivity rate of COVID-19 in a county;
 - (v) The response time for test results; and
 - (vi) Other factors specified by the Secretary that help identify and prevent the transmission of COVID-19.
- (2) Conduct testing in a manner that is consistent with current standards of practice for conducting COVID-19 tests;
- (3) For each instance of testing:
 - (i) Document that testing was completed and the results of each staff test; and
 - (ii) Document in the resident records that testing was offered, completed (as appropriate to the resident's testing status), and the results of each test.
- (4) Upon the identification of an individual specified in this paragraph

with symptoms consistent with COVID-19, or who tests positive for COVID-19, take actions to prevent the transmission of COVID-19.

(5) Have procedures for addressing residents and staff, including individuals providing services under arrangement and volunteers, who refuse testing or are unable to be tested.

(6) When necessary, such as in emergencies due to testing supply shortages, contact state and local health departments to assist in testing efforts, such as obtaining testing supplies or processing test results.

* * * * *

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 15. The authority citation for part 485 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 16. Section 485.640 is amended by adding paragraph (d) to read as follows:

§ 485.640 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

* * * * *

(d) *COVID-19 Reporting.* During the Public Health Emergency, as defined in § 400.200 of this chapter, the CAH must report information in accordance with a frequency as specified by the Secretary on COVID-19 in a standardized format specified by the Secretary.

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 17. The authority citation for part 488 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 18. Section 488.447 is added to read as follows:

§ 488.447 Civil Money Penalties imposed for failure to comply with 42 CFR 483.80(g)(1) and (2).

- (a) CMS may impose a civil money penalty for noncompliance with the requirements at § 483.80(g)(1) and (2) of this chapter as follows:
 - (1) *Minimum.* A minimum of \$1,000 for the first occurrence.
 - (2) *Increased amount.* An amount equal to \$500 added to the previously imposed civil money penalty amount for each subsequent occurrence, not to exceed the maximum amount set forth in § 488.408(d)(1)(iii).
 - (b) The penalty amounts in this section will be adjusted annually under 45 CFR part 102.
 - (c) Compliance with the requirements at § 483.80(g)(1) and (2) of this chapter will be assessed weekly. Facilities found

out of compliance with § 483.80(g)(1) and (2) of this chapter are not required to submit a plan of correction as indicated in § 488.408(f)(1).

(d) This section is in effect during and the Public Health Emergency (PHE), as defined in § 400.200 of this chapter, and will continue for up to one year after the end of the PHE.

PART 493—LABORATORY REQUIREMENTS

■ 19. The authority citation for part 493 is revised to read as follows:

Authority: 42 U.S.C. 263a, 1302, 1395x(e), the sentence following 1395x(s)(11) through 1395x(s)(16)).

■ 20. Section 493.2 is amended by revising the definition of “Condition level requirements” to read as follows:

§ 493.2 Definitions.

* * * * *

Condition level requirements means any of the requirements identified as “conditions” in § 493.41 and subparts G through Q of this part.

* * * * *

■ 21. Section 493.41 is added to subpart B to read as follows:

§ 493.41 Condition: Reporting of SARS-CoV-2 test results.

During the Public Health Emergency, as defined in § 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a “SARS-CoV-2 test”) must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.

■ 22. Section 493.555 is amended by adding paragraph (c)(6) to read as follows:

§ 493.555 Federal review of laboratory requirements.

* * * * *

(c) * * *

(6) Notify CMS within 10 days of any conditional level deficiency under §§ 493.41 or 493.1100(a).

■ 23. Section 493.1100 is amended by adding paragraph (a) and reserving paragraph (b) to read as follows:

§ 493.1100 Condition: Facility administration.

* * * * *

(a) *Reporting of SARS-CoV-2 test results.* During the Public Health Emergency, as defined in § 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible

case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.

(b) [Reserved]

■ 24. Section 493.1804 is amended by revising paragraph (c)(1) to read as follows:

§ 493.1804 General considerations.

* * * * *

(c) * * *

(1) CMS may impose alternative sanctions in lieu of, or in addition to principal sanctions. (Except for a

condition level deficiency under §§ 493.41 or 493.1100(a), CMS does not impose alternative sanctions on laboratories that have certificates of waiver because those laboratories are not routinely inspected for compliance with condition-level requirements.)

* * * * *

■ 25. Section 493.1834 is amended by adding paragraph (d)(2)(iii) to read as follows:

§ 493.1834 Civil money penalty.

* * * * *

(d) * * *

(2) * * *

(iii) For a condition level deficiency under §§ 493.41 or 493.1100(a), the penalty amount is \$1,000 for the first day of noncompliance and \$500 for each additional day of noncompliance.

* * * * *

Dated: August 14, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: August 21, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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