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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 [CMS-3401 IFC]

SUMMARY

On August 27, 2020, the Centers for Medicare and Medicaid Services (CMS) placed on public display an interim final rule with comment (IFC). The IFC revises prior COVID-19 regulations and requires more reporting of COVID-19 results. Among other provisions, the IFC requires hospitals, critical access hospitals (CAHs) and laboratories to report COVID-19 test results, requires Medicare and Medicaid long term care facilities (LTC) to conduct testing of residents and staff, makes updates to extraordinary circumstances exceptions (ECE) for value-based purchasing programs, clarifies premium reporting for issuers in the individual and small group markets for insurers, modifies application of the extreme and uncontrollable circumstances policy for calculation of the 2022 Part C and D Star Ratings, makes certain Merit-based Incentive Payment System (MIPS) updates, and revises its prior policy to limit COVID-19 testing without an order to one test of each type.

CMS believes it would be contrary to public interest to undertake normal notice and comment rulemaking; it waives both notice and comment rulemaking and the 30-day delay in the effective date of a final rule. **Most of the policies in the IFC are applicable on the date of publication in the *Federal Register*,** scheduled for September 2, 2020. New enforcement provisions for LTC facilities are applicable one year beyond the expiration of the public health emergency (PHE) for COVID-19. Definitions in §414.1305 and the expansion of telehealth codes used in beneficiary assignment for the CMS Web Interface and Consumer Assessment of Healthcare Providers & Systems (CAHPS) for MIPS survey are applicable beginning January 1, 2020. The 60-day comment period for the IFC ends at close of business on November 2, 2020.

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I. Background

On January 31, 2020, the Secretary of Health and Human Services (HHS) declared a Public Health Emergency (PHE) for the "coronavirus disease 2019" (known as COVID-19[1]) for the U.S. retroactive to January 27, 2020; the PHE was renewed on April 26, 2020 and again on July 23, 2020. On March 11, 2020, the World Health Organization (WHO) declared the COVID-19 outbreak as a pandemic. On March 13, 2020, the President declared the COVID-19 outbreak a national emergency retroactive to March 2020.

The Centers for Disease Control and Prevention (CDC) have reported that people at a higher risk of severe illness from COVID-19 include older adults, people with underlying medical conditions, and residents of long-term care (LTC) facilities.

CMS has issued previous regulations to increase the flexibilities in furnishing and providing services to combat the PHE for COVID-19 and to address and minimize the impact of the PHE for COVID-19 on other regulatory provisions. Earlier rules included the IFC published in the April 6, 2020 Federal Register (85 FR 19230) with an effective date of March 31st (referred to as the "March 31st COVID-19 IFC") 2020; and the IFC published in the May 8, 2020 Federal Register (85 FR 27550) with an effective date of May 8, 2020 (referred to as the "May 8th COVID-19 IFC").

In the current IFC, CMS revises regulations to strengthen CMS' ability to enforce LTC reporting requirements and to strengthen reporting of facility data related to COVID-19, to require universal reporting of COVID-19 data for surveillance of COVID-19 by hospitals and CAHs, and to improve consistency of laboratory reporting of SARS-CoV-2 test results. It revises prior policy to only permit one COVID-19 test of each type without an order from a qualified health care practitioner and 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

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

COVID-19. It revises the FY 2022 performance period under the Skilled Nursing Facility (SNF) VBP as a result of the PHE for COVID-19, provides clarification on premium reporting for health plans in the individual and small group markets for insurance for the purposes of risk adjustment and medical loss ratio calculations, among other provisions.

II. Provisions of the Interim Final Rule

CMS previously defined the term "Public Health Emergency" in the regulation at 42 CFR 400.200. This definition refers to the PHE determined to exist nationwide by the Secretary of HHS on January 31, 2020, under section 319 of the Public Health Service (PHS) Act and renewed effective July 25, 2020.

A. New Enforcement Requirement for LTC Facilities

Existing regulations at 42 CFR part 483 describe the federal participation requirements for LTC facilities including for SNFs participating in Medicare and nursing facilities (NF) participating in Medicaid. The regulations describe remedies, including civil money penalties, available to CMS to enforce those requirements (42 CFR part 488 subpart F).

CMS implements a new enforcement provision in §488.447, applicable to prevention and control reporting requirements imposed on LTC facilities in the May 8th, COVID-19 IFC. That rule added requirements for weekly facility reporting of suspected and/or confirmed COVID-19 cases and related facility data to the CDC National Healthcare Safety Network (NHSN). Specifically, the May 8th COVID-19 IFC required at §§483.80(g)(1) and (2) that facilities 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.

In this IFC, new §488.447 permits CMS to impose a minimum $1,000 civil money penalty (CMP) for the first occurrence of noncompliance with the reporting requirements under §§483.80(g)(1) and (2) as established in the May 8th COVID-19 IFC. For each subsequent failure to submit a timely report up to a maximum of 12 occurrences, the amount of the CMP will be increased by $500 subject to a maximum amount set forth in existing §488.408(d)(1)(iii) – the maximum amount of CMPs permitted for noncompliance under existing rules. CMS describes the maximum penalty permitted to be equal to $6,500. Penalty amounts under new §488.447 are subject to annual adjustments for inflation.

A plan of correction is not required although a facility may choose to submit one. CMS believes that such a plan will not be necessary because the CMP will be imposed each week at progressively increasing amounts. Facilities will be offered an opportunity for Independent Informal Dispute Resolution (under §488.431).

CMS explains its justification for waiving the normal notice-and-comment process under the Administrative Procedure Act. CMS believes that waiving those requirements is in the public

interest because of the heightened threat to health and safety of widespread infection of COVID-19. It asserts that tracking the incidence and impact of COVID-19 in nursing homes is crucial and the CMPs will help to deter noncompliance. In addition, CMS notes that requiring prior notice and comment is impractical because the provisions they address (and the PHE) may expire before a proposed rule could be finalized. For similar reasons, CMS is also waiving the 30-day delay in the effective date for the provisions. The penalties are applicable on the date of publication at the Office of the Federal Register and remain applicable one year beyond the expiration of the PHE.

B. Condition of Participation (CoP) Requirements for Hospitals and CAHs to Report COVID-19 Data

1. Policy

On March 4, 2020, CMS issued guidance 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, CMS is requiring hospitals and CAHs to report this information to HHS in accordance with a frequency, and in a standardized format, as specified by the Secretary during the COVID-19 PHE.

Examples of data elements that may be required to be reported include the number of staffed beds in a hospital and the number of those that are occupied, information about supplies, and a count of patients currently hospitalized who have laboratory-confirmed COVID-19. This list is not exhaustive. For the current list of data items specified, see: https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf

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) or 485.640(a)(3), each of which requires a facility to address any infection prevention and control issues identified by public health authorities.

The applicability date for §482.42(e) for hospitals and §485.640(d) for CAHs is the date of the publication of this rule.

2. Enforcement

CMS currently lacks the statutory authority to impose CMPs against hospitals and CAHs. Therefore, CMS will terminate a hospital or CAH's participation in Medicare for failure to consistently report test results throughout the duration of the PHE for COVID-19.

3. Paperwork Burden

CMS estimates 365 responses per hospital or CAH (5,550 total hospitals and CAHs) that would take 1.5 hours each at a cost of $70.48 per hour for registered nursing staff (including overhead and fringe benefits).

C. Requirements for Laboratories to Report SARS-CoV-2 Test Results

1. Policy

Section 18115(a) of the CARES Act requires every laboratory to report the results from each COVID-19 test to the Secretary until the end of the PHE. As indicated in HHS guidance issued on June 4, 2020, the Secretary has required that all data be reported through existing public health data reporting methods.

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 tests is not captured in its Clinical Laboratory Improvements Act (CLIA) information systems. While CMS collects this information when laboratories apply for an initial CLIA certificate, not all laboratories are required to submit information related to updating their test menu as long as the new testing falls under their current certificate.

By collecting testing information, the CLIA program will be able to identify quality and accuracy issues with laboratories performing SARS-CoV-2 testing during the COVID-19 PHE. In the interest of ensuring quality laboratory testing during the COVID-19 PHE, CMS is requiring each laboratory that performs a SARS-CoV-2 test must report SARS-CoV-2 test results for the duration of the PHE in such form and manner, and at such timing and frequency, as the Secretary may prescribe. CMS-deemed Accreditation Organizations (AO) and State Licensure Programs, Exempt States (ES) must 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).

2. Enforcement

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. 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 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 CMS expects 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 CMS expects ESs to have an equivalent penalty structure to CMS. The ESs are generally approved by CMS to operate their own oversight programs so CMS expects 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 above.

3. Paperwork Burden

Laboratories will have a cost to develop a mechanism to track SARS-CoV-2 test results; a cost to collect test and report test results; and to review regulations and update their policies. CMS estimates these costs will be for 30 percent of laboratories (77,024 in total) as follows:

- Developing a Tracking Mechanism: Costs would be for 5 to 7 hours of a management level employee ($110.74 including overhead and fringe benefits) and a database administrator/architect ($92.42 including overhead and fringe benefits).

- Collection: Costs would be for clinical laboratory technician ($52.68 per hour including salary and fringe benefits) for 20 tests results and 0.5 hours for a low volume laboratory and 500 test results and 3 hours for a high throughput laboratory.

- Reporting: Same estimate on the number of tests and time to report except the staff worker would be a health care support worker ($38.48 including overhead and fringe benefits).

- Reviewing Regulations and Updating Policies: One-time burden of 5 hours for a management employee at $110.74 including overhead and fringe benefits.

CMS estimates seven AOs and two ES would have one-time costs for a management level employee ($110.74) of 25 to 30 hours to identify the applicable legal obligations and development updated standards. These organizations would have additional one-time costs to develop policies and procedures for reporting (10 to 15 hours for a management level employee at $110.74) and ongoing costs to identify laboratories that do not report test reports in order to report these laboratories to CMS (2 to 4 hours per week for a computer network support specialist at $66.20 per hour).

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

In response to the COVID-19 PHE, CMS granted extraordinary circumstances exceptions (ECEs) in quality programs in an effort to alleviate the data collection and reporting burden during the pandemic. This included the following value-based purchasing programs:

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

Specifically, CMS provided a national exception for reporting of data for the fourth quarter of 2019, October 1, 2019 – December 31, 2019 (Q4 2019) and the first two quarters of 2020, January 1, 2020 – March 31, 2020 and April 1, 2020 – June 30, 2020 respectively (Q1 2020 and Q2 2020), but stated that data for these quarters that was voluntarily submitted would be used for scoring in these programs. The ECEs were announced on March 22, 2020 and detailed in a supplemental guidance memorandum issued by CMS on March 27, 2020. A summary table at the end of this section II.D displays the measures, reporting periods and deadlines affected by the national ECE for each of the programs.

In this IFC, CMS modifies the ECEs granted under four value-based purchasing programs. The changes are made out of concern for the national comparability of these data due to geographic variation in the incidence of COVID-19 cases and hospitalizations, along with the differential impact of COVID-19-related state and local laws and policy changes.

Under the modification, CMS will continue to score any data optionally submitted for Q4 2019 for these programs but will not use any data optionally reported for Q1 2020 or Q2 2020. That is, providers may not opt-out of the ECE by submitting data for those quarters. Because the PHE began on January 31, 2020, CMS is not concerned about national comparability or representativeness of Q4 2019 data. Further, it reports that most facilities and hospitals have submitted Q4 2019 data under these programs. However, CMS is eliminating use of data for Q1 or Q2 of 2020 because it is concerned about the comparability and representativeness of the voluntarily reported data for these quarters during which the PHE was in effect. Finally, for each program CMS announces that if it determines that it does not have sufficient data to reliably measure performance, it may propose through rulemaking not to calculate performance scores or make payment adjustments.

The IFC also changes the performance period under the SNF VBP Program for FY 2022. Details of the provisions for each program are discussed below. In the IFC, background on each program's ECE policies is also provided.

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 ECE Granted With Respect to First and Second Quarter (CY) 2020 ESRD QIP Data

Existing regulations at 413.178(d)(7) state that when an ESRD facility has been granted an ECE, it may notify CMS that it will continue to submit data, and CMS responds by notifying the facility that the previously granted exception has been withdrawn. The IFC updates this regulation to add that a facility will be deemed to have opted out of the ECE for COVID-19 if it submitted NHSN data for Q4 2019 by the March 31, 2020 deadline but did not notify CMS that it would do so, and to prohibit a facility from opting-out out of the ECE with respect to Q1 2020 or Q2 2020. Any ESRD QIP data that facilities optionally reported during these quarters will be excluded from the calculation of payment year (PY) 2022 total performance scores and from the baseline for PY 2023.

CMS notes that its announcement of the ECE was made shortly before the deadline for facilities to report NHSN data for Q4 2019, and that nearly all facilities (97.6 percent) timely reported Q4 2019 data on these measures. Because these data reflect performance prior to the start of the PHE, CMS is not concerned about national comparability or representativeness. With respect to data for Q1 or Q2 of 2020, however, CMS is eliminating the ability of facilities to opt-out of the ECE because it is concerned about the comparability and representativeness of the voluntarily reported data for these quarters. The policy that allows facilities to opt-out of an ECE and report quality data is intended for circumstances in which a facility believes it has not been impacted by the extraordinary circumstances. CMS notes that most facilities are impacted by COVID-19 in some way. For example, some patients may skip treatment sessions out of fear of being exposed to COVID-19, which would affect performance on quality metrics when the patients return. Further, CMS is concerned about the reporting bias that could result under voluntary reporting, as might occur, for example if only high performing facilities or those unaffected by COVID-19 were to report.

While the national ECE ended and data collection resumed effective July 1, 2020, CMS announces that if it does not have sufficient data to reliably score measures under the ESRD QIP it may propose to not score facilities or make the associated payment adjustments for the affected payment year. CMS is concerned about scenarios in which an accurate national comparison of dialysis facilities may not be possible because of the national ECE or individual ECEs that may be granted to facilities as the incidence of COVID-19 changes geographically during the pandemic. Insufficient data for an accurate national comparison might result from a shortened performance period or if only larger facilities meet the case minimums for calculation of a total performance score.

A proposal to suspend prospective application of program penalties or payment adjustments could be made through the annual ESRD PPS proposed rule; CMS may provide advance notice of its intentions to make such a proposal through routine communication channels to facilities, vendors and Quality Improvement Organizations (QIOs). This might include memos, emails, and notices on the QualityNet.org website.

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

CMS notes that although the March 2020 ECE guidance made reporting HAC Reduction Program data for Q4 2019 optional, nearly all hospitals (95.3 percent) had reported these data by the May 18, 2020 data submission deadline. In addition, these data reflect care provided prior to the start of the PHE. For these reasons, as announced in the March 27 ECE guidance, CMS will use any Q4 2019 data optionally reported by hospitals when calculating the Total HAC Scores for hospitals under the HAC Reduction Program.

However, in a change from the March 27, 2020 ECE guidance, CMS has decided to exclude any optionally reported data for Q1 2020 and Q2 2020 when calculating hospital performance under the HAC Reduction Program for the FY 2022 and FY 2023 program years. Under the guidance, CMS had already indicated that it would exclude qualifying claims for this period when calculating the patient safety composite measure PSI 90. In this IFC, CMS expresses concern that the voluntarily reported data would not be nationally comparable because of the geographic differences in the incidence of COVID-19 cases and hospitalizations, changes in referral patterns, and differences in state and local law and policy response to COVID-19. In addition,

CMS is concerned about introducing reporting bias if only high-performing or better- resourced hospitals chose to submit data. Finally, because the HAC Reduction Program relies on a relative scoring methodology, CMS believes that it would be inappropriate and could disparately impact hospitals to include voluntary data from the quarters excepted as a result of the COVID-19 PHE in calculating hospital performance for the HAC Reduction Program.

In order to maintain flexibility in addressing the impact of COVID-19 on the HAC Reduction Program, CMS announces that if it does not have sufficient data as a result of the granting of national or individual ECEs to reliably measure national performance for the HAC Reduction Program, it may propose not to score hospitals or make the associated payment adjustments to hospitals under the IPPS for the affected program year. Insufficient data for reliable measurement could occur if enough quarters were excepted from the program's 24-month performance period to lead to unreliable measure calculations, or if only larger hospitals were able to meet the required case minimums to be scored in the non-excepted part of the performance period. A proposal to suspend prospective application of program penalties or

payment adjustments could be made through the annual IPPS/LTCH PPS proposed rule, but CMS may provide subregulatory advance notice of its intentions through routine communication channels to hospitals, vendors, and QIOs such as memos, emails, and notices on the QualityNet.org website.

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

In the March 2020 ECE, CMS excepted data for Q1 and Q2 of 2020 from use in calculating excess readmission ratios for the HRRP. It did not except claims data for Q4 2019, which ended prior to the COVID-19 PHE. All HRRP data are from claims; no hospital reporting is required. In this IFC, parallel to the announcement discussed above with respect to the HAC Reduction Program, CMS announces that if it does not have sufficient data as a result of the granting of national or individual ECEs to reliably measure national performance for the HRRP, it may propose not to score hospitals or make the associated payment adjustments to hospitals under the IPPS for the affected program year. Insufficient data for reliable measurement could occur if enough quarters were excepted from the program's 24-month performance period to lead to unreliable measure calculations, or if only larger hospitals were able to meet the required case minimums to be scored in the non-excepted part of the performance period. A proposal to suspend prospective application of HRRP program penalties or payment adjustments could be made through the annual IPPS/LTCH PPS proposed rule, but CMS may provide subregulatory advance notice of its intentions through routine communication channels to hospitals, vendors, and QIOs such as memos, emails, and notices on the QualityNet.org website.

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

Similar to the provision with respect to the HAC Reduction Program described above and consistent with the March 27, 2020 ECE guidance, CMS will use any Q4 2019 data optionally reported by hospitals when calculating the Total Performance Score (TPS) for hospitals under the Hospital VBP Program for the FY 2021 payment year and in calculating baseline data for the FY 2023 payment year. The national ECE did not except claims data for Q4 2019, which will also be used calculating TPSs for the program years FYs 2021 through 2024 and baseline data for the program years FYs 2026 through 2029.

In addition, like for the HAC Reduction Program, CMS will not use any optionally reported data for Q1 2020 and Q2 2020 when calculating Hospital VBP Program TPSs for the FY 2022 through 2025 program years, or for calculating baseline scores for the program years FY 2024 through FY 2030. In explaining its decision, CMS cites concern about the potential for reporting bias from voluntarily reported measures, geographic differences in COVID-19 cases and hospitalizations, and changes in patterns of referral and hospitalizations.

CMS announces that if as a result of the granting of national or individual ECEs it does not have enough data to reliably measure national performance, it may propose to not score hospitals or make associated payment adjustments under the Hospital VBP Program for the affected program year. As for the HAC Reduction Program, such a proposal would be made through the IPPS/LTCH proposed rule, but CMS may provide subregulatory advance notice of its intentions through routine communication channels to hospitals, vendors, and QIOs such as memos, emails, and notices on the QualityNet.org website.

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

The March 2020 ECE excepted claims for Q1 and Q2 of 2020 from calculation of the SNF 30-day All-Cause Readmission Measure (SNFRM) used in the SNF VBP Program. By excluding 6 months of qualifying claims this policy will reduce the amount of data available to evaluate SNF performance for the FY 2022 SNF VBP program year. The performance period for FY 2022 payment under the SNF VBP Program is FY 2020 ((October 1, 2019 through September 30, 2020) so the resulting available data are limited to Q4 of 2019 and Q3 of 2020.
CMS is concerned that using qualifying claims for only 6 months across all SNFs in calculating the SNFRM will not result in reliable measure scores. As endorsed by the National Quality Forum and used in the SNF VBP Program to date, performance periods for the SNFRM are twelve months. CMS analysis found that using data for only 6 months would reduce the reliability of the SNFRM by one-third, resulting in unacceptably low measure reliability. It notes that if the limited data availability affected only several SNFs it would not have the same impact as it does with all SNFs affected.

To provide for sufficient data to produce measure reliability, CMS revises the performance period for the SNF VBP Program FY 2022 program year to include eligible SNF stays with admissions during the period from April 1, 2019 through December 31, 2019 and July 1, 2020 through September 30, 2020, totaling 12 months. CMS notes that 9 months of this 12-month period predates the COVID-19 PHE. While acknowledging a 6-momth overlap between this revised performance period and the performance period for the FY 2021 program year, CMS believes that the performance period it is adopting is the most feasible option for ensuring a reliable measure. It notes that there has been overlap in the past when the SNF VBP Program transitioned from calendar year to fiscal year performance periods. Beginning with the FY 2023 program year, the performance period will revert to past policy and will be FY 2021. CMS notes that the baseline period for the FY 2022 program year is unaffected by the COVID-19 PHE and will continue to be FY 2018.

CMS also announces that if it determines that as a result of national or individual ECEs it does not have sufficient data for reliable performance measurement under the SNF VBP Program it

may propose not to score facilities or make associated payment adjustments for the affected program year. Any such proposal would be made during SNF PPS rulemaking, and CMS may provide subregulatory advance notice through routine communication channels to facilities, vendors and QIOs. However, because it has modified the performance period for the FY 2022 program year, CMS is not applying this policy at this time.

Reporting Periods and Deadlines Affected by the March 2020 National ECEs		
Program and Measures	**Reporting Period**	**Reporting Deadline**
ESRD QIP		
CDC National Healthcare Safety Network (NHSN) measures • Blood stream infection (BSI) clinical measure • Dialysis Event reporting measure	Q4 2019 Q1 2020 Q2 2020	March 31, 2020 June 30, 2020 September 30, 2020
CROWNWeb data	Clinical months January 2020 February 2020 March 2020 April 2020 May 2020 June 2020	 March 31, 2020 April 30, 2020 June 1, 2020 June 30, 2020 August 3, 2020 August 31, 2020
ICH-CAHPS	May 1, 2020 – July 10, 2020 data collection	July 2020
Claims-based measures	March 1, 2020 – June 30, 2020	n/a
Data validation studies	Q1 and Q2 2019 discharge periods	60 days after request
HAC Reduction Program		
NHSN outcome measures: • Catheter-Associated Urinary Tract Infection (CAUTI) • Central Line-Associated Blood Stream Infection (CLABSI) • Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) • Facility-wide Inpatient Hospital-onset Methicillin-Resistant Staphylococcus aureus (MRSA) • Procedure Specific Surgical Site Infection (SSI)	Q4 2019 Q1 2020 Q2 2020	May 2020 August 2020 November 2020

Reporting Periods and Deadlines Affected by the March 2020 National ECEs		
Program and Measures	**Reporting Period**	**Reporting Deadline**
Claims-based measures PSI 90	Q1 and Q2 2020	n/a
HRRP		
Claims-based measures	Q1 and Q2 2020	n/a
HVBP Program		

• NHSN measures:
  ○ CAUTI
  ○ CLABSI
  ○ CDI
  ○ MRSA
  ○ SSI
	Q4 2019
	Q1 2020
	Q2 2020
		May 2020
		August 2020
		November 2020

• Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS)	Q4 2019 Q1 2020 Q2 2020	April 2020 July 2020 October 2020

Claims-based measures:
• Medicare Spending Per Beneficiary (MSPB)
• Measures of 30-day all-cause risk-standardized mortality rate following:
  ○ Acute Myocardial Infarction (AMI)
  ○ Heart Failure
  ○ Pneumonia
  ○ Chronic Obstructive Pulmonary Disease (COPD)
  ○ Coronary Artery Bypass Grafting (CABG)
• Total Hip Arthroplasty (THA)/ Total Knee Arthroplasty (TKA) Complication Rate
	Q1 and Q2 2020	n/a

SNF VBP Program		
Claims-based measure: • SNFRM	Q1 and Q2 2020	
Source: CMS March 2020 ECE guidance memo. https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf		

E. National Coverage Determination Procedural Volumes for Facilities and Practitioners to Maintain Medicare Coverage

CMS notes that because of the COVID-19 pandemic, there has been a reduction in hospitals and other practitioners performing nonessential procedures. Even though CMS issued guidance in June of 2020 to encourage providers to safely resume such care, CMS is concerned that with the reduced volume of such services, some facilities or practitioners may be unable to meet the volume requirements as conditions of coverage in place for specific items and services. As such, CMS is not enforcing procedural volume requirements in four national coverage determinations (NCDs) for facilities and practitioners that had, prior to the PHE for COVID-19, met the volume requirements. Those 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).

CMS notes that this enforcement discretion applies only during the PHE for COVID-19.

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

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, Medicare would not require an order from a physician or other applicable practitioner for COVID-19 testing during the COVID-19 PHE. In addition, CMS 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. FDA-authorized COVID-19 serology tests are included as covered tests during the COVID-19 PHE, as they are reasonable and necessary 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, CMS is revising the previous policy by establishing that one COVID-19 diagnostic test and one of each other related test (as listed here: https://www.cms.gov/files/document/covid-ifc-2-flu-rsv-codes.pdf) 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. For the COVID-19 and other related diagnostic tests for which an order is required, CMS is 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.

CMS is making this change because it believes that open-ended coverage of COVID-19 testing without an order from a physician, practitioner, or other healthcare professional presents significant potential for fraud, waste, and abuse, as well as public health and safety issues. The IFC outlines past issues of fraud and abuse involving laboratory testing. CMS says that the availability of broad COVID-19 and related testing without an order significantly increases the risk and scope of the fraud schemes, leading not only to considerable risk to taxpayer dollars, but also potential physical and financial harm to Medicare beneficiaries.

The public health and safety concerns outlined in the IFC include the beneficiary not receiving 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. CMS indicates that allowing Medicare payment for one test without an order will facilitate beneficiary access to urgent testing 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.

Much of the remainder of this section of the rule describes the many policies CMS has adopted to facilitate access to needed testing and other services, and to the medical oversight required to address the pandemic. CMS further notes that the policies described in this section apply to the Medicare program only (e.g. not group health plans and health insurance issuers offering group and individual health insurance coverage, Medicaid or the Children's Health Insurance Program).

G. Recognizing Temporary Premium Credits as Premium Reductions

1. Background

CMS describes the history and regulatory background of two Affordable Care Act (ACA) provisions. One provides for an annual permanent risk adjustment program for issuers in the individual and small group insurance markets. The program, which aims to reduce health plans' incentives to avoid high risk enrollees, provides payments to health insurance issuers that attract higher-than average risk populations. The payments are funded by collections from those issuers attracting lower-than average risk populations. The ACA also requires health insurers to submit an annual report to the Secretary that details the percentage of premium revenue spent paying for clinical services and quality improvement activities for enrollees. This "medical loss ratio" (MLR) may be no lower than a minimum specified amount. If the ratio of health care and quality spending drops below the minimum permitted level, the issuer is required to provide rebates to its enrollees.

On August 4, 2020, CMS announced the adoption of a temporary policy relaxing certain risk adjustment program rules as part of its response to the COVID-19 pandemic. CMS issued a memorandum permitting issuers in the individual and small group markets to temporarily offer premium credits for 2020 coverage when allowed under state law.[2] The flexibilities are intended 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. The memo also advised that future rulemaking would address risk adjustment data submissions and MLR reporting requirements for issuers that elect to provide the credits. Those data submission and reporting requirements are addressed in the IFC.

2. Clarifications

Under the risk adjustment program, plan premiums are used to calculate the risk adjustment transfer amounts. Average plans premiums and statewide average premiums both figure into that calculation. The IFC clarifies (in 45 CFR §153.320) that in calculating the state transfer formula for the 2020 benefit year, the plan average premium and statewide average premium will be calculated using plan premiums that have been adjusted downward to take into account any premium reductions that plans made pursuant to the August 4th flexibility. CMS clarifies and provides instruction for plans to report those amounts to their respective EDGE servers[3] for 2020 benefit year data submissions (in 45 CFR §153.610 and §153.710).

CMS also modifies MLR reporting requirements in 45 CFR part 158, to clarify that issuers must account for temporary premium credits as reductions in earned premium in the individual and small group markets for the purpose of MLR reporting.

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

CMS develops and publicly posts a 5-star rating system for Medicare Advantage (MA) and Part D plans to provide beneficiaries with comparative information. The MA and Part D Star Rating system is also used as the basis for determining quality bonus payment (QBP) status and the amount of beneficiary rebates for MA plans. The IFC provides brief background on the rating system.

In the March 31 2020 COVID IFC, CMS made changes to the 2021 and 2022 Star Ratings to accommodate the disruption in data collection and impact on performance resulting from the COVID-19 PHE. The changes were intended to account for potential decreases in measure-level

[2] August 4, 2020, "Temporary Policy on 2020 Premium Credits Associated with the COVID-19 Public Health Emergency", https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Premium-Credit-Guidance.pdf.

[3] Issuers report their plan information via a distributed data computing environment referred to as the EDGE servers. "Edge" servers are those that operate on the "edge" of a network.

scores for data collected in 2020 resulting from increased healthcare utilization due to COVID-19, reduced or delayed non-COVID-19 care, and changes in non-COVID-19 inpatient utilization.

Specifically, the March 31 2020 COVID IFC (1) replaced 2021 Star Ratings measures based on Health Effectiveness Data and Information Set (HEDIS) and CAHPS data collections with earlier values from the 2020 Star Ratings; (2) established an approach for calculating Star Ratings for 2021 in the event that CMS' functions are restricted to only essential Agency functions; (3) modified the rules for the 2021 Star Ratings to replace any measure that has a 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; (4) replaced 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 HOS data collection for 2020 cannot be completed, (5) removed guardrails for the 2022 Star Ratings; (6) expanded the hold harmless provision for the Part C and D Improvement measures to include all contracts for the 2022 Star Ratings; and (7) revised the definition of "new MA plan" for purposes of 2022 QBPs based on 2021 Star Ratings only to mean an MA contract offered by a parent organization that has not had another MA contract in the previous 4 years.

In this IFC, CMS makes further modifications to the 2022 Star Ratings (based on the 2020 measurement period) to address unintended consequences associated with the Star Ratings disaster policy for extreme and uncontrollable circumstances (See §422.166(i) and §423.186(i)). That policy was designed for disasters affecting defined geographic areas and not a global pandemic. Under the policy, 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, are used to adjust the Star Ratings calculation for the contract.

CMS reports that because plans in most of the country now meet the requirements for a Star Ratings adjustment under the extreme and uncontrollable circumstances policy, that policy is unworkable. As of July 28, 2020, 51 out of 55 states and territories covering all counties or county-equivalents within them have been designated as Individual Assistance areas due to COVID-19, and CMS notes that this number could grow throughout 2020 as the pandemic evolves. The policy provides that if 60 percent or more of a contract's enrollees are living in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, these contracts are excluded from the measure-level cut point calculations for non-CAHPS measures and from the performance summary and variance thresholds for the Reward Factor.[4] Therefore, for 2022 there will not be sufficient contracts to reliably make the calculations needed to assign Star Ratings for non-CAHPS measures or thresholds for the Reward Factor. CMS reports that under the 60 percent rule, close to 98 percent of contracts

[4]CMS applies a reward factor to the summary and overall ratings of contracts that demonstrate consistently high performance across measures. The range of factors applied for high performance is 0.1 to 0.4 stars.

would be removed 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. In addition, special rules that apply to contracts that have 25 percent or more of their enrollees living in FEMA-designated Individual Assistance areas would not be workable.[5] The bottom line is that under the circumstances of the COVID-19 PHE, CMS will not have enough measures with Star Ratings to calculate either the 2022 overall or summary Star Ratings or 2023 QBPs.

To prevent these unintended consequences, CMS creates a special rule for the 2022 Star Ratings only. It 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. In doing so, the performance of contracts in 2020 in service areas that would have been excluded will be used to calculate the cut points for all non-CAHPS measures and to calculate the Reward Factor. This 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, calculate the Reward Factor, and ultimately calculate overall and summary ratings for 2022 Star Ratings and 2023 QBPs. All other rules for calculating Star Ratings will apply, including those adopted in the March 31 COVID IFC.

In the Impact Analysis section of the IFC, CMS states that it does not anticipate this policy will result in a change in the distribution of Star Ratings compared with prior years.

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

1. Quality Update: Telehealth Codes for use in Beneficiary Assignment

The CMS Web Interface is an application supporting quality measure data collection and submission.[6] Accountable care organizations (ACOs) participating in the Medicare Shared Savings Program and the Next Generation ACO alternative payment model must report their quality results through the web interface, and groups or virtual groups of 25 or more eligible clinicians may choose to report in this manner. Web interface reporters also measure patient

[5] For these contracts, CMS applies various rules, including use of the "higher of" the current or previous year's measure-level rating. However, if the measure-level rating is missing for most measures for a contract in the current or prior year and a comparison cannot be done, the contract gets the current year's measure-level rating. Therefore, under current regulations, CMS could not apply the 25 percent rule to compare the 2022 measure-level Star Ratings to the 2021 measure-level Star Ratings.

[6] CMS has proposed in the CY 2021 Physician Fee Schedule proposed rule to sunset the CMS Web Interface beginning with the MIPS 2021 performance period (85 FR 50290).

experience of care using the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS survey.[7]

Web interface users must submit quality data on a sample of patients that is generated by CMS from the beneficiaries who are assigned to each ACO, group, or virtual group. CMS expresses concern that the method of beneficiary assignment, which incorporates the number and type of primary care services furnished by an ACO's or group's professionals, may no longer be accurate because of service delivery pattern changes induced by the COVID-19 PHE. CMS notes that telehealth and other communication-based technology (CBT) services (e.g., virtual check-in) are being furnished in lieu of face-to-face primary care evaluation and management (E/M) encounters, reducing viral exposure risks while maintaining beneficiary access to care. To address the potential impacts of beneficiary assignment on all who report quality data through the CMS Web Interface and the CAHPS for MIPS survey, CMS expands the definition of primary care services. The updated definition includes telehealth and CTB services authorized during for the PHE and will apply to the MIPS 2020 performance year and any subsequent performance year that starts during the COVID-19 PHE.[8] The revised primary care service list is codified at §414.1305 as shown below. CMS states that no additional burden is imposed by these changes as the number of beneficiaries selected for sampling will not change.

CPT codes added through this IFC:

- 99421, 99422, and 99423 (online digital E/M services), and
- 99441, 99442, and 99443 (telephone E/M services).

HCPCS codes added through this IFC:

- G2010 (remote evaluation of patient video/images), and
- G2012 (virtual check in).

Previously finalized CPT codes:

- 99201 through 99215 (office or other outpatient E/M visit);
- 99304 through 99318 (professional services furnished in a nursing facility; services identified by these codes but furnished in a skilled nursing facility are excluded);
- 99319 through 99340 (patient domiciliary, rest home, or custodial care visit);
- 99341 through 99350 (E/M services furnished in a patients' home);
- 99487, 99489 and 99490 (chronic care management); and
- 99495 and 99496 (transitional care management).

[7] The survey is administered by CMS-approved third party vendors to a sample of an ACO's or group's beneficiaries and the results are reported directly to CMS.

[8] CMS notes that these changes mirror those already made to the Shared Savings Program beneficiary assignment process in the May 8th COVID-19 IFC (85 FR 27583).

Previously finalized HCPCS codes:

- G0402 (Welcome to Medicare visit), and
- G0438 and G0439 (annual wellness visits).

2. Improvement Activities Update: COVID-19 Clinical Trials Modification

Changes to the Quality Payment Program's (QPP) Improvement Activities inventory normally are made through submission to the Annual Call for Activities process followed by notice-and-comment rulemaking. In the March 31st COVID-19 IFC, CMS made an exception to add IA_ERP_3 "COVID-19 Clinical Trials" for performance year 2020. This activity requires a clinician to participate in a clinical trial, treat a patient(s), and report clinical findings through a clinical data repository or a clinical data registry for the duration of the PHE. CMS added this activity to incent clinician participation in COVID-19 trials and to potentially accelerate the acquisition of research data that could improve patient outcomes from COVID-19.
CMS has learned that clinical data registries also are collecting data from clinicians who are not participating in clinical trials. Stakeholders shared with CMS their belief that clinicians caring for COVID-19 patients outside of clinical trials but who report their patients' data through a clinical registry should receive MIPS improvement activity credit. CMS agrees, noting that submission of clinical results by clinicians to a data registry outside of clinical trials also could accelerate knowledge acquisition relevant to improving COVID-19 clinical outcomes.
CMS, therefore, takes the following actions:

- Changes the title of IA_ERP_3 to "COVID-19 Clinical Data Reporting with or without Clinical Trial";
- Expands the availability of credit for IA_ERP_3 beyond the clinical trial setting to any clinician who participates in the care of COVID-19 patients and simultaneously submits relevant clinical data to a registry for COVID-19 research purposes;
- Maintains IA_ERP_3 as a "high-weight" activity; and
- Extends availability of the modified IA_ERP_3 through CY 2021.

CMS does not believe that burden is increased by these changes, as the number of improvement activities required for MIPS submission is not being affected. CMS concludes by stating that a clinician could claim Improvement Activity performance category credit for IA_ERP_3 and also could report COVID-19 data to a public health agency or clinical data registry for MIPS Promoting Interoperability category credit.

J. Requirement for Long-Term Care (LTC) Facilities to Test Facility Residents and Staff for COVID-19

1. New Testing and Documentation Requirements

CMS revises LTC facility infection control regulations at 42 CFR §483.80 to establish new requirements for LTC facilities to test residents and staff including individuals providing services under arrangement and volunteers. Specifically, new §483.80(h) requires a LTC facility to conduct COVID-19 testing consistent with parameters set by the Secretary including with respect to testing frequency; identification of those diagnosed with, presenting symptoms of, or suspected of being exposed to COVID-19 in the facility; criteria for testing; response time for results; and other factors specified by the Secretary to identify and prevent transmission of COVID-19.

CMS notes that CDC provides detailed recommendations for testing of residents and healthcare personnel at https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html. CMS also states that it expects that only individuals physically working on-site at the facilities will be required to be tested. With respect to state surveyors or ombudsmen who must have access to the facility or a resident, CMS refers to guidance to address those situations and notes that state agencies must ensure that surveyors are following CDC guidance for infection prevention and control.[9]

Under the IFC:

- Testing must be conducted in a manner that is consistent with current standards of practice for conducting COVID-19 tests. CMS notes that because the virus is new and our understanding of it is evolving, the standards of practice at the point at which the testing is provided may be changing. CMS urges that testing be consistent with current professional standards to ensure accurate and effective testing.

- LTC facilities are required to document that testing was completed and the results for staff. For residents, the facilities must document in the resident records that testing was offered, completed (as appropriate to the resident's testing status), and the results of each test. If a facility does not maintain staff personnel records, CMS expects the facility to provide an alternative way to document the results. CMS also notes that residents and staff have a right to refuse testing. Some may be unable to be tested because of medical or other contraindications. CMS requires that a facility have procedures for addressing such instances.

- If an individual is identified as having symptoms consistent with COVID-19, or tests positive for COVID-19, the facility must take actions to prevent its transmission. CMS

[9] CMS Quality, Safety, and Oversight Memorandum issued on April 24, 2020 and revised on July 9, 2020, and QSO-20-28-NH, https://www.cms.gov/files/document/qso-20-28-nh-revised.pdf.

notes that the CDC testing guidelines linked above include return to work criteria and that it expects facilities to take mitigation measures that could include resident cohorting consistent with CDC guidance on the matter.[10]

- Facilities must have procedures in place for addressing residents and staff, including individuals providing services under arrangement and volunteers, who refuse testing or are unable to be tested.

- When necessary, such as in emergencies due to testing supply shortages, facilities must contact state and local health departments for assistance in testing efforts, such as obtaining testing supplies or processing results.

2. Paperwork Burden and Regulatory Impact

CMS estimates that a total of 1.9 million staff and 1.3 million residents will be tested every 14 days or 30 days respectively. Documenting the results would take 2 minutes per test and would result in a total cost of documentation of $48.1 million over the course of the PHE.

CMS notes that the costs to facilities of required testing may vary dramatically depending on a large number of factors including the size of the facility and the extent of the outbreak in the community. As such, CMS provides a sensitivity analysis taking into account the significant potential variation in the number of facilities conducting an increasing number of rounds of testing.

CMS assumes a cost of $60 per test and follow-up intervention costs needing between 5 and 40 hours of a registered nurse. In its analysis, CMS finds that testing costs could vary from $10 million to $3.9 billion if intervention costs are at the low end of the distribution and between $12 million and $4.7 billion if intervention costs are at the high end of the distribution.

In addition, CMS provides an analysis of the potential benefits of catching and eliminating COVID-19 outbreaks at the facilities conducting the testing. CMS uses the concept of Quality Adjusted Life Years multiplied by the Value of a Statistical Life Year to estimate the impact of the testing on improving health and prolonging life. CMS assumes the Value of a Statistical Life is $10.1 million in 2020 and provides estimates of the number of life years needed to break even when netted against the costs of testing and intervention. (See Tables 7 – 9 of the IFC.)

III. Waiver of Proposed Rulemaking

In accordance with 5 U.S.C. 553(b) of the Administrative Procedure Act (APA) and section 1871 of the Act, CMS ordinarily publishes a notice of proposed rulemaking in the Federal Register

[10] 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.

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

In light of the COVID-19 pandemic, CMS finds good cause to waive notice and comment rulemaking as it believes it would be contrary to the public interest for it to undertake normal notice and comment rulemaking procedures. CMS provides the following specific reasons for such waivers:

- Required testing and reporting by hospitals, CAHs, CLIA laboratories, and nursing home staff and residents must be implemented as quickly as possible because we are in the midst of the PHE and it would be impracticable and contrary to the public interest for CMS to undertake normal notice and comment rulemaking or delay implementation by 30 days.
- Modifying the previous policy that had permitted COVID-19 testing without a physician order must be implemented immediately because of the policy's significant potential for fraud, waste, and abuse, as well as health and safety issues that could result from repeated testing without proper medical attention.
- Immediate clarification is necessary with respect to CMS' updates to the ECEs for ESRD QIP, HAC Reduction Program, HRRP and Hospital VBP Program.
- Changes to the calculation methodology for 2022 Star Ratings is urgently necessary for plan sponsors to know how their performance in the 2020 measurement period will be used to calculate its Star Ratings.
- Immediate clarification is necessary for plans to understand how risk adjustment payments will be calculated and to ensure adequate risk adjustment reporting to ensure stability in the individual and small group markets.
- New CPT and HCPCS codes for communications technology-based services and telephone evaluation and management services will permit CMS to adequately account for the ways in which beneficiaries are receiving primary care services during the PHE and to ensure groups and virtual groups have sufficient sample sizes to administer the 2020 CAHPS for MIPS survey.
- Provisions to expand improvement activity IA_ERP_3, update the title, and extend the activity through the CY 2021 performance period should be established as soon as possible because the PHE for COVID-19 continues to require considerable effort by clinicians and researchers. 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 and potentially could incentive clinicians to submit COVID-19 data to clinical data registries, which CMS views as imperative to help combat the PHE for COVID-19.

IV. Regulatory Impact Analysis

OMB has determined that this IFC is "economically significant" within the meaning of Executive Order 12866. It highlights the following:

- Requirements on laboratories performing COVID-19 tests to report those results will result in significant costs as estimated in Table 7 & 8 of the IFC placed on public display. Because many laboratories are considered small entities under the Regulatory Flexibility Act (RFA, Public Law 96-354) CMS provides an analysis of the number of entities likely to be impacted.
- CMS examines the impact on small rural hospitals as required under the RFA and expects a significant impact on the operations of a substantial number of those facilities.
- As required by Executive Order 13132 on Federalism, an analysis of the impact on state and local governments is provided. CMS expects two states to be impacted because they have laws related to laboratory requirements that are equal to or more stringent than CLIA requirements. New York and Washington would both need to update their standards, policies and procedures in order to maintain their ability their approval to license laboratories under CLIA. They would also need to develop CMPs that are at least as stringent as those implemented in the IFC.
- Specifying CMP amounts for noncompliance with reporting of COVID-19 related data will not result in any additional financial burden for LTC providers if they are compliant in their reporting. CMS notes that compliance with May 8th reporting requirements has been greater than 98 percent since June 28, 2020.
- CMS provides estimates of a range of potential costs that may be incurred by LTC facilities under the testing requirements in the rule and of the potential life-savings benefits using the Value of a Statistical life measure.
- Clarifications regarding the treatment of premium discounts for the purpose of risk adjustment in the individual and small group markets and MLR reporting would not impose any additional administrative burden on health insurance issuers. Some issuers, however, may be financially impacted as overall transfer payments will be reduced.

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