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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 (RIN 0938-AU33)

September 2, 2020

Background & Summary

On Tuesday, August 25, the Centers for Medicare & Medicaid Services (CMS) issued an interim final rule with comment period (IFC) which, among other provisions, establishes new requirements in the hospital and critical access hospital (CAH) Conditions of Participation (CoPs) for tracking the incidence and impact of COVID-19. The IFC also updates the extraordinary circumstances exceptions granted for the Hospital Acquired Condition Reduction Program (HACRP), Hospital Readmissions Reduction Program (HRRP), and Hospital VBP Program for the public health emergency (PHE) for COVID-19. In addition, the IFC establishes COVID-19 reporting requirements for all laboratories subject to the Clinical Laboratory Improvement Amendments of 1988 (CLIA) for the duration of the COVID-19 PHE.

Comments are due **November 2, 2020, at 5PM**. Because this is an interim final rule, most provisions in this regulation are effective immediately (September 2, 2020) and, generally, are applicable for the duration of the PHE for COVID-19.

Condition of Participation Requirements for Hospitals and CAHs to Report COVID-19 Data as Specified by the Secretary During the PHE for COVID-19

As required by law, hospitals, including short-term acute care hospitals, long-term care hospitals, rehabilitation hospitals, psychiatric hospitals, cancer hospitals, children's hospitals, and CAHs seeking to be Medicare and Medicaid providers must be certified as meeting federal participation requirements (e.g., conditions of participation (CoPs).

On March 4, 2020, CMS issued guidance stating that hospitals should inform infection prevention and control services, local and state public health authorities, and appropriate healthcare facility staff if a person is under investigation for COVID-19. In the IFC, CMS builds from its March guidance by revising CoPs for hospitals (§482.42) and CAHs (§485.640) for infection prevention and control and antibiotic stewardship programs, to require electronic reporting of certain COVID-19 information in accordance with a frequency (e.g., daily), and in a standardized format (e.g., excel, CSV), as specified by the Secretary during the PHE. The current list of data items

hospitals are required to report and other reporting information is available online (last updated July 29, 2020). However, CMS notes this list is not exhaustive of the data items and requirements (e.g., reporting channel options, format, frequency manner) that it may require hospitals and CAHs to submit in the future. CMS anticipates the average burden per response will be 1.5 hours and there will be 365 responses per respondent through the Department of Health and Human Services (HHS) Teletracking COVID-19 portal.

CMS indicates the data will be used to inform the White House Coronavirus Task Force's (COVID-19 Task Force) decisions on capacity and resource needs, tracking movement of the virus and identifying problems in the healthcare delivery system.

Enforcement of Requirements for Hospitals and CAHs to Report COVID-19 Data

In the IFC, CMS indicates that "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)." CMS notes it currently lacks statutory authority to impose civil monetary penalties (CMPs) against hospitals and CAHs.

Requirements for Laboratories to Report SARS-CoV-2 Test Results During the PHE for COVID-19

Laboratory data collected through the CLIA program includes only non-waived testing specialty and subspecialty information from laboratories issued a Certificate of Compliance (CoC), Certificate of Accreditation (CoA), or Certificate of Registration (CoR). Certificate of Waiver (CoW) and Certificate for Provider-Performed Microscopy (PM) laboratories are not required to submit updated information through the CLIA program. Several COVID-19 tests are considered waived complexity. Therefore, CMS (through the CLIA program), does not currently have a specific reporting requirement for the collection of COVID-19 testing information.

The Coronavirus Aid, Relief, and Economic Security (CARES) Act, which was signed into law during the PHE, 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 from each test to HHS until the end of the PHE. In addition, the CARES Act authorizes the Secretary to specify the form, manner, timing and frequency of such reporting. On June 4, HHS issued data reporting guidance to clarify laboratory reporting requirements, including where a laboratory should report data, when results should be reported, and which laboratories must report data.[1]

[1] According to COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115, released June 4, 2020, available at: https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf, "all laboratories—including laboratories, testing locations operating as temporary overflow or remote locations for a

In the IFC, CMS finalizes that during the PHE, each laboratory (including laboratories with a CoW) that performs a COVID-19 diagnostic test, including molecular, antibody and antigen tests, must report test results in a form, manner, timing and frequency that CMS prescribes (e.g., guidance documents). In addition, CMS indicates failure to submit COVID-19 diagnostic test results will be considered a violation of the new CLIA reporting requirements, resulting in condition level deficiencies[2] for which CMPs or other penalties may apply. CMP amounts that may be imposed are $1,000 for the first day of non-compliance with the new reporting requirements and $500 for each subsequent day the laboratory fails to report COVID-19 test results.

In addition, for the duration of the PHE, CMS is also requiring that CMS-deemed Accreditation Organizations (AO) and State Licensure Programs, Exempt States (ES), notify CMS within 10 days after identifying a laboratory failing to report COVID-19 diagnostic test results.

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

On March 22, 2020, CMS granted Extraordinary Circumstances Exceptions (ECEs) for hospitals and other facilities which relieved certain providers and facilities of the obligation to report data for the fourth quarter calendar year (CY) 2019, the first quarter CY 2020 and the second quarter CY 2020. CMS indicated it would score optionally reported data. Based on changes that occurred at the state and local levels, and concerns about the national comparability of data reported for value-based purchasing programs, CMS believes updates to the ECEs are warranted. In the IFC, CMS updates the ECEs it granted for the following programs:

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

More detail regarding the changes to HACRP, HRRP, and HVBP Program are described below. Generally, under the updated ECEs, CMS will only score data that was optionally reported for fourth quarter CY 2019. CMS will exclude all data that was optionally reported for the first or second quarter of CY 2020 from its calculation of performance.

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laboratory, and other facilities or locations performing testing at point of care or with at-home specimen collection related to SARS-CoV-2."

[2] "A condition-level deficiency is any deficiency of such character that substantially limits the provider's or supplier's capacity to furnish adequate care or which adversely affects the health or safety of patients." More information is available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R114SOMA.pdf

Updates to the Application of the HACRP ECE Policy in Response to the PHE

Although CMS exempted hospitals from the requirement to report fourth quarter CY 2019 data for the HACRP, CMS indicates nearly all hospitals (95.3 percent) reported data by the May 18, 2020 submission deadline (this reflects care provided before January 27, 2020 (the start of the PHE)).

Consistent with policy stated in March 2020, CMS will include fourth quarter CY 2019 data that were optionally reported when calculating hospitals' Total HAC Scores. These scores will continue to be used to identify the worst-performing hospitals in the program and assessing the 1 percent HACRP penalty.

For CY 2020 first and second quarter data, CMS will no longer use optionally reported data program calculations. In the IFC, CMS explains its belief that using such data may not provide a nationally comparable assessment of hospital performance.

As of July 1, 2020, data collection and reporting requirements began resuming. However, CMS recognizes geographic differences in COVID-19 incidence continue to change during the PHE and that future ECE policies (e.g., extension of the ECE for the whole country or individual ECE requests) may be granted. In the IFC, CMS announced that if it does not have enough HACRP data to reliably measure national performance, it may propose to either not score hospitals based on such limited data or make the associated payment adjustments to hospitals under the inpatient prospective payment system (IPPS) for the affected program year.

If circumstances warrant, CMS may propose to suspend prospective application of program penalties or payment adjustments through the annual IPPS/LTHC PPS Proposed Rule, but in the interest of time, CMS may provide subregulatory advance notice of these intentions.

CMS welcomes public comments on its policy to exclude any data submitted regarding care provided during the first and second quarter of CY 2020 from its calculation of performance for FY 2022 and CY 2023 program years.

Update to the HRRP ECE Granted in Response to the PHE

In applying the ECE policy for the PHE, CMS excepted the use of claims data from the first and second quarters of CY 2020 from the HRRP. CMS believes it would be inappropriate to include claims data submitted for care provided during first and second quarter of CY 2020 in its calculation of a hospital's performance to ultimately determine penalties for excess readmissions. In the IFC, CMS indicates it will exclude any data submitted regarding care provided during first and second quarter of CY 2020 from its calculation of performance for FY 2022, FY 2023 and FY 2024.

Finally, CMS notes that for the HRRP, data collection and reporting requirements have resumed July 1, 2020, but recognizes geographic differences in COVID-19 incidence continue to change during the PHE. In the IFC, CMS announced that if, as a result of the ECE policies (e.g., ECE for the whole country or individual ECE requests), it does not have enough data to reliably measure national performance, it

may propose to not score hospitals based on such limited data. In addition, CMS may not make the associated payment adjustments to hospitals under the IPPS for the affected program year.

If CMS grants another ECE in the future, CMS would not require that hospitals report the excepted data for the duration of the ECE. If circumstances warrant, CMS may propose to suspend prospective application of program penalties or payment adjustments through the annual IPPS/LTHC PPS Proposed Rule, but in the interest of time, CMS may provide subregulatory advance notice of these intentions.

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

Update to the Hospital VBP Program ECE Granted in Response to the PHE

On March 22, 2020, CMS granted an ECE to all hospitals participating in the Hospital VBP Program. Under the ECE, hospitals were not required (but were given the option) to report data for the National Healthcare Safety Network (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). In addition, under the ECE, CMS indicated would exclude qualifying claims data from certain 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).

In the IFC, CMS revises the current ECE granted for the Hospital VBP Program for the first and second quarter CY 2020 excepted data. Under the revised ECE, CMS will not use any optionally reported 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. However, CMS will still use optionally reported fourth quarter CY 2019 Hospital VBP Program data to calculate total performance scores for those hospitals for the FY 2021 through FY 2024 program years and baseline scores for the FY 2026 through FY 2029 program years.

NCD Procedural Volumes for Facilities and Practitioners to Maintain Medicare Coverage

CMS acknowledges that, due to the PHE, 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 certain national covered determinations (NCDs). As a result, for the duration of the PHE, CMS will not enforce procedural volume requirements contained in the following four NCDs for facilities and practitioners that, prior to the PHE for COVID-19, met the volume requirements:

- 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).

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

In the IFC, CMS establishes that one COVID-19 diagnostic test and one of certain related tests (as listed in the May 8th COVID-19 IFC) will be covered by Medicare without an order from a physician or other practitioner. This policy narrows previous policy provided in the May 8th COVID-19 IFC, which allowed for coverage of multiple COVID-19 tests for a single beneficiary without a physician or other practitioner order. The new policy is effective September 2, 2020 (the date the IFC was officially published), and any tests furnished prior to the effective date will not be considered for purposes of the limit on tests without a physician or other practitioner order.

In addition, in the IFC, CMS establishes a policy whereby COVID-19 and other related diagnostic 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 also notes that, consistent with policy provided in the May 8th COVID-19 IFC, CPT code 99211 can be billed (including "incident-to" billing) 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.

Merit-Based Incentive Payment System (MIPS) Updates

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

During the PHE, CMS expanded coverage of a range of telehealth services. While most of those services are included in CMS's definition of primary care services that is used in the MIPS beneficiary assignment methodology for the CMS Web Interface and CAHPS for MIPS survey, some services (communications technology-based services and telephone E/M services) are not included in the definition.

In the IFC, CMS expands the definition of primary care services for purposes of MIPS beneficiary assignment methodology for the CMS Web Interface and CAHPS for MIPS survey. The additional codes that CMS will be treating as primary care services for the duration of the PHE for COVID-19 are: CPT codes 99421-99423 (online digital E/M service (e-visit)) ; 99441-99443 (telephone E/M services) and HCPCS codes G2010 (remote evaluation of patient video/images) and G2012 (virtual check-in). CMS will be 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.

Improvement Activities Performance Category: Improvement Activities Inventory Update

In response to the PHE, CMS added one new improvement activity ("COVID-19 Clinical Trials) to the Improvement Activities Inventory for the CY 2020 performance period. Since adding this new improvement activity, CMS received several questions as related to clinical data registries and provides clarification in the IFC.

In the IFC, CMS clarifies that 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 clinical data registry for ongoing or future COVID-19 research.

Considering clinical data registries, CMS indicates the following requirements must be met for the purpose of the COVID-19 Clinical Trials Improvement activity: (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. CMS also notes, 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.

In the IFC, CMS recognizes that under the Promoting Interoperability performance category there is the required Public Health and Clinical Data Exchange Objective which includes data reporting to two different public health agencies or clinical data registries. CMS clarifies that the submission requirements for the Promoting Interoperability performance category would not be changed by the COVID-19 Clinical Trials improvement activity (e.g., COVID-19 data submission could be used for both the Promoting Interoperability performance category and as an improvement activity).

Additionally, in the IFC, CMS extends 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 experienced nationwide. Table 2 (pg. 119-120) displays a description of the improvement activity.

What's Next?

Unless otherwise specified, the IFC is effective September 2, 2020, which is when it was officially published. CMS is collecting comments until November 2, 2020 at 5PM.

Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this IFC. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions regarding any aspects of this proposed regulation – both positive reactions and provisions that cause you concern. Please direct your feedback to Jenna Stern, Sr. Regulatory Affairs and Public Policy Director in Vizient's Washington, D.C. office.