

CMS Issues Interim Final Rule to Enforce COVID-19 Reporting Requirements

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The Centers for Medicare and Medicaid Services (“CMS”) published an Interim Final Rule in the Federal Register on September 2, 2020 to supplement and strengthen the agency’s enforcement of COVID-19 reporting requirements. The final rule also modifies various aspects of Medicare reimbursement methodologies for health plans, physicians, and other providers. This post summarizes each of these regulatory changes, which are effective as of September 2, 2020.

1. New Enforcement Requirements for COVID-19 Related Data Reporting

To assist public health officials in detecting and tracking COVID-19 outbreaks and save lives, CMS is adding new reporting requirements for healthcare facilities along with expanded CMS enforcement authority to ensure compliance with such reporting requirements. The Interim Final Rule addresses reporting and related enforcement for three general categories of healthcare entities: long term care (LTC) facilities, hospitals and critical access hospitals (CAHs), and laboratories.

A. LTC Facilities

Under CMS regulations issued in May, LTC facilities are required to electronically report COVID-related data to the Centers for Disease Control and Prevention (CDC) on a weekly basis. Facilities must report a variety of information, including suspected and confirmed COVID-19 infections among residents and staff, the number of COVID-19 resident and staff deaths, the personal protective equipment and hand hygiene supplies in the facility, and more. The Interim Final Rule allows CMS to impose civil money penalties (“CMPs”) if a LTC facility fails to submit its weekly report. CMS may impose a minimum of \$1,000 for an initial violation. For every subsequent time the facility fails to report the required data, the CMP imposed will increase by \$500, up to a maximum of \$6,500. For example, a facility that fails to report for two consecutive weeks will be subject to a minimum CMP of \$2,500: \$1,000 for the first week and \$1,500 for the second week.

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CMS waived the normal notice-and-comment process due to the urgent need to track and contain COVID-19 infection outbreaks. LTCs are subject to these new penalties for reporting failures effective September 2, 2020, and the penalties will continue to be in effect for up to one year beyond the end of the COVID-19 public health emergency (“PHE”).

B. Hospitals and CAHs

The Interim Final Rule also makes daily reporting of COVID-related data a Condition of Participation in the Medicare and Medicaid programs for hospitals and CAHs. To support broader surveillance of the spread of COVID-19, CMS will require hospitals and CAHs to report certain COVID-related



information to the Department of Health and Human Services (“HHS”) daily, through a standardized format specified by HHS, set forth [here](#).

CMS does not have authority to impose CMPs on hospitals or CAHs who fail to provide this reporting. However, should a hospital or CAH fail to consistently report test results throughout the duration of the PHE, it will be non-compliant with the hospital and the CAH Conditions of Participation set forth at 42 CFR §§ 482.42(e) and 485.640(d), respectively, and consequently subject to CMS termination of its Medicare provider agreement.

C. Laboratories

Additionally, the Interim Final Rule modifies the Clinical Laboratory Improvement Amendments of 1988 (“CLIA”) to require all laboratories to report SARS-CoV-2 test results within 24 hours of a positive test result. Reports must be made throughout the PHE, as specified [here](#). If a laboratory fails to submit SARS-CoV-2 test results as required under the CLIA modifications, the Department of Health and Human Services may impose CMPs or other penalties on the laboratory.

CMS states that CMPs for reporting violations will be \$1000 for the first day of noncompliance, and \$500 for each subsequent day the laboratory fails to report SARS-CoV-2 test results. The applicable statute allows for the imposition of CMPs of up to \$10,000 for each violation.

2. LTCs Must Test Residents and Staff for COVID-19

In addition to reporting COVID-related data, LTCs are required under the new rule to test their facility residents and staff for COVID-19. Testing includes not only staff employees, but volunteers and those providing services under arrangements at the facility. Testing must be conducted in a manner consistent with current professional

standards of practice for COVID testing. Documentation of testing and resulting must be provided in staff personnel records, and in resident medical records.

CMS has published additional guidance [here](#) that addresses testing frequency, types of testing that should be conducted, and guidance on handling staff who refuse testing, among other topics.

3. Limitation on Medicare Coverage of COVID-19 Testing Without an Order

In a prior [Interim Final Rule with Comment Period](#), CMS expanded coverage for COVID-19 testing for Medicare beneficiaries by eliminating the need for an order from a treating physician or other practitioner.

CMS has now revised this policy, citing fraud and abuse concerns and clinical concerns that beneficiaries are receiving too many COVID-19 tests without medical attention and oversight. Consequently, beginning September 2 and continuing for the duration of the PHE, Medicare will cover only one (1) COVID-19 diagnostic test without the order of a physician or other practitioner. A single otherwise covered laboratory test each for influenza or a similar respiratory condition needed to obtain a final COVID-19 diagnosis, when performed in conjunction with a COVID-19 test, will also be covered. Medicare will cover additional COVID-19 tests only with the order of a physician or other practitioner.

Any COVID-19 test(s) that a beneficiary received prior to September 2, 2020 is disregarded for purposes of this new single COVID-19 test coverage rule.

CMS points out that this coverage rule applies to the Medicare program only; COVID-19 testing coverage policies for group health plans, health insurance issuers, and other public programs must comply with applicable law.

CMS is also allowing pharmacists and other practitioners allowed to order laboratory tests in accordance with state scope of practice and other laws to fulfill the requirements related to orders for covered COVID-19 tests for Medicare patients.

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

Early in the PHE, CMS granted several “Extraordinary Circumstances Exceptions” (“ECEs”) which relieved facilities of certain data collection and reporting obligations so that more time and resources could be directed to patient care. CMS used such data reporting to score certain program performance, resulting in adjustments of Medicare payments pursuant to certain value-based and quality-related features of Medicare reimbursement methodologies. CMS states that, although it was gathering data on these programs, it has concerns about the national comparability of data due to the geographic differences of COVID-19 incidence rates and hospitalizations and the impacts of varying state and local laws and policy changes implemented in response to COVID-19.

Therefore, the Department proposes updating the ECEs it 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 the updated ECEs, CMS will only score data that was voluntarily reported for the fourth quarter of calendar year 2019. Further, CMS will exclude all data reported for the first or second quarter of calendar year 2020, due to the significant and variable impacts COVID-19 had on facilities during this period.

In addition, the Interim Final Rule updates the performance period for the fiscal year 2022 SNF VBP Program, because CMS believes that the current measurement periods would not produce reliable results for measuring SNF quality of care as determined by hospital readmission rates. The measurement periods are changing from October 1, 2019 through December 31, 2019 and July 1, 2020 through September 30, 2020 to April 1, 2019 through December 31, 2019 and July 1, 2020 through September 30, 2020.

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

The Interim Final Rule acknowledges that, because of the PHE, far fewer non-essential procedures have been performed over the past several months. As a result, hospitals and practitioners may not be able to meet certain procedural volume requirements that are set forth in certain national coverage determinations (“NCDs”), including:

- 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).

Typically, failure to meet the procedural volume requirements would prevent Medicare payment for those categories of procedures. However, CMS will not enforce the procedural volume requirements contained in the four above-noted NCDs because of disruptions caused by the PHE. This waiver of enforcement only applies to facilities and practitioners that had met the volume requirements prior to the PHE for COVID-19. All

other non-volume based coverage requirements under these NCDs remain in effect.



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

CMS is making changes to the Merit-Based Incentive Payment

System (“MIPS”) for physicians and other clinicians, to reflect the manner in which Medicare beneficiaries are receiving primary care services during the PHE. For the 2020 MIPS performance year and any subsequent performance year that starts during the PHE, CPT and HCPCS codes for communications technology-based services and telephone evaluation and management services are to be included in the definition of primary care services under MIPS. This will allow those remote services to be included in CMS determinations of where Medicare beneficiaries receive a plurality of their primary care services for purposes of MIPS beneficiary assignment to physicians and other clinicians.

CMS is also modifying one of the Improvement Activities in MIPS relating to COVID-19 clinical trial participation, so that clinicians can receive credit under this Improvement Activity not only for participating in a COVID-19 clinical trial, but also for participating in the care of patients diagnosed with COVID-19 and simultaneously submitting relevant clinical data to a clinical data registry for ongoing or future COVID-19 research.

7. Recognizing Temporary Premium Credits as Premium Reductions

CMS previously adopted policies allowing health insurance issuers offering health insurance coverage in the individual and small group markets on the American Health Benefit Exchanges established under The Patient Protection and Affordable Care Act (Pub. L. 111-148) to grant temporary premium credits for individuals and small businesses that may be struggling to pay premium during the PHE. In this Interim Final Rule, CMS makes a number of technical changes and clarifications to ensure that health plan premium reporting takes into account any premium credits granted, including for purposes of medical loss ratio (MLR) reporting and rebates.

8. Part C and Part D Health Plan Star Ratings

Finally, CMS made changes to the Star Rating system for Medicare Part C and Part D health plans. The Star Rating system allows CMS to publish comparative information to beneficiaries about Medicare Advantage and Medicare Part D health plans, and is the basis for determining quality bonus payments to Medicare Advantage plan, as well as beneficiary rebates.

CMS currently excludes certain scores within the Stark Rating system if a plan has 60 percent or more of its enrollees living in a Federal Emergency Management Agency (FEMA)-designated Individual Assistance area. Because of the PHE, the maintenance of this rule would remove almost all plans from those scoring metrics. Consequently, CMS is removing that 60 percent rules for the 2022 Star Ratings (for which 2020 is the measurement year) to avoid having to exclude the vast majority of plans from the methodology.

This recent Interim Final Rule clearly indicates that CMS wants to ensure consistent reporting of COVID-19 related data from laboratories, hospitals and long term care facilities. It also illustrates the profound and widespread degree to which the PHE continues to impact Medicare reimbursement methodologies and systems.

If you have any questions about the Interim Final Rule or any of the topics addressed in this post, please contact the authors or any member of the Dorsey & Whitney Health Transactions & Regulations Practice Group.