Wynne Health Group

Memorandum

August 26, 2020

INTERIM FINAL RULE ESTABLISHES NEW ENFORCEMENT MECHANISMS AND REQUIREMENTS FOR COVID-19 SURVEILLANCE AND TESTING; INCLUDES MODIFICATIONS TO MIPS & STAR RATINGS

On August 25, 2020, the Centers for Medicare & Medicaid Services (CMS) **released an interim final rule with comment period (IFC) specifying new requirements for long-term care facilities, hospitals, laboratories, and other facilities in response to the COVID-19 public health emergency (PHE).** The rule builds off of recent regulations and guidance from the agency, largely strengthening CMS' enforcement authority to ensure compliance with new COVID-19 surveillance initiatives. The rule also modifies certain requirements and rules within the Merit-Based Inceptive Payment System (MIPS), as well as for Part C and Part D quality rating system.

The provisions in this rule are effective immediately upon its publication in the *Federal Register*, though CMS is collecting public comments through approximately October 26, 2020.

Highlights on the rule's major provisions follow.

- **New Enforcement Requirements for LTC Facilities** – In its May IFC (details), CMS required facilities to establish weekly reporting of COVID-19 cases to the Centers for Disease Control and Prevention (CDC). In this latest IFC, CMS is adding additional enforcement measures to better ensure facility compliance with these reporting requirements. Specifically, **CMS is imposing new civil monetary penalties (CMPs) for each time a facility fails to report the required data to the CDC**.

  CMS states it will levy a minimum of $1,000 for an initial CMP at the first occurrence of noncompliance with the reporting requirements. The agency will then issue a $500 CMP each time a facility fails to submit a timely report after the initial occurrence.

  This provision is effective immediately. See more detail beginning on p. 15.

- **Condition of Participation (CoP) Requirements for Hospitals and CAHs to Report COVID-19 Data As Specified by the Secretary During the PHE for COVID-19** – In guidance issued on March 4, 2020 (details), CMS stated that hospitals should inform infection prevention and control services, local public health authorities, and facility staff about the presence of individuals under investigation for having contracted COVID-19. In this IFC, **CMS is now requiring hospitals and critical access hospitals (CAHs) to report this information according to a standardized frequency and format**.

  The Department of Health and Human Services (HHS) Secretary will later specify these parameters, though CMS offers some examples of what may be required in the meantime. For example, CMS states that it may require the following elements to be reported: number of staffed

beds in a hospital, the number of beds that are occupied, information about supplies, and a count of patients currently hospitalized who have confirmed cases of COVID-19.

See p. 22 for more.

- **Requirements for Laboratories to Report SARS-CoV-2 Test Results During the PHE for COVID-19** – CMS is imposing new regulations **requiring all laboratories, including those holding a Certificate of Waiver (CoW), to report COVID-19 test results to HHS** for the duration of the COVID-19 public health emergency. Failure to comply with these requirements, CMS states, could result in the imposition of CMPs on non-compliant laboratories. The HHS Secretary will further specify the format and frequency for laboratories to report this information. See more on p. 27.

- **Requirement for LTC Facilities to Test Facility Residents and Staff for COVID-19** – The interim final rule establishes a new infection control requirement for LTC facilities to test residents and staff members (including volunteers) based on parameters set by the HHS Secretary that aim to identify and prevent the spread of COVID-19 (e.g., testing frequency; see p. 124 for complete list). CMS is seeking comments on other factors that should be considered for LTC facility COVID-19 testing and will issue guidelines via CMS memoranda (timing was not specified).

  The interim final rule also requires LTCs to:

  - Conduct testing in a manner "consistent with current standards of practice for conducting COVID-19 tests." CMS points to CDC's Interim SARS-CoV-2 Testing Guidelines for Nursing Home Residents and Healthcare Personnel;
  - Document the conduct and results of COVID-19 tests administered to staff and residents;
  - Take actions to prevent the spread of COVID-19 upon the identification of an individual who exhibits symptoms consistent with COVID-19 or tests positive;
  - Have procedures for addressing residents and staff who refuse testing or are unable to be tested; and
  - Contact state and local health departments to assist in testing efforts if there are testing supply shortages.

  Non-compliant LTC facilities may face civil monetary penalties in excess of $400 per day, or over $8000 for an incident of noncompliance, depending on its severity.

- **Addressing the Impact of COVID-19 on Part C and Part D Quality Rating Systems** – The interim final rule modifies the "extreme and uncontrollable circumstances" policy for the 2022 Star Ratings to account for the majority of states/territories (51 out of 55 as of July 28, 2020) that have been designated by the Federal Emergency Management Agency (FEMA) as "Individual Assistance" areas due to COVID-19, and therefore are eligible for the extreme and uncontrollable circumstance adjustment. These changes are intended to enable CMS to calculate overall and summary ratings for 2022 Star Ratings and 2023 quality bonus payments. See discussion beginning on p. 94.

  Specifically, the interim final rule will **not** exclude the performance data for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance Area during the 2020 performance measurement period from the: "clustering algorithms; or the "the determination of the performance summary and variance thresholds for the Reward Factor." CMS

explains that 2020 performance data will be used to set "cut points for non-CAHPS measures" and the "Reward Factor" for the 2022 Star Ratings.

CMS states that the "25 percent rules" will **not** be modified and acknowledges that most contracts have at least 25 percent of their service area in a FEMA-designated Individual Assistance area, and therefore are eligible for an adjustment to their measure level-ratings for the 2022 Star Ratings. The agency explains that contracts will receive the higher of their measure-level rating from 2021 or 2022 for 2022 Star Ratings.

- **Merit-Based Incentive Payment System (MIPS) Updates** – The interim final rule makes several updates to MIPS. First, CMS codifies the definition of "primary care services" to and include previously finalized CPT codes (e.g., E/M office visit; see pp. 108-109 for a full list) as well as the following new codes:

    - Online digital E/M services (e-visit) – CPT codes 99421, 99422, and 99423;
    - Telephone E/M services – CPT codes 99441, 99442, and 99443;
    - Remote evaluation of patient video/image – HCPCS code G2010; and
    - Virtual check-in – HCPCS code G2012.

    CMS notes a clinician is not allowed to bill separately for online digital E/M services, remote evaluations of patient video/image, and virtual check-ins if such services are related to a visit within the past seven days or lead to a visit within the following 24 hours or next available appointment. Therefore, only telephone E/M services may be billed separately during the public health emergency.

    The interim final rule also modifies the "COVID-19 Clinical Trials" improvement activity in the Quality Payment Program. Specifically, CMS expands the improvement activity to include MIPS-eligible "clinicians participating in the care of a patient diagnosed with COVID-19 who simultaneously submit their clinical patient data to a clinical data registry for research." Currently, the improvement activity only includes clinicians participating in a COVID-19 clinical trial that treats COVID-19 patients with a drug or biological product and submits their findings through a clinical data repository or clinical data registry. The interim final rule also extend this newly modified improvement activity through the calendar year 2021 performance period.

    See p. 114 for clinical data registry requirements and Table 2 on p. 119 for a summary of the modified improvement activity.

- **Quality Reporting** – Beginning on p. 33, CMS notes that on March 22, the agency granted extraordinary circumstances exceptions (ECEs) to end-stage renal disease (ESRD) facilities, hospitals, and skilled nursing facilities (SNFs) to reduce data collection and reporting burden during the pandemic. CMS further explains that data from fourth quarter of calendar year (CY) 2019, and first and second quarters of CY 2020 would be scored if optionally reported. The agency asserts that excepted data from during the pandemic is important, but they are concerned about the national comparability and these data due to geographic differences of COVID-19 incidence rates and hospitalizations.

    Because of these varying impacts CMS is updating the ECEs for the ESRD Quality Incentive Program (QIP); the Hospital Acquired Conditions (HAC) Reduction Program; the Hospital Readmission Reduction Program (HRRP); and the Hospital Value-Based Purchasing Program (HVBP). Under the update, CMS will only score data that was optionally reported for the fourth

quarter of CY 2019. Additionally, CMS is updating the performance period for the fiscal year (FY) 2022 SNF Value-Based Purchasing Program to be April 1, 2019 through December 31, 2019 and July 1, 2020 through September 30, 2020.

- **NCD Procedural Volumes for Facilities and Practitioners to Maintain Medicare Coverage** – On p. 69, CMS details that due to the public health emergency and the resulting disruption in non-essential procedures, the agency will not enforce procedural volume requirements for the following National Coverage Determinations (NCDs):

    - 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); and
    - NCD 20.9.1 Ventricular Assist Devices (VADs).

- **Limits on COVID-19 and Related Testing without an Order and Expansion of Testing Order Authority** – Beginning on p. 71, CMS establishes that agency will pay for one COVID-19 diagnostic test and one influenza virus or respiratory syncytial virus test, without an order from a physician or other practitioner. The agency notes that coverage of multiple respiratory diagnostic tests is applicable when performed in conjunction with a COVID-19 diagnostic test in order to obtain a final diagnosis. CMS asserts that it is contrary to public interest to allow open-ended coverage of COVID-19 testing without an order from a physician, practice, or other healthcare professional and eliminates the potential for fraud, waste, and abuse. This limitation on tests without an order applies beginning on the effective date of this rule.

  Additionally, CMS establishes that the agency will cover COVID-19 diagnostic tests, and other related diagnostic tests, such as influenza, when ordered by a pharmacist or other healthcare professional is who authorized to order diagnostic lab tests in accordance with state scope of practice. CMS notes that pharmacists cannot be paid directly under the Medicare program and still need to be functioning in an incident-to arrangement with a physician or non-physician to be paid under Part B for front-end assessment and specimen collection.

- **Recognizing Temporary Premium Credits as Premium Reductions** – CMS details the recent adoption of temporary policies that allow all issuers offering individual and small group coverage to offer premiums credits for those who may struggle to pay premium due to pandemic. On p. 85, the agency clarifies that issuers of risk adjustment-covered plans that provide temporary premium credits must report to their dedicated distributed data environment (EDGE server) adjusted plan premiums that reflect actual premiums billed to enrollees. Additionally, CMS clarifies that HHS's calculation of risk adjustment payment and charges for the 2020 benefit year under the state payment transfer formula will be calculated using statewide average premium that reflects actual premiums billed.

  CMS also clarifies that medical loss ratio (MLR) reporting and rebate requirements for issuers that elect to provide temporary premium credits must report as earned premium the actual premium billed to enrollees, taking into account any temporary premium credits as a reduction in premium.