



Selected Highlights of [CMS Interim Final Rule](#) Released August 25, 2020

Hospital Data Reporting as Condition of Participation

- **New Requirement(s):** Hospitals must report information in accordance with frequency and standardized format as specified by Secretary,* as a condition of participation in Medicare.
 - *Refers hospitals to information listed in the [Secretary's Facility Data Reporting FAQs](#) as the current list of data items specified (see pp. 3-10 for a complete list of items that need to be submitted).
 - Effective date is when this is published in the Federal Register.
 - Failure to consistently report test results during the public health emergency may result in hospital's termination from Medicare.
- **Rationale:** Necessary for CMS to monitor whether individual hospitals are appropriately tracking, responding to, and mitigating the spread and impact of COVID-19 on patients, staff, and general public.
- All hospitals participating in Medicare are subject to these requirements:
 - Short-term acute care hospitals, LTC hospitals, rehabilitation hospitals, psychiatric hospitals, cancer hospitals, children's hospitals, and critical access hospitals (CAHs)

Laboratory Data Reporting as CLIA Requirement

- **New Requirement(s):** Each lab that performs SARS-CoV-2 tests (molecular, antigen, or antibody) must report the results in such form and manner, and at such timing and frequency, as Secretary may prescribe.* Failure to submit these test results to the Secretary considered condition-level violation of new Clinical Laboratory Improvement Amendments (CLIA) reporting requirements and results in civil monetary penalties (CMPs).
 - *[Guidance from June 4th](#) is mentioned, but not as explicitly linked as for the hospital reporting requirement and guidance.
 - CMPs calculated at \$1000 for first day of violation and \$500 per each subsequent day lab fails to report results (CMPs ultimately not to exceed \$10,000 for each violation [e.g., per sample not reported] or for each day of substantial noncompliance).
 - CMS also expects Accreditation Organizations (AOs) and State Licensure Programs for Exempt States (ES) to report within 10 days of identification of failure to report test results. AOs can't impose CMPs, but ES's can.
- **Rationale:** CMS claims that they do not know the complete universe of labs performing COVID testing because of the variety of COVID testing that is available (e.g., molecular vs. antibody vs. antigen methods).
 - The end goal for this reporting requirement is so that CMS can use their oversight authority to survey the labs and determine whether they are performing testing within their appropriate CLIA certificate and that they're meeting applicable CLIA requirements to perform accurate and reliable testing.

Long-Term Care Facilities (LTCs) Enforcement Requirements

- **New Requirement(s):** Enforcement action in the form of CMPs for previously enacted infection control requirements provisions to establish weekly facility reporting of suspected and/or

confirmed COVID-19 cases, among other information, through CDC National Healthcare Safety Network (NHSN).

- Minimums \$1000 initial CMP for first time LTC fails to submit timely report to CDC NHSN, with a \$500 incremental increase for each subsequent time LTC fails to report.
 - Increase CMP amounts for up to 12 subsequent noncompliance occurrences, which would be \$6,500 per occurrence of noncompliance.
- After each CMP is imposed, CMS will place the facility back into compliance without requiring Plan of Correction.
- **Rationale:** CMS believes financial penalty will help deter noncompliance and encourage facilities to establish procedures that result in prompt weekly COVID-19 related data reports, which will help track the incidence and impact of COVID-19 in nursing homes.

Limits on COVID-19 Testing Without Order

- **New Limitation(s):** Only one COVID-19 diagnostic test and one of each other related test* without an order from physician or other practitioner is reasonable and necessary for Medicare payment purposes.
 - *Test list available [here](#).
 - This is a change from prior interim final rule that did not have a limit on tests without orders.
 - Limitation begins on effective date of the rule.
- **Rationale:** CMS believes it is contrary to public interest to allow open-ended coverage of COVID-19 testing without an order from physician, practitioner, or other healthcare professional. They are concerned with fraud, waste, and abuse for the tests administered, and also cite public health and safety issues (e.g., “a negative test does not rule out the disease” or the need to provide counseling on isolation and quarantine guidelines).
- **New Permission(s):** Pharmacists and other practitioners that are allowed to order lab tests in accordance with state scope of practice and other pertinent laws permitted to give order for COVID-19 test and specific related tests.
 - Caveat that pharmacists still cannot be paid directly under Medicare program, so they may need to make arrangements with physician or non-physician practitioner to get paid.

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

- **New Requirement(s):** LTC facilities must test residents and onsite working staff for COVID-19 according to parameters set by Secretary.*
 - *Testing guidelines will be made available via CMS memos, CMS website, and CDC website.
 - Staff includes facility employees, individuals providing services under arrangements, and volunteers.
 - Each instance of staff or resident testing must be documented that the testing was completed and the results.
 - Staff testing to be kept in staff personnel record.
 - Resident testing to be kept in medical record.
 - Reaffirms existing regulations that facilities are required to electronically report information about COVID-19 in a standardized format as specified by Secretary, which includes reporting suspected and confirmed COVID-19 infections among residents and staff.

MHA is working to digest the totality of this interim final rule. This summary is based on MHA's initial read of the rule and focuses on the provisions deemed most likely to immediately impact hospitals' and other providers' operations.

- Residents retain right to refuse and/or discontinue treatment; staff retain right to refuse COVID-19 testing. LTC must have procedures for addressing residents and staff who refuse or are unable to be tested.