PUBLICATION

CMS Amps Up Penalties on Long Term Care Facilities for Failing to Report COVID-19 Data and Mandates Staff Testing for the Virus

Authors: Amy Wilmot Schrader, Stefanie J. Doyle

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Effective September 2, 2020, the Centers for Medicare and Medicaid Services (CMS) implemented an interim final rule with comment period to bolster its regulatory authority in addressing a number of issues relating to CMS's response to the COVID-19 public health emergency (PHE). Among other provisions, this wide-ranging rule contains two notable directives that nursing homes and other federally regulated long term care (LTC) facilities should be aware of and that will directly impact operations: (1) an increase in civil monetary penalties (CMP) for failure to timely report information relating to COVID-19; and (2) a new requirement for LTC facilities to conduct COVID-19 testing of residents and staff. The directive regarding civil monetary penalties is applicable for one year beyond the expiration of the PHE. CMS believes that the urgency of the PHE constitutes good cause to waive the normal notice-and-comment process, and the agency has already issued some guidance to LTC facilities and surveyors describing the implementation of the testing provision. We also note that, while the federal government is setting standards under the rule regarding testing frequency, individual states may also require more frequent testing by law, rule or order. Comments must be received no later than 5 p.m. ET on November 1, 2020.

New Enforcement Requirements for Long Term Care Facilities

CMS has revised regulations to strengthen its ability to enforce recent LTC requirements, previously published in its May 8, 2020 COVID-19 interim final rule, that require facilities to report data related to COVID-19 and infection control to the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) on at least a weekly basis. The required data includes, among other things, suspected and confirmed COVID-19 infections among residents and staff, including residents previously treated for COVID-19; total deaths attributable to COVID-19 among residents and staff; and personal protective equipment and hand hygiene supplies in the facility.

The new regulations specify the CMP amounts that may be imposed for a facility's failure to electronically report the required COVID-19 data to NHSN each week. On a weekly basis, CMS will identify facilities that failed to timely report information to CDC. Noncompliance with reporting requirements for each weekly reporting cycle will be cited at a scope of widespread, and a severity of no actual harm with potential for more than minimal harm that is not immediate jeopardy, which constitutes a level "F" deficiency. CMS will impose a minimum initial CMP of \$1,000 for the first week of noncompliance, with an incremental increase of \$500 per additional week the facility is out of compliance. For example, if a facility fails to timely report for a second time in a subsequent week, CMS will assess a CMP of at least \$1,500; a third infraction will raise the minimum CMP to \$2,000. CMS will increase the CMP amounts by a minimum of \$500 for each additional infraction to a maximum of \$6,500 per infraction.

After each CMP is imposed, CMS will place the facility back into compliance, without requiring a Plan of Correction in accordance with 42 C.F.R. § 488.408(f). Facilities are also offered an opportunity for Independent Informal Dispute Resolution under 42 C.F.R. § 488.431 to address any technical issues or other legitimate reasons why the data could not be timely updated. Facilities should take care to adequately document any

circumstances that prevent timely submission of COVID-19 data to challenge the assessment of these increased CMP amounts.

Requirement for LTC Facilities to Test Facility Residents and Staff for COVID-19

CMS is revising the LTC facility infection control regulations by adding a new section at 42 C.F.R. § 483.80(h) that establishes six salient provisions to govern the agency's new mandate that all LTC facility residents and staff are tested for COVID -19. CMS's definition of "staff" under the new rule is expansive in that it includes not only any individuals employed by the facility, but any on-site facility volunteers and any individuals who have arrangements to provide on-site services to the facility. Thus, facilities should immediately identify all individuals who qualify as "staff" to arrange for testing as soon as possible.

Although the parameters for conducting resident and staff testing have not yet been provided, facilities can expect to receive this information from the Secretary in upcoming CMS memoranda, in addition to posting on the CMS and CDC websites. CMS plans to include parameters such as the frequency of testing; the identification of any facility resident or staff diagnosed with, who has symptoms consistent with, or with known or suspected exposure to COVID-19; the criteria for testing asymptomatic facility residents and staff, such as the county's COVID-19 positivity rate; the response time for test results; and any other factors specified by the Secretary that help identify and prevent the transmission of COVID-19. The agency notes that the parameters are not limited to the items identified on the list and solicits comments on other factors that the Secretary should consider.

CMS is requiring that all resident and staff testing be conducted in a manner that is consistent with "current professional standards of practice." To accommodate evolving testing practices, CMS has defined "current professional standards of practice" to mean "those professional standards that apply at the time that the care or service is delivered." Thus, tests must be conducted in accordance with standards recognized nationally at the time the service is delivered and must meet the turnaround time for results that will be specified by the Secretary to ensure effectiveness.

CMS advises that LTC facilities must coordinate with state and local health departments to ensure the availability of sufficient testing supplies and processing test results when necessary, also coordinating with their local certified CLIA laboratories where appropriate. The facility's infection prevention and control plan must include considerations regarding access to adequate testing supplies and arrangements for acquiring testing supplies. In addition, the testing plan must include the arrangements necessary to conduct, process and receive test results before the required tests are administered. Facilities should also maintain documentation of resident and staff testing in the medical and staff personnel records currently maintained for each individual. For staff that are providing on-site services under arrangement, CMS expects that the agreement for the services provided would include a process for documenting the test results.

Additionally, CMS expects LTC facilities to continue taking actions to prevent the spread of COVID-19 by reducing the interaction of those facility staff and residents with symptoms consistent with COVID-19 or who test positive for the virus with other staff and residents in the facility. Facilities should restrict access for any staff member who presents with symptoms of or a positive test for COVID-19 until the staff member meets the specified return-to-work criteria to be set by the Secretary in the forthcoming testing guidelines. Similarly, it is expected that the facility have procedures for addressing residents and staff who refuse or are unable to be tested by taking steps, including limiting staff access to the facility and cohorting residents, to maintain the health and safety of its staff and residents who have not been diagnosed with COVID-19.

Lastly, the rule also includes a reminder that facilities are expected to assess their ability to replace workers who can no longer work with trained personnel, and to maintain appropriate staffing levels to ensure a safe work environment and safe resident care at all times. CMS expects that facilities will make adjustments to work and time off schedules, leverage the use of volunteers, and be prepared to contact federal, state and local health care partners to assist with staffing shortages.

Baker Donelson is assisting nursing homes in implementing the rule as efficiently and as effectively as possible. For specific guidance or more information on this alert, please contact Amy Schrader, Stefanie Doyle or any member of Baker Donelson's Long Term Care Team. For more information and general guidance on how to address legal issues related to COVID-19, please visit the Coronavirus (COVID-19): Navigating the Path Ahead information page on our website.