

Y. Requirement for Facilities to Report Nursing Home Residents and Staff Infections, Potential Infections, and Deaths Related to COVID-19

Under sections 1866 and 1902 of the Act, providers of services seeking to participate in the Medicare or Medicaid program, or both, must enter into an agreement with the Secretary or the state Medicaid agency, as appropriate. Long-term care (LTC) facilities seeking to be Medicare and Medicaid providers of services must be certified as meeting federal participation requirements. LTC facilities include SNFs for Medicare and NFs for Medicaid. The federal participation requirements for SNFs, NFs, and dually certified facilities, are set forth in sections 1819 and 1919 of the Act and codified in the implementing regulations at 42 CFR part 483, subpart B.

Sections 1819(d)(3) and 1919(d)(3) of the Act explicitly require that LTC facilities develop and maintain an infection control program that is designed, constructed, equipped, and maintained in a manner to protect the health and safety of residents, personnel, and the general public. In addition, sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act explicitly authorize the Secretary to issue any regulations he deems necessary to protect the health and safety of residents. Infection prevention and control is a primary goal of initiatives taking place in LTC facilities during the COVID-19 PHE. Under the explicit instructions of Congress, existing regulations at § 483.80 require facilities to, among other things, establish and maintain an infection prevention and control program (IPCP) designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections. Furthermore, current § 483.80(a)(2) requires facilities to have written standards, policies, and procedures for the program, which among other things, must include a system of surveillance designed to identify possible communicable diseases or

infections before they can spread to other persons in the facility and when and to whom possible incidents of communicable disease or infections should be reported. In an effort to support surveillance of COVID-19 cases, we are revising the requirements to establish explicit reporting requirements for confirmed or suspected cases. Specifically, we are revising our requirements by adding a new provision at § 483.80(g)(1), to require facilities to electronically report information about COVID-19 in a standardized format specified by the Secretary. The report includes, but is not limited to, information on: suspected and confirmed COVID-19 infections among residents and staff, including residents previously treated for COVID-19; total deaths and COVID-19 deaths among residents and staff; personal protective equipment and hand hygiene supplies in the facility; ventilator capacity and supplies available in the facility; resident beds and census; access to COVID-19 testing while the resident is in the facility; staffing shortages; and other information specified by the Secretary. This information will be used to monitor trends in infection rates, and inform public health policies.

In addition, at § 483.80(g)(2), facilities are required to provide the information specified above at a frequency specified by the Secretary, but no less than weekly to the Center for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) (OMB Control Number 0920-1290). Furthermore, we note that the information reported will be shared with CMS and we will retain and publicly report this information to support protecting the health and safety of residents, personnel, and the general public, in accordance with sections 1819(d)(3)(B) and 1919(d)(3) of the Act. The Freedom of Information Act (FOIA) (found in Title 5 of the United States Code, section 552) provides that, upon request from any person, a Federal agency must release any agency record unless that record falls within one of the nine statutory exemptions and three exclusions (see <https://www.foia.gov/faq.html> for detailed information).

Further, FOIA requires that agencies make available for public inspection copies of records, that because of the nature of their subject matter, the agency determines the records have become or are likely to become the subject of subsequent requests for substantially the same information. We have received, and expect to continue to receive, COVID-19 related FOIA requests. These requirements will support our efforts to proactively inform interested parties and ensure that the most complete information on COVID-19 cases is available. The new reporting requirements at § 483.80(g)(1) and (2) do not relieve LTC facilities of the obligation to continue to comply with § 483.80(a)(2)(ii), which requires facilities to report possible incidents of communicable disease and infections. This includes complying with state and local reporting requirements for COVID-19.

At § 483.80(g)(3), we are adding a new provision to require facilities to inform residents, their representatives, and families of those residing in facilities of confirmed or suspected COVID-19 cases in the facility among residents and staff. This reporting requirement supports the overall health and safety of residents by ensuring they are informed participants in the care that they receive as well as providing assurances of the mitigating steps the facility is taking to prevent and control the spread of COVID-19. Facilities must inform residents, their representatives, and families by 5 p.m. the next calendar day following the occurrence of either: a single confirmed infection of COVID-19; or three or more residents or staff with new-onset of respiratory symptoms that occur within 72 hours of each other. Also, cumulative updates to residents, their representatives, and families must be provided at least weekly by 5 p.m. the next calendar day following the subsequent occurrence of either: each time a confirmed infection of COVID-19 is identified; or whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other. This information must be reported in

accordance with existing privacy regulations and statute, and must not include Personally Identifiable Information (PII). Facilities must include information on mitigating actions implemented to prevent or reduce the risk of transmission, including if normal operations in the nursing home will be altered such as restrictions or limitations to visitation or group activities. For purposes of this reporting requirement, facilities are not expected to make individual telephone calls. Instead, facilities can utilize communication mechanisms that make this information easily available to all residents, their representatives, and families, such as paper notification, listservs, website postings, and/or recorded telephone messages.

These reporting requirements along with public reporting of the data support our responsibility to protect and ensure the health and safety of residents by enforcing the standards required to help each resident attain or maintain their highest level of well-being. As noted, sections 1819(d)(3)(B) and 1919(d)(3) of the Act requires that a facility must establish an infection control program that is designed, constructed, equipped, and maintained in a manner to protect the health and safety of residents, personnel, and the general public. We believe that these reporting requirements are necessary for CMS to monitor whether individual nursing homes are appropriately tracking, responding, and mitigating the spread and impact of COVID19 on our most vulnerable citizens, personnel who care for them, and the general public. The information provided may be used to inform residents, families, and communities of the status of COVID-19 infections in their area. We believe that this action strengthens CMS' response to the PHE for the COVID-19 pandemic, and reaffirms our commitment to transparency and protecting the health and safety of nursing home residents.

As discussed in section III. of this IFC, "Waiver of Proposed Rulemaking", we believe the urgency of this COVID-19 PHE constitutes good cause to waive the normal notice-

andcomment process under the Administrative Procedure Act and section 1871(b)(2)(C) of the Act. Waiving notice and comment is in the public interest, because time is of the essence in informing residents, their families, and the general public of the incidence of COVID-19; such information will assist public health officials in detecting outbreaks and saving lives.

The applicability date for § 483.80(g)(1) through (3)(iii) is the date of the publication of this rule (that is, the effective date as noted in the “DATES” section of this notice).