



Administrator

Washington, DC 20201

June 18, 2020

The Honorable Robert P. Casey, Jr.
United States Senate
Washington, DC 20510

Dear Senator Casey:

Thank you for your letters regarding the Trump Administration's efforts to safeguard the health and safety of nursing home residents. The Centers for Medicare & Medicaid Services (CMS) is committed to ensuring America's health care facilities and clinical laboratories are prepared to respond to the spread of the 2019 Novel Coronavirus (COVID-19), including—and especially at—nursing homes, where residents who are often medically frail and suffer from multiple comorbidities are especially susceptible to complications from this virus. I appreciate the opportunity to tell you about the important work that CMS is doing to protect some of our most vulnerable beneficiaries and other residents in nursing homes.

CMS's commitment to improving and protecting nursing home residents' health and safety has never been stronger, and this focus is not new. In 2019, I announced a five-part strategy for ensuring safety and quality in nursing homes. This strategy outlined the steps the agency has taken and plans to take to keep nursing home residents safe: strengthening oversight, enhancing enforcement, increasing transparency, improving quality, and putting patients over paperwork. This framework is our guide to making enhancements and improvements in how we ensure nursing home safety and quality.

Every Medicare participating facility in the nation's healthcare system must adhere to standards for infection prevention and control to provide safe, high quality care. Faced with the potential spread of COVID-19, CMS took quick action. A chart listing CMS' public health actions for nursing homes during this pandemic is attached to this response. On February 1, 2019, CMS updated surveyor instructions to ensure nursing homes include planning for infectious diseases—including emerging infectious diseases—in the all-hazards approach to their emergency preparedness programs.¹ On February 6, 2020, CMS reiterated this requirement and re-published additional information on infection control policies and practices in light of the emerging spread of COVID-19 for all healthcare facilities.² Facilities should be implementing these because the responsibility for keeping patients and residents safe begins with the nursing home itself.

¹ Emergency Preparedness – Updates to Appendix Z of the State Operations Manual (SOM). February 1, 2019.

Available at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO19-06-ALL.pdf>

² Information for Healthcare Facilities Concerning 2019 Novel Coronavirus Illness (2019-nCoV). February 6, 2020.

Available at: <https://www.cms.gov/files/document/qso-20-09-all.pdf>

We quickly followed this initial release by publishing new guidance on March 4 for health care providers across the country to use to ensure they are implementing infection control procedures, which they are required to maintain at all times.³ This guidance included critical answers to common questions about addressing cases of COVID-19 and was designed to improve facilities' infection control and prevention practices to prevent the transmission of COVID-19. This guidance included new information about screening staff and visitors with questions about recent travel, the process for transferring residents and patients between nursing homes and hospitals in cases when COVID-19 is suspected or diagnosed, and circumstances when providers should take precautionary measures (like isolation or use of respirators). On March 10 the agency issued guidance that expanded the types of respirators or facemasks that health care workers can use to protect themselves and their patients, and on March 13, CMS issued updated guidance on infection control and prevention of COVID-19 in nursing homes, and on.^{4,5} On March 23, CMS announced a targeted, streamlined survey process that surveyors will use to focus their work during this unprecedented pandemic.⁶

Going forward, we are also focused on increasing the availability of COVID-19 testing at nursing homes. We have called on state and local leaders to work with nursing homes to prioritize testing for these facilities. On April 2, we issued a set of recommendations to state and local leaders on nursing homes.⁷

And, on April 15, CMS announced an increase in the payment for certain lab tests that use high-throughput technologies to rapidly diagnose large numbers of COVID-19 cases.⁸ In addition, CMS has provided flexibilities to expand the availability of testing in community settings by making changes to how providers and laboratories can be paid for specimen collection.⁹ Medicare will pay for collection and travel when laboratories send trained technicians to collect a sample from a homebound beneficiary or a non-hospital inpatient for COVID-19 diagnostic testing. Now, practitioners can be paid for assessment and specimen collection for COVID-19 testing for all patients, not just established patients. This increased testing capability will be an important aspect of the surveillance activities that are part of the Opening Up America Again effort.

³ Guidance for Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in nursing homes. March 4, 2020. Available at: <https://www.cms.gov/files/document/qso-20-14-nh.pdf>

⁴ Guidance for Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in nursing homes (REVISED). March 9, 2020. Available at: <https://www.cms.gov/files/document/qso-20-14-nh-revised.pdf>

⁵ Guidance for use of Certain Industrial Respirators by Health Care Personnel. March 10, 2020. Available at: <https://www.cms.gov/files/document/qso-20-17-all.pdf>

⁶ Kirkland, Washington Update and Survey Prioritization Fact Sheet. March 23, 2020. Available at: <https://www.cms.gov/newsroom/fact-sheets/kirkland-washington-update-and-survey-prioritization-fact-sheet>

⁷ COVID-19 Long-Term Care Facility Guidance. April 2, 2020. Available at <https://www.cms.gov/files/document/4220-covid-19-long-term-care-facility-guidance.pdf>.

⁸ CMS Increases Medicare Payment for High-Production Coronavirus Lab Tests. April 15, 2020. Available at <https://www.cms.gov/newsroom/press-releases/cms-increases-medicare-payment-high-production-coronavirus-lab-tests-0>.

⁹ Laboratories: Medicare Flexibilities to Fight COVID-19. April 29, 2020. Available at <https://www.cms.gov/files/document/covid-19-laboratories.pdf>.

We are encouraged by the leadership of governors across America to innovate and implement solutions for nursing home quality and safety that work for their communities. In Maryland and Indiana, for example, the governor has created “strike teams” using the National Guard to help at overburdened nursing homes. We continue to see states take the lead with new initiatives to protect the vulnerable residents at their nursing homes. To make sure these innovations are shared nationwide, on May 13, CMS released a new toolkit developed to aid nursing homes, Governors, states, departments of health, and other agencies who provide oversight and assistance to these facilities, with additional resources to aid in the fight against the COVID-19 pandemic within nursing homes.¹⁰

While we continue to work with nursing homes and states, CMS is also focused on supporting residents and families. On April 19, we announced a critical new COVID-19 transparency effort to keep nursing home residents safe. These new regulatory requirements, which were included in an April 30 Interim Final Rule (CMS-5531 IFC), requires nursing homes to inform residents, their families and representatives of COVID-19 cases in their facilities. This measure augments longstanding reporting of infectious disease to State and local health departments. As mentioned earlier, CMS also now requires nursing homes to report cases of COVID-19 directly to the CDC. The information must be reported in accordance with existing privacy regulations and statute, and this data—on the numbers of COVID-19 cases and deaths—will be released publicly. On May 6, CMS released a memorandum to State Survey Agency directors with more details about this requirement.¹¹ For the first time, all 15,000 nursing homes will be reporting this data directly to the CDC through its reporting tool. This reporting requirement is the first action of its kind in the agency’s history.

Most recently, on June 1, CMS unveiled enhanced enforcement for nursing homes with violations of longstanding infection control practices. These enhanced and targeted accountability measures are based on early trends in the most recent data regarding incidence of COVID-19 in nursing homes, as well as data regarding the results of the agency’s targeted infection control inspections. CMS is increasing enforcement (e.g., civil money penalties (CMPs)) for facilities with persistent infection control violations, and imposing enforcement actions on lower level infection control deficiencies to ensure they are addressed with increased gravity. Also on June 1, CMS released information on COVID-19 cases and deaths in nursing homes as a result of a new requirement for nursing homes to report this data directly to the Centers for Disease Control and Prevention (CDC). On June 4, we published the underlying CDC-collected data at a link from Nursing Home Compare so the public can view general information of how COVID-19 has impacted nursing homes.

During this pandemic, we remain focused on keeping residents safe and holding nursing homes accountable. To this end, CMS has developed a three-pronged process of focused surveys. First, CMS will continue its responsiveness to Immediate Jeopardy situations (cases that represent a situation in which the provider’s noncompliance with federal requirements has caused or is likely to cause the health and safety of recipients in its care serious injury, serious harm, serious

¹⁰ Available at <https://www.cms.gov/files/document/covid-toolkit-states-mitigate-covid-19-nursing-homes.pdf>.

¹¹ Available at: <https://www.cms.gov/files/document/qso-20-29-nh.pdf>.

impairment or death); second, CMS developed a streamlined focused infection control survey tool based on our longstanding requirements and enhanced practices that facilities should be implementing to prevent the spread of COVID-19. We worked with the Centers for Disease Control and Prevention (CDC) to identify areas at risk of COVID-19 spread where surveyors are using the new focused survey tool to ensure providers are compliant with federal infection control requirements; third, CMS has adapted its focused survey to be used as a voluntary self-assessment tool so facilities can review their own compliance with federal infection control requirements. Quality Improvement Organizations have been calling nursing homes that have had a high number of infection control deficiencies to encourage these facilities to use the self-assessment tool and answer any questions they have about its use. This tool is available online, and CMS has encouraged nursing home residents and their families to ask their facilities if they have completed the self-assessment.

While focusing our surveys, we are working on multiple fronts to inform this effort by looking at facilities' past infection control history and proactively reaching out to facilities with our own clinicians and through Quality Improvement Organizations. Under CMS's focused survey process, only the following types of federal surveys will be prioritized and conducted:

- **Complaint surveys:** State Survey Agencies will continue to conduct surveys related to complaints and facility-reported incidents that are triaged at the Immediate Jeopardy level. These include allegations such as physical or sexual abuse, neglect, or other conditions that may create an imminent threat to the health and safety of patients and residents. In addition to investigating Immediate Jeopardy concerns, surveyors will also use the streamlined Infection Control review tool to evaluate infection control practices, regardless of the Immediate Jeopardy allegation.
- **Targeted Infection Control surveys:** Federal and state surveyors will conduct targeted infection control inspections of facilities identified through CMS collaboration with the CDC and ASPR. These surveyors will use the streamlined infection control review tool to minimize the impact on facility activities while ensuring facilities are implementing actions to protect health and safety. The goal of these surveys will be to provide a quick, focused assessment of a facility's infection control practices in those areas where such increased oversight will be most effective. Facilities will then receive immediate feedback to allow them to address any potential gaps or shortcomings.
- **Self-Assessments:** The Infection Control checklist will also be shared with facilities to allow for self-assessment of their Infection Control plans and practices. This may be the best solution for facilities to identify gaps in Infection Control practices, as well as areas for improvement.

During this time frame, because of the risk to surveyors and the ongoing stress being placed on the healthcare system by the COVID-19 pandemic, the following surveys will not be conducted:

- Standard surveys for nursing homes, hospitals, home health agencies, intermediate care facilities for individuals with intellectual disabilities, and hospices; and
- Revisit surveys not associated with Immediate Jeopardy.

Additionally, initial inspections will be conducted in accordance with current guidance and prioritization and remain authorized to increase health care capacity. Because revisit surveys to verify compliance with non-Immediate Jeopardy deficiencies will not be authorized during this time in order to focus on Immediate Jeopardy and infection control concerns, CMS is suspending current enforcement actions until revisits are authorized, including denials of payment for new admissions. Enforcement remedies associated with identified and unresolved Immediate Jeopardy, however, will continue.

As the spread of COVID-19 presents a unique threat to the nation's health care system, this is an extraordinary measure. However, because the number of needed facility surveys has been exceeding the limited capacity of state surveyors for the last several years, setting priorities for these activities is a regular part of our operations.¹² The Secretary's authority to establish the protocols for surveys of skilled nursing facilities and to revise their priority can be found in Section 1819 of the Social Security Act. CMS will be updating information regarding this guidance on our website.¹³

State survey agencies should refer to guidance from the CDC when working in facilities where there are confirmed or presumed cases of COVID-19.¹⁴ In line with the CDC's guidance, training of surveyors includes being medically cleared and appropriately fit-tested and trained in the proper use of respirators, including their safe removal and disposal, and medical contraindications to respirator use.¹⁵ State surveyors include health care professionals who are trained to work in medically sensitive environments, including on how to prevent the spread of infectious disease.

CMS's Infection Control review tool was developed in concert with the CDC and includes assessing whether a facility has adequate supplies of personal protective equipment (PPE). CMS is working with CDC and ASPR to communicate with facilities on what they should do in the event they experience shortages of PPE. For instance, facilities should notify their local public health department if a shortage is occurring. To help with this effort, CMS analyzed our staffing data and made this public through a memorandum issued to State Survey Agency directors on

¹² FY2020 Mission & Priority Document (MPD). December 11, 2019. Available at: <https://www.cms.gov/files/document/admin-info-20-03-all.pdf>

¹³ Coronavirus. Updates for State Surveyors and Accrediting Organizations. March 4, 2020. Available at: <https://www.cms.gov/medicare/quality-safety-oversight-general-information/coronavirus>

¹⁴ Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings. February 21, 2020. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>

¹⁵ Occupational Safety and Health Administration. Respiratory Protection eTool. Available at: https://www.osha.gov/SLTC/etools/respiratory/respirator_basics.html

April 24.¹⁶ This data was used by the Federal Emergency Management Agency (FEMA) for its effort to distribute PPE to nursing homes.

We also announced that, as part of CMS's ongoing coordination with CDC, we deployed an infection prevention specialist to CDC's Atlanta headquarters to assist with guidance development. While in Atlanta over several weeks, this CMS staff member participated in COVID-19 meetings, helped to identify key individuals needed for response across multiple agencies, and coordinated the sharing of information and documents between agencies. Expanding on this work, CMS and CDC are working together on a nursing home safety work group that continues to coordinate our efforts on this critical issue.

Regarding some of CMS's regulatory efforts from last year, particularly our requirements that nursing facilities employ an infection preventionist, while the current regulations require that facilities have an expert on staff "at least part time," we proposed to change this obligation to require "sufficient time." While the current regulations require that facilities have an expert on staff "at least part time," we proposed to change this obligation to require "sufficient time." A part-time infection preventionist may not be sufficient for many large facilities, but this "at least part time" requirement allows facilities to meet CMS' standards without putting in sufficient controls around infection control. Our proposed change would allow surveyors to ensure that nursing homes are appropriately addressing infection control issues with adequate staff and expertise based on the unique needs and environment of each facility. For example, requiring facilities to have the infection preventionist on staff for "sufficient time" may require a nursing home to employ several individuals, instead of the current requirement of just one part-time staff. This is just a proposal, and CMS continues to receive stakeholder feedback. Our goal will be to finalize requirements that strengthen infection control and hold nursing homes accountable for keeping residents safe.

CMS has continued to follow up with providers and facilities, including nursing homes, with additional guidance during the ongoing COVID-19 pandemic, and we conduct weekly calls with nursing homes to discuss new regulations and recommendations. These actions and others are focused on protecting American patients and residents by ensuring health care facilities have up-to-date information on how to respond to COVID-19 concerns. CMS also continues to release waivers for the healthcare community that provide the flexibilities needed to take care of patients during the COVID-19 public health emergency (PHE). We recently provided additional blanket waivers for the duration of the PHE that:

- Expand hospitals' ability to offer long-term care services ("swing beds");
- Waive distance requirements, market share, and bed requirements for Sole Community Hospitals;
- Waive certain eligibility requirements for Medicare-Dependent, Small Rural Hospitals (MDHs); and

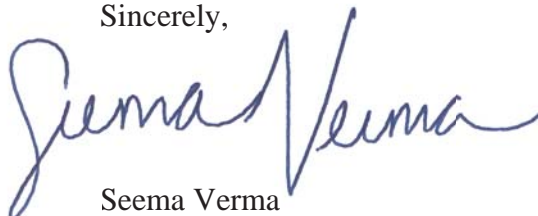
¹⁶ Available at: <https://www.cms.gov/files/document/qso-20-29-nh.pdf>.

- Update specific life safety code requirements for hospitals, hospice, and long-term care facilities.¹⁷

In addition, as a part of President Trump's Opening Up America Again effort, CMS has announced a new independent Commission that will conduct a comprehensive assessment of the nursing home response to the COVID-19 pandemic. The Commission will provide independent recommendations to the contractor to review and report to CMS to help inform immediate and future responses to COVID-19 in nursing homes. CMS has repeatedly taken early, unprecedented, aggressive and decisive action to protect nursing home residents during this pandemic. This action takes it one step further by asking that the independent Commission provide recommendations to further enhance efforts at the federal, state and local level, and help strengthen the nation's response to Coronavirus to keep residents safe in nursing homes.

We appreciate and share your concern for nursing home residents during the spread of COVID-19 and will keep you updated on CMS activities to keep our beneficiaries safe. If you have additional questions, please contact the CMS Office of Legislation. I will share this response with the co-signers of your letters.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Seema Verma', with a stylized flourish at the end.

Seema Verma

¹⁷ More information on these waivers is available at <https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf>.

Attachment A

CMS Public Health Action for Nursing Homes on COVID-19 as of June 4, 2020

| Date | Action |
|------------------|--|
| February 6, 2020 | <p>CMS took action to prepare the nation's healthcare facilities for the COVID-19 threat.</p> <p>https://www.cms.gov/newsroom/press-releases/cms-prepares-nations-healthcare-facilities-coronavirus-threat</p> |
| March 4, 2020 | <p>CMS issued new guidance related to the screening of entrants into nursing homes.</p> <p>https://www.cms.gov/newsroom/press-releases/cms-announces-actions-address-spread-coronavirus</p> |
| March 10, 2020 | <p>CMS issued guidance related to the use of personal protective equipment (PPE).</p> <p>https://www.cms.gov/newsroom/press-releases/covid-19-response-news-alert-cms-issues-key-protective-mask-guidance-healthcare-workers</p> |
| March 13, 2020 | <p>CMS issued guidance for a nationwide restriction on nonessential medical staff and all visitors.</p> <p>https://www.cms.gov/files/document/qso-20-14-nh-revised.pdf</p> |
| March 20, 2020 | <p>CMS announced a suspension of routine inspections, and an exclusive focus on immediate jeopardy situations and infection control inspections.</p> <p>https://www.cms.gov/files/document/qso-20-20-allpdf.pdf</p> |
| March 30, 2020 | <p>CMS announced that hospitals, laboratories, and other entities can perform tests for COVID-19 on people at home and in other community-based settings outside of the hospital – including nursing homes.</p> <p>https://www.cms.gov/newsroom/press-releases/trump-administration-makes-sweeping-regulatory-changes-help-us-healthcare-system-address-covid-19</p> |
| April 2, 2020 | <p>CMS issued a call to action for nursing homes and state and local governments reinforcing infection control responsibilities and urging leaders to work closely with nursing homes on access to testing and PPE.</p> <p>https://www.cms.gov/newsroom/press-releases/trump-administration-issues-key-recommendations-nursing-homes-state-and-local-governments</p> |
| April 15, 2020 | <p>CMS announced the agency will nearly double payment for certain lab tests that use high-throughput technologies to rapidly diagnose large numbers of COVID-19 cases.</p> <p>https://www.cms.gov/newsroom/press-releases/cms-increases-medicare-payment-high-production-coronavirus-lab-tests-0</p> |

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| April 19, 2020 | <p>CMS announced it will require nursing homes to report cases of COVID-19 to all residents and their families, as well as directly to the CDC. On April 30, 2020, CMS codified this guidance.</p> <p>https://www.cms.gov/newsroom/press-releases/trump-administration-announces-new-nursing-homes-covid-19-transparency-effort</p> <p>https://www.cms.gov/newsroom/press-releases/trump-administration-issues-second-round-sweeping-changes-support-us-healthcare-system-during-covid</p> |
| April 24, 2020 | <p>CMS published a memorandum that included our analysis of facility staffing data. This release also included a section of frequently asked questions about the agency's actions during the pandemic.</p> <p>https://www.cms.gov/files/document/qso-20-29-nh.pdf</p> |
| April 30, 2020 | <p>CMS awarded a contract which includes a new Commission to advise the contractor for reporting to CMS on addressing patient safety in safety and quality in nursing homes.</p> <p>https://www.cms.gov/newsroom/press-releases/cms-announces-independent-commission-address-safety-and-quality-nursing-homes</p> |
| May 6, 2020 | <p>CMS released a memorandum to State Survey Agency directors with more details on the reporting requirement announced on April 19.</p> <p>https://www.cms.gov/files/document/qso-20-29-nh.pdf</p> |
| May 13, 2020 | <p>CMS published a new toolkit comprised of recommendations and best practices from a variety of front line health care providers, governors' COVID-19 task forces, associations and other organizations and experts and is intended to serve as a catalogue of resources dedicated to addressing the specific challenges facing nursing homes as they combat COVID-19.</p> <p>https://www.cms.gov/files/document/covid-toolkit-states-mitigate-covid-19-nursing-homes.pdf</p> |
| May 18, 2020 | <p>CMS issued guidance for state and local officials on the reopening of nursing homes.</p> <p>https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfo/policy-and-memos-states-and/nursing-home-reopening-recommendations-state-and-local-officials</p> |
| June 1, 2020 | <p>CMS issued guidance to states on COVID-19 survey activities, CARES Act funding, enhanced enforcement for infection control deficiencies, and quality improvement activities in nursing homes. CMS also issued a letter to Governors.</p> <p>https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfo/policy-and-memos-states-and/covid-19-survey-activities-cares-act-funding-enhanced-enforcement-infection-control-deficiencies-and</p> <p>https://www.cms.gov/files/document/6120-letter-governors.pdf</p> |

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| June 4, 2020 | <p>CMS posted the first set of underlying COVID-19 nursing home data and results from targeted inspections conducted by the agency since March 4, 2020 linked on Nursing Home Compare.</p> <p>https://www.cms.gov/files/zip/nursing-home-infection-control-surveys.zip</p> |
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