



October 28, 2020

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-3401-IFC
PO Box 8016
Baltimore, Maryland 21244-8016

Dear Administrator Verma:

Thank you for the opportunity to comment on the interim final rule CMS-3401-IFC “Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Provisions in Response to the COVID-19 Public Health Emergency.”

We represent more than 5,000 aging-focused organizations that touch millions of lives every day. Alongside our members and 38 state partners, we address critical issues by blending applied research, advocacy, education, and community-building. We bring together the most inventive minds in our field to support older adults as they age wherever they call home. We make America a better place to grow old. The provisions of this IFR have a significant impact on the approximately 2,000 mission-driven nursing home providers that we serve since its implementation on September 2, 2020.

This virus has had a devastating effect on older adults, particularly those living in congregate care settings such as nursing homes. LeadingAge and its members are committed to providing high quality care in environments that preserve the health and well-being of the individuals living and working within them.

Since the outset of this public health emergency, LeadingAge has advocated for a fully federally-funded national testing strategy. We recognize the important and unparalleled role that testing plays in the mitigation of this virus. While the multiple systems that hold our nation together have suffered from the lack of a comprehensive, coordinated testing strategy, we appreciate the attention the long-term care field has received, including the allocation by the Administration of point-of-care testing devices and test cards to certified nursing homes throughout the country. However, the need far exceeds the supply, particularly with the implementation of the testing requirements outlined in this rule. Our concerns fall into 4 major categories, as outlined below.

Testing of Residents and Staff

Nursing homes are required to conduct 3 types of testing: testing of any residents or staff who show symptoms consistent with COVID-19, base-line and repeat testing of all residents and staff in response to an outbreak until the outbreak has been mitigated, and routine testing of all staff based on county positivity rates. Our members understand

the importance of all 3 categories of testing. However, we question if there is a more efficient way to utilize testing for the safety of residents and staff that addresses the significant barriers of the cost of testing, access to supplies and timely results, and staff resources required to meet testing and reporting requirements.

Under this rule, nursing homes are required to conduct routine testing of all staff at a frequency based on the county positivity rate. A nursing home with 150 employees in a county with a medium positivity rate (between 5 and 10%) will pay approximately \$3,750 for one week of tests if conducting point-of-care antigen testing. One week of PCR testing, if the nursing home was unable to access point-of-care tests or was prohibited from using these tests, would cost \$15,000. These staggering figures represent only the cost of tests. Additional costs include the cost of personal protective equipment and disinfection and sanitation supplies.

CDC [recommends](#) that staff wear an N95 respirator, eye protection, isolation gown, and gloves for specimen collection. Gloves must be changed between each specimen collection. Other PPE can be utilized under extended use practices provided the PPE does not become damaged or soiled. Hand hygiene must be performed between each specimen collection and disinfection of surfaces must be performed at least hourly and any time the area is visibly soiled. Terminal cleaning of specimen collection areas must be completed at the end of each day.

In our example above of a nursing home with 150 employees, one employee would need to collect the specimen, perform disinfection and hand hygiene, and change PPE every 2 minutes in order to complete all 150 tests in one shift. The required terminal clean is not included in this time calculation. In a best-case scenario, this would amount to a minimum of 150 pairs of gloves, plus hand sanitizer, and disinfecting wipes or spray. Any splashes, sprays, or other contact with bodily fluids would require additional PPE, hand hygiene, and disinfection supplies, as would sharing the burden of specimen collection among more than one staff member. This time estimate also does not include the time required for reporting point-of-care testing and all time spent conducting and reporting testing is time taken away from resident care and quality improvement activities.

We note that under this rule, nursing homes are required to perform routine testing of all staff, not simply the staff who have direct contact with residents. A staff member working in the billing office, who has absolutely no face-to-face contact with residents or with staff who provide direct care to residents, must be tested routinely (monthly, weekly, or bi-weekly). Similarly, if any staff member tests positive during routine testing, this triggers outbreak testing of all staff and residents, regardless of the level of contact or exposure between the index case and other staff and residents.

We urge CMS to work with public health partners at the Centers for Disease Control & Prevention (CDC) to re-evaluate requirements for routine staff testing and testing in response to an outbreak to determine if the burden of testing can

safely be reduced to direct scarce and costly testing resources to the most effective use. Specifically, we recommend evaluating the following:

- Utilizing pool testing methods for routine testing of all staff.
- Focusing routine staff testing on staff who have the greatest risk of exposure or transmission, such as those staff who have direct contact with residents.
- Targeting outbreak response testing first to those staff and residents who have the greatest risk of exposure or transmission, such as residents who live or staff who work on the unit where the index case or confirmed cases have been identified.

Testing of State and Federal Surveyors

On multiple occasions throughout the public health emergency, LeadingAge has engaged in conversation with CMS around the lack of testing of state and federal surveyors. CMS has stated that testing of surveyors was not required because surveyors posed a relatively low risk of transmission compared with other nursing home staff.

We note, as expressed in [this letter](#) to CMS Administrator Seema Verma in September 2020, that during the course of a routine survey, state and federal surveyors move about resident care areas, including between resident rooms. Surveyors spend time in close proximity to residents and staff conducting interviews and observing care such as wound care, medication administration, dining assistance, and observing testing for SARS-CoV-2. Further, like nursing home staff and visitors, surveyors are living in communities where positivity rates may climb over 10%. Surveyors are equally at risk for contracting the virus and carrying it into the nursing home in an asymptomatic or pre-symptomatic state as compared to nursing home staff. In a recent example provided by a nursing home member whose community had no cases of COVID, a surveyor who had been in a building with COVID infection the day before came into the member community and did not wear PPE while interviewing dietary staff. A few days later, a dietary staff member who had been interviewed tested positive, as did a resident. **We urge CMS to implement routine surveillance testing of federal and state surveyors.**

Reporting Requirements

Data collection is essential to learning more about this virus. As providers of care to one of the populations most vulnerable to serious illness from this virus, and a highly-regulated field, it is unsurprising that nursing homes are required to report various data related to COVID-19 infection. However, the volume of reporting now required of nursing homes creates unnecessary hurdles.

We appreciate the collaboration between CDC and HHS to create an opportunity for point-of-care testing data to be reported through NHSN, rather than through a separate state reporting platform. However, the October 19 requirement issued by HHS

potentially complicates reporting and increases burden. First, we expressed concern about potential duplicative reporting if states choose to continue requiring a separate reporting process. Both CMS and CDC expressed optimism that all states would accept the federal requirement and abandon state-level processes. We encourage CMS and CDC to continue collaboration with states on this issue.

Secondly, as we have expressed to both CDC and CMS, no CSV file template currently exists for the point-of-care test reporting tool. Without this CSV file, nursing homes must manually enter data for each individual into the system, rather than uploading a single data file. This is extremely time-consuming and because of the security level required to access this tool within the COVID-19 module, it is likely that only one or 2 individuals within a given organization would be able to input the data. This means that if point-of-care testing is conducted on a Saturday, the facility administrator is spending Sunday inputting data to the NHSN system. This requirement must be delayed until CDC has made a CSV file available for this reporting tool.

Additionally, we urge CMS to reconsider the timeline for required reporting of SARS-CoV-2 testing. Nursing homes are uniquely disadvantaged by this requirement in that, unlike a laboratory, processing and reporting on tests is not the primary role of this provider. For each test conducted, a minimum of 18 data elements must be reported. Were nursing homes conducting only diagnostic testing on staff or residents with symptoms consistent with COVID-19, this reporting might simply be another task of care. However, given the requirement to perform facility-wide testing in response to an outbreak, with repeated rounds of testing until all test negative, and routine testing of all staff based on county positivity rates, this reporting quickly becomes a problem.

Consider, again, the example of the nursing home with 150 employees. After expending the required resources including testing supplies, disinfection supplies, PPE, and staff time to complete one round of weekly routine staff testing, 2,700 data elements must now be reported. Even if it takes only 10 seconds to enter each data element, this requires 7.5 hours of staff time. Recalling that this data must be entered within 24 hours, that is one entire shift each week spent entering data that is not even used in positivity rate calculations. And should the nursing home have an outbreak, or be located in a county with high positivity rates that requires twice per week routine staff testing, this reporting becomes untenable. **We urge CMS to extend reporting deadlines to allow more than 24 hours in which to report COVID-19 testing data.**

Civil Monetary Penalties for Non-Reporting

HHS Secretary Alex Azar has said that “improving infection control in many nursing homes is not a matter of will but of skill.” LeadingAge agrees and has long advocated for CMS to take a less punitive, more collaborative approach to quality improvement. Enforcing civil monetary penalties (CMPs) for noncompliance, especially for paper noncompliance such as reporting, creates a direct barrier to quality of care.

We urge CMS to abandon the enforcement of civil monetary penalties for non-reporting. Nursing homes are penalized \$1,000 for every instance of noncompliance with requirements to report COVID data into NHSN, with an additional penalty increasing incrementally by \$500 for each subsequent week of noncompliance. CMPs of \$1,000 plus \$500 for each subsequent day of noncompliance are assessed for failure to report testing data. That \$1,000 could have been used to purchase approximately 50 point-of-care antigen tests; approximately 33 hours of registered nurse time. Surely, the nursing home can make better use of that money than the state CMP program.

LeadingAge appreciates your consideration of the recommendations above as we work toward the common goal of improving the lives of older adults living in nursing homes. Please do not hesitate to contact Jodi Eyigor jeyigor@leadingage.org with questions.

Sincerely,

A handwritten signature in black ink that reads "Jodi Eyigor". The signature is written in a cursive, flowing style.

Jodi Eyigor
Director, Nursing Home Quality & Policy