The National CONSUMER VOICE for Quality Long-Term Care formerly NCCNHR

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Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–3401–IFC
P.O. Box 8010
Baltimore, Maryland 21244

Re: 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

Submitted electronically: http://www.regulations.gov

Dear Administrator Verma:

The National Consumer Voice for Quality Long-Term Care (Consumer Voice) is a national non-profit organization that advocates on behalf of long-term care consumers across care settings. Our membership consists primarily of consumers of long-term care and services, their families, long-term care ombudsmen, individual advocates, and citizen advocacy groups. Consumer Voice has more than 40 years' experience advocating for quality nursing home care.

Consumer Voice supports routine testing of nursing home staff and the testing of all residents and staff during a COVID-19 outbreak in a facility. The new Interim Rule requiring facilities to implement a COVID-19 testing protocol under §483.80 Infection Control is crucial to help prevent 1) the introduction of COVID-19 into facilities by routinely testing nursing home staff and excluding staff members who test positive from facilities; and 2) the spread of COVID-19 within the facility after a staff member or resident tests positive. Testing for COVID-19 will save the lives of nursing home residents and staff, while also protecting the communities in which nursing home staff reside.

We commend CMS for publishing this important rule. At the same time, we believe that the rule must be strengthened to better ensure that it achieves its ultimate purpose of protecting nursing home residents.

Our detailed comments and recommendations are outlined below. New proposed language is indicated in bold, italicized font.

§ 483.80(h)(1)(iv) Criteria for testing of asymptomatic individuals; county positivity rate

Consumer Voice supports use of the positivity rate for the county in which the facility is located to determine the frequency of routine testing, but we are concerned that using the facility's county alone is not sufficient to protect residents. Until recently, and still in many states, the only individuals allowed in facilities were facility staff. Accordingly, infections introduced after the lockdown were most likely brought into facilities by staff. Not all staff live in the county in which a facility is located. Many staff could live in counties with high COVID-19 positivity rates, yet work in a facility in a county with a low positivity rate. Failing to account for this places residents at a higher risk of infection. Additionally, as CMS is well aware, many facility staff work in multiple facilities, some of which will be in different counties. For that reason, testing protocols must account for staff with multiple places of employment.

Moreover, while the rule leaves open the possibility of routine testing of asymptomatic residents, the accompanying guidance does not require it. Although routine testing of asymptomatic residents may not be necessary when the COVID-19 positivity rate in the surrounding counties is low, we are concerned that failing to test all residents when the positivity rate becomes high in either the county in which the facility is located or in counties where employees reside, could contribute to the spread of COVID-19 in facilities.

Routine testing of both residents and staff when the COVID-19 positivity rate in either the county in which the facility is located or in the counties where employees reside or work increases the likelihood that COVID-19 will be detected early, and that the facility will be able to take steps to prevent it from spreading further in the facility.

Recommendation:

Revise § 483.80(h)(1)(iv) to read:

> (iv) "The criteria for conducting testing asymptomatic individuals specified in this paragraph, such as the positivity rate ***of COVID-19 in the county in which the facility is located or the county or counties in which facility staff reside or are employed; and providing for the routine testing of all residents and facility staff when the COVID-19 positivity rate is high in the county in which the facility is located or in the county or counties in which facility staff reside or are employed."***

§ 483.80(h)(1)(v) Testing response time

To ensure COVID-19 outbreaks are prevented, the expediency of testing response time is a top priority. Facilities unable to conduct rapid response testing (point-of-care testing) must be required to have an arrangement with an outside laboratory that is able to process test results within 48 hours. Facilities that are unable to enter into an agreement with an outside laboratory due to supply shortages or testing process delays must document their efforts to obtain rapid response testing.

Recommendation:

Revise § 483.80(h)(1)(v) as follows:

(v) The response time for test results ***requiring:***

(A) Facilities unable to conduct rapid response (point-of-care testing) to have an agreement with an outside laboratory that is able to process test results within 48 hours;

(B) Facilities unable to enter into an agreement specified in (A) due to testing supply shortages or processing delays to document their efforts to enter into such agreement, and any other efforts, including, but not limited to, contacting state or local health departments; and

§ 483.80(h)(2) Testing Consistent with Current Standards of Practice

While Consumer Voice appreciates CMS requiring testing to be conducted in a manner that is consistent with current standards of practice, we believe this language lacks specificity. Our concern, in part, arises from the CMS-issued guidance accompanying the rule (CMS-3401-IFC, "the guidance"), in which the guidance states facilities may satisfy their testing obligations through the use of rapid point-of-care (POC) diagnostic testing. Allowing facilities to satisfy their testing obligation by only using POC antigen tests runs contrary to CDC guidance and places nursing home residents at risk.

The CDC has issued a significant amount of guidance on testing in nursing homes. In the guidance, the CDC notes that POC antigen tests are not as accurate as reverse-transcriptase polymerase chain reaction [RT-PCR], noting that some POC antigen tests are only 84% sensitive.[1] The CDC recommends that when a symptomatic resident tests negative for COVID-19 using an antigen test, the facility should immediately perform RT-PCR testing.[2] Additionally, the CDC notes that RT-PCR testing "might be needed prior to making clinical decisions" such as cohorting or excluding a staff member from the facility.[3]

The need to confirm negative tests in symptomatic residents is key to preventing harm to the resident and other residents in the facility. The guidance contradicts the CDC recommendation and is not "consistent with current standard of practice for conducting COVID-19 testing".

Recommendation:

Revise § 483.80(h)(2) as follows:

(2) Conduct testing ***in accordance with the Centers for Disease Control and Prevention's guidance for testing nursing home residents for COVID-19;***

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[1] https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html

[2] Id.

[3] Id.

§ 483.80(h)(4) Taking action to prevent the transmission of COVID-19

Consumer Voice urges CMS to include language from CDC guidance regarding the courses of action a facility must take when facility staff displays symptoms of COVID-19 or tests positive for COVID-19. First, CMS should mandate that individuals who test positive may not return to the facility until they meet the CDC "Criteria for Return to Work for Healthcare Personnel with SARS-CoV2 Infection" guidelines. However, symptomatic individuals who have tested negative for COVID are advised to follow facility guidelines for return to work. Allowing symptomatic staff who have tested negative only once for COVID-19 to return to work without another COVID-19 test raises the risk of transmission to residents and other staff. This policy is particularly problematic since antigen tests produce false negatives, sometimes at a rate of 16%. Instead, CMS should direct facilities to follow CDC guidance, which states that health care staff who display symptoms of COVID-19 but test negative using antigen testing, should immediately undergo RT-PCR testing.[4] Accordingly, symptomatic staff should be required to be tested a second time with RT-PCR testing, along with being symptom-free, before returning to work.

Recommendation:

Revise § 483.80(h)(4) by adding:

(4) Upon the identification of an individual specified in this paragraph with symptoms consistent with COVID-19, or who tests positive for COVID-19, take actions to prevent the transmission of COVID-19 ***including, but not limited to, excluding:***

(i) All facility staff who test positive for COVID-19 until they meet the criteria for returning to work established by the Centers for Disease Control and Prevention;

(ii) All facility staff who display symptoms of COVID-19 but initially tested negative until they:

a. Undergo repeat COVID-19 testing using reverse-transcriptase polymerase chain reaction testing to confirm the negative result or follow the most recent CDC guidance; and

b. are free of symptoms.

§ 483.80(h) Facility Staff Testing

Consumer Voice commends CMS for requiring all facility staff to be routinely tested and for defining facility staff broadly. However, we are concerned that some individuals who fall under "facility staff" may, without a facility's knowledge, pose a risk to residents and staff. For instance, an individual providing services under arrangement may not return to the facility for a very long time, if ever. Yet this individual could conceivably test positive for COVID-19 following his/her visit. It is also possible that this individual had COVID-19 during his/her time in the facility. But unless the individual notifies the facility, the latter may never know of this positive

[4] Id.

result. As a result, the facility will not be able to take appropriate measures to guard against the potential spread of infection in the facility.

To ensure the safety of residents and staff, facilities must be required to enter into agreements with all staff not directly employed by the facility who test positive for COVID-19 within at least two weeks[5] of his or her visit to the facility to notify the facility of this positive test.

Recommendation:

Revise § 483.80(h) to add a new section (5) as follows:

> ***(5) Have agreements with all facility staff not directly employed by the facility who test positive for COVID-19 within 14 days of their last visit to the facility to notify the facility of the positive result.***

§ 483.80(h)(5) Procedures for addressing residents and facility staff that refuse testing

Because the interventions necessary to address the refusal by a resident to be tested differ from when facility staff refuse testing, these issues should be addressed separately in the rule. We suggest addressing procedures for staff in a new number (6), and residents in a new number (7).

For staff: Although CMS provides guidance about actions related to staff, we find parts of it problematic. Facility staff who refuse testing, whether it is routine or outbreak testing, must be excluded from the facility until they undergo testing. It is not sufficient that staff only be excluded until outbreak testing is completed, or to require facilities to follow local health policies when staff refuse routine testing. Similarly, staff who are unable to be tested should also be excluded. Allowing staff to forgo testing of any kind for any reason undermines the entire testing protocol and places residents at risk. While we encourage facilities to take steps to retrain and/or address a staff member's concern or health need, these measures are not sufficient.

Recommendation:

Renumber current § 483.80(h)(5) as (h)(6) and revise as follows:

> (~~5~~)***(6)*** Have procedures ***that exclude all facility staff who refuse COVID-19 testing or who are unable to be tested from the facility until the facility staff agrees to be tested and the results are negative.***

For residents: We are concerned that the rule does not mandate that facilities engage with residents who refuse testing. Residents may be apprehensive because of the type of testing

[5] CDC guidance notes it can take 2-14 days for symptoms of COVID-19 to appear after becoming infected. https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html#:~:text=Symptoms%20may%20appear%202%2D,exposure%20to%20the%20virus.

(fearing that it will hurt or be too invasive) or may fear how they will be treated should they test positive. They may also not know the consequences of refusing.

It is certainly a resident's right to refuse testing. However, the rule must be clear about the steps a facility must take when a resident refuses testing because there is frequently an underlying reason for such refusal. Facilities should be required to speak with the resident to 1) educate the resident about the importance of testing, 2) hear his or her concerns and attempt to ascertain why the resident is refusing, 3) explain the consequences/risks of refusing testing, and 4) present alternatives. Facilities should be required to document these discussions with residents.

This need for specific requirements is highlighted by the accompanying guidance, which is contradictory. On the one hand, the guidance states that a facility should be "extremely vigilant" when a resident refuses testing, but two paragraphs later, the guidance prescribes transmission-based precautions for the same scenario. For uniformity of practice, CMS should prescribe a course of action consistent with guidance from the CDC.

Finally, it is unclear under what circumstances a resident would be "unable to be tested." It appears that CMS may be conflating consent to be tested with ability to be tested. If there is a true distinction, we urge CMS to identify situations when a resident could not be tested. If not, we recommend eliminating this language to avoid confusion.

Recommendation:

Revise § 483.80(h) by inserting a new section (7):

> ***(7) Have procedures for addressing residents who refuse testing, including,***
> ***i) Educating the resident about the importance of being tested;***
> ***ii) Engaging with the resident to learn why he or she is refusing testing;***
> ***iii) Discussing and presenting alternative methods of testing;***
> ***iv) Explaining the consequences and risks of not being tested;***
> ***v) Documenting the discussion in the resident's record; and***
> ***vi) Following CDC guidance for residents who refuse COVID-19 testing.***

§ 483.80(h) Notification of family members and/or resident representatives when a resident tests positive.

Although CMS has promulgated rules requiring facilities to notify families and resident representatives when there is a new COVID-19 case in a facility, CMS does not mandate that facilities notify these individuals when a resident tests positive for COVID-19. While facilities should do this under *§483.10(g)(14) Notification of Changes. (i) A facility must immediately inform the resident; consult with the resident's physician; and notify, consistent with his or her authority, the resident representative(s) when there is— (B) A significant change in the resident's physical, mental, or psychosocial status (that is, a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications*), this is not always the case. Too often during the pandemic, we have heard from families who were not

informed that their loved ones tested positive for COVID-19 – sometimes not learning until the resident was in the hospital or had died.

It is not acceptable that a resident's family and/or representative is not provided with such critical information. Unless the resident indicates otherwise, CMS should require facilities to notify families/representatives when the resident tests positive.

Recommendation:

Amend § 483.80(h) by inserting a new section:

> ***(8) Have procedures for the notification of a resident's representative, consistent with his or her authority, when a resident tests positive for COVID-19, unless the resident prohibits notification. Notification should occur immediately, but no later than within twenty-four (24) hours.***

§ 488.447 Civil Monetary Penalties for failure to comply with 42 C.F.R. § 483.80(g)(1)

We strongly support the assessment of civil monetary penalties for a facility's failure to properly report data in compliance with § 483.80(g)(1) and (2). This data is essential to CMS, state and local health officials, and families so that they may gauge the status of COVID-19 in a particular facility and act accordingly. CMS and state and local health officials must be made aware of facilities with COVID-19 outbreaks as well as facilities experiencing staff or supply shortages.

Because this information is essential for the protection of nursing home residents, the civil monetary penalty should be mandatory.

Recommendation:

Amend § 488.447(a) to read:

> (a) CMS ***shall*** impose a civil monetary penalty for noncompliance with the requirements at § 483.80(g)(1) and (2) of this chapter as follows.

Consumer Voice thanks CMS for its consideration of these comments.

Sincerely,

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