

July 7, 2020

Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-5531-IFC  
P.O. Box 8010  
Baltimore, Maryland 21244

**Re: Medicare and Medicaid Programs, Basic Health Program, and Exchanges;  
Additional Policy and Regulatory Revisions in Response to the COVID-19  
Public Health Emergency and Delay of Certain Reporting Requirements for the  
Skilled Nursing Facility Quality Reporting Program  
CMS-5531-IFC**

**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. Consumer Voice's 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 of experience advocating for quality nursing home care.

California Advocates for Nursing Home Reform (CANHR) is a statewide non-profit organization dedicated to improving the choices, care, and quality of life for California's long-term care consumers since 1983. CANHR's goal is to educate and support long term care consumers and advocates regarding rights and remedies under the law, and to create a united voice for long term care reform and humane alternatives to institutionalization.

Consumer Voice and CANHR support the collection of COVID-19 data in nursing facilities and appreciates the time and effort that CMS has spent crafting this rule. The new Interim Final Rule requiring facilities to report COVID-19 data under §483.80 Infection control is critically important. The data will permit facilities, and local, state, and national officials to monitor the spread of COVID-19, identify the best interventions, and determine where resources and assistance are needed. In addition, it will allow nursing home residents, their representatives and families, staff, and the public to know the status of COVID-19 in any Medicare and/or Medicaid funded facility. Residents and staff need to have this information because it directly impacts the place where they live or work. The data also enables both current and prospective residents and families to make informed decisions regarding their options for care.

*The National Consumer Voice for Quality Long-Term Care (formerly NCCNHR) is a 501(c)(3) nonprofit membership organization founded in 1975 by Elma L. Holder that advocates for quality care and quality of life for consumers in all long-term-care settings.*

We commend CMS for publishing this important rule and including many essential provisions. At the same time, we believe the rule should be strengthened to address gaps in reporting requirements that make it difficult to gain a true picture of what is happening within facilities.

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

#### **§483.80 Infection control**

##### **§483.80 (g)(1) COVID-19 Reporting**

We appreciate that CMS is requiring mandatory reporting on a standardized format so the data will be uniform and easy to compare from facility to facility. We are also pleased that CMS is seeking a range of information, and glad to see that the number of total deaths is required as well as COVID-19 deaths. The total number of deaths is essential if we are to truly understand what happened in facilities during the pandemic.

However, to get a more in-depth, comprehensive understanding of the extent and impact of COVID-19 on nursing home residents, we urge CMS to require that the following also be reported for residents and staff:

- Race, ethnicity, sex, age, disability status, primary language, sexual orientation, gender identity, socio-economic status, urban/rural locations.

We believe that demographic characteristics contribute to disparities in COVID-19 infections and deaths. For instance, it has become clear that COVID-19 is having a disproportionate impact on communities of color. A study from Yale found that black people were 3.5 times more likely to die from COVID-19 when compared with the white population.<sup>1</sup> A recent *New York Times* article reports that homes with a significant portion of minority residents, regardless of their geographic location, were 2 times more likely to be hit by COVID-19 than homes made up mostly of white residents.<sup>2</sup>

Tracking demographic data, if obtained in a way consistent with residents' rights and privacy, for those who have been infected or hospitalized, or who have recovered or died from COVID-19 helps identify groups that may have a higher likelihood of getting sick and experiencing severe illness from COVID-19 as the pandemic progresses. It can help state, tribal and local agencies, health systems, hospitals, and health care providers invest in and direct resources to provide access to testing, health care, and social services for diverse populations with different needs. Finally, it can help policymakers prioritize and distribute resources based on anticipated need.<sup>3</sup>

- Number of hospitalizations. Reports of age and disability discrimination in care have been made during the pandemic. Collecting the number of hospitalizations, in addition

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<sup>1</sup> <https://www.medrxiv.org/content/10.1101/2020.05.07.20094250v1.full.pdf>

<sup>2</sup> <https://www.nytimes.com/article/coronavirus-nursing-homes-racial-disparity.html>

<sup>3</sup> COVID-19 Demographic Data Sign-on Letter to Congressional Leaders. May 4, 2020.

to demographic data of individuals sent to the hospital, would assist in determining if this is a problem, and if so, the extent of the problem.

- Number of residents and staff who have recovered from COVID-19. Recovery data can help us gain a better understanding of what factors contribute to survival.

Further clarity is needed in other areas as well. Because there is no definition of “suspected” cases in the rule, we request that CMS define “suspected” infections of COVID-19 using the definition provided in the National Health Safety Network (NHSN) system, Instructions for Completion of the COVID-19 Long-term Care Facility Resident Impact and Facility Capacity Form (CDC 57.114.0). We also ask that the regulations specifically state that deaths of residents who have been transferred to the hospital or elsewhere be reported. We acknowledge and are glad that CMS addressed the inclusion of deaths occurring outside the facility in its May 6, 2020 FAQs (question 11). However, we are hearing that some facilities continue to omit those deaths in their reporting.

**Recommendation:**

Revise (g)(1)(i)-(ii) as follows:

- (i) Suspected ***infections of COVID-19, defined as any resident or staff with signs and symptoms suggestive of COVID-19 as described by CDC’s guidance***, and confirmed COVID– 19 infections among residents and staff, ~~including residents previously treated for COVID–19;~~
- (ii) ***Recovered COVID-19 cases among residents and staff;***
- (iii) ***Hospitalizations of residents and staff;***
- (iv) Total deaths ***including deaths occurring at the hospital or other outside location*** and COVID–19 deaths among residents and staff;
- (v) ***For (i) (ii) (iii) and (iv) aggregate data for race, ethnicity, sex, age, gender, disability status, primary language, sexual orientation, gender identity, socio-economic status, and urban/rural locations must also be reported.***

**§483.80 (g)(1) (iii) Personal Protective Equipment and Hand Hygiene Supplies**

We are concerned about the lack of specificity regarding the types of personal protective equipment (PPE) a facility is using. The regulation should identify PPE as including N95 masks, surgical masks, eye protection, and gloves. These items correspond to what facilities must report in the NHSN.

**Recommendation:**

Add the following language:

- (vi) Personal protective equipment, ***including N95 masks, surgical masks, eye protection, and gloves***, and hand hygiene supplies in the facility.

**§483.80 (g)(1) (vi) Access to Testing**

We are pleased that CMS is requiring facilities to report information pertaining to testing. However, the language, “access to testing” is overly broad and unclear. It could, for instance,

mean a testing facility open in the neighborhood. Also, a facility could technically have access to testing, but not be testing. Furthermore, “access to testing” does not provide sufficient information. It does not indicate the frequency of testing or whether facilities are paying for the tests or passing the costs along to staff and/or residents. Finally, the requirement should, but does not, apply to staff.

**Recommendation:**

Revise as follows:

- (vii) Access to COVID-19 testing while the resident is in the facility ***including:***
  - (a) How many residents have been tested?***
  - (b) How many staff members have been tested?***
  - (c) Percentage of total residents tested.***
  - (d) Percentage of total staff tested.***
  - (e) Frequency of resident testing.***
  - (f) Frequency of staff testing.***
  - (g) Number of available tests.***
  - (h) Whether the facility pays for the testing.***

**§483.80 (g)(1) (vii) Staffing Shortages**

We thank CMS for requiring that staffing information be reported to the CDC. However, we are concerned about use of the term “staffing shortages.” Although the NHSN instructions discuss what is meant by staffing shortages, the Interim Final Rule does not include a definition. The NHSN definition should be spelled out in the rule.

Moreover, because there is currently no federal requirement for minimum staffing standards, it is difficult for facilities to determine that they are short staffed unless they are egregiously so. Requiring facilities to provide daily staffing levels by shift would address this issue. We note that facilities are already mandated to post this information inside the facility.

Additionally, the requirement about staffing fails to indicate who is included in the term “staff.” Once again, this information is included in the NHSN instructions, but not in the rule. We recommend that the list of staff used in the NHSN be incorporated into the Interim Final Rule.

Finally, due to a waiver of certain nurse aide requirements, there are now individuals employed as nursing assistants who have not met training and certification requirements. To understand the extent to which facilities are using these temporary nursing assistants, facilities should be required to report the number of this new type of employee.

**Recommendation:**

Add the following language:

- (viii) ***Staffing.***
  - (a) For the purposes of this rule, staffing is considered to be:***
    - ***Nursing Staff: registered nurse, licensed practical nurse, or vocational nurse.***
    - ***Clinical Staff: physician, physician assistant, or advanced practice nurse.***
    - ***Aide: certified nursing assistant, nurse aide, medication aide, or medication***

*technician.*

- ***Other staff or facility personnel: that are not included in the above categories, regardless of clinical responsibility or resident contact. These personnel may include, but are not limited to, environmental services, cook, dietary, pharmacists, pharmacy techs, activities director, care givers, wound care, physical therapy, shared staff, etc.***

***(b) Daily nurse staffing levels by shift (as required under 42 C.F.R. 483.35(g)(iii)).***

***(c) Number of temporary nursing assistants.***

***(d) Staffing shortages. A staffing shortage is determined by the facility based on its needs and internal policies for staffing ratios.***

#### **§483.80 (g)(2) Providing Information to the CDC and posting publicly**

We strongly support the public posting of COVID-related data; public availability of this information is long overdue. However, because we are in the midst of a public health emergency, and this data can change so rapidly, we urge CMS to require daily, rather than weekly, reporting as well as posting. CDC itself recommends daily reporting; its NHSN instructions state: ... “daily reporting will provide the timeliest data to assist with COVID-19 emergency response efforts....”

Facility reporting of this information should not be limited to CDC. Other agencies and programs require data to assist in their response as well. These include the state survey agency, CMS, the State Long-Term Care Ombudsman Program, and the Protection and Advocacy Agency. Equally important, this information should be provided to residents, their representatives and families, and staff because residents and staff are the most at risk. This information also permits residents and families to make informed decisions regarding their options for care. Residents, their representatives, family members, and staff should not be forced to search through CMS data to determine the status of COVID-19 in their facility.

Finally, we are very concerned that the rule does not require retroactive reporting back to January 1, 2020. Currently some facilities are reporting back to January 1, 2020, while others are reporting beginning in May 2020. This creates inaccurate, unreliable, unclear data that is difficult to analyze. All facilities should be required to submit weekly reports from May 2020 back to January 1, 2020 to ensure consistency within the data and to get a true picture of COVID-19’s impact on nursing facilities.

#### **Recommendation:**

Revise the language as follows:

(2) Provide the information specified in paragraph (g)(1):

(i) ***Daily*** to the Centers for Disease Control and Prevention’s National Healthcare Safety Network, ***the state survey agency, CMS, the State Long-Term Care Ombudsman Program, the Protection and Advocacy Agency, residents, their representatives and families, and staff.***

(ii) ***Weekly for the period from January 1, 2020-May 8, 2020.***

(iii) The information in (i) and (ii) must be posted publicly by CMS ***daily on the Nursing Home Compare website or any subsequent version of Nursing Home Compare*** to support protecting the health and safety of residents, personnel, and the public.

### **§483.80 (g)(3) Informing Residents, their Representatives, and their Families**

We thank CMS for requiring that facilities provide certain information about COVID-19 to residents, their representatives, and their families. In many situations, residents are confined to their rooms and are not able to fully assess the situation in their facility. They are therefore dependent on the facility to relay this information to them. At the same time, most families no longer have direct access to facility staff and administration, so they, too, rely more than ever on facilities for information. We have heard of many cases in which family members were in agony because the facility would not tell them if there were COVID-19 cases in the building. Staff, too, should know when there are new or possible cases of the virus.

However, as written, the language in (g)(3) and (g)(3)(iii) is very confusing. The time frames for notification are difficult to understand, and the concept of three or more residents or staff with new onset of respiratory symptoms occurring within 72 hours of each other is unnecessarily complex. Furthermore, the new onset symptoms should not be limited to respiratory symptoms since the list of symptoms identified by CDC has changed. We recommend that CMS simplify the language in (g)(3) by mandating that residents, their representatives, their families, and staff be informed about suspected cases, rather than a certain number of people with new onset of respiratory symptoms.

But residents, their representatives, their families, and staff want and need to know more than the number of suspected and confirmed cases. In fact, they are concerned about all the information that facilities must report in (g)(1). Since this information is public, there is no reason why the facility should not provide it to these individuals. They should not have to search for it on a cumbersome dataset online.

To that end, we suggest that with one exception, the same information that facilities report to the CDC be reported to residents, their representatives, families, and staff. This would reduce provider burden. The one difference would be that residents, their representatives, their families, and staff would also be informed about mitigation actions.

To simplify the delivery of this data, we propose that a standardized form be created. This would ensure that information is provided in a uniform, consistent manner. Finally, by requiring daily dissemination of this form, residents, their representatives, their families, and staff will learn about both new and cumulative cases.

#### **Recommendation:**

Revise as follows:

(g)(3) Inform residents, their representatives, families of those residing in facilities, **and staff daily, on a standardized form specified by the Secretary, of the following:**

- (i) Suspected infections of COVID-19, defined as any resident or staff with signs and symptoms suggestive of COVID-19 as described by CDC's guidance, and confirmed COVID-19 infections among residents and staff;**
- (ii) Recovered COVID-19 cases among residents and staff;**
- (iii) Hospitalizations of residents and staff;**
- (iv) Total deaths including death occurring at the hospital or other outside location and COVID-19 deaths among residents and staff;**

- (v) *For (i) (ii) (iii) and (iv) aggregate data for race, ethnicity, sex, age, gender, disability status, primary language, sexual orientation, gender identity, socio-economic status, and urban/rural locations must also be reported;*
- (vi) *Personal protective equipment, including N95 masks, surgical masks, eye protection, and gloves, and hand hygiene supplies in the facility;*
- (vii) *Access to COVID-19 testing while the resident is in the facility, including:*
- a. *How many residents have been tested?*
  - b. *How many staff members have been tested?*
  - c. *Percentage of total residents tested.*
  - d. *Percentage of total staff tested.*
  - e. *Frequency of resident testing.*
  - f. *Frequency of staff testing.*
  - g. *Number of available tests.*
  - h. *Whether the facility pays for testing.*
- (viii) *Staffing.*
- a. *For the purposes of this rule, staffing is considered to be:*
    - *Nursing Staff: registered nurse, licensed practical nurse, or vocational nurse.*
    - *Clinical Staff: physician, physician assistant, or advanced practice nurse.*
    - *Aide: certified nursing assistant, nurse aide, medication aide, or medication technician.*
    - *Other staff or facility personnel: that are not included in the above categories, regardless of clinical responsibility or resident contact. These personnel may include, but are not limited to, environmental services, cook, dietary, pharmacists, pharmacy techs, activities director, care givers, wound care, physical therapy, shared staff, etc.*
  - b. *Daily nurse staffing levels by shift (as required under 42 C.F.R. 483.35(g)(iii)).*
  - c. *Number of temporary nursing assistants.*
  - d. *Staffing shortages. A staffing shortage is determined by the facility based on its needs and internal policies for staffing ratios.*
- (ix) *Mitigating actions implemented to prevent or reduce the risk of transmission, including if normal operations of the facility will be altered.*

#### **§483.80 (g)(4) Method for Providing Information to Families**

We are concerned that the rule does not lay out requirements regarding the method of providing information to residents, their representatives and families, and staff in **§483.80 (g)(1)&(3)**. We agree with the language set forth in QSO-10-29-NH.

F885: COVID-19 Reporting to Residents, their Representatives, and Families “...We note that there are a variety of ways that facilities can meet this requirement, such as informing families and representatives through email listservs, website postings, paper notification, and/or recorded telephone messages. We do not expect facilities to make individual telephone calls to each resident’s family or responsible party to inform them that a resident in the facility has laboratory-confirmed COVID-19. However, we expect

facilities to take reasonable efforts to make it easy for residents, their representatives, and families to obtain the information facilities are required to provide.”

We recommend that a modified version of this language be included in regulatory language.

**Recommendation:**

Include the following new language:

***(g)(4) The facility must make all reasonable efforts to ensure that it is easy for residents, their representatives and families, and staff to obtain this information. Information should be provided to residents orally and in writing. Methods to provide information to resident representatives, families, and staff may include email listserv, website postings, paper notifications, and/or recorded telephone messages. This information must also be posted inside the facility and at facility entrances.***

**§483.80 (g)(5) Informing the General Public**

We thank CMS for requiring that the data in (g)(1) be posted publicly online. Since the agency’s stated goal (see (g)(2)) of this posting is to support the health and safety of the general public along with others, we urge CMS to make it easier for the public to obtain this data. Facilities should provide this information in writing or orally to anyone upon request. Prospective residents and families should receive COVID-19 information when they call or email facilities to help them make an informed decision about where they, or their loved one, should live. Additionally, because this information is public information, facilities should make it available to reporters or any member of the community that contacts them with questions about their COVID-19 status.

**Recommendation:**

Include the following new language in the regulation:

***(g)(5) Inform members of the public, upon request, of***

- (i) Suspected infections of COVID-19, defined as any resident or staff with signs and symptoms suggestive of COVID-19 as described by CDC’s guidance, and confirmed COVID-19 infections among residents and staff;***
- (ii) Recovered COVID-19 cases among residents and staff;***
- (iii) Hospitalizations of residents and staff;***
- (iv) Total deaths including death occurring at the hospital or other outside location and COVID–19 deaths among residents and staff;***
- (v) For (i) (ii) (iii) and (iv) aggregate data for race, ethnicity, age, gender, disability status, and urban/rural locations must also be reported;***
- (vi) Personal protective equipment, including N95 masks, surgical masks, eye protection, and gloves, and hand hygiene supplies in the facility;***
- (vii) Access to COVID-19 testing while the resident is in the facility, including:***
  - a. How many residents have been tested?***
  - b. How many staff members have been tested?***
  - c. Percentage of total residents tested.***
  - d. Percentage of total staff tested.***
  - e. Frequency of resident testing.***
  - f. Frequency of staff testing.***
  - g. Number of available tests.***



*h. Whether the facility pays for testing.*

*(viii) Staffing.*

*a. For the purposes of this rule, staffing is considered to be:*

- Nursing Staff: registered nurse, licensed practical nurse, or vocational nurse.*
- Clinical Staff: physician, physician assistant, or advanced practice nurse.*
- Aide: certified nursing assistant, nurse aide, medication aide, or medication technician.*
- Other staff or facility personnel: that are not included in the above categories, regardless of clinical responsibility or resident contact. These personnel may include, but are not limited to, environmental services, cook, dietary, pharmacists, pharmacy techs, activities director, care givers, wound care, physical therapy, shared staff, etc.*

*b. Daily nurse staffing levels by shift (as required under 42 C.F.R. 483.35(g)(iii)).*

*c. Number of temporary nursing assistants.*

*d. Staffing shortages. A staffing shortage is determined by the facility based on its needs and internal policies for staffing ratios.*

#### **§483.80 (g)(6) Penalty for Failure to Report**

We appreciate that in **F884: COVID-19 Reporting to CDC**, CMS lays out a penalty for a facility's failure to report this data to the CDC. However, we believe the penalty needs to be strengthened and expanded to include failure to report to residents, their representatives and families, and staff.

#### **§483.80 (g)(7) Reporting Requirements for Other Settings**

We strongly support expanding the reporting requirements to other institutional and congregate settings. People with disabilities and older adults in these facilities are also at serious risk related to COVID-19. As noted in a letter from the Consortium of Citizens with Disabilities (CCD), there have been similar outbreaks and deaths in Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF-IIDs), including in Illinois (where the outbreak has been so significant that the National Guard has been called in), Massachusetts (where nearly half of the residents in a state- operated ICF are infected), Utah, Texas, and New Jersey; Institutions for Mental Disease (IMDs) and other psychiatric and substance use disorder treatment facilities, including in Washington state, District of Columbia, and New York; and in group homes across the country, including across New York, Maryland, and New Jersey. We urge CMS to extend these same requirements to all institutional settings -- including ICF-IIDs, IMDs, substance use disorder treatment facilities, and psychiatric residential treatment facilities -- and other Medicaid-funded congregate settings where older adults and people with disabilities live, including group homes and assisted living facilities. The need for transparency, information and data collection is equally as critical to protecting the safety and welfare of people in these settings as they are for residents of nursing facilities.<sup>4</sup>

Consumer Voice and CANHR thank CMS for its consideration of these comments.

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<sup>4</sup> Letter from the Consortium for Citizens With Disabilities to Secretary Azar, HHS; Administrator Verma, CMS; and Director Redfield, CDC. April 21, 2020.

Sincerely,

The National Consumer Voice for Quality Long-Term Care  
California Advocates for Nursing Home Reform