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July 6, 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:

Disability Rights California (DRC) submits this letter in response to the Centers for Medicare & Medicaid Service's (CMS) Notice of Proposed Rulemaking (proposed rule) to express support in part, and to offer constructive suggestions that promote and improve the principle aspiration of the rule. DRC is California's designated Protection & Advocacy agency and an independent, private, nonprofit, federally funded disability rights organization. We are the largest disability rights group in the nation, established under federal law to protect and advocate for the rights of people with disabilities. In the state of California, DRC has helped hundreds of thousands of people through our litigation, policy work, trainings, and publications. Particularly, DRC is firmly committed to the advancement of

quality nursing home care across our state, and we strongly encourage effective oversight, transparency, and communication.

DRC supports the collection of COVID-19 data in nursing facilities, and we appreciate the work that CMS has spent crafting this rule. The new Interim Final Rule that requires facilities to report COVID-19 data under §483.80 Infection control is critically important. The data will permit facilities, as well as 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 our state, as across the nation, we have an urgent need for data collection under §483.80. Undoubtably, COVID-19 has had a dramatically disproportionate impact on nursing home residents. In California, more than forty (40) percent of COVID-19 related deaths are estimated to come from nursing facilities, which are currently being operated with significantly less oversight.¹

At a time when the federal government has halted non-emergency state inspections to limit the spread of the virus,² data collection has never been more important to maintain the critical monitoring and supervision of these facilities. Among the 1,223 skilled nursing facilities in California, there have been 13,538 positive cases and 2,480 deaths as of June 30, 2020.³

As a result of these circumstances, vulnerable communities are effectively cut-off from the advocates assigned to protect them,⁴ and it is essential that both patients and their families have the necessary data to make informed decisions regarding their care.

While we commend CMS for publishing this important rule, DRC recommends that it be strengthened to address gaps in reporting and monitoring requirements. DRC's detailed comments and recommendations

¹ Jocelyn Wiener, *Who's watching now? COVID-19 cases swell in nursing homes with poor track records*, CALMATTERS (June, 15, 2020), <https://calmatters.org/health/coronavirus/2020/06/nursing-homes-coronavirus-deaths-infections-inspections-violations-kingston-california/>.

² *Updates for State Surveyors and Accrediting Organizations*, CENTER FOR MEDICARE AND MEDICAID SERVICES May, 1 2020, 2:15pm), <https://www.cms.gov/medicare/quality-safety-oversight-general-information/coronavirus>.

³ *Skilled Nursing Facilities: COVID-19*, CALIFORNIA DEPARTMENT OF PUBLIC HEALTH (June, 9 2020), https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/SNFsCOVID_19.aspx.

⁴ Wiener, *supra* note 1.

are outlined below. New proposed language is indicated in bold, italicized font.

483.80 Infection control

§483.80 (g)(1) COVID-19 Reporting

DRC greatly appreciates that CMS is requiring mandatory reporting in a standardized format so the data will be easily comparable from facility to facility. We are also pleased that CMS is seeking a range of information, including the requirement that the total number of deaths be reported as opposed to just COVID-19 related deaths. The total number of deaths is essential to establish a thorough understanding of what happened in these 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

DRC believes that demographic characteristics significantly contribute to disparities in COVID-19 infections and deaths. For instance, not only are racial minorities more vulnerable, but it has become overwhelmingly clear that individuals with intellectual or developmental disabilities who contract COVID-19 die at higher rates than the rest of the population.⁵

Tracking relevant demographic data for those who have been infected or hospitalized, or who have recovered or died from COVID-19, helps identify additional groups that may have a higher likelihood of experiencing severe illness from COVID-19 as the pandemic progresses. Additionally, this information can help local and state agencies direct resources to provide access to testing, health care, and social services for diverse populations

⁵ Joseph Shapiro, *COVID-19 Infections And Deaths Are Higher Among Those With Intellectual Disabilities*, NATIONAL PUBLIC RADIO (June 9, 2020, 5:00am), <https://www.npr.org/2020/06/09/872401607/covid-19-infections-and-deaths-are-higher-among-those-with-intellectual-disabili>.

with diversified needs. Finally, it can also assist policymakers to prioritize and distribute resources based on anticipated demand.⁶

We also urge CMS to require that facilities report the number of hospitalizations related to COVID-19. DRC is deeply troubled by reports that suggest that people with disabilities are being discriminated against during the pandemic. Collecting the number of hospitalizations, in addition to demographic data of individuals sent to the hospital, would assist in determining the extent of this problem. Furthermore, recovery data from residents and staff who have recovered from COVID-19 can help determine what factors contribute to survival.

Further clarity is needed in other areas as well. Due to the fact that there is no definition of “suspected” cases in the rule, DRC requests that CMS define “suspected” infections of COVID-19 based on 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). DRC also requests that the regulations specifically mandate reporting of resident deaths that occurred after an individual was transferred to the hospital or elsewhere. We acknowledge and applaud that CMS specifically addressed the inclusion of deaths occurring outside the facility in its May 6, 2020 FAQs (question 11). However, it is important to identify facilities that 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;***

⁶ Letter from Asian & Pacific Islander American Health Forum, to Congressional Leaders (May 4, 2020), https://www.apiahf.org/wp-content/uploads/2020/05/2020.05.04_COVID-19-Demographic-Data-Sign-on-Letter-to-Congressional-Leaders.pdf.

- (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

Disability Rights California is concerned about the lack of specificity in regard to the use of personal protective equipment (PPE) in nursing facilities. 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

DRC is 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 is open in the neighborhood. Also, a facility could technically have access to testing, but not actually *be* testing their residents and staff. Furthermore, “access to testing” does not provide sufficient information. It does not indicate the frequency of testing or whether facilities are subsidizing the tests as opposed to 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

DRC commends CMS for the included requirement that staffing information be reported to the CDC. However, we are concerned about use of the term “staffing shortages.” Although the NHSN instructions provide guidance as to what is meant by staffing shortages, the Interim Final Rule does not include a definition. The NHSN definition should be included in the rule.

Due to the fact that there is no current federal requirement for minimum staffing standards, it is difficult for facilities to determine a sufficient staffing threshold. 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, this requirement does not indicate what persons are included in the term “staff.” The relevant information is included in the NHSN instructions, but not included 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 that temporarily eliminated particular nurse aide requirements, certain individuals employed as nursing assistants have not completed all the training and certification requirements. Facilities should be required to report how many of these individuals they currently employ.

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 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

DRC supports the public posting of COVID-related data; public availability of this information is long overdue. However, because the United States is 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. The response from other agencies and programs would be greatly improved by access to this data. These include the state survey agency, CMS, the State Long-Term Care Ombudsman Program, and the Protection and Advocacy Agency (which, in California, is DRC). Equally important, this information should be readily available to residents, their representatives, their families, and staff. They should not be forced to search through CMS data to determine the status of COVID-19 in their facility.

Finally, DRC is very concerned that the rule does not require retroactive reporting back to January 1, 2020. Presently, some facilities are reporting

back to January 1, 2020, while others are only reporting back to May 2020. This discrepancy 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 ensure an accurate representation 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

DRC appreciates CMS's requirement 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 unable to fully assess the situation in their facility. Therefore, they are dependent on the facility to relay information to them. At the same time, most families no longer have direct access to facility staff and administration. As a result, clear and comprehensive correspondence between the families and the facilities is exceptionally important. Staff, too, should be notified when new cases of the virus arise.

However, as written, the language in (g)(3) and (g)(3)(iii) is ambiguous and opaque. The time frames for notification are difficult to understand, and the concept of three (3) or more residents/staff developing an onset of respiratory symptoms within the same seventy-two (72) hour window is unnecessarily complex. Furthermore, the new onset of symptoms should

not be narrowed to only include respiratory manifestations 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 of suspected cases, rather than being informed when individuals develop unusual respiratory symptoms.

Importantly, residents, their representatives, their families, and staff need to know more than just 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, DRC suggests that the information that facilities report to the CDC also be reported to residents, their representatives, families, and staff. This would dramatically 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 and universal form be created. This would ensure that information is provided in a uniform and 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

DRC is concerned that the rule does not lay out sufficient 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

DRC appreciates that CMS requires 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 safety and welfare of the general public, we urge CMS to make it easier for the public to obtain this data. Upon request, facilities should provide this information either orally or in writing. 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

DRC appreciates that in **F884: COVID-19 Reporting to CDC**, CMS provides a penalty for a facility's failure to report required 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

DRC strongly supports expanding the reporting requirements to other institutional and congregate settings. As previously mentioned, individuals with intellectual and developmental disabilities are seriously susceptible to risks related to COVID-19. On a national scale, COVID-19 has devastated

congregate living settings for people with disabilities. Individuals living in these settings make up less than one (1) percent of the population, but almost fifty (50) percent of COVID-19 related deaths.⁷

We urge CMS to extend these same requirements to all institutional settings -- including ICF-IIDs, IMDs, substance abuse treatment facilities, and psychiatric residential treatment facilities -- and other Medicaid-funded congregate settings where people with disabilities live, including group homes and assisted living facilities. The need for transparent data collection is equally important to individuals living in all types of congregate care settings.

Thank you for the opportunity to submit comments on the Notice of Proposed Rulemaking. Please do not hesitate to contact Liz Logsdon for further information.

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Sincerely,



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⁷ Susan Mizner, *COVID-19 Deaths in Nursing Homes are Not Unavoidable – They are the Result of Deadly Discrimination*, AMERICAN CIVIL LIBERTIES UNION (June 23, 2020), <https://www.aclu.org/news/disability-rights/covid-19-deaths-in-nursing-homes-are-not-unavoidable-they-are-the-result-of-deadly-discrimination/>.