July 12, 2021

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Lauren Oviatt
Kim Roche
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Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Blvd.
Baltimore MD 21244-1850

Re: Medicare and Medicaid Programs; COVID-19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff, Interim Final Rule, RIN 0938-AU57

Dear Ms. Corning, Ms. Oviatt, Ms. Roche, and Ms. Shifflett:

The undersigned members of the Consortium for Citizens with Disabilities (CCD) Rights Task Force submit these comments in response to the above-captioned Interim Final Rule. CCD is the largest coalition of national organizations working together to advocate for Federal public policy that ensures the self-determination, independence, empowerment, integration and inclusion of children and adults with disabilities in all aspects of society.

We strongly support CMS's imposition of requirements that Long-Term Care Facilities (LTCFs) and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF-IIDs) offer COVID-19 vaccinations to all residents and staff and provide vaccine education programs that are appropriately tailored to the needs of residents and staff. Where vaccine education efforts are aimed at guardians or other representatives, they should also include the represented person. We also support CMS's requirement that LTCFs report vaccination data to the CDC. We urge CMS, however, to require such reporting also for ICF-IIDs, and to apply the vaccination, education, and reporting requirements, at a minimum, to other Medicare/Medicaid participating congregate settings such as psychiatric hospitals and psychiatric residential treatment facilities (PRTFs). We also urge that certain requirements concerning vaccine

education efforts be moved from the Preamble to the text of the final rule and applied to all covered congregate care facilities.

I. The requirements for LTCFs and ICF-IIDs are critically important

We strongly support CMS's decision to require LTCFs and ICF-IIDs to offer COVID-19 vaccinations to all residents and staff and to provide appropriately tailored and accessible vaccine education efforts. As CMS is aware, the COVID-19 pandemic had a destructive impact on all types of congregate care facilities, including nursing facilities and ICF-IIDs. CMS rightly points out in its Interim Final Rule that nursing facility residents account for less than 1% of the U.S. population but comprised over one-third of the country's deaths from COVID-19. While less information was publicly available concerning deaths in other types of congregate care facilities, countless news articles described devastating outbreaks and high death rates including in psychiatric hospitals and ICF-IIDs.

In light of the devastating impact of COVID-19 on people in congregate care facilities, it is urgent that CMS require these facilities to offer vaccination but also to conduct appropriate education activities to make residents and staff aware of the benefits of vaccination. As CMS notes, this is particularly true given the heightened vulnerability of many individuals in these settings to contracting and dying from COVID-19. For example, studies have shown higher rates of COVID-19 and death in people with intellectual disabilities, including a recent study showing that people with intellectual disabilities are 2.5 times as likely as others to be diagnosed with COVID-19 and 5.9 times as likely to die from it.[1]

While deaths in congregate care facilities have significantly declined as the pandemic recedes in the United States, the risks that remain make these requirements critical. In areas of the country where vaccination rates are low, COVID-19 rates are once again rising rapidly. Given that concern and the fact that the highly contagious Delta variant is now the predominant strain of COVID-19 in the U.S., CMS must ensure the availability of COVID-19 vaccination, vaccine education efforts, and reporting on COVID-19 for individuals in LTCFs, ICF-IIDs, and other Medicare/Medicaid participating congregate care facilities.

II. ICF-IIDs should be required to report COVID-19 vaccination data to the CDC

We urge CMS to impose the same requirement to report on COVID-19 vaccinations and therapeutics that it imposes on LTCFs to ICF-IIDs and also to other Medicare/Medicaid participating congregate care facilities such as psychiatric hospitals. As CMS points out, such reporting affords important opportunities to identify facilities that need focused infection control surveys, and that have low vaccination acceptance rates and need targeted assistance and tailored strategies. In addition, reporting would afford a better national picture of whether vaccination efforts are succeeding in particular types of facilities and whether additional federal regulatory or technical assistance efforts are needed.

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[1] Jonathan Gleason et al., *The Devastating Impact of COVID-19 on Individuals with Intellectual Disabilities in the United States*, NEJM Catalyst (Mar. 5, 2021), https://catalyst.nejm.org/doi/full/10.1056/CAT.21.0051.

CMS points out that few ICF-IIDs are enrolled in the National Health Safety Network (NHSN) and that enrollment might entail certain burdens and might take more time than is available to enable compliance by the effective date of the Interim Final Rule. However, the inability to achieve compliance by the effective date of the Interim Final Rule does not preclude imposing a reporting requirement altogether. CMS could set a later effective date for that portion of the rule or do a separate rulemaking if necessary. Further, the mere potential of administrative burden entailed in enrolling in the NHSN should not preclude the imposition of reporting requirements on any ICF-IID or other facility. Additionally, most psychiatric hospitals are already required to be enrolled in the NHSN.

Given the importance of this reporting and the lack of information demonstrating that NHSN enrollment and reporting would be infeasible, CMS should require it. CMS should also require that the data reported be disaggregated by race, ethnicity, disability status, age, sex, sexual orientation, gender identity, preferred language, rural/urban environment, and service setting, to the extent possible.

III. Psychiatric Hospitals, Psychiatric Residential Treatment Facilities, and Other Medicare/Medicaid Participating Congregate Settings Should be Subject to the Vaccination, Education, and Reporting Requirements

We applaud CMS's imposition of vaccination, education and reporting requirements for certain congregate care facilities but we strongly urge CMS to impose these requirements on other types of congregate care facilities as well—including, at a minimum, those facilities that participate in Medicare/Medicaid such as psychiatric hospitals and PRTFs. These other facilities were similarly hard hit by COVID-19 and residents and staff face similar risks.

CMS states that it considered applying the rule to psychiatric hospitals and PRTFs, over which it has regulatory authority, but that it believes doing so would not be feasible at this time. We urge CMS to reconsider; applying the regulation to psychiatric hospitals and PRTFs would be feasible for the reasons below.

CMS says that it did not apply the rule to psychiatric hospitals because many individuals may stay only for short periods of time. But this is not a reason to exclude individuals and staff in these facilities from all of the protections of this rule. First, individuals routinely stay in state psychiatric hospitals for weeks and months. Second, even private psychiatric hospitals, where the average length of stay is much shorter, must comply with CMS Conditions of Participation that require discharge planning including ensuring that appropriate arrangements for post-hospital follow-up care are made before discharge. 42 C.F.R. 482.43(a)(1). For individuals who only received a first vaccination shot before discharge, hospital discharge planners could arrange for an appointment for a second shot after discharge. Third, even if individuals received only a first shot, that vaccination would afford significant protection against infection and transmission. Studies have shown the first shot of the Pfizer and Moderna vaccines to be 80% effective against COVID-19.[2] Fourth, nearly all psychiatric hospitals and psychiatric units within hospitals are

[2] Centers for Disease Control and Prevention, *Interim Estimates of Vaccine Effectiveness of BNT162b2 and mRNA-1273 COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Health Care*

already required to screen patients for flu immunization status and to offer flu vaccination before discharge if indicated.[3] These facilities are required to enroll in the CDC's National Healthcare Safety Network, which is used for COVID-19 vaccination reporting. According to a study of 2018 data, an average of 84% of inpatient psychiatric facility patients were screened for flu vaccination status and received an immunization before discharge if indicated.[4] Thus, these facilities have the necessary infrastructure for COVID-19 vaccination and education.

CMS says that it did not apply the rule to PRTFs because these facilities are only for children and youth under 21, and vaccinations have only been approved for individuals 16 and older. However, the FDA approved vaccinations for children 12 and up beginning several days before CMS's proposed rule was published in the Federal Register.[5] Nearly 70% of individuals served in PRTFs are 12 and over.[6]

Further, the factors cited by CMS justifying its imposition of these requirements on other facilities also apply to psychiatric hospitals and PRTFs. A substantial number of studies have identified the high risk of contracting COVID-19, hospitalization, and death faced by individuals with psychiatric disabilities.[7] Individuals with a diagnosis of schizophrenia are 2.7 times as likely to die from COVID-19 as individuals without psychiatric diagnoses, controlling for demographic factors such as age, race and sex and for known medical risk factors.[8] In addition,

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Personnel, First Responders, and Other Essential and Frontline Workers — Eight U.S. Locations, December 2020–March 2021 (Apr. 2, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7013e3.htm.

[3] Jonathan D. Brown and Naida Bell, Mathematica, *The role of psychiatric hospitals in the equitable distribution of COVID-19 vaccines* (May 28, 2021), https://ps.psychiatryonline.org/pb-assets/journals/ps/homepage/The%20Role%20of%20Psychiatric%20Hospitals%20in%20the%20Equitable%20Distribution%20of%20COVID-19%20Vaccines.pdf.

[4] *Id.*

[5] U.S. Food and Drug Administration, Coronavirus (COVID-19) Update: FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Adolescents in Another Important Action in Fight Against Pandemic (May 10, 2021), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use.

[6] Kathleen Sebelius, Secretary of Health and Human Services, Report to the President and Congress Medicaid Home and Community-Based Alternatives to Psychiatric Residential Treatment Facilities Demonstration (July 2013), at 4, https://actiononyouthmentalhealth.org/wp-content/uploads/2019/03/7-Psych-Residential-Treatment-Facility-HHS-report-to-Congress.pdf.

[7] *See* Victor Mazereel et al., *COVID-19 vaccination for people with severe mental illness: why, what, and how?*, Lancet, Feb. 3, 2021, https://www.thelancet.com/action/showPdf?pii=S2215-0366%2820%2930564-2 (identifying eight studies); Katlyn Nemani et al., *Association of Psychiatric Disorders With Mortality Among Patients With COVID-19*, J. Amer. Med. Ass'n, at E1, https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2775179.

[8] *Id.*

people with serious mental illnesses experience dramatic disparities in physical health comorbidities including conditions that are also high risk for COVID-19 morbidity and mortality, such as obesity, diabetes and COPD.[9]

While CMS notes that it may be difficult for individuals to leave other types of congregate care facilities to receive vaccinations elsewhere, individuals generally cannot leave psychiatric hospitals or PRTFs at all; even when they have been admitted on a voluntary basis, they typically are not permitted to leave unless they have been first assessed to determine whether they should be subject to involuntary commitment proceedings. In addition, as with ICF-IIDs, staff in psychiatric hospitals may also work in other facilities including nursing facilities.

IV. CMS Should Include Portions of the Preamble Language Concerning Vaccine Education Efforts in the Text of the Final Rule and Apply it to All Covered Congregate Care Facilities

CMS describes in detail the expectations for vaccine education efforts in LTCFs and ICF-IIDs in the preamble of the Interim Final Rule. This description contains important elements relevant to people with disabilities in all types of congregate care facilities, including LTCFs and psychiatric hospitals. These requirements should be included in the text of the final rule and applied to all covered congregate care facilities. For example, the preamble states that for individuals in ICF-IIDs:

> *It is important to talk to clients and representatives to learn why they may be declining vaccination and tailor educational messages accordingly, that is by addressing specific questions or concerns.*
> *…*
> *…[E]ducation of clients and representatives should cover the fact that, at this time while the U.S. Government is purchasing all COVID-19 vaccine in the United States for administration through the CDC COVID-19 Vaccination Program, all ICF-IID clients are able to receive the vaccine without any copays or out-of-pocket costs.*
> *…*
> *Education for clients and representatives must also provide the opportunity for follow up questions, and be conducted in a manner that is reasonably understood by the clients and representatives. That is, educational materials and delivery must meet relevant standards in Section 504 of the Rehabilitation Act, which may include making such material available in large print, Braille, and American Sign Language, and using closed captioning, audio descriptions, and plain language for people with vision, hearing, cognitive, and learning disabilities.*[10]

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[9] Razzano, L.A., Cook, J.A., Yost, C., Jonikas, J.A., Swarbrick, M., Carter, T.M., & Santos, A. (2015). Factors associated with co-occurring medical conditions among adults with serious mental disorders. *Schizophrenia Research, 161*, 458–464.

[10] 86 Fed. Reg. 26306, 26318 (May 13, 2021) *("ICF-IDD Clients").*

The Preamble contains similar provisions for individuals in LTCFs, although it omits the provisions concerning compliance with Section 504 accessibility standards.[11] The LTCF provisions also state:

> *Thus, we expect that this required education would be in a language that the resident or the resident representative understands.*[12]

To ensure that these requirements are understood and observed, they should be included in the final rule itself.

We urge CMS to include these provisions (including the language concerning Section 504 compliance) in the text of the final rule, and to apply them to all types of covered congregate care facilities.

Thank you for the opportunity to comment on this important rulemaking.

Sincerely,

The Arc of the United States

American Therapeutic Recreation Association

Association of University Centers on Disabilities

Autistic Self Advocacy Network

Bazelon Center for Mental Health Law

CommunicationFIRST

Disability Rights Education and Defense Fund

Epilepsy Foundation

Family Voices

National Association of Councils on Developmental Disabilities

National Council on Independent Living

National Disability Rights Network (NDRN)

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[11] *Id*. at 26315 (*"LTC Facility Residents and Resident Representatives*").

[12] *Id*. at 26324.

National Down Syndrome Congress

National Health Law Program

Partnership for Inclusive Disaster Strategies

United Cerebral Palsy

United Spinal Association

World Institute on Disability