January 4, 2022

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-2444-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Omnibus COVID-19 Health Care Staff Vaccination
CMS-3415-IFC, ANCOR Written Comments

Dear Administrator Books-LaSure:

On behalf of the American Network of Community Options and Resources (ANCOR), thank you for the opportunity to provide feedback to the Centers for Medicare & Medicaid Services (CMS) Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule (IFR). We understand and support CMS's intent to protect facility staff and beneficiaries from exposure to COVID-19. However, we are concerned that areas of the rule remain unclear in implementation and the timeframe for compliance may further exacerbate the current workforce crisis impacting services and supports for individuals with intellectual and developmental disabilities (I/DD).

ANCOR is a national, nonprofit trade association representing more than 1,600 private providers of community-based services to people with intellectual and developmental disabilities (I/DD). Combined, we support over one million individuals with disabilities and work collaboratively to shape policy, share solutions, and strengthen community. Our members assist people with I/DD to live full and independent lives by providing services and support for instrumental activities of daily living.

ANCOR offers the following comments, suggestions, and requests for clarification to the IFR. Our recommendations are framed to support uniformity in implementation with acknowledgment of the impact of the rule on the current direct care workforce crisis. We have organized our feedback by section below, touching upon broad themes and specific recommendations that arose within those topics.

Direct Care Workforce Crisis

For decades, the United States has witnessed a significant shortage of direct care workers due to stagnant reimbursement rates and the inability of providers to offer wages that enable them to compete with industries offering entry-level positions, such as fast-food restaurants or retail and convenience stores. The effects of underinvestment in the direct care workforce can be seen in turnover rates which hover near 50% nationally. With the onset of COVID-19, new pressures and hazards of providing essential, close-contact services during the pandemic have further

exacerbated and accelerated the workforce crisis. While many in the private sector pivoted by offering increased wages and hazard pay, community providers—who rely almost exclusively on Medicaid funding and are thus beholden to paying wages that Medicaid reimbursement rates will permit—lacked the resources to fund these kinds of unanticipated programmatic costs. At $12 per hour, the median wage for direct care workers nationally is simply insufficient to slow the exodus of direct care workers from the field.

ANCOR surveyed community providers over a five-week period beginning in August 2021 to glean a deeper understanding of the impact of the COVID-19 pandemic on the direct care workforce crisis and, in turn, providers' ability to deliver the highest-quality supports possible.[1] Survey results found that 77% of providers were turning away new referrals, 58% of providers were discontinuing programs and services, and 84% of providers were delaying the launch of new programs or services due to lack of staffing. Survey results further indicated that nearly 3 in 10 (29%) respondents reported spending more than $500,000 annually in costs related to high turnover and vacancy rates, while more than 1 in 6 respondents (18%) reported spending more than $1 million annually. Nearly all providers agreed that the COVID-19 pandemic continues to deeply impact their ability to hire and retain direct care workers.

Providers continue to struggle with vaccine hesitancy and refusal from the remaining direct care frontline staff. In a recent survey tracking the experience of direct support professionals during the COVID-19 pandemic, the University of Minnesota in partnership with the National Alliance for Direct Support Professionals (NADSP) found only 69% of respondents nationally were fully vaccinated against COVID-19 with individual state profiles ranging as low as 60%.[2] Of the unvaccinated respondents, 54% reported they did not feel it was safe, 22% reported they did not feel they need it, and 21% reported they did not believe in the worth of vaccinations.

These relentless challenges illustrate why increased funding is critical to begin addressing the magnitude of unmet need in our communities. While we understand and appreciate the importance of vaccination, we urge CMS to focus attention and support for competitive wages in tandem with new vaccination requirements. Without the ability to offer livable wages and benefits, providers are unable to reliably replace staff who refuse vaccination and maintain access for individuals relying on their care.

Implementation Extension

ANCOR requests that CMS delay the IFR comment period for thirty (30) days and compliance dates for six (6) months with a good faith showing of progress toward compliance.

Allowing additional time to review comment and provide appropriate guidance prior to compliance deadlines supports consistency in implementation. With CMS's recent update to the External FAQ[3], it appears compliance activities are moving forward in only half the country. As the remaining 25 states are currently under a federal preliminary injunction, it is unclear when and how those states may be required to come into compliance creating inconsistencies across

[1] The State of America's Direct Support Workforce 2021
[2] Direct Support Workforce and COVID-19 National Report: 12- Month Follow-up
[3] External FAQ – CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule

the nation. Moreover, additional information and changes may be forthcoming following the January 7, 2022, oral arguments with the U.S. Supreme Court on the preliminary injunctions.

Additional time will also be necessary for CMS to confer with the Occupational Safety and Health Administration (OSHA) to clarify expectations between overlapping interim final rules and direct necessary funding increases. OSHA's Vaccination and Testing Emergency Temporary Standard[4] is also under legal challenge and scheduled for oral argument with the U.S. Supreme Court on January 7, 2022. Furthermore, OSHA recently announced intent to promulgate a new permanent standard of vaccination and testing for healthcare providers.[5]

Through the ongoing litigation and changes in standards, providers have repeatedly reached out to CMS and OSHA to clarify expectations and publish guidance for providers struggling to remain in compliance with competing federal and state rules and regulations. With underfunding and the workforce crisis, providers have already reduced and terminated programs, employee benefits, and general administrative maintenance to remain operational. Providers struggle to remain accessible to beneficiaries with new employee expectations and expenses under current budgetary constraints without additional state and federal financial support and guidance.

Overlapping Standards

ANCOR requests further clarification and guidance regarding the relationship between and implementation of CMS's and OSHA's vaccination standards.

Community providers may be simultaneously subject to CMS's IFR, OSHA's Vaccination and Testing Emergency Temporary Standard, and OSHA's healthcare rules. Community providers typically offer a diversified array of services and supports which rely on a range of types of personnel. These services are further regulated and delivered in accordance with differing state policy. While this creates opportunity for individualized and person-centered supports, it also prevents industry-wide application of new interim final rules. Each provider will need to assess which of the new regulatory requirements applies to their organization, in which settings, and for which staff.

There has been little guidance offered to support community providers struggling to apply these competing standards. CMS has yet to issue interpretive guidance and the ongoing federal litigation has only added confusion and further resistance from staff waiting on clarification from the courts. For example, if you are a provider with more than 100 employees in a state for which there is currently a preliminary injunction, the timeline for compliance is difficult to track. The IFR was the primary vaccination standard until the preliminary injunction was first put in place on November 29, 2021. Then OSHA's Healthcare Emergency Temporary Standard[6] would have held until it expired on December 21, 2021 and was officially withdrawn on six days later. For now, the primary standard is likely OSHA's Vaccination and Testing Emergency Standard, although that also is subject to change again after oral arguments on January 7, 2022.

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[4] 29 CFR 1910.501 *et seq*
[5] Statement on the Status of the OSHA COVID-19 Healthcare ETS
[6] 29 CFR 1910.502 *et seq*

Compliance becomes more complicated for providers in states where vaccination mandates are prohibited by state executive order or statute. For those providers, their ability to impose vaccination requirements is only available while the IFR is effective. This creates further tension and instability as the policies remain in a constant state of flux.

Facility Staff

ANCOR requests further clarification to the term "facility staff" and specific guidance governing the relationship of the IFR to facility staff not employed by the impacted provider.

Definition

While there is no formal definition of "facility staff", the IFR speaks broadly to the inclusion of "facility employees; licensed practitioners; students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the facility and/or its clients, under contract or by other arrangement."[7] In its background, CMS includes reference to administrative staff, facility leadership, volunteer or other fiduciary board members, housekeeping and food services, and others as inclusive of facility staff. The only exceptions speak specifically to facility staff "who do not have any direct contact with residents and other staff."[8]

This creates ambiguity in the rule for providers offering multiple services. The rationale for the rule appears to use the term "facility" and "provider" interchangeably, as though the provider employs staff and contracts exclusively for the impacted facility. However, providers frequently offer a variety of services delivered in a variety of settings which are both covered and not covered by the IFR. For example, providers of ICF/IID services often also offer Home and Community-based Services (HCBS). ICF/IIDs are an identified facility impacted by the IFR, while "CMS's health and safety regulations do not cover providers of Home and Community-based Services."[9]

It is unclear if providers should separate standards for their multiple services by program or proximity. If the HCBS is unrelated to the ICF/IID and its clients, but located in the same building, are staff across both programs required to be vaccinated? If the HCBS and the ICF/IID are physically separated, do the staff operate under two different standards? If administrators and administrative staff of both programs interact, are both required to be vaccinated regardless of the program they oversee?

By Contract or Other Arrangement

It is also common for ICF/IIDs to contract with other providers offering HCBS on behalf of certain beneficiaries to offer choice of provider and access to other services. As the beneficiary is unable to bill Medicaid directly for these services, the state Medicaid program typically

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[7] 42 C.F.R. § 483.430(f)(1)
[8] 42 C.F.R. § 483.430(f)(2)(i,ii)
[9] External FAQ - Scenarios - *Q: Does this requirement apply to Medicaid home care services, such as Home and Community-based Services (HCBS), since these providers receive Medicaid funding but are not regulated as certified facilities?*

reimburses the cost of service to the ICF/IID to pay on behalf of the beneficiary. In this way, the ICF/IID acts more as an intermediary for the beneficiary rather than a provider contracting with individuals on behalf of the facility as contemplated by the rule.

Providers report concern that ICF/IIDs and HCBS alike are disincentivized to offer these arrangements if it creates a new burden on both providers to ensure vaccination of the HCBS staff. As referenced, CMS has made clear that providers of HCBS are not subject to the rule. Impacted by the same direct care workforce crisis, providers of HCBS are equally concerned that introducing the potential of new requirements may further exacerbate turnover and vacancies.

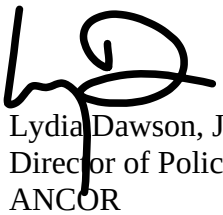
If applicable, it is also unclear how the ICF/IID provider will ensure the vaccination of another employer's staff. CMS's updated FAQ states "Ultimately, it is up to the facility to ensure that it has a process or plan in place for capturing COVID-19 vaccination status for all staff, *including individuals who provide services under contract or other arrangements*."[10] <Emphasis added.> However, in the example of the ICF/IID and HCBS provider, this would require significant communication and transparency from the HCBS provider to open its employment records and health records of its employees with a potential competitor for staff during a workforce shortage. Without additional guidance and support, this provision has the potential to reduce access to community support services for individuals utilizing ICF/IID services.

Conclusion

Our submitted comments should not be construed as opposition to vaccination. We fully embrace the importance of vaccination for those who care for people with I/DD and currently participate in a grant administered by the Centers for Disease Control and Prevention to address vaccine hesitancy in direct support professionals. However, we are also acutely aware of the state of America's direct support workforce crisis and remain cautious in our approach to policy changes which have the potential to further exacerbate this crisis and threaten access to services. To be successful, the imposition of vaccine requirements must allow sufficient time, financial support, and clear guidance to ensure continuity of care through the transition.

Thank you for this opportunity to provide comment. Please reach out to me at ldawson@ancor.org if we can provide further clarification or information regarding the above.

Sincerely,



Lydia Dawson, J.D.
Director of Policy, Regulatory, and Legal Analysis
ANCOR

[10] External FAQ - Requirements - *Q: What are the documentation requirements for staff vaccinations? Are these the same for venders?*