

January 4, 2022

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
200 Independence Avenue, SW
Washington, DC 20101

RE: CMS-3415-IFC: Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination

Dear Administrator Brooks-LaSure:

The National Hospice and Palliative Care Organization (NHPCO) appreciates the opportunity to provide comments on provisions pertaining to hospice and palliative care delineated in the Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination proposed rule (CMS-3415-IFC) (or “the COVID-19 Vaccination Rule”).¹ We are proud that NHPCO was among the first national provider organizations to support the Administration’s call for a [nationwide vaccine mandate](#) for health care workers, and we continue to strongly support the mandate.

NHPCO is the nation’s largest membership organization for hospice providers and professionals who care for people affected by serious and life-limiting illness. NHPCO members provide care in more than 4,000 hospice and palliative care locations and care for over two-thirds of the Medicare beneficiaries served by hospice.

Our comments focus on the potential impact of these proposals on the care hospice and palliative care providers offer patients with serious and life-limiting illness and their families. Specifically, our comments pertain to the following sections:

Implementation Dates

When CMS-3415-IFC was first published, the primary area of concern for many providers was the impact of the preliminary injunctions issued on November 29 and 30, 2021² and the ongoing appeals to those injunctions. Hospice providers located in the states included in the injunctions find themselves in limbo and still need guidance regarding deadlines and enforcement. Hospice providers providing services spanning multiple states are currently faced with the complexities

¹ Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61555 (proposed Nov. 5, 2021) (to be codified at 42 C.F.R 418).

² *Missouri et al. v. Biden*, No. 4:21-cv-01329-MTS (E.D. Mo. Nov. 29, 2021); *Louisiana et al. v. Becerra et al.*, No. 3:12-CV-03970 (W.D. La. Nov. 30, 2021)

and burden that come with implementation of the CMS vaccine mandate in some states but not in others.

Although it is difficult to predict the outcome or timing of pending litigation, we request guidance on how CMS will respond to the 25 states now a party to the litigation should the preliminary injunction be overturned or if the court finds the mandate constitutional. Providers in these 25 states are in various stages of planning and preparedness and are anxiously awaiting the decision of the court. As stated in the IFC, “instantaneous compliance, or compliance within days, with these regulations is not possible”³ and with the uncertainty of the timing of the litigation, providers are in the dark about the process for implementation and when compliance will be enforced.

NHPCO Recommendation: NHPCO commends CMS for the December 28, 2021, guidance for Medicare providers with Attachment C: Guidance for Hospices. NHPCO recommends that similar or identical guidance be prepared for the remaining 25 states to assist providers in planning for the vaccine mandate requirement as soon as court proceedings have concluded.

In addition, NHPCO recommends giving hospice providers in the states included in the stay the same timeframes for compliance as issued in the December 28, 2021 guidance once the court has a final order. CMS should notify providers imminently of the intention to provide additional time for compliance. By affording this additional time, it will allow providers adequate time to comply with the rule once the cases have been litigated as well as to plan for the administrative tasks necessary to implement.

Documenting Vaccination Status

NHPCO commends CMS for the guidance for Medicare providers regarding staff vaccination status. As the nation faces what may be the greatest surge in COVID-19 infections since the start of the pandemic, we also commend CMS for acknowledging the importance of tracking and documenting COVID-19 vaccination status of any and all staff who have obtained a booster dose.

We note, however, the new regulatory requirement at § 418.60(d) does not address the now essential booster dose and believe the new requirement is incomplete.

NHPCO Recommendation: NHPCO recommends addressing the booster dose in § 418.60 (d)(3)(v) “A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC.”

Suggested language (underlined):

“(d)(3)(v) A process for ensuring all staff specified in paragraph (d)(1) receive a timely appropriate booster as well as tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC.”

³ 86 Fed. Reg. 61555, at 312.

Location of Staff Vaccination Documentation

NHPCO believes it is vitally important to provide specific guidance on tracking and documenting vaccine status, including the list of examples of where vaccine documentation could be stored and the essential notification of the vaccine status as a part of one's medical record and therefore must be kept confidential and stored separately from an employer's personnel files.

We commend CMS for the new regulatory requirement at § 418.60(d)(3)(iv) and the focus on securely documenting vaccine status.

NHPCO Recommendation: In regulatory text and in [L-tag 900](#) in Appendix M – Hospice Interpretive Guidelines, State Operations Manual, we request CMS to include examples of appropriate places for vaccine documentation. As surveyors will be reviewing vaccine documentation, what the surveyor is entitled to see should also be noted.

Vaccination Exemptions

NHPCO commends CMS for guidance on vaccination exemptions. In § 418.60(3), the list of policies and procedures and their required components include extensive detail in 418.60(3)(viii) of the process for “ensuring that all documentation, which confirms recognized contraindications to COVID-19 vaccines, and which supports staff requests for medical exemptions from vaccination.” In § 418.60(3)(ix), the regulation outlines a “process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed...”

In the guidance released by CMS on December 28, 2021, there is a section with details on non-medical exemptions, including religious exemptions. In NHPCO's experience during this time, there have been numerous questions about how to handle non-medical or religious exemptions. NHPCO has referred providers to the EEOC manual as a reference.

[Attachment C: Hospice Guidance](#)

Non-Medical Exemptions, Including Religious Exemptions:

Requests for non-medical exemptions, such as a religious exemption in accordance with Title VII, must be documented and evaluated in accordance with each hospice's policies and procedures. We direct hospices to the [Equal Employment Opportunity Commission \(EEOC\) Compliance Manual on Religious Discrimination](#) for information on evaluating and responding to such requests.

However, NHPCO notes there is no section of the hospice regulation at § 418.60(d) or in the L-tag L-900 in Appendix M, Hospice Interpretive Guidelines, State Operations Manual, addressing non-medical exemptions, including religious exemptions. The lack of guidance for non-medical exemptions, including religious exemptions, in § 418.60(3) is problematic and could cause greater confusion or lack of consistency between hospice providers about this important exemption.

NHPCO Recommendation: NHPCO recommends the addition of a section in § 418.60(3) to provide policies and procedures for hospice providers that define non-medical exemptions, including religious exemptions.

In addition, NHPCO recommends an addition to L-tag 900 in Appendix M – Hospice Interpretive Guidelines, State Operations Manual to mirror the additional section added to § 418.60(3)

We appreciate your consideration of NHPCO's comments on this interim final rule and your commitment to supporting hospice and palliative care providers during the COVID-19 public health emergency. We welcome continued engagement with you and your staff and the opportunity to meet to discuss our recommendations. If you have questions or to schedule a meeting, your staff should feel free to contact Judi Lund Person, Vice President, Regulatory and Compliance at JLundPerson@NHPCO.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'Edo Banach', written in a cursive style.

Edo Banach, JD
President and CEO