July 12, 2021

FILED ELECTRONICALLY

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–3414–IFC
P.O. Box 8010
Baltimore, MD 21244–1850

Re: *[CMS–3414–IFC; RIN 0938–AU57] 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*

To Whom It May Concern:

The First Church of Christ, Scientist (Church)[1] appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) interim final rule titled, "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."

The Church files this comment in support of its members who are patients of, or Christian Science nurses working in, Christian Science nursing facilities certified to participate in Medicare as religious nonmedical health care institutions (RNHCIs). Although the provisions of this interim final rule do not apply to RNHCIs, CMS has requested comment on whether the policies regarding COVID-19 vaccination reflected in the rule should be extended to other Medicare provider types.

As explained in detail below, the Church suggests that the existing public health measures in place during the current public health emergency (PHE) and facilities' responsiveness to those measures have been sufficient to protect patients from COVID-19. Therefore, there is no need to extend the policies reflected in this rule to RNHCIs. However, should CMS decide to undertake similar rulemaking applicable to RNHCIs in the future, we are grateful for the opportunity to offer suggestions for how these policies might be implemented appropriately.

[1] The Church is a 501(c)(3) organization with branches in the United States and approximately 70 other countries. It is the world headquarters of the Christian Science religion. Christian Science was founded during the latter part of the 19th century by Mary Baker Eddy. It is based on the Bible and the teachings of Jesus, and has at its core the belief that people can find healing of problems of all kinds (including health problems) through prayer, scriptural study, and gaining a better understanding of one's relationship to God.

I. Background

A. Christian Science Nursing Facilities

Christian Science nursing facilities provide care to individuals who have elected to rely on the teachings of Christian Science rather than medical treatment for health problems and require care in an inpatient setting. At the present time, there are 13 such facilities around the country that are Medicare-certified as RNHCIs. All of these facilities are small (typically less than 20 beds) and operated by not-for-profit organizations.[2] Some have been providing skilled nonmedical care to Christian Scientists since the early part of the twentieth century.

B. The RNHCI Benefit under Medicare

The RNHCI benefit is a required benefit under Medicare Part A available to individuals for whom "the acceptance of [voluntary] medical treatment would be inconsistent with their sincere religious beliefs."[3] For care to be covered, an individual must sign a notarized form electing the RNHCI benefit and have a health condition that requires inpatient care in a hospital or a skilled nursing facility.[4] The Medicare Act recognizes the need to ensure that payments for RNHCI services are made correctly and only for covered services.[5] It also respects beneficiary choice of care, providing in relevant part that:

> (A)(i) In administering this subsection and section 1395i-5 of this title, **the Secretary shall not require any patient of a religious nonmedical health care institution to undergo medical screening, examination, diagnosis, prognosis, or treatment or to accept any other medical health care service**, if such patient (or legal representative of the patient) objects thereto on religious grounds.
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> (B)(i) In administering this subsection and section 1395i-5 of this title, **the Secretary shall not subject a religious nonmedical health care institution or its personnel to any medical supervision, regulation, or control, insofar as such supervision, regulation, or control would be contrary to the religious beliefs observed by the institution or such personnel.**

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[2] These providers are 501(c)(3) organizations independent of the Church. However, they maintain a cooperative relationship with the Church, and provided input concerning the issues discussed in this comment.

[3] 42 U.S.C. § 1395i-5(b)(2)(A)(ii).

[4] *See* 42 U.S.C. § 1395i-5(a)(2). This provision of the Medicare Act also refers to qualification for home health services. Although at one point a pilot project authorized Medicare payment for RNHCI services provided in the home, authorization for that pilot project was not renewed and ended on December 31, 2006. *See generally*, § 706, Medicare Prescription Drug Improvement and Modernization Act of 2003, P.L. 106-173 (December 8, 2003).

[5] 42 U.S.C. §§ 1395x(ss)(3)(A)(ii) and 1395x(ss)(3)(B)(ii).

The statutory definition of a RNHCI also prohibits these facilities from employing or having relationships with medical personnel.[6] Among other things, the definition provides that a RNHCI "on the basis of its religious beliefs, **does not provide** through its personnel or otherwise medical items and services (including **any medical screening**, examination, diagnosis, prognosis, treatment, **or the administration of drugs**) for its patients"[7] The conditions of participation for RNHCIs are located in 42 C.F.R. 403, Subpart G, and guidance regarding those regulations is found in Appendix U of the State Operations Manual.

II. Comments on the Interim Final Rule

A. General Comments

As an initial matter, the Church commends CMS for its responsiveness to the ongoing COVID-19 PHE and the degree to which it has considered the interests of patients, Medicare providers, and the community in crafting its policies during this time of need. This same responsiveness is reflected in the provisions of the interim final rule. In particular, we appreciate the provisions of the rule that support informed consent by patients and staff, and allow individuals to make their own decisions about COVID-19 vaccination.

In this regard, it is worth stressing that the Church does not dictate the decisions of its members in any respect, whether about health care, vaccination, or any other matter. Individuals who practice Christian Science thus typically turn to prayer as taught in Christian Science to meet their health needs because they have found it to be effective in their lived experience. It is also relevant to know that the founder of Christian Science counseled following the Golden Rule in our actions with one another and our communities, as well as conscientious compliance with law, including directives for the handling of contagious disease.

Throughout the PHE, Christian Science nursing facilities have been actively monitoring and complying with federal, State, and local public health measures, including those regarding isolation and quarantine, COVID-19 testing, and the appropriate use of personal protective equipment. It is our understanding that this has resulted in a notably low number of positive COVID-19 test results in these facilities throughout the PHE and no significant outbreaks.

In consulting with Christian Science nursing facilities to prepare this comment, we learned that the overwhelming majority of these facilities already inform their staff and patients of the availability of the COVID-19 vaccine, leaving the decision of whether to vaccinate to each individual. It is our understanding that some staff and patients have chosen to accept the vaccine while others have declined, and that the facilities are taking this information into account in determining how best to respond to the evolving public health guidelines in their communities.

[6] 42 U.S.C. § 1395x(ss)(1).
[7] 42 U.S.C. § 1395x(ss)(1)(F) (emphasis added).

For this reason, the Church respectfully requests that the policies reflected in the interim final rule not be extended to RNHCIs. The public health measures already in place have proven to be effective at protecting staff and patients while supporting individual decision-making about vaccination, which is consistent with the overarching goals of the rule. Additionally, given what is already being done by these facilities, extending the interim final rule policies to them would place an unnecessary burden on these small providers without yielding significantly different results.

Should CMS decide to extend the rule's policies to RNHCIs in the future, however, the Church would like to offer suggestions and observations about how they might be applied in a manner that is consistent with the Medicare Act and the sincerely held religious beliefs of patients and staff.

As a threshold matter, we offer no comments regarding the requirement that facilities offer patients and staff the opportunity to accept or decline the COVID-19 vaccine.[8] This is already being done by Christian Science nursing facilities across the country. Instead, our comments primarily relate to the educational requirement for staff and residents, specifically regarding the risks and benefits of the COVID-19 vaccine.

B. Education for Patients and Staff Regarding COVID-19 Vaccination

The Church supports the right of each individual to make an informed decision about whether to receive the COVID-19 vaccine. However, the ability of RNHCI staff to provide specific information about the risks and benefits of vaccination is limited by the fact that, under the Medicare Act, RNHCIs are not permitted to employ or have relationships with medical personnel or to perform any type of medical intervention or treatment. RNHCI staff are not qualified to discuss the particulars of an individual's medical situation as it relates to vaccination, nor are they qualified to identify situations where vaccination is contraindicated or to respond to adverse side effects.

Credible public information regarding the risks and benefits of COVID-19 vaccination is widely available,[9] however, and recipients receive vaccine-specific information at the time of administration. Should CMS decide to extend the provisions of the interim final rule to RNHCIs, this type of information should be considered to satisfy the educational requirement in the RNHCI context. Staff receiving the vaccine will be able to receive more specific, medically appropriate information about vaccination from medical professionals qualified to administer it. RNHCI patients will likely be unable to access the vaccine independently.[10] Accordingly, we

[8] CMS is not requiring long-term care facilities to provide the vaccine directly. 86 Fed.Reg. 26306, 26312 (May 13, 2021). For obvious reasons, this same policy should apply to RNHCIs.
[9] *See, e.g.*, CDC, COVID-19 Vaccine Emergency Use Authorization (EUA) Fact Sheets for Recipients and Caregivers (last reviewed January 21, 2021).
[10] *See,* 86 Fed.Reg. at 26310. (Noting challenges of most long-term care facility residents in accessing vaccination).

suggest that facilities be required to assist patients who desire vaccination to obtain the vaccine in a manner that is safe and meets their individual needs.

The Church agrees that, in offering the opportunity to be vaccinated, facilities should inform patients that they may receive the vaccine at no cost during the PHE. However, there are potential financial consequences to acceptance of the vaccine that are unique to RNHCI patients under the provisions of the Medicare Act. These should be addressed in developing any potential rule.

Under the Medicare Act, individuals must sign an election form to receive the RNHCI benefit. The voluntary receipt of medical care paid for by Medicare causes a revocation of the election unless such care is "excepted medical care."[11] Beneficiaries who have revoked their election more than once are required to wait specified periods of time before they are again permitted to access the RNHCI benefit.[12] 42 C.F.R.§ 403.702 defines "medical care" as "health care furnished by or under the direction of a licensed physician that can involve diagnosing, treating, or preventing disease . . . It may involve the use of pharmaceuticals, . . . and technical procedures." The same regulation defines "excepted medical care" as "medical care that is **received involuntarily or required under Federal, State, or local laws**"[13] (emphasis added).

Vaccinations are typically covered under Medicare Part B.[14] COVID-19 vaccination is not currently required by law, although CMS, and State and local public health officials alike, is actively encouraging it. While this development is perfectly understandable in the context of the PHE, it creates a revocation-related dilemma for RNHCI patients. These patients are at risk of incurring a penalty (in the form of a year-long waiting period for benefit access) if they receive a vaccination that is paid for by Medicare. The penalty period may extend even longer if they have already revoked the benefit once and then receive a two dose vaccine. This runs contrary to the existing public health goal of encouraging as many people as possible to accept COVID-19 vaccination.

Accordingly, we request that CMS consider waiving the revocation rules for RNHCI patients who receive the COVID-19 vaccine. Alternatively, CMS should require RNHCIs to educate Medicare patients about the possibility of causing a revocation of election and the consequences of revocation if they accept the COVID-19 vaccine and it is paid for by Medicare.

C. Reporting of COVID-19 Vaccination Data

The Church requests that the reporting requirements in the interim final rule not be applied to RNHCIs. Notably, CMS has declined to extend the reporting requirement to intermediate care

[11] 42 U.S.C. § 1395i-5(b)(3).
[12] 42 U.S.C. § 1395i-5(b)(4).
[13] *See also*, 42 U.S.C. § 1395i-5(b)(5)(A)(ii)
[14] We have heard anecdotally that individuals are requested to provide their Medicare information at the time of vaccine administration, and assume that this information would be used to bill Medicare.

facilities for individuals with intellectual disabilities (ICF-IID), largely because those facilities have not historically participated in national reporting programs and are typically small providers with fewer resources to dedicate to reporting. We suggest that similar reasoning applies to RNHCIs.

The 13 Christian Science nursing facilities that are certified as RNHCIs nationwide are small in size and operated by not-for-profit organizations. Staff in these facilities often fill multiple roles. Like ICF-IIDs, RNHCIs have not historically been part of national reporting initiatives. Accordingly, the reporting requirements would impose a considerable administrative burden on these providers, including potential equipment acquisition and training costs related to enrollment in the NHSN. In addition, RNHCIs are not long-term residential care facilities, but are instead intended for short term stays for those with serious health conditions. Patient turnover could make vaccination rates among patients more difficult to monitor. Finally, and based upon feedback that the Church received from Christian Science nursing facilities that participate as RNHCIs, we expect that some staff and patients would have significant privacy and security concerns about the sharing of individually identifiable information in connection with their vaccination status.

III. Conclusion

Thank you for your consideration of the comments set forth above. The interim final rule serves the laudable goal of preventing additional COVID-19 outbreaks in LTC facilities while respecting the autonomy of residents and staff. The Church feels it is unnecessary to extend the rule to RNHCIs for the reasons stated above, and we hope that CMS finds the information in this comment helpful in considering how these issues could reasonably be addressed in the context of patients and staff that hold sincere religious beliefs that are inconsistent with the receipt of medications and medical treatment.

The Church looks forward to continuing to work with CMS as it considers these important issues moving forward. Please do not hesitate to let us know if we can provide any additional information, or if you would like to meet with us to learn more about the comments above.

Sincerely,

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