

Report on Medicare Compliance Volume 31, Number 2. January 17, 2022

CMS Vaccine Mandate Is Universal With Supreme Court Ruling; Surveys Are Provider Specific

By Nina Youngstrom

The Supreme Court has cleared the way for CMS to enforce its COVID-19 vaccine mandate nationally at hospitals and other facilities regulated by the Medicare conditions of participation, with state surveyors using guidance that has been at their disposal since Dec. 28. In a Jan. 13 decision, the high court ruled that HHS Secretary Xavier Becerra “did not exceed his statutory authority in requiring that, in order to remain eligible for Medicare and Medicaid dollars, the facilities covered by the interim rule must ensure that their employees be vaccinated against COVID-19.”^[1]

Although the effective date of CMS’s Omnibus COVID-19 Health Care Staff Vaccination regulation^[2] has been delayed a bit by a legal standoff with 25 states, facilities now must ensure their employees and others have the first dose of the vaccine by Jan. 27 and the second dose by Feb. 28, unless they have a pending or approved medical or religious exemption or medically necessary delay in the vaccination.^[3] State surveyors are standing by with facility-specific guidance to evaluate compliance with the mandate.

“It’s in effect for the time being,” said Richelle Marting, an attorney in Olathe, Kansas. The decision lifts the preliminary injunctions that have been holding up the vaccine mandate in states that sued CMS. Marting expects providers in those states to have a difficult time rolling out the vaccine requirement by the first deadline and could face enforcement actions. But there’s talk that CMS may update guidance and give facilities in the states where the injunction was lifted by the Supreme Court decision more time to comply.

The question before the Supreme Court wasn’t whether the vaccine mandate was legal, said attorney Sandra DiVarco, with McDermott Will & Emery in Chicago. The question was whether the injunction should be stayed, and that question is decided based on whether the “underlying case has a likelihood of succeeding on the merits,” she explained. “That means the mandate is now enforceable in the entire country.” But the Supreme Court decision may not be the last word. “States could continue to challenge the mandate,” Marting said. In fact, it’s likely the 25 states will return to court to try to stop the vaccine mandate based on the merits of the case, DiVarco said. “This back and forth continues to have health care facilities and their employees on edge with uncertainty, particularly in areas with low vaccination rates,” Marting remarked.

CMS rolled out the vaccine mandate in November, with two phases: By Dec. 6, providers were required to have a plan for vaccinating staff, providing medical or religious exemptions and accommodations, and tracking and documenting vaccinations. Employees and other people (e.g., licensed practitioners, students, trainees, contracted staff and others “who provide care, treatment or other services at the facility”) must have the one-dose vaccine or the first shot of the two-dose vaccine by that date or have requested an exemption. Everyone was required to be fully vaccinated by Jan. 4 unless an exemption had been granted. The dates have changed, but the substance of the regulation, with its copious documentation requirements, remains the same.

The regulation was challenged in separate lawsuits. One lawsuit led by Missouri on behalf of 10 states was filed in

the U.S. District Court for the Eastern District of Missouri, which granted a preliminary injunction Nov. 29.^[4] Then 15 more states led by Louisiana on Dec. 30 got a preliminary injunction from the U.S. District Court for the Western District of Louisiana, which stayed the vaccine mandate for the whole country (except the 10 states that had already gotten relief).^[5]

CMS appealed to the Supreme Court, asking it to stay the preliminary injunctions. Meanwhile, CMS announced it would enforce the vaccine regulation in the 25 states that had not resisted the mandate.

Court: ‘Vaccination Requirements are a Common Feature’

In its decision, the Supreme Court noted that HHS “routinely imposes conditions of participation that relate to the qualifications and duties of healthcare workers themselves.” For example, employees must be trained on infection control. “When asked at oral argument whether the Secretary could, using the very same statutory authorities at issue here, require hospital employees to wear gloves, sterilize instruments, wash their hands in a certain way and at certain intervals, and the like, Missouri answered yes: ‘[T]he Secretary certainly has authority to implement all kinds of infection control measures at these facilities.’ Tr. of Oral Arg. 57–58. Of course the vaccine mandate goes further than what the Secretary has done in the past to implement infection control. But he has never had to address an infection problem of this scale and scope before. In any event, there can be no doubt that addressing infection problems in Medicare and Medicaid facilities is what he does. And his response is not a surprising one. Vaccination requirements are a common feature of the provision of healthcare in America: Healthcare workers around the country are ordinarily required to be vaccinated for diseases such as hepatitis B, influenza, and measles, mumps, and rubella.”

The Supreme Court’s decision wasn’t a surprise, DiVarco noted. “This is the outcome most people who have been watching the cases anticipated.” What will be interesting to watch next is whether CMS pushes the compliance dates out further because hospitals and other facilities that may have slowed their efforts at compliance awaiting a decision only have two weeks from the date of the court decision to comply. “Many of their providers may have slow-walked their compliance and now in theory need to be fully compliant with phase one and have 100% of covered providers have a first shot in two weeks,” DiVarco said. “In certain parts of the country that’s not the case.” The other intriguing aspect is what enforcement will look like, she said. CMS issued guidance for state surveyors on enforcing the vaccine mandate on Dec. 28 in the other 25 states, and “facilities are already concerned about enforcement of the phase 1 requirements, which hasn’t happened as of yet.”

CMS Survey Memo: Full Compliance in 90 Days

Hospitals and other facilities will now face the prospect of surveyors assessing their compliance with the vaccine mandate in their conditions-of-participation surveys. In the Dec. 28 memo from the Center for Clinical Standards and Quality to surveyors, CMS conveys that facilities risk their Medicare participation unless they fully comply with the mandate.^[6] “Facility staff vaccination rates under 100% constitute noncompliance under the rule,” CMS states. “Within 90 days and thereafter following issuance of this memorandum, facilities failing to maintain compliance with the 100% standard may be subject to enforcement action.” CMS also released separate guidance for each type of facility subject to the vaccine mandate (e.g., hospitals, nursing homes, ambulatory surgery centers). In the survey guidance for hospitals, for example, CMS states that: “Compliance will be assessed through observation, interview, and record review as part of the survey process. ... Surveyors will ask hospitals to provide vaccination policies and procedures. At a minimum, the policy and procedures must provide: A process for ensuring all required staff have received, at a minimum, the first dose of a multi-dose COVID-19 vaccine, or a one-dose COVID-19 vaccine, before staff provide any care, treatment, or other services for the hospital and/or its patients.”^[7]

The memo also stated that surveyors should “examine the documentation of each staff identified as unvaccinated due to medical contraindications.” Although the mandate is a fait accompli unless the 25 states that challenged it go back to court and win on the merits, that doesn’t make staffing problems disappear in low-vaccination states and facilities, Marting said. In long-term care facilities in many midwestern states, for example, there’s a staffing shortage exacerbated by vaccine resistance, she said. Sometimes they’re forced to rely on staffing agencies that rotate staffers in and out, making it hard to track their vaccination status or exemptions and to evaluate whether exemptions were given in good faith, she noted. How carefully does the facility question religious exemptions before they’re accepted or declined? “The survey guidance will not scrutinize religious exemption requests,” Marting noted.

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1 Biden, et al. v. Missouri, et al., 595 U. S. ____ (2022), <https://bit.ly/3tpzOnI>.

2 Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555 (November 5, 2021), <https://bit.ly/3mPyG9y>.

3 “Current emergencies,” Centers for Medicare & Medicaid Services, last modified January 12, 2022, <https://go.cms.gov/2MVnAgi>.

4 State of Missouri et al. v. Joseph R. Biden, Jr. et al., Case No. 4:21-cv-01329-MTS (E.D. Mo., November 29, 2021), <https://bit.ly/3ddtrLa>.

5 State of Louisiana et al v. Xavier Becerra et al, Case No. 3:21-CV-03970 (W.D. La., November 30, 2021), <https://bit.ly/3I9LwrE>.

6 CMS, Center for Clinical Standards and Quality, Quality, Safety & Oversight Group, “Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination,” QSO-22-07-ALL, December 28, 2021, <https://go.cms.gov/3FsnyFp>.

7 CMS, Center for Clinical Standards and Quality, Quality, Safety & Oversight Group, “Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination: Hospital Attachment,” QSO-22-07-ALL, accessed January 14, 2022, <https://go.cms.gov/3GvmFo7>.

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