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CMS Vaccine Mandate Is in Effect Despite Lawsuits, Attorneys Say

By Nina Youngstrom

Notwithstanding the lawsuit filed by 12 states against CMS over its Nov. 5 COVID-19 vaccination regulation for Medicare and Medicaid facilities less than a week after 10 other states did the same thing, it's in effect, and health care organizations should be moving toward compliance, lawyers say.^[1] The Omnibus COVID-19 Health Care Staff Vaccination Regulation, an interim final rule, is being challenged on the grounds that it was implemented without proper notice and comment rulemaking and without statutory authority.^[2] CMS crafted the regulation to withstand the substantive challenges, but it may lose on procedural grounds, which would delay the vaccine mandate, not defeat it, an attorney said.

"For now, December and January deadlines are in effect and likely the deadlines will remain in effect," said Chris Kenny, an attorney with King & Spalding in Washington, D.C., at a Nov. 16 webinar sponsored by the firm.^[3] They are "the law of the land unless a judge enjoins the rule and perhaps remands it."

Some states also are considering laws prohibiting vaccine mandates that could complicate compliance, although CMS anticipated them as well and insists in the regulation that it pre-empts state laws and executive orders because of the supremacy clause of the U.S. Constitution, which states that federal laws supersede any conflicting state laws, Kenny said. "Be prepared to comply while the deadlines are in effect and if that changes, provider responses will have to be recalibrated along those lines."

The Mandate Extends Beyond the PHE

According to the omnibus vaccine regulation, providers are required to have a plan for vaccinating staff, providing exemptions and accommodations, and tracking and documenting vaccinations by Dec. 6. 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. Everyone must be fully vaccinated by Jan. 4 unless they have an exemption. Board members and volunteers also must be vaccinated, said Kim Roeder, an attorney with King & Spalding, at the webinar.

The vaccine mandate doesn't apply to staff who don't have direct contact with patients or other facility staff. That includes people who exclusively provide telehealth services or work remotely 100% of the time, such as accounting or payroll services. Frequency isn't a factor, which means therapy providers and others who pop in and out to perform services must be vaccinated because "they have the potential to have contact with people at the site of care," Roeder said. "CMS does discuss some staff who would not be covered by this rule who provide ad hoc services, such as annual elevator inspections" or who come into the facility for specific limited purposes (e.g., delivery or repair persons).

CMS requires facilities to allow medical and religious exemptions from the COVID-19 vaccine if people qualify. With the medical exemption, the reason why the vaccines are clinically contraindicated for the staffer must be documented, with a statement from "the authenticating practitioner recommending that the staff member be exempted," according to answers to frequently asked questions.^[4] Requests for a religious exemption must be

documented by facilities “and evaluated in accordance with applicable federal law and as a part of a facility’s policies and procedures.”

The vaccination requirements will be enforced through the Medicare conditions of participation (CoPs). That’s no different from how CMS enforces other CoPs, Kenny said. CMS will work with state survey agencies to set the ground rules for reviewing COVID-19 vaccination policies and processes and vaccination numbers “to see if they’re making an impact.” Surveyors also have leeway to “make observations and conduct interviews of provider staff during surveys,” Kenny said.

If a provider is out of compliance with the CoPs, “the nuclear option is termination,” Kenny said. That’s reserved for cases where surveyors believe beneficiary health and safety is in immediate jeopardy. There are also intermediate consequences, including civil monetary penalties or suspension of Medicare payments. For minor noncompliance, providers must submit a plan of correction. “Suffice it to say, because the rule is so sweeping and issued on an interim basis, the agency is not messing around and will be reviewing staff lists very closely and demanding proof that if someone is unvaccinated after January 4, there was a valid exception,” Kenny said.

Because it’s not tied to the duration of the public health emergency, the vaccine regulation will extend beyond the public health emergency, Roeder said. But it expires in three years because it’s an interim final rule.

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