CMS COVID-19 Health Care Staff Vaccination Interim Final Rule Update

Client Update
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Contents

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NOTE: This has been updated to reflect the dismissal of the Texas challenge to the rule and the newly issued compliance deadlines for Texas facilities.

On January 13, the U.S. Supreme Court, in a *per curiam* decision lifted a stay that prevented implementation of the the Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule (Rule) that was issued by CMS in November of last year.

In front of the Supreme Court were preliminary injunctions entered in two legal challenges brought by 24 states in the U.S. District Courts for the Western District of Louisiana and the Eastern District of Missouri.[1] The Supreme Court's decision stays those preliminary injunctions pending review by the respective federal appeals courts. It makes the Rule enforceable across covered health care entities—i.e., those certified providers and suppliers subject to the Rule—nationwide.[2]

Importantly, the Supreme Court's opinion is definitive that the rule falls within the authority of the Secretary of Health and Human Services to promulgate based on the statutory authority conferred by Congress through the Social Security Act. Specifically, the court found that the Rule allows the Secretary to impose conditions of participation on the receipt of Medicare and Medicaid funds that are necessary in the interest of the health and safety of individuals who furnish services reimbursable under those programs and the federal program beneficiaries that they serve.

Overview of the Rule at Issue

As discussed in more detail in our alert following its issuance, the Rule amended the CMS Conditions of Participation, Conditions for Coverage and Requirements for Participation in Medicare to create a SARS-CoV-2 vaccination obligation for employees and staff, with related tracking and documentation requirements, and an obligation to follow nationally recognized infection prevention and control guidelines to mitigate the transmission and spread of SARS-CoV-2. These requirements apply to the following types of health care entities and will be enforced through state survey agencies, as discussed in our prior alert.

- Ambulatory Surgical Centers (ASCs) (§ 416.51)
- Hospices (§ 418.60)
- Psychiatric residential treatment facilities (PRTFs) (§ 441.151)

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[1] The Louisiana case was brought by the following 14 states: Arizona, Alabama, Georgia, Idaho, Indiana, Kentucky, Louisiana, Mississippi, Montana, Ohio, Oklahoma, South Carolina, Utah, and West Virginia. (*Louisiana v. Becerra*, No. 3:21-cv-03970 (W.D. La. Nov. 30, 2021)) and is on appeal to the U.S Court of Appeals for the Fifth Circuit (*Louisiana v. Becerra*, No. 21-30734 (5th Cir. Dec. 15, 2021)).

The Missouri case was brought by the following 10 states: Alaska, Arkansas, Iowa, Kansas, Missouri, Nebraska, New Hampshire, North Dakota, South Dakota and Wyoming, (*Missouri v. Biden*, No. 4:21-cv-01329 (E.D. Mo. . Dec. 1, 2021)) and is on appeal to the U.S. Court of Appeals for the Eighth Circuit (*Missouri v. Biden,* No. 21-03725 (8th Cir. Dec. 7, 2021)).

There are currently two other challenges pending: a case brought by Texas in the U.S. District Court for the Northern District of Texas (*Texas v. Becerra*, No. 2:21-cv-00229 (N.D. Tex. Dec. 15, 2021)) and one brought by Florida in the U.S. District Court for the Northern District of Florida (*Florida v. HHS*, No. 3:21-cv-02722 (N.D. Fla. Nov. 20, 2021)).

[2] The Texas case was enjoined by the district court in response to the order from the U.S. Court of Appeals for the Fifth Circuit that limited the injunction in the Louisiana case to only the 14 states that were parties to that challenge. Since the Texas injunction was not part of the appeal to the Supreme Court it was not stayed by the high Court's ruling. However, after the CMS appealed the injunction to the Fifth Circuit, Texas asked for and was granted a dismissal without prejudice. As a result, the injunction is enforceable nationwide with no exceptions.

However, in the Florida case, neither the district court nor the U.S. Court of Appeals for the Eleventh Circuit (*Florida v. HHS*, No. 21-30734 (11th Cir. Dec. 6, 2021)) entered an order stopping the rule, so Florida was never in the group of states in which the rule was enjoined.

- Programs of All-Inclusive Care for the Elderly (PACE) (§ 460.74)
- Hospitals (acute care hospitals, psychiatric hospitals, hospital swing beds, long term care hospitals, children's hospitals, transplant centers, cancer hospitals, and rehabilitation hospitals/inpatient rehabilitation facilities) (§ 482.42)
- Long Term Care (LTC) Facilities, including Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs), generally referred to as nursing homes (§ 483.80)
- Home Health Agencies (HHAs) (§ 484.70)
- Comprehensive Outpatient Rehabilitation Facilities (CORFs) (§§ 485.58 and 485.70)
- Clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services (§ 485.725)
- Community Mental Health Centers (CMHCs) (§ 485.904)
- Rural Health Clinics (RHCs)/Federally Qualified Health Centers (FQHCs) (§ 491.8)

The following facilities are included in the original Rule and are included in the Court's order, so they are currently covered by the requirement.

- Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) (§ 483.430)
- Inpatient Psychiatric Hospital Services for Individuals Under Age 21 (§ 441.151)
- End-Stage Renal Disease (ESRD) Facilities (§ 494.30)
- Home Infusion Therapy (HIT) suppliers (§ 486.525)
- Critical Access Hospitals (CAHs) (§ 485.640)

However, a footnote in the Court's opinion introduces some question as to whether these facilities will continue to be included after the appeals courts have completed their review.

In his dissenting opinion, Justice Thomas pointed out that the five statutory provisions that define these provider and supplier entities and that the Centers for Medicare & Medicaid Services relied on in crafting the Rule, do not contain the express health and safety language that framed the underpinnings of the Court's opinion. He argued that this difference opens the door for an interpretation that the CMS may not have the authority to promulgate the Rule with respect to those providers and suppliers.

Addressing that point, the Court's *per curiam* decision in a footnote argues that "employees at these facilities—which include end-stage renal disease clinics and home infusion therapy suppliers—represent less than 3% of the workers covered by the rule." Additionally the Court notes that "We see no reason to let the infusion-clinic tail wag the hospital dog, especially because the rule has an express severability provision."

This footnote could potentially be read as an opening from the Court to entertain the lower court approving the full Rule but severing those entities from the list of impacted entities. However, in its current opinion, the Supreme Court performed no such surgery on the Rule and instead allowed the full Rule as written to go into effect.

Indirectly covered entities

Entities that are not listed above are not directly subject to the Rule, and this includes some notable exceptions. For example, physicians and physician offices are not subject to the Rule directly because they do not have CMS Conditions for Coverage (physicians are classified as "suppliers" under Medicare law) and are not surveyed by state survey agencies.

That said, a physician who has staff privileges at a hospital would be subject to the Rule by virtue of its application to the hospital. DMEPOS suppliers, such as pharmacies, are another example of a Medicare enrollment that is not directly subject to the Rule. Organ Procurement Organizations and Portable X-Ray suppliers are another example.

What staff are covered?

As discussed in our prior alert, the CMS Rule applies to eligible staff working at facilities that participate in the Medicare and Medicaid programs, regardless of clinical responsibility or patient contact. The requirement includes all current staff as well as any new staff who provide any care, treatment, or other services for the facility and/or its patients. This includes facility employees, licensed practitioners, students, trainees, and volunteers. This also includes individuals who provide care, treatment, or other services for the facility and/or its patients under contract or other arrangements.

However, employees who work remotely on a full-time basis through telework are not covered by the Rule. The Rule contemplates certain other fact-specific circumstances under which ad hoc service providers, such as annual elevator inspection personnel, may not be covered by the Rule.

Compliance

The dates for compliance with the Rule have been adjusted from the original dates in the Rule based on an earlier nationwide injunction against the Rule. The new dates were put in place during the last week of December, after that nationwide injunction was scaled back to apply only to the states that directly challenged the Rule in court. The CMS administrator announced that the legal challenges to the Rule do not affect the current timetable for the 24 states (California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Tennessee, Vermont, Virginia, Washington, and Wisconsin), the District of Columbia and the U.S. territories that did not challenge the Rule in court, as well as the state of Florida, whose pending challenge has not resulted in an injunction. Entities in those states are still subject to the following compliance dates:

Phase 1: As of January 27, 2022, all covered individuals must have either completed the initial dose of a primary series of vaccine or applied for an exemption for religious or health reasons.

Phase 2: As of February 28, 2022, all covered individuals must have either completed the primary series of vaccine or been approved for an exemption for religious or health reasons. The employee need not have passed through the two-week post-vaccination period that generally defines complete vaccination; they need only have received their complete series of vaccines.

However, the states involved in the injunctions and challenges heard before the Supreme Court will have more time to come into compliance to account for the time that elapsed while their injunctions were pending before the Court. For those states (Alaska, Alabama, Arizona, Arkansas, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, New Hampshire, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Utah, West Virginia and Wyoming) the following compliance dates apply:

Phase 1: As of February 14, 2022, all covered individuals must have either completed the initial dose of a primary series of vaccine or applied for an exemption for religious or health reasons.

Phase 2: As of March 15, 2022, all covered individuals must have either completed the primary series of vaccine or been approved for an exemption for religious or health reasons. The employee need not have passed through the two-week post-vaccination period that generally defines complete vaccination; they need only have received their complete series of vaccines.

Finally, as a result of Texas dropping its challenge to the rule, the CMS issued a third set of deadlines, this one only impacting facilities in Texas:

Phase 1: As of February 22, 2022, all covered individuals must have either completed the initial dose of a primary series of vaccine or applied for an exemption for religious or health reasons.

Phase 2: As of March 21, 2022, all covered individuals must have either completed the primary series of vaccine or been approved for an exemption for religious or health reasons. The employee need not have passed through the two-week post-vaccination period that generally defines complete vaccination; they need only have received their complete series of vaccines.

The Rule requires the immunized staff to have received EITHER one of the FDA authorized vaccines OR one from the World Health Organization list of approved vaccines.

There is no option for affected providers and suppliers to choose to test their employees regularly instead of implementing the vaccine mandate across the company. However, should an employee obtain a religious or medical exemption from the mandate, the provider or supplier must implement procedures to minimize the spread of COVID-19 in the workplace (i.e., regular testing and masking).

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