

## Guidance on the CMS Vaccine Mandate

In light of the U.S. Supreme Court's decisions on January 13, 2022, on the U.S. Centers for Medicare & Medicaid Services (CMS) vaccine mandate and the Occupational Safety and Health Administration (OSHA) Emergency Temporary Standard, the Montana Department of Public Health and Human Services issues the following guidance for Montana health care facilities and providers with respect to the CMS mandate.

### The Vaccine Mandates Potentially Applicable to Montana Health care Providers

The Biden Administration has issued three vaccine mandates potentially applicable to Montana health care providers:

- CMS Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule (CMS mandate). The CMS mandate is the subject of this guidance and is discussed in more detail below.
- OSHA COVID-19 Vaccination and Testing; Emergency Temporary Standard Interim Final Rule (OSHA mandate). The OSHA mandate requires employers with at least 100 employees to require their employees to receive the COVID-19 vaccination, except for employees who agree to obtain a weekly COVID-19 test and wear a mask each workday. A number of challenges to the OSHA mandate were filed. On January 13, 2022, the Supreme Court concluded that it was likely that the OSHA mandate exceeds OSHA's statutory authority and is otherwise unlawful, and stayed the OSHA mandate pending final resolution of the challenges to the rule (including any review by the Supreme Court).
- Federal Contractor Mandate. Pursuant to Executive Order 14042, federal agencies are required to mandate, with respect to certain contracts entered into, extended, or renewed after October 15, 2021, that contractors impose a COVID-19 vaccine requirement on their employees. The federal contractor mandate was challenged and has been enjoined nationwide pending final resolution in federal court.

### The CMS Vaccine Mandate

The CMS mandate was published on November 5, 2021. It requires that Medicare and Medicaid-certified facilities subject to Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements establish a policy ensuring that all covered staff have received the first dose of a two-dose COVID-19 vaccine, or a one-dose COVID-19 vaccine within 30 days and have received the necessary shots to be fully vaccinated within 60 days.<sup>1</sup> **The CMS mandate provides for exemptions for staff as a reasonable accommodation for a disability, for sincerely held religious belief, observance or practice, and for medical reasons, and requires facilities to have a process for permitting such exemptions.**

#### Covered Facilities

There are 21 health care provider and supplier types covered by the CMS mandate. The following facilities are covered by the CMS mandate if they participate in the Medicare or Medicaid programs:

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<sup>1</sup> Under the CMS mandate, a staff member is "fully vaccinated" two weeks after completion of their primary vaccination series for COVID-19 (the single dose of a one-dose vaccine or the second dose of a two-dose vaccine).

- Ambulatory Surgery Centers
- Community Mental Health Centers
- Comprehensive Outpatient Rehabilitation Facilities
- Critical Access Hospitals
- End-Stage Renal Disease Facilities
- Home Health Agencies
- Home Infusion Therapy Suppliers
- Hospices
- Hospitals
- Intermediate Care Facilities for Individuals with Intellectual Disabilities
- Outpatient Therapy Providers (Certified and Surveyed by a State Agency or CMS-approved Accrediting Organization), including Clinics, Rehabilitation Agencies and Public Health Agencies that provide outpatient therapy and speech-language pathology services
- Psychiatric Residential Treatment Facilities (PRTFs)
- Programs for All-Inclusive Care for the Elderly (PACE) organizations
- Rural Health Clinics/Federally Qualified Health Centers
- Long Term Care Facilities

Religious Nonmedical Health Care Organizations, Organ Procurement Organizations, and Portable X-ray Suppliers are not covered by the CMS mandate. The CMS mandate also does not apply to Assisted Living Facilities, Group Homes, physician offices, noncertified therapy providers (e.g., therapists in private practice or group practices (Therapists in Private Practice or TPPs)), or providers of Home and Community-Based Services. It also does not apply to schools that receive Medicaid funding. EMS providers are not subject to the CMS mandate unless such providers have a contractual relationship with a facility covered by the mandate that would require them to be vaccinated.

#### Covered Staff

The CMS mandate applies to all eligible staff working at a facility that participates in the Medicare or Medicaid program, regardless of clinical responsibility or patient contact. It applies to all current and new staff who provide any care, treatment, or other services for the facility and/or its patients. It covers employees, licensed practitioners, students, trainees, and volunteers, as well as individuals who provide services for a covered facility, or its patients, under contract or other arrangements. Physicians who having admitting privileges in a hospital or who treat patients in-person at a hospital are considered part of the hospital's covered staff.

CMS has indicated that facilities are not required to ensure vaccination of vendors, volunteers or professionals who infrequently provide ad hoc, non-health care services or services that are performed exclusively off-site and not at or adjacent to any site of patient care. CMS guidance indicates that facilities may choose to extend COVID-19 vaccination requirements to these individuals. **However, such action would be inconsistent with, and not permitted under, Montana law.** See MCA 49-2-312.

The CMS mandate does not apply to the personal visitors of patients, such as family members or friends.

#### **Status of the CMS Mandate and Related Litigation**

A number of States, including Montana, and health care providers challenged the CMS mandate, including in the Eastern District of Missouri and the Western District of Louisiana (the lawsuit in which Montana is a plaintiff). District court judges in the Eastern District of Missouri and the Western District of Louisiana issued preliminary injunctions against the CMS mandate, finding that the States (and other plaintiffs) were likely to succeed on the merits. CMS asked the Eighth Circuit and the Fifth Circuit, respectively, to stay the preliminary injunctions pending appeal; both rejected CMS's motions. CMS requested that the Supreme Court issue a stay of the preliminary injunctions. On January 13, 2022, the Supreme Court, in a 5-4 per curiam decision, concluded that HHS/CMS did not exceed its statutory authority in issuing the CMS mandate, and granted CMS's application for stay, pending disposition of CMS's appeals of the preliminary injunctions (including any review by the Supreme Court). **There remain legal questions unresolved by the Supreme Court's decision, and the State of Montana will continue to press its claims that the CMS mandate is unconstitutional and otherwise unlawful in the district and appellate courts.** However, the Supreme Court has stayed the previously entered preliminary injunctions, which permits CMS to implement and enforce the CMS mandate for now.

On January 14, 2022, CMS issued guidance to State Survey Agencies that specifically addresses compliance in the States which had challenged the CMS mandate in the Eastern District of Missouri and the Western District of Louisiana. Under this guidance, covered facilities in Montana will be considered compliant with the CMS mandate if

- Within 30 days of January 14, 2022, the facility demonstrates that
  - It has developed and implemented policies and procedures for ensuring all facility staff are vaccinated for COVID-19; and
  - 100% of staff have received at least one dose of COVID-19 vaccine, have a pending or granted request for a medical or religious exemption, or have been identified as having a temporary delay as recommended by the U.S. Centers for Disease Control and Prevention (CDC).
- Within 60 days of January 14, 2022, the facility demonstrates that
  - It has developed and implemented policies and procedures for ensuring all facility staff are vaccinated for COVID-19; and
  - 100% of staff have received the necessary doses to complete the vaccine series (one dose of a single dose vaccine or two doses of a two-dose vaccine series), have a pending or granted request for a medical or religious exemption, or have been identified as having a temporary delay as recommended by CDC.

For each time period, the guidance identifies levels at which facilities could be subject to enforcement, depending on the severity of the deficiency and the type of facility. CMS also notes that, after 90 days, facilities failing to maintain compliance with the 100% standard may be subject to enforcement action.

#### Policies and Procedures

The CMS mandate requires that covered facilities develop and implement policies and procedures/processes:

- To ensure that all covered staff (except for those who have pending requests for, or who have been granted, exemptions to the vaccination requirements, or those for whom COVID-19 vaccination must be temporarily delayed, as recommended by CDC, due to clinical precautions

and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to providing any care, treatment, or other services for the hospital and/or its patients.

- Temporary delay is recommended due to clinical precautions and considerations for
  - Individuals with current SARS-COV-2 infection.
  - Individuals with acute illness secondary to COVID-19.
  - Individuals who received monoclonal antibodies or convalescent plasma for COVID-19 prophylaxis or treatment.
  - Individuals with a history of multi-system inflammatory syndrome in adults.
  - Individuals with myocarditis or pericarditis.
- To ensure that all covered staff are fully vaccinated for COVID-19, except for those who have been granted exemptions, or for whom COVID-19 vaccination must be temporarily delayed, as recommended by CDC, due to clinical precautions and considerations noted above.
- To ensure the implementation of additional precautions to mitigate the transmission and spread of COVID-19, for staff who are not fully vaccinated for COVID-19.
- To track and document the COVID-19 vaccination status of all covered staff, including those who have obtained any booster doses.
- For staff to request an exemption from the COVID-19 vaccination requirements based on an applicable Federal law (e.g., medical or religious exemptions) and to track and document the information provided by those who have requested, and for whom the hospital has granted, an exemption.
- To ensure that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains:
  - All information specifying the COVID-19 vaccines that are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications.
  - A statement by the practitioner recommending that the staff member be exempted from the vaccination mandate based on the recognized clinical contraindications.
- To ensure the tracking and documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed.
- For contingency plans for staff who are not fully vaccinated for COVID-19.

#### Medical and Disability Exemptions

As indicated above, the CMS mandate requires facilities to allow exemptions for staff members (1) with a disability as an accommodation under the Americans with Disabilities Act, or (2) with medical conditions for which vaccines are contraindicated. With respect to medical contraindications, the CMS mandate requires that facilities obtain documentation signed by a licensed practitioner (who is not the individual requesting the exemption), acting within their scope of practice based on state/local law, that confirms the recognized clinical contraindications to the COVID-19 vaccine. The mandate requires that the documentation contain “all information” specifying the COVID-19 vaccine(s) which are

contraindicated for the staff member and the recognized clinical reasons for the contraindications. The documentation signed by the licensed practitioner must also include a statement that the practitioner recommends that the staff member be exempted from the facility's COVID-19 vaccination requirements.

### Religious Exemptions

The CMS mandate requires facilities to allow exemptions for staff members who object on the basis of religious beliefs, observances or practices, under Title VII of the Civil Rights Act of 1964. CMS guidance refers covered facilities to the Equal Employment Opportunity Commission's (EEOC) Compliance Manual on Religious Discrimination, under Title VII (employment) of the Civil Rights Act of 1964, for information on evaluating and responding to requests for religious exemptions. Accordingly, pursuant to Title VII and federal case law (and MCA 49-2-303), covered facilities must incorporate the following guidance, derived from the EEOC Compliance Manual, into their policies and procedures/processes. Failure to issue religious exemptions may subject a covered facility to liability under Title VII and the Montana Human Rights Act.

CMS indicates that, in conducting surveys or investigations, surveyors will not evaluate the details of a religious exemption request, nor a facility's rationale for accepting or denying the request, but will review the policies and procedures/processes to ensure the facility has an effective processes for staff to request a religious exemption for a sincerely held religious belief.

The following guidance is derived from the EEOC Compliance Manual.

Religious Belief or Practice. The EEOC manual notes that federal law protections apply whether the religious beliefs or practices in question are common or non-traditional, and regardless of whether they are recognized by any organized religion. It points out that Title VII defines "religion" to include "all aspects of religious observance and practice as well as belief," not just practices that are mandated or prohibited by a tenet of the individual's faith. Under federal case law, a belief is "religious" for Title VII purposes if it is "religious" in the person's "own scheme of things," i.e., it is a "sincere and meaningful" belief that "occupies a place in the life of its possessor parallel to that filled by . . . God." Furthermore, as the EEOC points out, an employee's belief, observance, or practice can be "religious" under Title VII even if the employee is affiliated with a religious group that does not espouse or recognize that individual's belief, observance, or practice, or if few – or no – other people adhere to it.<sup>2</sup>

The EEOC points out that, under federal caselaw, religious beliefs include "moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional religious views." Religion typically concerns "ultimate ideas" about "life, purpose, and death." Social, political, or economic philosophies, as well as mere personal preferences, are not religious beliefs protected by Title VII. However, as the EEOC notes, the overlap between a religious and political view does not place the religious view/belief outside the scope of Title VII's religion protections, as long as that view is part of a comprehensive religious belief system.

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<sup>2</sup> This is also true under Montana law: religious exemptions also encompass sincerely held personal religious beliefs, not just religious beliefs or tenets of an established or recognized religion. See 44 Opinions of the Montana Attorney General 33, 36-37 (Feb. 27, 1991) (religious exemption to mandatory student immunization encompasses sincerely held religious belief and not only religious beliefs or tenets of an established or recognized religion, citing federal and state cases) (Racicot, Att'y Gen.).

Sincerity of Belief. The EEOC manual states that the sincerity of an employee's stated religious belief is usually not in dispute and is "generally presumed or easily established." Further, it notes that the EEOC and the courts "are not and should not be in the business of deciding whether a person holds religious beliefs for the 'proper' reasons. [The EEOC] thus restrict[s] [its] inquiry to whether or not the religious belief system is sincerely held; [it] do[es] not review the motives or reasons for holding the belief in the first place." The individual's sincerity in espousing a religious observance or practice is "largely a matter of individual credibility." Moreover, "a sincere religious believer doesn't forfeit his religious rights merely because he is not scrupulous in his observance," although "[e]vidence tending to show that an employee acted in a manner inconsistent with his professed religious belief is, of course, relevant to the factfinder's evaluation of sincerity." The EEOC manual notes, however that an individual's beliefs – or degree of adherence – may change over time, and therefore an employee's newly adopted or inconsistently observed religious practice may nevertheless be sincerely held. Similarly, an individual's belief may be to adhere to a religious custom only at certain times, even though others may always adhere, or, fearful of discrimination, he or she may have forgone his or her sincerely held religious practice during the application process and not revealed it to the employer until after he or she was hired or later in employment. An employer also should not assume that an employee is insincere simply because some of his or her practices deviate from the commonly followed tenets of his or her religion, or because the employee adheres to some common practices but not others.

**The EEOC manual counsels that, because the definition of religion is broad and protects beliefs, observances, and practices with which the employer may be unfamiliar, the employer should ordinarily assume that an employee's request for religious accommodation is based on a sincerely held religious belief.<sup>3</sup>**

Reasonable Accommodation. As the EEOC notes, Title VII requires an employer, once on notice, to reasonably accommodate an employee whose sincerely held religious belief, practice, or observance conflicts with a work requirement, unless providing the accommodation would create an undue hardship. The EEOC notes that employers who unreasonably request unnecessary or excessive corroborating evidence risk being held liable for denying a reasonable accommodation request, and having their actions challenged as retaliatory or as part of a pattern of harassment.<sup>4</sup>

Under the EEOC manual, where there is more than one reasonable accommodation that would not pose an undue hardship, the employer is not obliged to provide the accommodation preferred by the employee. However, an employer's proposed accommodation will not be "reasonable" if a more favorable accommodation is provided to other employees for non-religious purposes, or, for example, if it requires the employee to accept a reduction in pay rate or some other loss of a benefit or privilege of employment and there is an alternative accommodation that does not do so.

Furthermore, the EEOC manual indicates that an employer may have to make an exception to its policies, procedures, or practices in order to grant a religious accommodation.

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<sup>3</sup> Under Montana law, entities should refrain from challenging the sincerity of an individual's religious belief, absent established standards. See 44 Opinions of the Montana Attorney General at 40-41 (absent use of established, uniform standards or procedures, a school district should refrain from challenging an affidavit claiming a religious exemption from mandatory immunization).

<sup>4</sup> The same is true under Montana law. See MCA 49-2-303.