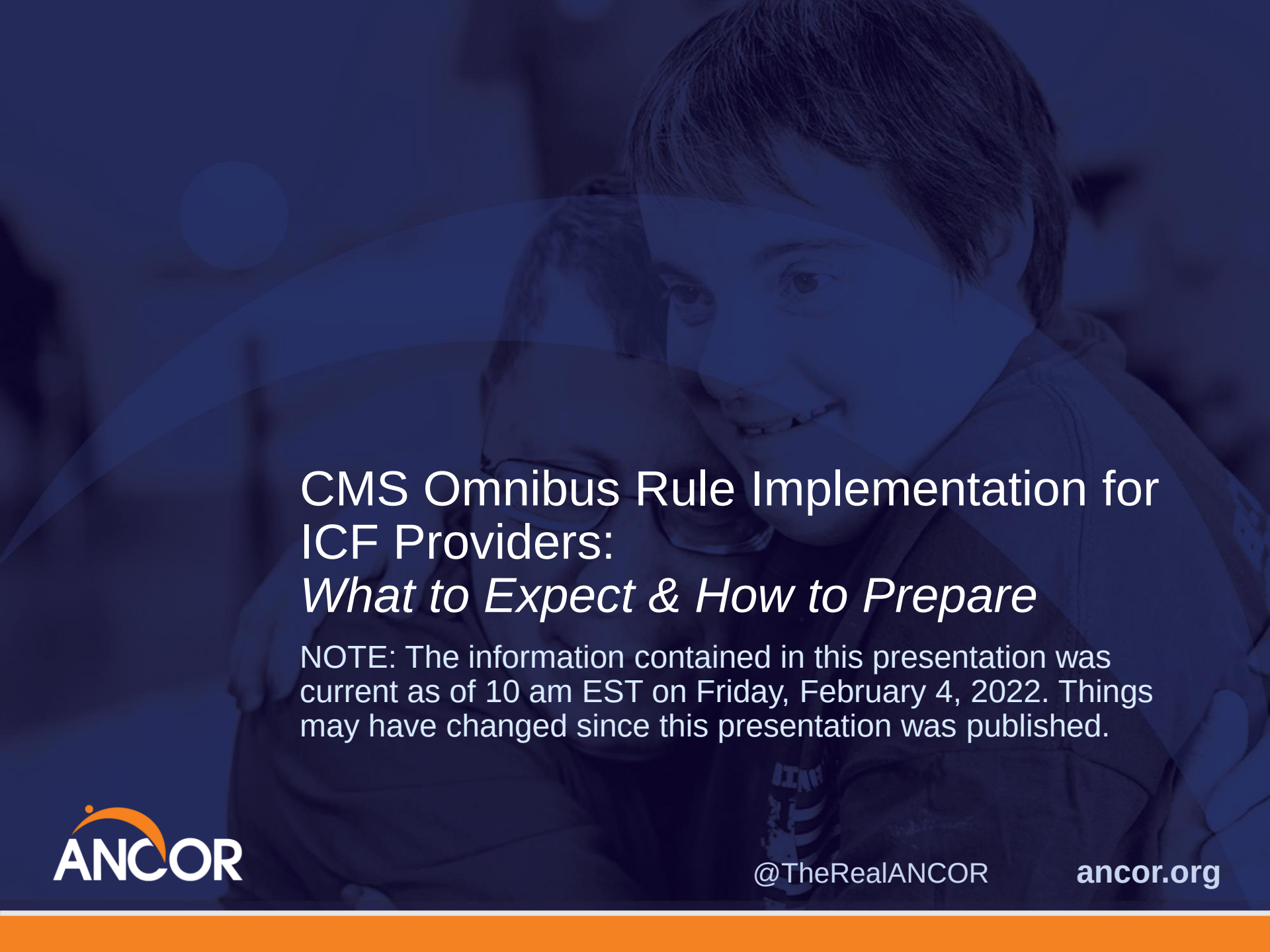

CMS Omnibus Rule Implementation for ICF Providers:
What to Expect & How to Prepare

NOTE: The information contained in this presentation was current as of 10 am EST on Friday, February 4, 2022. Things may have changed since this presentation was published.

This ANCOR webinar was issued on February 4, 2022 pursuant to ANCOR's understandings of the regulations at that time. However, legal standards may change and consulting an attorney engaged to protect your interest is best practice in interpreting and applying state and federal law and regulation. This presentation and information contained is intended to convey general information only and should not be construed as legal advice or opinion.

Contact Information

Lydia Dawson, J.D.
Director of Policy, Regulatory and Legal Analysis
American Network of Community Options and Resources
1101 King Street, Suite 380
Alexandria, VA 22314
Office: 703.535.7850 x117
Direct Line: 571.932.5375
ldawson@ancor.org
www.ancor.org

Prior to SCOTUS Decision

Headed into oral arguments:

- OSHA COVID-19 Vaccination and Testing ETS
  - Required vaccination or weekly negative testing for employers with 100+ employees
  - Sixth Circuit Court of Appeals dissolved the stay
- CMS Omnibus COVID-19 Health Care Staff Vaccination Rule
  - Requires vaccination of facility staff at facilities governed by conditions of participation
  - Fifth Circuit Court of Appeals narrowed the nationwide preliminary injunction to half the country

SCOTUS Decision

- OSHA COVID-19 Vaccination and Testing ETS
  - **In a 6-3 opinion blocked the ETS from going into effect pending lower court review.**

- CMS Omnibus COVID-19 Health Care Staff Vaccination Rule
  - **In a 5-4 opinion allowed the IFR to go into effect pending lower court review.**

* While the decision was technically limited to the decision to whether the interim final rules go into effect pending lower court review, it is highly unlikely the lower courts will reach a conclusion different than the Supreme Court.

Highlight Quotes – ETS

The Majority opinion largely hinged on whether the OSH Act plainly authorized OSHA to regulate what it considered universal risk; ultimately finding the ETS to have the unauthorized effect of a broad public health measure than a workplace safety standard.

Although COVID-19 is a risk that occurs in many workplaces, it is not an occupational hazard in most. COVID-19 can and does spread at home, in schools, during sporting events, and everywhere else that people gather. That kind of universal risk is no different from the day-to-day dangers face from crime, air pollution, or any number of communicable diseases. Permitting OSHA to regulate the hazards of daily life-simply because most Americans have jobs and face those same risks while on the clock-would significantly expand OSHA's regulatory authority without clear congressional authorization.

Highlight Quotes – ETS

However, the Majority did appear to signal that a smaller, more targeted ETS would likely pass scrutiny.

That is not to say OSHA lacks authority to regulate occupation-specific risks related to COVID-19. Where the virus poses a special danger because of the particular features of an employee's job or workplace, targeted regulations are plainly permissible. We do not doubt for example, that OSHA could regulate researchers who work with the COVID-19 virus. So too could OSHA regulate risks associated with working in particularly crowded or cramped environments.

Highlight Quotes – ETS

The Dissent argued the ETS was narrowly tailored allowing exemptions and the ability to exempt-or-test and OSHA's authority was not negated by the fact that COVID-19 exists in both the workplace and day-to-day life.

When we are wise, we know enough to defer on matters like this one. When we are wise, we know not to displace the judgments of experts, acting within the sphere Congress marked out and under Presidential control, to deal with emergency conditions. Today we are not wise.

Highlight Quotes – CMS IFR

The Majority opinion found the vaccination requirements to fit squarely within Congress' authorization to impose conditions on the receipt of Medicaid and Medicare funds that "the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services." 42 USC 1395x(e)(9)

The rule thus fits neatly within the language of the statute. After all, ensuring that providers take steps to avoid transmitting a dangerous virus to their patients is consistent with the fundamental principle of the medical profession: first, do no harm. It would be the "very opposite of efficient and effective administration for a facility that is supposed to make people well to make them sick with COVID-19." Florida v. Department of Health and Human Servs. 19 F. 4th 1271, 1288 (CA11 2021).

Highlight Quotes – CMS IFR

The Dissent argued that the decision hinged on the Government's ability to make a strong showing that it is likely to succeed on the merits, finding Congress had not specifically authorized a mandate of this breadth.

Had Congress wanted to grant CMS power to impose a vaccine mandate across all facility types, it would have done what it has done elsewhere- specifically authorize one.

CMS Statement

As a result of today's decision, health care providers subject to the Omnibus Health Care Staff Vaccination rule in the 24 states (Alabama, Alaska, 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) covered by this decision will now need to establish plans and procedures to ensure their staff are vaccinated and to have their employees receive at least the first dose of a COVID-19 vaccine.

**Today's decision does not affect compliance timelines for providers in the District of Columbia, the territories, and the 25 states where the preliminary injunction was previously lifted.*

CMS' Omnibus COVID-19 Health Care Staff Vaccination Rule ("CMS IFR")

- Interim Final Rule
- CMS FAQ
- CMS Webinar
- CMS Slides
- Survey Training and Transcript

- Effective Date: 11/5/21
- Comment Period: 60 Days

CMS IFR Overview

- Covered facilities must ensure that all eligible staff have received the first dose of a two-dose COVID-19 vaccine or a one-dose COVID-19 vaccine prior to providing any care, treatment, or other services by February 14, 2022*. (Phase 1)
  - Covered facilities – providers regulated under Conditions of Participation, Conditions for Coverage, and Requirements
  - Eligible staff – facility employees; licensed practitioners; students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the facility and/or its patients under contract or other arrangement.

- All eligible staff must have received the necessary shots to be fully vaccinated – either two doses of Pfizer or Moderna or one dose of Johnson & Johnson by March 15, 2022*. (Phase 2)

CMS IFR Overview

Covered facilities:

Ambulatory Surgical Centers, Hospices, Programs of All-Inclusive Care for the Elderly (PACE), Hospitals, Long Term Care Facilities, Psychiatric Residential Treatment Facilities, **Intermediate Care Facilities for Individuals with Intellectual Disabilities**, Home Health Agencies, Comprehensive Outpatient Rehabilitation Facilities, Critical Access Hospitals, Clinics (rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services), Community Mental Health Centers, Home Infusion Therapy Suppliers, Rural Health Clinics/Federally Qualified Health Centers, and End-Stage Renal Disease Facilities

*Any services not listed and unregulated by Conditions of Participation are not subject to the CMS IFR (e.g. HCBS)

CMS IFR Overview

Covered facilities must:

- Implement a process or plan for vaccinating all eligible staff;
- Implement a process or plan for tracking exemptions and accommodations for those who are exempt (EEOC);
- Implement a process or plan for tracking and documenting staff vaccinations.

CMS IFR Overview

The policies and procedures do not apply to staff who

- Exclusively provide telehealth or telemedicine services outside of the facility setting and who do not have any direct contact with residents and other staff or
- Provide support services for the facility that are performed exclusively outside of the center setting and who do not have any direct contact with residents and other staff.

CMS IFR Overview

Facilities are required to allow exemptions to staff in accordance with federal law and develop a process for implementing additional precautions for any staff who are not vaccinated.

For requested medical exemptions, the facility must ensure all documentation is signed and dated by a licensed practitioner, contain all information specifying why the COVID-19 vaccines are clinically contraindicated for the staff member and documentation must include a statement by the authenticating practitioner recommending exemption.

CMS IFR Overview

CMS will work directly with the State Survey Agencies to regularly review compliance with the CMS IFR through recertification surveys and complaint surveys.

Facilities that are out of compliance will be cited and provided an opportunity to return to compliance.

CMS may use enforcement remedies (e.g. civil penalties, payment denial and recoup, termination) as a final measure.

*CMS stated it will offer further interpretive guidelines

**Not associated or tied to the PHE declaration

State Survey Director Guidance

Group A (December 28, 2021)

California, Colorado, Connecticut, Delaware, Florida, 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.

Group B (January 14, 2022)

Alabama, Alaska, 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.

*Group C (January 20, 2022)

Texas

Public Health Emergency Declaration

Effective January 16, 2022, HHS Secretary Becerra renewed the public health emergency declaration for another ninety days as a result of the continued consequences of the COVID-19 pandemic.