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# NAVIGATING THE NEXT.

## CMS Mandatory Vaccine Rule: What Does the Future Hold?

Susan Feigin Harris, Jake Harper, Jessica Totten Johnson  
December 1, 2021

# Presenters



**Susan Feigin Harris**



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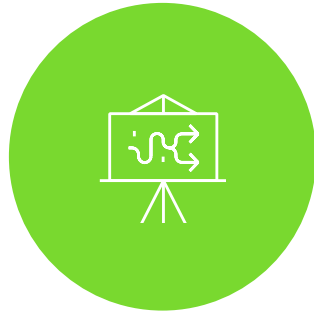
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# Introduction



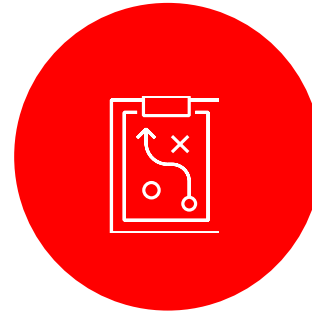
**Basics of CMS  
IFC**



**Intersection  
between OSHA  
ETS, Federal  
Contractor EO,  
and CMS IFC**



**Litigation  
Update**



**Scenarios and  
Common  
Questions**



**Wrap Up**

# Basics of CMS IFC



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# COVID-19 Healthcare Staff Vaccination Rule

- CMS IFC requires providers and suppliers to fully implement mandatory vaccination of staff as a condition of participation in the Medicare and Medicaid programs
- Issued in conjunction with OSHA ETS
- Both rules cover employees, OSHA rules allows testing option

# COVID-19 Healthcare Staff Vaccination Rule

## Important Dates

**Issued Nov. 5, 2021**

**1st implementation phase:  
Dec. 5, 2021; all "facility staff" must have  
rec'd at least 1st dose**

**Comments due Jan. 4, 2022**

**2nd implementation phase:  
Jan. 4, 2022; all applicable facility staff  
"fully vaccinated"**

# COVID-19 Healthcare Staff Vaccination Rule

- Basic Requirement:
  - a facility must develop and implement policies and procedures to ensure all staff are fully vaccinated for COVID-19
  - the IFC specifically amends the regulations governing the conditions of participation for each applicable facility, defined in the regulations to cover 15 specified entities that includes providers and suppliers subject to the conditions of participation
  - the term “fully vaccinated” is defined
  - there is no testing opt out provision

# Facilities Covered

- Hospitals
- ASCs
- Home Health Agencies
- Hospices
- End Stage Renal Disease (ESRD) Facilities
- Home Infusion Therapy (HIT) Suppliers
- Long Term Care (LTC) Facilities
- Rural Health Clinics and FQHCs
- Critical Access Hospitals
- PACE providers
- CORFs
- Clinics, Rehab Agencies, Public Health Entities
- ICFs-IID
- Psychiatric Residential Treatment Facilities
- Community Mental Health Centers



# Basics: COVID-19 Vaccination of Facility Staff

## Is Applicable to

Facility staff who provide “any care, treatment of other services for the facility or its residents”

- Facility employees

- Licensed practitioners

- Students, trainees, volunteers

- Individuals who provide care, treatment, or “other services for the facility or its residents, under contract or by other arrangement”

# Basics: COVID-19 Vaccination of Facility Staff

## May or may not be applicable to

### Physicians

The CMS rule does not directly apply to physician office, but may apply as members of medical staff of covered facility.

### Home Based Care

The CMS rule applies to providers and suppliers that routinely care for clients outside of a covered facility

### Telehealth

The CMS rule does not apply to those staff who exclusively provide telehealth or telemedicine services outside of a facility setting and who do not have direct contact with residents or patients or other healthcare workers who may otherwise be covered.

### Staff who do not provide patient care

The CMS rule does apply even if no direct contact with patients in a covered facility where they may encounter those who directly treat patients.

### Contracted Vendors

The CMS rule does apply to those who service covered facilities like food service providers, laundry, janitorial service, valet parking, medical device suppliers, medical equipment, etc.

# Basics: Implementation

**“Fully Vaccinated”- means two weeks or more after completion of a “primary vaccination series” which includes either one dose of an approved FDA vaccine or the one dose version of an FDA approved vaccine.**

**Phase I: Staff must have received, at a minimum, the first dose of a primary series or a single-dose COVID-19 vaccine prior to providing care, treatment or other services to patients or have been granted an exemption within 30 days of the publication of the CMS Rule— which is December 5th**

**Phase II: requires that all staff are fully vaccinated unless granted an exemption by January 4th. Staff are considered fully vaccinated if they have at least obtained the single dose or second dose of a 2- dose series, without having completed the 14-day waiting period for full vaccination.**

**Facilities must develop policies and procedures.**

**Facilities must track and securely document the COVID-19 vaccination status of each staff member.**

# Basics: Enforcement and Compliance

- Enforcement via onsite compliance reviews by state survey agencies and accreditation organizations
- CMS indicates that it will work to first bring a facility into compliance, only applying the most severe of corrective action status of “immediate jeopardy” sparingly.
- Termination of a facility would only occur after a facility has been given the opportunity to make corrections.
- The CMS FAQs, issued alongside the rule, make a distinction regarding penalties for entities such as nursing homes, home health agencies and hospice—enforcement will include CMPs, denial of payment and termination from the program as a last resort.

# Basics: Applicable Guidance

- CMS FAQs: Appear to be updated continually and provide guidance on some scenarios
  - CMS Open Door Forum/Slide Deck publicly available
  - CMS indicates new Survey and Certification Manual guidance may be published - keep an eye out
  - Opportunity to comment:
    - <https://www.regulations.gov>

# Intersection between OSHA ETS, Federal Contractor EO, and CMS IFC

# Intersection Between OSHA ETS, EO, and CMS IFC

Major Categories of Questions Raised to date:



**Contractors/ Vendors who contract with facilities and concern about staffing shortage issues**

**Gray areas for employees of vendors who may not be covered but who physically intermingle with those who are clearly covered by the mandate**

**The intersection of the OSHA ETS and the CMS IFC**

**Balance between the business ongoing concern with losing vendor contract vs. business concerns about losing critical staff**

**Practical Issues Regarding Intersection between state laws prohibiting the vaccine mandate and the federal law that implements the vaccine mandate**

# Extension of CMS Rule Outside the Four Walls of the Covered Facility

- Regardless of frequency of patient contact, facility policies must apply to all staff including those providing services in a home setting
- Include administrative staff, facility leadership, volunteers, board members, housekeeping and food services “and others”
- Some discretion for “ad hoc non-healthcare services”
- Discretion for facilities to go further
- Preamble examples include plumbers making emergency repairs/no contact with and wears mask v. construction workers who regularly intermingle with healthcare staff



# Intersection of OSHA ETS, EO and CMS IFC

- Fate of OSHA ETS in 6th circuit hands for now
- OSHA ETS was permanently stayed by 5th circuit
- OSHA acknowledged stay on its website- “suspending activities related to the implementation and enforcement of the ETS pending future developments in the litigation
- In fate of uncertainty with OSHA ETS, many businesses are continuing to plan if the ETS survives, such as collecting information about their EEs vaccination status and developing ETS compliant policies
- Federal Contractor EO-11/20/21 KY District Court enjoined EO in Kentucky, Ohio and Tennessee
- In analyses, if CMS IFC doesn’t cover workforce, would have looked to OSHA ETS and EO- patchwork on the EO analysis and now we have uncertainty regarding OSHA ETS and CMS IFR

# Litigation Update



# Lawsuits Challenging IFC

## Missouri v. Biden

- 10 state challenge
- District Court granted Motion for Preliminary Injunction and the federal government appealed

## Louisiana v. Becerra

- 14 state challenge
- District Court granted Motion for Preliminary Injunction

## Texas v. Becerra

- Plaintiffs filed a Motion for Temporary Restraining Order and Preliminary Injunction
- Hearing scheduled for 12/2/21

## Florida v. Department of Health and Human Services

- District Court denied Motion for Preliminary Injunction and Florida appealed
- Florida filed a Motion for Injunction Pending Appeal with 11th Circuit on 11/29/21




# Western District of Louisiana Decision

- Yesterday, November 30, 2021, the Western District of Louisiana granted a motion for a preliminary injunction

*Finding: Plaintiff States likely to succeed on the merits in their argument that the Government Defendants do not have the authority to implement the CMS Mandate and denial of the preliminary injunction would cause irreparable harm*

- The order applies nationwide and enjoins federal agencies from implementing the CMS IFC
- Judge acknowledged “This matter will ultimately be decided by a higher court than this one.”

# Scenarios and Common Questions

The background of the slide is a composite image. At the top, there is a dark blue space filled with stars and a glowing, multi-colored horizon (orange, yellow, blue) that suggests a celestial body or a distant galaxy. Below this, a night view of a city is shown, with its lights and buildings. Overlaid on the city and extending upwards is a network of glowing lines and nodes, primarily in blue and orange, which represents a global or digital network. The overall aesthetic is futuristic and high-tech.

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# Scenarios and Common Questions

- Large national company comprised of multiple divisions. Some of the divisions provide direct patient care and employees will be in patient homes or in hospitals or other facilities providing care and in contact with patients.
- Other divisions provide administrative support, such as billing, accounting, collection, management and oversight.
- Workers in divisions frequently commingle within the same office space.
- Administrative division contracts with several federal contractors to provide administrative services and received federal dollars.

# Scenarios and Common Questions

- Large company serves as vendor to hospital system chains and regularly delivers supplies to the loading docks of hospitals. While most of the employee base may be vaccinated, the client-facing employee base is largely vaccine-hesitant.
- Hospitals under their subcontracts with vendors are sending requests for attestations and policies and procedures to company requesting compliance and validation of compliance to ensure the hospital is in compliance with Conditions of Participation in anticipation of potential enforcement action



# Scenarios and Common Questions

- What is a “clinic”?
- Many facilities use contracted professionals and vendors, especially for non-clinical operations – where do they fit in?
- What about companies that might be sending employees to a facility for marketing, administrative, or care coordination services?
- Home health agencies and hospices are covered facilities – where is the “facility?”

# Questions

The image is a composite graphic. At the top, the word "Questions" is written in a large, white, sans-serif font. Below the text, the background is a deep blue space filled with stars. A bright, glowing horizon line, likely representing the Earth's atmosphere, curves across the middle. Below this, a cityscape is visible at night, with lights from buildings and streets. Overlaid on the city and globe is a network of blue lines connecting various nodes, suggesting a global network or data flow.

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# Thanks and Be Well!



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Named Texas' 2018 Lawyer of the Year, Susan Feigin Harris concentrates on the regulatory, business, corporate, governance, compliance, and contracting needs of a diverse group of healthcare clients. She regularly addresses federal and state healthcare regulations, and works with state and federal healthcare agencies involving Medicare and Medicaid licensing, certification, reimbursement, compliance, enforcement, and recoupment actions. Susan's clients include hospitals, physician groups, lab companies, post-acute providers, and healthcare innovations companies.

# Thanks and Be Well!



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# Thanks and Be Well!



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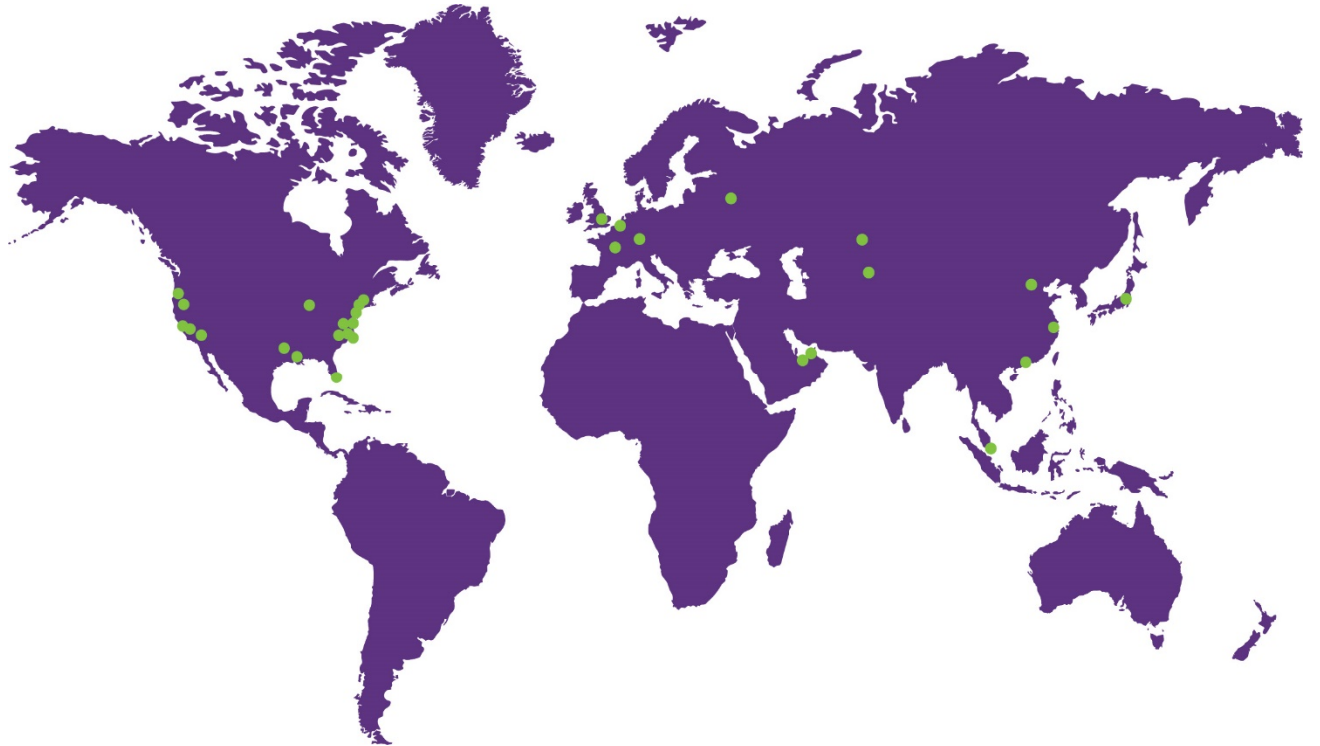
Jessica Totten Johnson focuses her practice on the transactional, regulatory, and compliance needs of healthcare clients. She advises clients on reimbursement issues and disputes, government investigations, fraud and abuse, privacy, and other healthcare regulatory and compliance matters. During law school, Jessie served as a notes and comments editor on the Houston Law Review and competed as a member of the Moot Court Team. Before attending law school, she worked in the pharmaceutical industry.

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