

2021 Healthcare Regulatory and Compliance Update

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Agenda

1. Changes to the Physician Self-Referral Law (the “Stark” Law)
2. Information Blocking
3. COVID-19 Vaccination Mandates
4. OSHA Requirements for Employers
5. OIG Exclusion Lists

THE “STARK” LAW

Stark Law

- Prohibits **physician referrals** for **Designated Health Services (DHS)** payable by **Medicare** to entities where they (or an immediate family member) have a **financial relationship** unless all elements of an exception are satisfied.
 - **Designated Health Services:** Include laboratory services, radiology and certain other imaging services, inpatient/outpatient hospital services, outpatient prescription drugs, DME, prosthetics/orthotics, PT/OT, parenteral and enteral nutrients, equipment and supplies, home health, and radiation therapy services and supplies.
 1. Is there a referral from a physician for DHS?
 2. Does the physician (or their immediate family member) have a financial relationship with the entity furnishing the DHS?
 3. Does the financial relationship fit an exception?

Stark Law Exceptions

- The Stark Law is a strict liability statute - evidence of intent to violate the Stark Law is not required.
- If all of the requirements of an exception under the Stark Law are met, it is permissible for a physician to make a referral to an entity where they have a financial relationship.
- Common exceptions include:
 - Fair Market Value Compensation
 - Personal Service Arrangements
 - Rental of Equipment
 - Rental of Office Space
 - Physician Recruitment
 - Bona Fide Employment
 - Nonmonetary Compensation
 - Whole Hospital
 - In-Office Ancillary Services

Stark Law Changes for Group Practices

There are new rules for physician compensation in a **group practice effective January 1, 2022:**

- A physician in a group practice may be paid a share of **overall profits** that is not directly related to the volume or value of the physician's referrals.
- Groups are required to allocate profits, not revenues, from ancillary services.
- Overall profits must be aggregated before distributing. The group may aggregate profits from all DHS of the entire group, or divide the practice into components consisting of at least 5 physicians and aggregate profits from all DHS of the component.
- Groups may not distribute profits from DHS on a service-by-service basis.
 - A practice providing both clinical laboratory services and diagnostic imaging that wants to qualify as a group practice to meet the In-Office Ancillary Services exception may not distribute profits from clinical laboratory services to one subset of its physicians and distribute the profits from diagnostic imaging to a different subset of its physicians.
- The methodology for calculating and distributing profits from DHS or ancillary services must be set prospectively. The group may share overall profits by one or more of the following methods:
 - per capita (per member of the group or per physician in the group);
 - based on the group's revenues attributed to services that are not DHS; or
 - in amounts that equal 5% or less of physician's total compensation if revenues derived from DHS constitute less than 5% of the group's total revenues.

Group Practice

Example: A group practice of 15 physicians furnishes multiple types of DHS.

- The group practice divides its physicians into three components of five physicians (component A, component B, and component C) for distributing overall profits.
 - A group practice may establish components of at least 5 physicians by including physicians with similar practice patterns, who practice in the same location, with similar years of experience, with similar tenure with the group practice, or who meet other criteria determined by the group practice
- For each component, the group practice must aggregate the profits from all DHS furnished by the group and referred by any of the 5 physicians in the component.
- The group practice must utilize the same methodology for distributing overall profits for every physician in the component.
 - The group practice may distribute overall profits from all DHS of component A using one methodology (for example, a per-capita distribution methodology), distribute the overall profits from all DHS of component B using a different methodology (for example, a personal productivity methodology), and distribute the overall profits from all DHS of component C using a third methodology that does not directly relate to the volume or value of referrals.

Stark Law Update – Physician Compensation

- New exception for **limited physician compensation**
- Up to \$5,000 each calendar year for items or services provided, if the following conditions are met:
 - Compensation does not take into account volume or value of referrals or other business generated;
 - Compensation does not exceed fair market value; and
 - The arrangement is commercially reasonable.

Stark: Value-Based Care Exceptions

- New exceptions for **Value-Based Arrangements**.
- Compliance requirements are tiered based on the amount of risk.
- New Terminology
 - **Value-Based Arrangement**: An arrangement for the provision of at least one value-based activity for a target population between the value-based enterprise and one or more of its VBE participants or VBE participants in the same value-based enterprise.
 - **Value-Based Enterprise (VBE)**: Two or more VBE participants collaborating to achieve at least one value-based purpose, with an accountable body responsible for oversight, and a governing document describing the VBE and how the participants intend to achieve its value-based purposes.
 - **Target Patient Population**: An identified patient population selected based on *legitimate and verifiable criteria*. A patient population may be selected based on characteristics such as health status, geography or payor status but may not be selected to avoid costly or noncompliant patients.

Stark: Value-Based Care Exceptions

- **Value-Based Activity**: Activities that are reasonably designed to achieve at least one value-based purpose of the value-based enterprise:
 - the provision of an item or service;
 - the taking of an action; or
 - refraining from taking an action.
- **Value-Based Purpose**:
 - coordinating and managing the care of a target population;
 - improving the quality of care for a target population; appropriately reducing costs or growth in expenditures of payors without reducing the quality of care for a target population; or
 - transitioning from healthcare delivery and payment mechanisms based on the volume of items and services provided, to mechanisms based on the quality of care and control of costs of care for a target patient population.

New Exceptions for Value-Based Arrangements

	Full Financial Risk	Meaningful Downside Risk	Value- Based
Remuneration for Value-Based Activity	X	X	X
May not limit medically necessary items or services	X	X	X
Remuneration is not conditioned on referrals of patients not in the target patient population	X	X	X
Writing Requirement		X	X
Compensation methodology set in advance		X	X
Commercial reasonableness			X
Outcome measures set in advance and modifications in writing			X
Monitoring			X

Eligibility for the Value-Based Safe Harbors, the Patient Engagement and Support Safe Harbor, and the Personal Services and Management Contracts Safe Harbor for Outcomes-Based Payment

Entity Type	Care Coordination Arrangements 42 C.F.R. § 1001.952(ee)	Substantial Downside Risk 42 C.F.R. § 1001.952(ff)	Full Financial Risk 42 C.F.R. § 1001.952(gg)	Patient Engagement and Support 42 C.F.R. § 1001.952(hh)	Outcomes-Based Payments 42 C.F.R. § 1001.952(d)(2)
Providers and Suppliers (<i>e.g.</i> , hospitals, post-acute care providers, and physicians)	Eligible	Eligible	Eligible	Eligible	Eligible
Pharmacies Other Than Compounding Pharmacies	Eligible	Eligible	Eligible	Eligible	Eligible
Compounding Pharmacies (<i>i.e.</i> , pharmacies that primarily compound drugs or primarily dispense compounded drugs)	Ineligible	Ineligible	Ineligible	Ineligible	Ineligible
Manufacturer of a Device or Medical Supply (as defined in 42 C.F.R. § 1001.952(ee)(14)(iv))	Eligible, but only for in-kind remuneration that is digital health technology	Ineligible	Ineligible	Eligible, but only for tools and supports that are digital health technology	Ineligible
DMEPOS Suppliers (other than pharmacies or physicians, providers, or other entities that primarily furnish services)	Eligible, but only for in-kind remuneration that is digital health technology	Ineligible	Ineligible	Ineligible	Ineligible
Pharmacy-Benefit Managers	Ineligible	Ineligible	Ineligible	Ineligible	Ineligible
Pharmaceutical Manufacturers, Distributors, Wholesalers	Ineligible	Ineligible	Ineligible	Ineligible	Ineligible
Laboratory Companies	Ineligible	Ineligible	Ineligible	Ineligible	Ineligible
Physician-Owned Distributors (PODs)	Ineligible	Ineligible	Ineligible	Ineligible	Ineligible
Health Technology Companies Not Otherwise Covered by an Entity Type on This List	Eligible	Eligible	Eligible	Eligible	Eligible

DISCLAIMER: This chart is current as of the date issued. It is an educational resource; it is not intended to create any rights, privileges, or benefits. Although every reasonable effort has been made to ensure the accuracy of this chart, the ultimate responsibility for complying with the Federal fraud and abuse laws lies with the party or parties seeking compliance with such laws. We refer readers to the [final rule published in the Federal Register](#) for additional and official information.

Stark: Value-Based Exceptions

Full Financial Risk:

- VBE must be responsible for the entire cost of patient care items and services on a prospective basis for a target patient population.
 - Full financial risk may take the form of capitation payments (a predetermined payment per patient per period of time, or global budget payment from a payor that compensates a VBE for providing all patient care items and services for a target patient population)
- Monetary or in-kind remuneration permitted.
- Examples from CMS in the final rule:
 - VBE participants could each sign the contract for the VBE to assume full financial risk from a payor or contractual arrangements among themselves that assign risk jointly and severally.
 - If the VBE is at full financial risk for the total cost of care for all of a commercial payor's enrollees in a particular county, the exception will not protect an arrangement between an entity and a physician that are VBE participants in the VBE if the entity requires the physician to refer Medicare patients who are not part of the target patient population.
 - The exception will not protect an arrangement related to knee replacement services furnished to Medicare beneficiaries if the arrangement requires that the physician perform all his or her other orthopedic surgeries at the hospital.

Stark: Value-Based Exceptions

Meaningful Downside Risk to the Physician:

- The physician must be at risk to repay or forgo at least 10% of the value of the remuneration receiving under the arrangement.
- A description of the nature and extent of physician's risk must be in writing.
- The compensation methodology must be set in advance.

Examples:

1. A physician is entitled to a base payment of \$50,000 with the ability to earn an additional \$25,000 for performing certain value-based activities.
 - Meaningful downside risk equals at least 10% of the total compensation of \$75,000, or \$7,500. The \$25,000 that is at risk exceeds the 10% requirement but receipt must also be tied to the achievement of the value-based purpose(s) of the VBE.
2. A value-based arrangement between an entity and a physician that are the only participants in the VBE under which the total remuneration potentially due to the physician is \$100,000, but \$20,000 is withheld and payable only upon successfully completing the value-based activities.
 - Meaningful downside financial risk equals at least 10% of the total \$100,000 or \$10,000. The \$20,000 withhold in this example exceeds the 10% requirement.

Stark: Value-Based Exceptions

Value-Based Arrangements (No Risk)

- Written agreement must include:
 - a description of the value-based activities undertaken;
 - how the activities are expected to further the value-based purpose;
 - the target patient population;
 - the type of remuneration;
 - the methodology for determining compensation; and
 - the outcome measures.
- The arrangement must be commercially reasonable.
- Progress must be monitored annually or at least once during any term that is less than one year. If monitoring indicates that an outcome measure is unattainable, corrective action must be taken within certain time limits.

Stark: Value-Based Exceptions

Value-Based Arrangement (No Risk) Example: A hospital revised its protocol for screening for a certain type of cancer to incorporate new guidelines recommending combining two modalities to achieve more accurate results. The hospital observes physicians continue to refer patients to the hospital for single-modality screening. To align referring physician practices with the hospital's revised care protocol, the hospital offers to pay physicians \$10 for each instance that they order dual-modality screening in accordance with the revised care protocol during a 2-year period beginning on January 1, 2021. The hospital expects that it would take approximately 2 years to shape physician behavior to always follow the protocol.

- Here, the **value-based enterprise** is the hospital and identified community physicians.
- The **target patient population** is patients in the hospital's service area that receive screening for the particular disease.
- The **value-based activity** is adherence with the hospital's revised care protocol by ordering dual-modality screening instead of single-modality screening.
- The **value-based purpose** of the **VBE** is to improve the quality of care for patients in the hospital's service area by detecting more cancers and avoiding potential unnecessary overtreatment of false positive results.
- Provided the arrangement satisfies all the requirements, the physician's referrals of DHS to the hospital and the hospital's submission of claims to Medicare for the DHS referred by the physician would not violate Stark.

Stark: Value-Based Exceptions

Value-Based Arrangements (No Risk) Example (Continued) :

- However, assume the hospital determines through its monitoring that its data analysis indicates that the use of dual-modality screening not only does not result in earlier detection of cancer, but results in more false positive results, invasive biopsies, and unnecessary treatment than single-modality screening.
- The compliance monitoring, which occurred in the first year of the arrangement, has identified that the continuation of the value-based activity, dual-modality screening, is no longer expected to further the value-based purpose of improving the quality of care for patients in the hospital's service area by detecting more cancers and avoiding potential unnecessary overtreatment of false positive results.
- Once the hospital has identified the ineffective activity, it has two options to maintain compliance with the physician self-referral law:
 - the parties could terminate the arrangement within 30 consecutive calendar days of the date of completion of the monitoring indicating that the value-based activity was ineffective, or
 - the parties could modify the arrangement to terminate the ineffective value-based activity within 90 consecutive calendar days of completion of the monitoring and, if they choose, replace it with a different value-based activity with prospective applicability.
- For more information regarding the new Value-Based Exceptions: <http://weaverjohnston.com/new-value-based-stark-exceptions-and-anti-kickback-safe-harbors/>



Information Blocking

ONC's Cures Act Final Rule: Information Blocking

- On December 13, 2016, the **21st Century Cures Act** was signed into law.
 - Defines information blocking
 - Identifies HHS - OIG to investigate claims and outlines penalties.
 - Directs agencies to publish rules that advance interoperability and support the exchange, access, and use of electronic health information (EHI).
- Office of the National Coordinator for Health Information Technology (ONC) published a Final Rule implementing Title IV of the Cures Act in May 1, 2020.
 - Became effective April 5, 2021.
 - Prohibits “**Information Blocking**”
 - a practice—not required by law—that is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI.

Information Blocking

- **Information Blocking:** a practice that is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI.
- **Three categories of regulated “actors”:**
 1. Healthcare providers
 2. Developers of Certified Health IT
 3. Health information networks or exchanges
- **Electronic health information (EHI)**
 - The Rule initially only regulates practices that interfere with certain categories of electronic health information and later expands to regulate additional categories.
 - **Until October 6, 2022**, “EHI” is limited to the data elements in the United States Core Data for Interoperability ([USCDI](#)).
 - **After October 6, 2022**, the scope of “EHI” will expand to apply to all individually identifiable health information that is transmitted or maintained in electronic media, to the extent that it would be included in a designated record set as defined in 45 CFR 164.501, regardless of whether the group of records are used or maintained by or for a covered entity as defined in 45 CFR 160.103, **except:**
 - Psychotherapy notes as defined in 45 CFR 164.501; or
 - Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding

Information Blocking - Examples

Practices that are likely to constitute interfering with EHI:

- Delaying test or lab results for any period of time to allow the physician to review the results or personally inform the patient before the patient can electronically access the results.
- Using written agreements or policies and procedures to delay or limit disclosures that are permissible under state and federal law.
- A delay that “occurs after a patient logs in to a patient portal to access EHI that a health care provider has and such EHI is not available – for any period of time – through the portal.” [Information Blocking FAQs](#).
- Imposing fees that make exchanging EHI cost prohibitive.
- Technology designed or implemented in non-standard ways that lessen the ability to exchange and use information with others.
- Patients or healthcare providers become “locked in” to a particular technology or healthcare network because their EHI is not portable.

Information Blocking – 8 Exceptions

Exceptions that involve **not** fulfilling requests:

1. Preventing harm
2. Privacy
3. Security
4. Infeasibility
5. Health IT Performance

Exceptions that involve **procedures** for fulfilling requests:

1. Content and Manner
2. Licensing
3. Fees

Preventing Harm Exception

45 C.F.R. § 171.201

Protects practices that are reasonable and necessary to prevent harm to a patient or another person, if:

- The provider holds a reasonable belief that the practice will substantially reduce a risk of harm;
- The practice is not broader than necessary;
- The practice satisfies at least one condition from each of the following categories: type of risk, type of harm, and implementation basis; and
- The patient has the right to request a review of any individualized determination of risk.

Privacy Exception

45 C.F.R. § 171.202

It will not be information blocking if an actor does not fulfill a request in order to protect an individual's privacy:

- If a precondition has not been satisfied that is required by state or federal law (such as a patient consent or authorization);
- In order to comply with an individual's request not to share information; or
- Denials that are permitted under the HIPAA Privacy Rule.

Security & Health IT Exceptions

- **Security Exception:** Practices that interfere with the access, exchange, or use of EHI in order to protect the security of EHI will not be considered information blocking if certain conditions are met.
 - The practice is:
 - implementing a qualifying organizational security policy or determination;
 - directly related to safeguarding the confidentiality, integrity, and availability of EHI;
 - tailored to specific security risks; and
 - implemented in a consistent and non-discriminatory manner. 45 CFR § 171.203.
- **Health IT Performance Exception:** May block access to EHI for maintenance and improvement of Health IT, if implemented for a period of time no longer than necessary and in a consistent and non-discriminatory manner. If the unavailability is initiated by a health IT developer or exchange, it must be consistent with existing service agreements. 45 CFR § 171.205.

Infeasibility Exception

45 C.F.R. § 171.204

It will not be information blocking if a provider does not fulfill a request to access, exchange, or use EHI due to the infeasibility of the request, if:

- Requestor is provided a written response of why the request is infeasible within 10 days; and
- Request is infeasible due to one of the following:
 - **Uncontrollable events:** a natural or human-made disaster, public health emergency, public safety incident, war, terrorist attack, civil insurrection, strike or other labor unrest, telecommunication or internet service interruption, or act of military, civil or regulatory authority;
 - **Segmentation:** inability to segment requested EHI; or
 - **Infeasibility under the circumstances:** demonstrates through documentation that complying with request would be infeasible under the circumstances.

Information Blocking: Exceptions

Exceptions that involve **procedures for fulfilling requests**, provided certain conditions are met:

- **Content and Manner Exception:** It will not be information blocking for an actor to limit the content of its response to a request to access, exchange, or use EHI or the manner in which it fulfills a request to access, exchange, or use EHI,
- **Fees Exception:** It will not be information blocking for an actor to charge fees, including fees that result in a reasonable profit margin, for accessing, exchanging, or using EHI, provided certain conditions are met.
- **Licensing Exception:** It will not be information blocking for an actor to license interoperability elements for EHI to be accessed, exchanged, or used, provided certain conditions are met.

Information Blocking

Enforcement

- Information blocking complaints can be reported on the [ONC portal](#). ONC may refer to OIG.
- Based on OIG determinations, **Providers** may be referred to the appropriate agency to be “subject to appropriate disincentives using authorities under applicable Federal law, as the Secretary sets forth through notice and comment rulemaking.”
- **Developers, networks, and exchanges** subject to civil monetary penalties up to \$1,000,000 per violation, after final rule is published. See [Rulemaking Docket](#) - Information Blocking Penalty Rules; [Proposed Rule](#).

Resources

- Information Blocking FAQs: <https://www.healthit.gov/curesrule/resources/information-blocking-faqs>
- Exceptions: <https://www.healthit.gov/cures/sites/default/files/cures/2020-03/InformationBlockingExceptions.pdf>
- ONC Final Rule: <https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interopability-information-blocking-and-the-onc-health-it-certification>



COVID-19 VACCINATION MANDATES

President Biden - Vaccine Mandates

- President Biden announced the COVID-19 Action Plan: “Path Out of the Pandemic” on September 9, 2021.
- **Healthcare Facilities**
 - The Plan provides that the Centers for Medicare & Medicaid Services (CMS) mandate COVID-19 vaccination for all staff working in healthcare facilities that participate in Medicare or Medicaid.
 - CMS announced a forthcoming rule (expected in October 2021) to mandate COVID-19 vaccination for staff in healthcare facilities such as nursing homes, hospitals, dialysis facilities, ambulatory surgical settings, and home health agencies as a condition for participating in Medicare or Medicaid. The requirement will apply to all staff and will not be limited to those involved directly in patient care.
 - CMS previously issued rules requiring long term and intermediate care facilities educate residents and staff about vaccines, offer a COVID-19 vaccine when available, and report the vaccination status of clients and staff on a weekly basis to the CDC’s National Healthcare Safety Network (NHSN).
- **Federal Employees and Contractors:** President Biden signed an Executive Order issuing directives to each federal agency to implement a program requiring COVID-19 vaccination for all federal employees and contractors.
- **Private Employers:** the Plan provides that the Occupational Safety and Health Administration (OSHA) will issue an Emergency Temporary Standard (ETS) requiring employers with 100 or more employees to ensure all employees are vaccinated, require any workers who remain unvaccinated to be tested at least weekly, and may subject private employers to potential fines of up to \$14,000 for each violation.

Employers and Vaccine Mandates

- Federal law does not prevent an employer from requiring all employees **physically entering the workplace** to be vaccinated for COVID-19, subject to the reasonable accommodation provisions of Title VII and the Americans with Disabilities Act (ADA).
 - It is unlawful to impose a vaccination requirement in a way that treats employees differently based on disability, race, color, religion, sex (including pregnancy, sexual orientation and gender identity), national origin, age, or genetic information.
- Title VII requires employers to reasonably accommodate an employee's sincerely held religious belief, practice, or observance that prevents the employee from being vaccinated.
- The ADA requires employers to reasonably accommodate an employee's medical condition or disability that would make receiving the vaccine dangerous or otherwise inappropriate for that individual. If a vaccination requirement screens out individuals with a disability, the employer must show that an employee who is not vaccinated poses a direct threat in the workplace through:
 - an individualized assessment regarding the duration of the risk; the nature and severity of the potential harm; the likelihood that the harm will occur; and the imminence of the potential harm; and
 - a determination based on current medical knowledge about COVID-19; the type of work environment (whether the employee works alone or with others or works inside or outside); available ventilation; the frequency and duration of direct interaction the employee typically will have with others; the number of partially or fully vaccinated individuals already in the workplace; whether other employees are wearing masks or undergoing routine screening testing; and the space available for social distancing.

Employers and Vaccine Mandates

- The employer must consider whether providing a **reasonable accommodation** would reduce or eliminate the threat.
 - Potential accommodations might include requiring the employee to wear a mask, work a staggered shift, making changes in the work environment, permitting telework if feasible, or reassigning the employee to a vacant position in a different workspace.
 - Under Title VII, an employer should thoroughly consider all possible reasonable accommodations, including telework and reassignment.
- If an employee seeks an exemption from a vaccine requirement due to pregnancy, the employer must ensure that the employee is not being discriminated against compared to other employees similar in their ability or inability to work. A pregnant employee may be entitled to job modifications, including telework, changes to work schedules or assignments, and leave to the extent such modifications are provided for other employees who are similar in their ability or inability to work.
- If an employee cannot be accommodated, employers should determine if any other rights apply under the EEO laws or other federal, state, and local authorities before taking adverse employment action against an unvaccinated employee.

Patients and Vaccine Mandates – Texas Law

- **Senate Bill 968:** Effective June 16, 2021, prohibits businesses in Texas from requiring a *COVID-19 vaccine passport* as a condition to a customer gaining entry or access to the business or to receiving services from the business.
 - “A business in this state may not require a customer to provide any documentation certifying the customer's COVID-19 vaccination or post-transmission recovery on entry to, to gain access to, or to receive service from the business. A business that fails to comply with this subsection is not eligible to receive a grant or enter into a contract payable with state funds.”
 - Does not prohibit verbal inquiries regarding vaccination status or screening and infection control protocols in accordance with state and federal law.
 - May prohibit any verification of vaccination status if enforced broadly.
 - State agencies who issue a license, permit, or other state authorization necessary for conducting business in Texas are tasked with enforcing the new law; it is unknown at this time whether the Texas Medical Board will be enforcing SB 968.
- **Executive Order No. GA-3:** “Any public or private entity that is receiving or will receive public funds through any means, including grants, contracts, loans, or other disbursements of taxpayer money, shall not require a consumer to provide, as a condition of receiving any service or entering any place, documentation regarding the consumer’s vaccination status for any COVID-19 vaccine. No consumer may be denied entry to a facility financed in whole or in part by public funds for failure to provide documentation regarding the consumer’s vaccination status for any COVID-19 vaccine.”
- **Texas Medical Board Requirements:** If there is an existing patient-physician relationship, patient care may only be terminated with reasonable notice to the patient.

Patients and Vaccine Mandates

- Decisions concerning whether an individual is a candidate for treatment should be based on an individualized assessment of the patient based on the best available objective medical evidence.
- Health care providers are prohibited from declining to treat a patient who refused vaccination for a reason that is protected under applicable federal law: Section 1557 of the Affordable Care Act, Section 504 of the Rehabilitation Act, or the ADA.
- The ADA requires public and private hospitals and health care facilities to provide services to people with disabilities in a nondiscriminatory manner and prohibits refusing to treat a patient based on their disability unless the individual poses a direct threat or significant risk to the health and safety of others that cannot be eliminated by adequate precautions or reasonable modification of policies, practices or procedures.
- **The Emergency Medical Treatment and Labor Act (EMTALA):** A provider may not decline to provide treatment if the patient presents with an emergency medical condition. Under EMTALA, a hospital with a dedicated emergency department must provide a medical screening exam, stabilizing treatment for emergency conditions; and/or an appropriate transfer of the patient. Participating hospitals with specialized capabilities must accept the transfer of patients with unstable emergency medical conditions.



New OSHA Requirements for Healthcare Employers

OSHA – COVID-19 ETS

- The **Occupational Safety and Health Administration (OSHA)** announced a new **emergency temporary standard (ETS)** in June 2021.
- Applies to settings where employees provide healthcare or healthcare support services, including hospitals, nursing homes, assisted living facilities, home healthcare facilities, and some ambulatory care facilities.
- **Healthcare employers are required to implement the following:**
 - **COVID-19 plan:** Develop and implement a COVID-19 plan (in writing if more than 10 employees) that includes a designated safety coordinator with authority to ensure compliance, a workplace-specific hazard assessment, involvement of non-managerial employees in hazard assessment and plan development/implementation, and policies and procedures to minimize the risk of transmission of COVID-19.
 - **Patient screening and management:** Limit and monitor points of entry to settings where direct patient care is provided; screen and triage patients, clients, and other visitors and non-employees; implement patient management strategies.
 - **Standard and Transmission-Based Precautions:** Develop and implement policies based on CDC guidelines.

OSHA – COVID-19 ETS

(Continued) Employer Requirements

- **Personal protective equipment (PPE):** Provide and ensure each employee wears a facemask when indoors and when occupying a vehicle with other people for work purposes; provide and ensure employees use respirators and other PPE for exposure to people with suspected or confirmed COVID-19, and for aerosol-generating procedures on a person with suspected or confirmed COVID-19.
- **Aerosol-generating procedures on a person with suspected or confirmed COVID-19:** Limit employees present to only those essential; perform procedures in an airborne infection isolation room, if available; and clean and disinfect surfaces and equipment after the procedure is completed.
- **Physical distancing:** Keep people at least 6 feet apart when indoors.
- **Physical barriers:** Install cleanable or disposable solid barriers at each fixed work location in non-patient care areas where employees are not separated from other people by at least 6 feet.
- **Cleaning and disinfection:** Follow standard practices for cleaning and disinfection of surfaces and equipment in accordance with CDC guidelines in patient care areas, resident rooms, and for medical devices and equipment; in all other areas, clean high-touch surfaces and equipment at least once a day and provide alcohol-based hand rub that is at least 60% alcohol or provide readily accessible handwashing facilities.

OSHA – COVID-19 ETS

(Continued) Employer Requirements

- **Ventilation:** Ensure that employer-owned or controlled existing HVAC systems are used in accordance with manufacturer's instructions and design specifications for the systems and that air filters are rated Minimum Efficiency Reporting Value (MERV) 13 or higher if the system allows it.
- **Health screening and medical management:** (1) Screen employees before each workday and shift; (2) Require each employee to promptly notify the employer when the employee is COVID-19 positive, suspected of having COVID-19, or experiencing certain symptoms; (3) Notify certain employees within 24 hours when a person who has been in the workplace is COVID-19 positive; (4) Follow requirements for removing employees from the workplace; (5) Employers with more than 10 employees, provide medical removal protection benefits in accordance with the standard to workers who must isolate or quarantine.
- **Vaccination:** Provide reasonable time and paid leave for vaccinations and vaccine side effects.
- **Training:** Ensure all employees receive training so they comprehend COVID-19 transmission, tasks and situations in the workplace that could result in infection, and relevant policies and procedures.

OSHA – COVID-19 ETS

(Continued) Employer Requirements

- **Anti-Retaliation:** Inform employees of their rights to the protections required by the standard and do not discharge or in any manner discriminate against employees for exercising their rights under the ETS or for engaging in actions required by the standard. Requirements must be implemented at no cost to employees.
- **Recordkeeping:** Establish a COVID-19 log (if more than 10 employees) of all employee instances of COVID-19 without regard to occupational exposure and follow requirements for making records available to employees/representatives. Report work-related COVID-19 fatalities and in-patient hospitalizations to OSHA.

Exceptions:

- The ETS exempts fully vaccinated employees from the requirements for PPE, physical distancing, and physical barriers in well-defined areas where there is no reasonable expectation that any person with suspected or confirmed COVID-19 will be present.
- In order for an employer to be exempt from providing these controls in a well-defined area based on employees' fully vaccinated status, the COVID-19 plan must include policies and procedures to determine employees' vaccination status.

EXCLUSION LISTS

OIG Exclusion List

- OIG maintains a List of Excluded Individual/ Entities (**LEIE**).
- Anyone who hires an individual or entity on the LEIE may be subject to civil monetary penalties.
- To avoid hiring excluded individuals or entities, providers should check **the HHS-OIG exclusion website, SAM Exclusions Extract, and the relevant state exclusion list monthly**.
 - “OIG updates the LEIE monthly, so screening employees and contractors each month best minimizes potential overpayment and CMP liability.” [Special Advisory Bulletin](#) on the Effect of Exclusion from Participation in Federal Health Care Programs, OIG (2013).

OIG Exclusion List

- OIG recommends that providers screen contractors, subcontractors, and the employees of contractors using the same analysis that they would for their own employees.
- The risk of CMP liability is greatest for employees and contractors that provide items or services **integral to the provision of patient care** because it is more likely that such items or services are payable by the Federal health care programs. For example, nurses provided by staffing agencies, physician groups that contract with hospitals to provide emergency room coverage, and billing or coding contractors.
- If screening will be conducted by a contractor, OIG recommends validating that the contractor is conducting the screening by requesting and maintaining screening documentation from the contractor.

LEIE Tips

- Any former names used (e.g., maiden name, previous married name, etc.) should be searched in addition to the individual's current name
- In order to achieve the most accurate results, enter only the first few letters of the first and last names.
- Maintain documentation of the initial name search performed and any additional searches conducted in order to verify results of potential name matches.
- If checking only a few names, use the Online Searchable Database to search up to five names at once. For searching a large number, consider downloading the entire list via the LEIE Downloadable Database and using a spreadsheet or database program to perform searches.
- Verify identify using the Social Security Number (SSN) for an individual or Employer Identification Number (EIN) for an entity. (Note: The Privacy Act prohibits the distribution of SSNs so they cannot be included in the Downloadable Database).
 - If a search result does not contain a DOB, UPIN, NPI, EIN, or SSN, it is not available from OIG. Contact the Exclusions Branch to determine if there is any other information available.

Federal and State Exclusion Databases

- **OIG-HHS Exclusions Database**

<https://exclusions.oig.hhs.gov/>

- **System for Award Management (SAM)**

<https://www.sam.gov/SAM/pages/public/searchRecords/advancedPIRSearch.jsf>

- **Texas Exclusions Database**

<https://oig.hhsc.texas.gov/exclusions>

Questions?

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