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HEALTHCARE PROVIDER UPDATES

GUIDELINES ON THE USE OF FACEMASKS AND OTHER PPE: OSHA IMPLICATIONS AND THE PREP ACT

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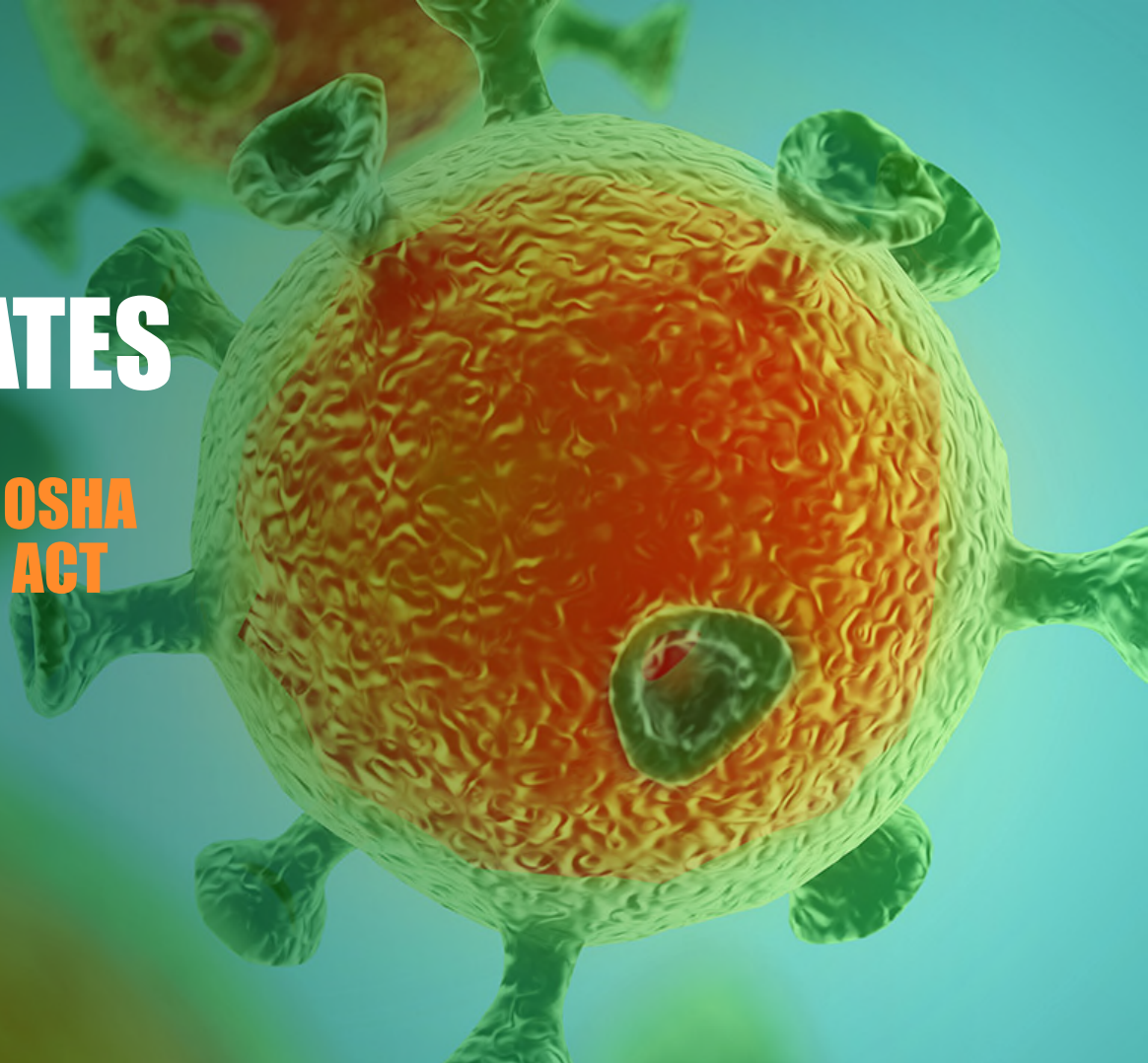

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Agenda

- How OSHA and CDC guidelines intersect in the health care provider environment
- What does the changing guidance means for OSHA complaints? How should healthcare providers manage this?
- Liability Issues arising with COVID-19 state and federal immunity
- The Public Readiness and Emergency Preparedness (PREP) Act: updates, immunity, limitations and questions relating to PPE

CDC GUIDANCE

Current Landscape: Shortages of N95 Respirators

- N95 respirators are the PPE most often used to control exposures to infections transmitted via the airborne route.
- There is currently a nationwide shortage of N95 respirators, and CDC has issued guidance to public health officials and leaders in healthcare settings to address how the optimization of existing supplies within OSHA's guidelines.
- Respirators must be used in the context of a comprehensive, written respiratory protection program that meets the requirements of OSHA's Respiratory Protection Standards.
  - The program should include medical evaluations, training, and fit testing.

Strategies for Optimizing the Supply of N95 Respirators

- CDC's guidance is broken down into three categories of capacity:
  - Conventional capacity
  - Contingency capacity
  - Crisis capacity

Contingency and Crisis Capacity

- Contingency capacity practices should be employed when a shortage of supplies is pending.
- This includes use of N95 respirators beyond the manufacturer-designated shelf life and extended use of N95 respirators on a limited basis without removal.
- Crisis capacity practices should be employed when supplies are running low. In addition to contingency practices, CDC allows for limited re-use of N95 respirators. CDC recommends prioritizing the use of N95s but allows for the use of other NIOSH approved respirators if faced with shortages.
- If respirators run out, CDC recommends excluding high-risk HCP from caring for COVID patients and designating HCP who have recovered from COVID to provide care to these patients. CDC also recommends engineering controls including patient isolation rooms and ventilated headboards.

RECENT OSHA ENFORCEMENT DIRECTIVES

OSHA Enforcement Directives

- OSHA released two enforcement directives addressing the N95 respirator shortage and compliance with OSHA's Respiratory Protection Standard.
- OSHA expressly incorporates the CDC's COVID-19 respirator guidance documents, including the strategies for optimizing supply of N95 respirators.
- The directives provide a measure of enforcement discretion on the fit testing for certain types of respirators as well as signal flexibility on the use of alternative products and using respirators in different ways including beyond the shelf life in certain situations.
- OSHA has also recently issued a press release reminding employers that they cannot retaliate against any workers who report unsafe or unhealthful work environments during the pandemic. The press release also reminds employees that they have the right to file a whistleblower complaint with OSHA.

March 14, 2020 Enforcement Directive

- Addresses the required annual fit-testing of the Respiratory Protection Standard.
- Reiterates that appropriate respiratory protection is required for all HCP providing direct care to COVID-19 patients, incorporating the CDC's hospital checklist for HCPs.
- OSHA "recommends HCP employers follow existing CDC guidelines" including conserving supplies of N95 FFRs.
- One example is providing HCP with another respirator of equal or higher protection, such as N99 or N100 FFRs.
- OSHA states that employers may "change the method of fit testing from a destructive method (i.e., quantitative) to a non-destructive method (i.e., qualitative)," referencing 29 CFR § 1910.134, Appendix A.

Enforcement Discretion

- OSHA urges enforcement discretion so long as employers:
  - Make good faith compliance efforts;
  - Use only NIOSH-certified respirators;
  - Implement CDC and OSHA strategies
  - Perform initial fit tests;
  - Inform employers about suspension of annual fit testing and the importance of performing a user seal check;
  - Conduct a fit test if there are visual changes in the employee's physical condition that could affect respirator fit; and
  - Remind workers that they should inform their supervisor or their respirator program administrator if the integrity and/or fit of their N95 filtering facepiece respirator is compromised.

April 3, 2020 Enforcement Directive

- Employers must continue to manage their Respiratory Protection Programs and account for shortages of N95 FFRs, including assessment of changes that can be made to decrease the need for N95 FFRs.
- If respiratory protection must be used, employers may consider alternative classes of respirators that provide equal or greater protection, so long as they are NIOSH-approved.
- If alternatives are not available, extended use or reuse of N95 FFRs, or use beyond their shelf life, is permitted so long as certain procedures are followed.
- For HCP, expired N95 FFRs must not be used when performing surgical procedures or procedures where respiratory secretions are likely on a COVID-19 patient.
- For HCP, OSHA advises that in accordance with CDC guidance, employers should prioritize the use of N95 FFRs by activity type.
- The OSHA guidance does not address "scenarios in which other crisis standards of care may need to be considered."

Enforcement Discretion

- Enforcement discretion should be used in cases where:
  - The employer has made a good faith effort to obtain other alternative respirators;
  - The employer has monitored their supply of N95s and prioritized their use according to CDC guidance;
  - Surgical masks and eye protection (e.g., face shields, goggles) were provided as an interim measure to protect against splashes and large droplets; and
  - Other feasible measures, such as using partitions, restricting access, cohorting patients (healthcare), or using other engineering controls, work practices, or administrative controls that reduce the need for respiratory protection, were implemented to protect employees.

Whistleblower and OSHA Press Release

- OSHA has also recently issued a press release reminding employers that they cannot retaliate against any workers who report unsafe or unhealthful work environments during the pandemic. The press release also reminds employees that they have the right to file a whistleblower complaint with OSHA.

News Release

U.S. Department of Labor | April 8, 2020

U.S. Department of Labor Reminds Employers That They Cannot Retaliate Against Workers Reporting Unsafe Conditions During Coronavirus Pandemic

CIVIL LIABILITY IMMUNITY/ STATE AND FEDERAL

Two Potential Legal Sources Of Immunity

- State
  - Orders
  - Legislation
- Federal
  - PREP Act
  - Declaration of HHS

State Law Immunity

- Numerous states have enacted temporary limitations on liability in response to COVID-19
  - Bars on medical malpractice claims based on negligence; requiring at least "gross negligence"
  - Loosened restrictions on practice by non-licensed practitioners
  - Loosened recordkeeping requirements
- Typically
  - Tied specifically to COVID-19 treatment
  - Good faith treatment
  - Time limited waiver

State Law Immunity

- Provisions enacted in:
  - Connecticut
  - Illinois
  - Kentucky
  - Louisiana
  - Maryland
  - Michigan
  - Nevada
  - New Jersey
  - New York
  - Utah

State Law Immunity

- NY Executive Order No. 202.10 (issued 3/23/20)

- Subdivision (2) of section 6527, Section 6545, and Subdivision (1) of Section 6909 of the Education Law, to the extent necessary to provide that all physicians, physician assistants, specialist assistants, nurse practitioners, licensed registered professional nurses and licensed practical nurses shall be immune from civil liability for any injury or death alleged to have been sustained directly as a result of an act or omission by such medical professional in the course of providing medical services in support of the State's response to the COVID-19 outbreak, unless it is established that such injury or death was caused by the gross negligence of such medical professional;

PREP Act

- The Public Readiness and Emergency Preparedness Act was signed into law (Public Law 109-148) in December, 2005.
- Allows the HHS Secretary to issue a declaration to provide Federal and State liability immunity to "Covered Persons" against any claim of "loss" relating to the manufacture, distribution, administration, or use of "Covered Countermeasures," except for claims involving "willful misconduct."
- Has been used, for example, for outbreaks including:
  - Ebola
  - Zika
  - H1N1

PREP Act *(cont.)*

- Ostensible primary purpose was to insulate manufacturers producing vaccines for public health crises from liability
- However, HHS officials now are using the statutory authority more broadly
- The HHS Declaration pertaining to COVID-19 was published on March 17, retrospective to February 4, 2020, and continues through October 1, 2024
- Tracking the statute, the Declaration addresses the following key considerations:
  - Recommended Activities
  - Covered Persons
  - Covered Countermeasures

PREP Act *(cont.)*

- Recommended Activities
  - the manufacture, testing, design, development, distribution, administration, and use of the Covered Countermeasures
- Administration includes physical provision of the countermeasures, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures, management and operation of countermeasure programs, or management and operation of locations for purpose of distributing and dispensing countermeasures.

PREP Act *(cont.)*

- Covered Persons
  - Manufacturers
    - a contractor or subcontractor of a manufacturer, or its officials, agents, and employees; a supplier or licenser of any product, intellectual property, service, research tool or component or other article used in the design, development, clinical testing, investigation or manufacturing of a Covered Countermeasure; and any or all the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer
  - Distributors
  - Program planners - State or local government . . . or other person who supervised or administered a program with respect to the administration . . . of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer . . . a covered countermeasure
  - Qualified persons – A licensed healthcare professional

PREP Act *(cont.)*

- Covered Countermeasures
  - Any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product,
  - a product to address a condition caused by a pandemic therapy, e.g., therapy to address adverse events, or
  - a product used to enhance the effectiveness of a countermeasure, e.g., vaccine adjuvant.
- Covered Countermeasures must be "qualified pandemic or epidemic products," or "security countermeasures," or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.

PREP Act *(cont.)*

- Amendment March 18, 2020
- Expanded definition of "Covered Countermeasures" to include "personal respiratory protective device(s)" that are:
  - Approved by NIOSH;
  - Subject to an Emergency Use Authorization; and
  - Used in response to COVID-19 between 1/27/20 and 10/1/24
- Effectively expands PREP Act protection to use of NIOSH masks that are not surgical grade
  - FDA issued EUA 3/2/20 for NIOSH respirators
  - FDA expanded EUA 3/27 and 3/28/20, includes respirators that were past expiration date and held in strategic stockpiles or decontaminated through authorized system

PREP Act *(cont.)*

- In order to qualify for immunity, the Covered Person, Covered Activities and Covered Countermeasures, must be related to:
  - Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements; or
  - Activities authorized in accordance with the public health and medical response of the "Authority Having Jurisdiction" to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a "Declaration of an Emergency".

PREP Act *(cont.)*

- Impact of compliance with the PREP Act
  - Immunity from Federal or State law, including tort immunity, relating to death, injury, trauma, or damage to property
  - Note that immunity matures at the point of tort claim adjudication—either through administrative action or in federal court.
  - Liabilities not associated with the COVID treatment are not covered, even if they arise during COVID treatment

PREP Act *(cont.)*

- Willful Misconduct
  - Acts as an exception to the immunity
  - Includes acts taken for a wrongful purpose, without justification, or in blatant disregard that the risks outweigh the potential benefits

Biography

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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.

Biography

Jonathan Snare
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Jonathan L. Snare brings the perspective of a former US Department of Labor (DOL) official to his practice, which focuses on labor-related legislative, regulatory, and administrative issues at local, state, and federal levels. Leader of the firm's occupational safety and health practice, Jon advises on workplace safety and health issues involving enforcement, compliance, workplace investigations, and emergency response matters, including disputes before the Occupational Safety and Health Administration (OSHA), Chemical Safety Board, Mine Safety and Health Administration (MSHA), and OSHA state plan departments.

Biography

John P. Lavelle Jr.
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John P. Lavelle, Jr., represents clients in crisis management and complex litigation, including product liability, commercial, class action, and election law matters, both at trial and on appeal. John has successfully defended clients in product liability disputes involving medical devices, pharmaceuticals, vaccines, nutritional supplements, consumer products, chemicals, and industrial equipment. John's class action practice includes the defense of consumer products, telecommunications, insurance, and financial services companies in US federal as well as state courts.

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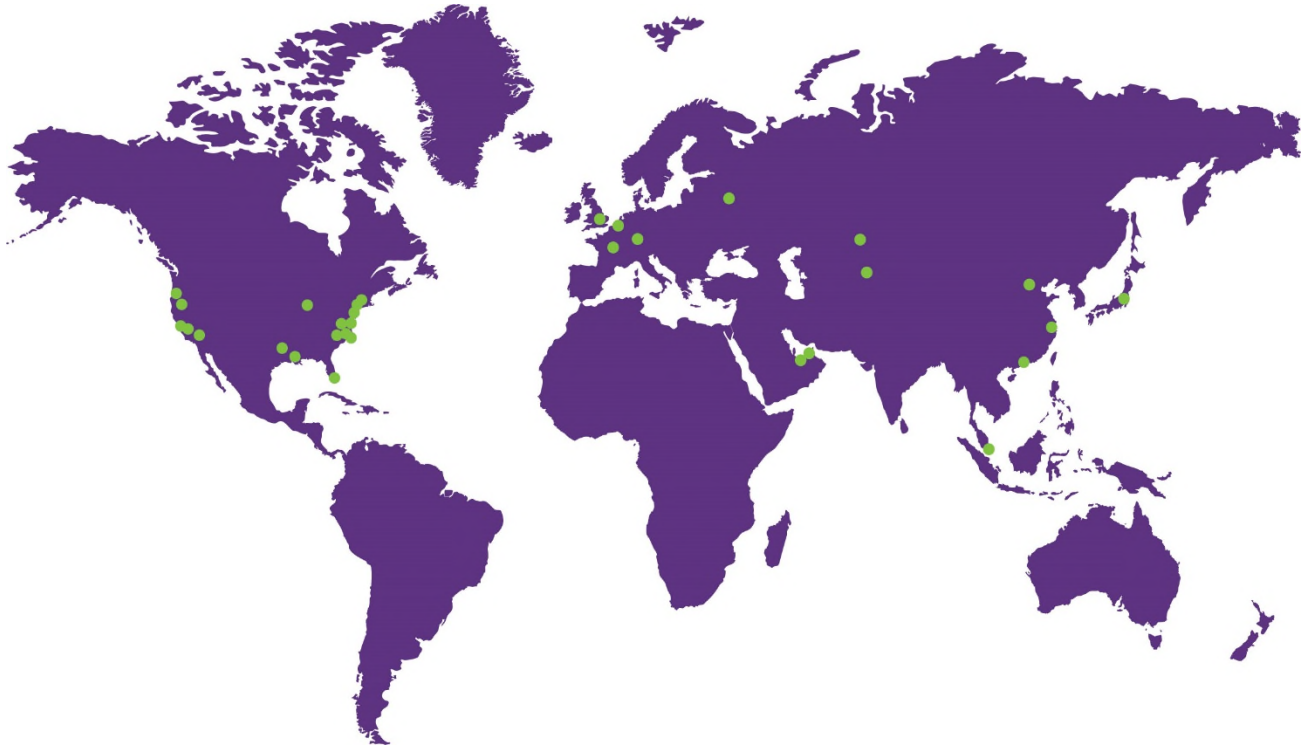

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