

COVID Vaccine Legal, Billing and Operational Issues

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JANUARY 15, 2021

Agenda

- Liability Issues
- Patient Informed Consent
- Employment Law Considerations
- Billing and Coding

Disclaimer

DISCLAIMER: Please note that the situation surrounding COVID-19 is evolving and that the subject matter discussed in these publications may change on a daily basis.

Information contained in this presentation is for the general education and knowledge of participants. It is not designed to be, and should not be used as, the sole source of information when analyzing and resolving a legal problem, and it should not be substituted for legal advice, which relies on a specific factual analysis. This information is not intended to create, and receipt of it does not constitute, an attorney-client relationship.

PREP Act Immunity

- The **P**ublic **R**eadiness and **E**mergency **P**reparedness **A**ct (PREP Act) (2005), authorizes the Secretary of Health and Human Services (HHS) to limit legal liability for losses relating to the administration of medical countermeasures.

PREP Act Immunity

- Requirements:
 - The individual or entity must be a **“covered person”**;
 - The legal claim must be for a **“loss”**;
 - The loss must have a **“casual relationship”** with the administration or use of a covered countermeasure; and
 - The medical product that caused the loss must be a **“covered countermeasure”**.

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PREP Act Immunity

- **Covered Persons –**

Include, among others, “qualified persons” who prescribe, administer or dispense covered countermeasures.

-42 U.S.C. 247d(i)(2)-(4), (6), (8)(A) and (B)

PREP Act Immunity

- **Claims for loss –**

Include death; physical, mental or emotional injury; illness; disability or condition; fear of such injury including medical monitoring costs; and loss of or damage to property, including business interruption loss.

PREP Act Immunity

- A loss has a **casual relationship** if –
 - Pertaining to the “design, development, clinical testing or investigation, manufacture, labeling, distribution, packaging, marketing, promotion, sale, purchase, donation, **dispensing, prescribing, administration**, licensing or use of a covered countermeasure.
 - A “**covered countermeasure**” includes COVID-19 vaccines.

PREP Act Immunity

- Secretary of HHS Alex Azar invoked the PREP Act, effective February 4, 2020, and declared COVID-19 to be a public health emergency warranting liability protections for covered countermeasures.

PREP Act Immunity

- The HHS Secretary has said that the PREP Act precludes liability claims
 - Alleging "negligence by a health care provider in prescribing the wrong dose, absent willful misconduct" and
 - "Relating to the management and operation of a countermeasure distribution program or site, such as a slip-and-fall injury or vehicle collision by a recipient receiving a countermeasure"
 - But "an injury occurring at the site that was not directly related to the countermeasure activities is not covered"

PREP Act Immunity

- Limited Case Law
 - *Estate of Maglioli v. Andover SubAcute Rehab Ctr.*, 2020 WL 4671091 (D.N.J. August 12, 2020)
 - Lawsuit brought on behalf of nursing home residents who died allegedly due to the nursing homes' failure to take precautions against COVID-19.

PREP Act Immunity

- State law causes of action: negligence, wrongful death, and medical malpractice.
- Defendants removed the case on the theory that the PREP Act preempted the state law claims.
- The court disagreed and sent the case back to state court.

PREP Act Immunity

According to the court,

Nothing in the language of the [PREP] Act suggests that it was intended to more broadly displace state-law causes of action for, e.g., malpractice or substandard care – even if proper care possibly would have entailed administration of such countermeasures.

PREP Act Immunity

The court added that the PREP Act:

[C]overs the administration and distribution of products meant to curb the spread of COVID-19, but does not, by its plain terms, cover more generally the care received by patients in healthcare facilities.

PREP Act Immunity

At least two (2) other courts have adopted the same reasoning and ruled that the PREP Act does not preempt claims for *failure* to take preventative measures.

- *Lutz v. Big Blue Healthcare, Inc.*, 2020 WL 4815100
- *Sherod v. Comprehensive Healthcare Mgmt. Servs, LLC*

PREP Act Immunity

To summarize:

According to the decision rendered so far, immunity under the PREP Act is limited to claims resulting from the administration or use of a covered countermeasure, not the decision not to use the vaccine or of the failure to use it.

Oklahoma Product Protection Act

- SB 1947 (76 O.S. 112)
- Applies to any claim arising on or after March 15, 2020.

D. . . . a . . . health care facility, health care provider, . . . that utilizes a product meeting the qualifications of either subsection C or D of this section, shall not be liable in a civil action alleging personal injury, death or property damage caused by or resulting from the selection, distribution, or use of such product.

Oklahoma Product Protection Act

- **“Qualified product”** means personal protective equipment used to protect the wearer from COVID-19 or the spread of COVID-19 . . . **medications used to treat COVID-19** patients including medications prescribed or dispensed for off-label use to attempt to combat COVID-19; tests to diagnose or determine immunity to COVID-19; and components of qualified products.

	National Vaccine Injury Compensation Program (NVICP)	Countermeasures Injury Compensation Program (CICP)
Application	Vaccines routinely administered to children	Covered countermeasures during a declared public health emergency
Examples	Polio Vaccine, Flu Vaccine, DTaP Vaccine	COVID Vaccine, Ebola Vaccine, Anthrax Vaccine
Funding	Excise tax on all childhood vaccines	Congressional appropriation after declaration of a public health emergency
Coverage	Injuries listed on the Vaccine Injury Table	“Serious” injuries
Appeals	Yes	No, although claimants may request reconsideration.
Opt Out	Yes, claimant may reject compensation award and sue manufacturer in civil court	Extremely limited: only in cases in which the claimant can show “willful misconduct” by clear and convincing evidence
Statute of Limitations	3 years from injury	1 year from date of vaccine administration

CICP

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

Patient Informed Consent

- <https://abrihealthcare.com/wp-content/uploads/2020/12/PharmScriptCOVID-Vaccine-Consent-Form-Instructions-merged-2.pdf>.
 - https://www.inova.org/sites/default/files/covid-19/documents/Inova_COVID_Vaccine_Consent.pdf.
 - <https://www.emoryhealthcare.org/ui/pdfs/covid/english-pfizer-vaccine-consent-form.pdf>.
 - <https://www.omnicare.com/covid-19-vaccine-resource>.
-
- In light of immunity statutes, it is as equally important to get patient's refusal of the vaccine.
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- Get patient's acknowledgement of age, allergies, other conditions.
 - Pfizer-BioNTech vaccine: 16 years and older
 - Moderna: 18 years and older

Patient Informed Consent

Confusion Reigns Over Issue Of Consent In Nursing Home Vaccinations

The New York Times (12/17) reports, “There remains widespread confusion about a key element of the plan to protect some of the most vulnerable Americans against the coronavirus,” which is “how nursing homes will get consent to vaccinate residents who aren’t able to make their own medical decisions.”

Some states “are starting vaccinations in their nursing homes this week, but a broader nationwide effort will start in earnest on Monday as CVS and Walgreens employees begin to arrive at tens of thousands of nursing homes and assisted-living facilities to vaccinate staff and residents.” A CVS executive “said such residents’ legal representatives will be able to provide consent to nursing homes electronically or over the phone, but officials at multiple large nursing home chains said they were not aware of that.”

Employer Liability

- EEOC
 - Discrimination laws apply to employers with 15 or more employees
- OSHA
 - Failure to maintain safe work place
- Workers Compensation
 - WC claim by employee who suffers adverse reaction to mandatory vaccine
 - WC claim by employee who contracts COVID from unvaccinated co-worker

Employer Liability

Employers Who Mandate COVID-19 Vaccines Must Be Prepared To Exempt Employees With Disabilities, Religious Objections, EEOC Says

[Reuters](#) (12/16, Wiessner) reports, “The U.S. agency that enforces workplace discrimination laws said on Wednesday that employers who choose to require workers to be vaccinated against COVID-19 must be prepared to exempt employees with disabilities and religious objections.” The guidance was issued by the Equal Employment Opportunity Commission (EEOC) “on its website after the U.S. Food and Drug Administration cleared the way for a COVID-19 vaccine developed by Pfizer Inc and German partner BioNTech.” According to the EEOC, “companies that choose not to have vaccines administered at the workplace can require employees to provide proof that they received a vaccination without violating the Americans with Disabilities Act,” but the law only allows “employers to ask workers why they have refused to be vaccinated if the information is ‘job related and consistent with business necessity,’ the agency said.”

Employer Liability

Link to EEOC Guidance:

<https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws>.

Employer Liability

Employers who choose to require vaccinations, must:

- Exercise due care in administering it;
- Refrain from asking any unnecessary screening questions;
- Keep confidential any medical information received from their employees; and
- Be prepared to engage in an interactive process with any employees who request accommodation or seek exemption from being vaccinated for health-related or religious reasons.

Employer Liability

Despite signaling that an employer may require COVID-19 vaccinations of its employees, the EEOC's guidance does not give employers carte blanche to vaccinate their employees.

- For instance, because the administration of a COVID-19 vaccine likely would require an employee to provide certain pre-screening information – information that may be necessary to determine whether an employee can be vaccinated – the disclosure of that information can trigger the ADA's provision prohibiting disability-related inquires, which can expose an employer to liability.
- If the employer administers the vaccine, it must show that such pre-screening questions are “job-related and consistent with business necessity” to comply with the ADA.

Sample Mandatory Policy

All employees are required to receive vaccinations as determined by [*insert relevant department or safety committee*], unless a reasonable accommodation is approved. Employees not in compliance with this policy will be placed on unpaid leave until their employment status is determined by the human resources department.

Sample Procedures

Employees will be notified by the human resources department as to the type of vaccination(s) covered by this policy and the timeframe(s) for having the vaccine(s) administered. [Company Name] will provide either onsite access to the vaccines or a list of locations to assist employees in receiving the vaccine on their own.

[Company Name] will pay for all vaccinations. When not received in-house, vaccinations should be run through employees' health insurance where applicable and otherwise be submitted for reimbursement.

All employees will be paid for time taken to receive vaccinations. For offsite vaccinations, employees are to work with their managers to schedule appropriate time to comply with this policy.

Before the stated deadlines to be vaccinated have expired, employees will be required to provide either proof of vaccination or an approved reasonable accommodation to be exempted from the requirements.

Sample Voluntary Policy

All employees are encouraged to receive COVID-19 vaccinations.

Sample Procedures

Same as mandatory, but for consequences if elect not to be vaccinated:

Employees should provide proof of vaccination before the stated deadlines to be vaccinated have expired. Employees who do not provide timely proof of vaccination will be required to wear an approved face covering at all times while in the workplace and when engaging with patients/customers, unless an approved exemption from wearing a face covering has been provided.

Mandatory Vaccine - Pros

- Speed return to normalcy.
- Avoid conflicts between vaccinated and unvaccinated employees.
- Instill customer/patient confidence.
- Competitive edge.
- Lend protection to high risk employees.
- Bolster position of safe work place (OHS/A issues).
- Prevent employees from spreading to third parties.

Mandatory Vaccine - Cons

- Administrative burdens.
- Potential for extraordinary conflict with employees.
- Potential litigation.
- Unease in first generation vaccine -only temporarily approved for emergency use.

Instead of mandating. . .

For example, employers may want to:

- Develop vaccination education campaigns.
- Make obtaining the vaccine as easy as possible for employees.
- Cover any costs that might be associated with getting the vaccine.
- Provide incentives to employees who get vaccinated.
- Provide paid time off for employees to get the vaccine and recover from any potential side effects.

Billing and Coding

<https://www.ama-assn.org/press-center/press-releases/ama-announces-vaccine-specific-cpt-codes-coronavirus-immunizations>.

Vaccine Product Codes:

91300 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL_dosage, diluent reconstituted, for intramuscular use [**Pfizer**]

91301 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage, for intramuscular use [**Moderna**]

Billing and Coding

0001A Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted; **first dose [Pfizer]**

0002A Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted; **second dose [Pfizer]**

0011A Immunization administration by intramuscular injection of Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage; **first dose [Moderna]**

0012A Immunization administration by intramuscular injection of Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage; **second dose [Moderna]**

Billing and Coding

The Codes “are both distinct to each coronavirus vaccine and the specific dose in the required schedule. This level of specificity is a first for vaccine CPT codes, but offers the ability to track each vaccine dose, even when the vaccine product is not reported (e.g. when the vaccine may be given to the patient for free). These CPT codes report the actual work of administering the vaccine, in addition to all necessary counseling provided to patients or caregivers and updating the electronic record.”

Billing and Coding

Providers generally cannot bill payers for vaccine doses they receive for free, providers will be able to submit claims for the administration of the vaccine and, eventually, doses it purchases from drug manufacturers.