December 16, 2020

Fourth Time's the Charm? Amended HHS Declaration Expands Application of PREP Act Immunity and Preemption for COVID-19 Response

On December 3, 2020, Secretary Alex Azar (the "Secretary") of the U.S. Department of Health and Human Services ("HHS") issued the fourth amendment to his previously issued declaration under the Public Readiness and Emergency Preparedness Act ("PREP") Act for medical countermeasures against COVID-19 (the "Declaration").[1] The amended Declaration expands the application of the PREP Act and its associated immunity protections for individuals and entities ("Covered Persons") against claims of loss relating to certain COVID-19 countermeasures ("Covered Countermeasures"). In particular, the amended Declaration, among other things:

- Expands PREP Act coverage to health care personnel using telehealth to order or administer Covered Countermeasures for patients in states where the personnel are not permitted to practice;
- Adds a new option for satisfying the Declaration's "Limitations on Distribution" that does not require an agreement with the federal government or an authorization from a public health authority; and
- Clarifies that not administering a Covered Countermeasure can be covered under the PREP Act in certain circumstances.

This significant development continues HHS's efforts to use the PREP Act as a way to expand access to and encourage the use of Covered Countermeasures. For background on the PREP Act, the Declaration, and previous advisory opinions from the HHS Office of General Counsel ("OGC"), refer to Ropes & Gray's prior Alert.

Revisions Related to Use of Telehealth for Covered Countermeasures

The amended Declaration defines the term "qualified person" (a type of Covered Person) to include health care personnel using telehealth to order or administer Covered Countermeasures for patients located in a state other than the state in which the health care personnel are permitted to practice. Such health care personnel ordering and administering Covered Countermeasures through telehealth must comply with the legal requirements of the state in which they are licensed or permitted to practice. Significantly, any state laws that prohibit or effectively prohibit the qualified health care personnel from ordering and administering the Covered Countermeasures through telehealth are preempted, including licensing laws.

PREP Act immunity and preemption do not apply to telehealth services unrelated to ordering or administering Covered Countermeasures. While a number of states have authorized out-of-state health care personnel to deliver telehealth services to in-state patients (either in the context of COVID-19 or generally), health care providers should carefully consider the following before ordering or administering Covered Countermeasures through telehealth:

- Verification of Covered Countermeasures. Providers should ensure that the product being ordered or administered via telehealth qualifies as a Covered Countermeasure under the Declaration. For example,

laboratory-developed tests ("LDTs") for COVID-19 that have not received FDA clearance or an emergency use authorization would not qualify as Covered Countermeasures because Covered Countermeasures must, among other things, be approved, cleared, licensed, or authorized for emergency use by FDA or subject to an investigational new drug application or investigational device exemption. Given the number of LDTs currently on the market for COVID-19 without an EUA,[2] this could present a significant limitation to the scope of preemption with respect to COVID-19 testing.

- Health Information Privacy and Security. Telehealth platforms must comply with applicable health information and privacy and security laws. On March 17, 2020, the Office for Civil Rights ("OCR") at HHS issued a notification of enforcement discretion providing that OCR will not impose penalties against health care providers for noncompliance with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") rules in connection with health care providers' use of telehealth in good faith during the COVID-19 public health emergency. Notably, this enforcement discretion applies narrowly to health care provider-covered entities and not to health plans or business associates (*e.g.*, third-party care management organizations) that may also be utilizing telehealth. Telehealth service providers must also be aware of applicable state data protection laws that may be more restrictive than HIPAA (*e.g.*, California's Consumer Privacy Act and New York's SHIELD Act).

- Corporate Practice of Medicine and Similar Prohibitions. The amended Declaration preempts state licensing laws with respect to health care *personnel* ordering and administering but may not preempt state prohibitions on the corporate practice of health professions with respect to the *employers* of these health care personnel. In these corporate practice states, professional services can only be offered by individuals licensed in the applicable health profession or by authorized professional organizations. The "effectively prohibit" language of the Declaration's preemption of laws may preempt these corporate practice prohibitions, but state attorneys general and health licensing boards in strict corporate practice states could argue that the preemption only applies to individual practitioners. Therefore, health care organizations seeking to expand their services beyond their initial states of operation should ensure their business structure comports with applicable state laws.

- Reimbursement. Providers should be vigilant with respect to documentation requirements for billing for telehealth services and closely examine payer reimbursement policies for telehealth services to determine whether Covered Countermeasures are covered under those policies.

- Other State and Federal Requirements Applicable to Telehealth. Providers should keep in mind specific rules around establishing a patient-provider relationship, particularly with respect to online prescribing, and evaluate with legal counsel which of those requirements may be preempted by the Declaration.

Revisions to Expand Options for Satisfying the Declaration's "Limitations on Distribution"

Prior to the December 3 amendment, the "Limitations on Distribution" set forth in the Declaration provided that the liability immunity afforded to Covered Persons applied only to activities involving Covered Countermeasures that were related to the following:

- Present or future 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.

The amended Declaration adds another option for satisfying the Limitations on Distribution that extends PREP Act coverage to additional private-distribution channels. Specifically, the Limitations on Distribution are also satisfied for activities related to any Covered Countermeasure that is either:

- licensed, approved, cleared, or authorized by the FDA (or that is permitted to be used under an IND or IDE) to treat, diagnose, cure, prevent, mitigate, or limit the harm from COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom; or

- a respiratory protective device approved by NIOSH that the Secretary determines to be a priority for use to prevent, mitigate, or limit the harm from COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom.

To satisfy this new option, the Covered Countermeasure must be manufactured, tested, developed, distributed, administered, or used "pursuant to" the applicable marketing authorization from FDA or NIOSH. Thus, off-label uses of Covered Countermeasures will not qualify for this option; however, the other Limitations on Distribution options could potentially still apply if, for example, the off-label use occurs pursuant to guidance from a state or local public health authority.

Since the Secretary first issued a Declaration in March, many stakeholders have struggled to understand how their response activities could satisfy the Limitations of Distribution, including what it means for an activity to be authorized by an Authority Having Jurisdiction. The Secretary's significant expansion of the ways in which the Limitations on Distribution can be satisfied appears to be an attempt to assuage those concerns.

Revisions Relevant to Prioritization Decisions for Covered Countermeasures

The amended Declaration clarifies that *not* administering a covered countermeasure to a particular individual can satisfy the Declaration and receive PREP Act immunity in certain circumstances. The Declaration describes a scenario in which only one dose of a COVID-19 vaccine is available and a health care professional decides to vaccinate a person from a more vulnerable population instead of a person from a less vulnerable population. The Declaration asserts that the failure to administer the vaccine to the less vulnerable individual relates to the administration to the more vulnerable person. Such prioritization and "purposeful allocation" decisions regarding Covered Countermeasures are covered by the PREP Act, "particularly if done in accordance with a public health authority's directive." In this regard, the Declaration furthers an interpretation of the PREP Act previously espoused in HHS OGC Advisory Opinion 20-04 and rejects the rationale of a 2014 New York state court decision that addressed PREP Act immunity in the context of an H1N1 vaccine shortage.[3]

Other Key Revisions Relevant to Future Litigation

The amended Declaration includes other key changes that will likely be relevant to COVID-19-related litigation implicating the PREP Act.

Effect of Advisory Opinions. The amended Declaration states that it "must be construed in accordance with" HHS OGC advisory opinions and expressly incorporates HHS OGC's four existing advisory opinions as part of the Declaration.[4] HHS OGC advisory opinions are technically nonbinding and lack the force and effect of law. Yet through the statements in the amended Declaration, HHS is clearly attempting to give them binding effect on courts interpreting the scope of the PREP Act and the Declaration.

Federal Question Jurisdiction. The amended Declaration states that there are "substantial federal legal and policy issues" and "substantial federal legal and policy interests" (within the meaning of the 2005 U.S. Supreme Court decision in *Grable & Sons Metal Products, Inc. v. Darue Eng'g. & Mf'g.*[5]) in having a unified, national response to COVID-19. In *Grable & Sons*, the Supreme Court held that state-law claims that raise disputed and substantial federal issues are enough to establish federal question jurisdiction in federal courts.[6] Through the amended Declaration, HHS is attempting to persuade courts that federal question jurisdiction should apply to cases implicating the PREP Act.

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If you have any questions about this Alert or the amended Declaration, please contact any member of Ropes & Gray's FDA regulatory or health care practices or your usual Ropes & Gray advisor.

1. The amended Declaration was published in the Federal Register on December 9. 85 Fed. Reg. 79,190 (Dec. 9, 2020).
2. Refer to Ropes & Gray's prior Alert regarding FDA's evolving review priorities for COVID-19 LDTs.
3. *Casabianca v. Mt. Sinai Med. Ctr.*, 2014 WL 10413521 (N.Y. Sup. Dec. 12, 2014) (holding that PREP Act immunity "only applies to the actual use of the vaccine").
4. *See* Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration under the Act, Apr. 17, 2020, as Modified on May 19, 2020; Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, May 19, 2020; Advisory Opinion 20-03 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, Oct. 22, 2020, as Modified on Oct. 23, 2020; Advisory Opinion 20-04 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, Oct. 22, 2020, as Modified on Oct. 23, 2020.
5. 545 U.S. 308 (2005).
6. *See id.* at 314 ("[T]he question is, does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities.").