



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

The General Counsel  
Washington, D.C. 20201

### ADVISORY OPINION 20-03 ON THE PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT AND THE SECRETARY'S DECLARATION UNDER THE ACT OCTOBER 22, 2020, AS MODIFIED ON OCTOBER 23, 2020

This Advisory Opinion addresses three vaccination-related issues that have arisen under the Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. § 247d-6d, as follows:

1. Does the PREP Act preempt state licensing laws that are less stringent than the federal standards under the Third Amendment to the Secretary's March 10, 2020 PREP Act Declaration?<sup>1</sup>
2. May a state require a pharmacist to enter into a collaborative-practice agreement with a licensed physician as a condition of administering ACIP-recommended vaccines to children between ages 3 and 18?
3. Is epinephrine, when used to treat a severe acute vaccine reaction, a "covered countermeasure" within the meaning of the PREP Act?

States or their sub-units may not impose any requirement that would prohibit or effectively prohibit activities authorized by the Secretary in a PREP Act declaration. Accordingly, state-licensing laws that are less stringent than those in the Secretary's Declaration are not preempted, because they do not prohibit or effectively prohibit the activity in question—namely, vaccination.

Conversely, any state or local law requiring a pharmacist to enter into a collaborative-practice agreement would be preempted if that requirement prohibits or effectively prohibits a pharmacist from ordering and administering vaccines as set forth in the Third Amendment and related issuances.

Drugs, such as epinephrine, when used to counteract an ACIP-recommended vaccine reaction, are covered countermeasures and subject to PREP Act immunity and preemption.

#### I. ANALYSIS

On June 4, the Secretary amended the Declaration to clarify that "covered countermeasures" include products that limit the harm that COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, might otherwise cause.<sup>2</sup> On August 24, the Secretary issued the Third Amendment.<sup>3</sup> It amended the category of disease, health condition, and threat for which the Secretary recommends the administration or use of covered countermeasures to include the decrease in the rate of

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<sup>1</sup> See Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198 (Mar. 17, 2020) (Declaration); 85 Fed. Reg. 21,012 (Apr. 15, 2020) (First Amendment); 85 Fed. Reg. 35,100 (June 8, 2020) (Second Amendment); 85 Fed. Reg. 52,136 (Aug. 24, 2020) (Third Amendment).

<sup>2</sup> See 85 Fed. Reg. at 35,102.

<sup>3</sup> See 85 Fed. Reg. 52,136.

childhood immunizations during the pandemic.<sup>4</sup> To make routine childhood vaccinations more accessible during this pandemic, the Third Amendment also identified state-licensed pharmacists and pharmacy interns as “qualified persons” when the pharmacist orders and either the pharmacist or the supervised intern administers Advisory Committee on Immunization Practices (ACIP)-recommended vaccines to individuals ages three through 18 pursuant to certain requirements.<sup>5</sup>

#### A. LESS STRINGENT STATE REQUIREMENTS

The PREP Act specifies two types of “qualified persons” who are eligible for PREP Act immunity. Under § 247d-6d(i)(8)(A), a qualified person may be “a licensed health professional or other individual who is authorized to prescribe, administer, or dispense [covered] countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed.” And under § 247d-6d(i)(8)(B), a qualified person may also be “a person within a category of persons so identified in a declaration by the Secretary.”<sup>6</sup>

The Third Amendment identifies, as qualified persons under § 247d-6d(i)(8)(B), certain pharmacists who are *not* authorized to order and administer, and certain pharmacy interns who are *not* authorized to administer, certain childhood vaccines to certain children under state law.<sup>7</sup> To become “qualified persons” under the Declaration, pharmacists and pharmacy interns who are not authorized to order or administer these childhood vaccines under state law must satisfy the requirements set forth in the Third Amendment.<sup>8</sup> Pharmacists and pharmacy interns who *are* authorized to order or administer childhood vaccines under state law do not need to satisfy those requirements to be “qualified persons” under § 247d-6d(i)(8)(A).

The Third Amendment preempts *narrower* state scope-of-practice laws for pharmacists and pharmacy interns who meet the requirements set forth in the Third Amendment. But the Third Amendment does not affect *broader* state scope-of-practice laws. The preamble to the Third Amendment specifies that “nothing herein shall preempt State laws that permit additional individuals to administer vaccines that ACIP recommends to persons age 18 or younger according to ACIP’s standard immunization schedule.”<sup>9</sup>

For example, the Third Amendment requires the licensed pharmacist seeking PREP Act coverage to “complete a practical training program of at least 20 hours.”<sup>10</sup> Some states require less than 20 hours of such training for a licensed pharmacist to order and administer vaccinations to individuals ages 3 to 18. The Third Amendment does not affect such less-stringent, state-law requirements.

So a pharmacist who seeks PREP Act coverage under § 247d-6d(i)(8)(B) and the Third Amendment—*e.g.*, because the pharmacist is not authorized to vaccinate under the state scope-of-practice law—must satisfy the 20-hour requirement. But a pharmacist in a state that requires less than

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<sup>4</sup> See 85 Fed. Reg. at 52,141.

<sup>5</sup> See 85 Fed. Reg. at 52,138.

<sup>6</sup> 42 U.S.C. 247d-6d(i)(8)(B).

<sup>7</sup> See 85 Fed. Reg. at 52,138-39.

<sup>8</sup> *Id.*

<sup>9</sup> 85 Fed. Reg. at 52,139.

<sup>10</sup> 85 Fed. Reg. at 52,140.

20 hours may still vaccinate under state law even if the pharmacist does not complete 20 hours of training as required under the Third Amendment. And as explained above, such a pharmacist would be a “qualified person” under § 247d-6d(i)(8)(A), and therefore eligible for PREP Act coverage if the pharmacist satisfies those other requirements of the PREP Act and Declaration not associated with being a “qualified person.”

## B. COLLABORATIVE-PRACTICE AGREEMENTS

Certain states require a protocol or a collaborative-practice agreement (CPA) to administer vaccinations to children of certain ages. Whether the Third Amendment preempts these state requirements depends on whether those requirements prohibit or effectively prohibit qualified pharmacists from ordering and administering (and qualified interns from administering) ACIP-recommended vaccines to children ages 3-18.

The Third Amendment provides, “Notwithstanding any State or local scope-of-practice legal requirements, (1) qualified licensed pharmacists are identified as qualified persons to order and administer ACIP-recommended vaccines and (2) qualified State-licensed or registered pharmacy interns are identified as qualified persons to administer the ACIP-recommended vaccines ordered by their supervising qualified licensed pharmacist.”<sup>11</sup> The Office of the General Counsel’s Advisory Opinion 20-02 explains that under the PREP Act, state and local authorities “may not prohibit or effectively prohibit ‘qualified persons’ from ordering and administering covered countermeasures.”<sup>12</sup>

Therefore, during the effective period of the PREP Act declaration, states cannot use any protocol or CPA to prohibit or effectively prohibit “qualified persons” from ordering and administering ACIP-recommended childhood vaccines in a manner consistent with that specified in the Third Amendment.<sup>13</sup>

## C. EPINEPHRINE

CDC recommends that immediate intramuscular epinephrine is the treatment of choice for severe acute vaccine reactions involving respiratory or cardiovascular symptoms, or other signs or symptoms of anaphylaxis.<sup>14</sup> The preamble to the Second Amendment explained, “The Secretary intended section VI of the March 10, 2020 Declaration to include all qualified pandemic and epidemic products defined under the PREP Act and described in the preamble to the Declaration.”<sup>15</sup> And under the PREP Act, “covered countermeasures” include qualified products “manufactured, used,

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<sup>11</sup> *Id.*

<sup>12</sup> Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary’s Declaration under the Act at 2 (May 19, 2020) (PREP Act Advisory Opinion 20-02), <https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf> (last visited Oct. 23, 2020) (discussing the PREP Act’s preemption provision).

<sup>13</sup> See also 42 U.S.C. 247d-6d(b)(8).

<sup>14</sup> See, e.g., *Preventing and Managing Adverse Reactions*, CDC, <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html> (last visited Oct. 23, 2020) (For severe acute vaccine reaction involving “respiratory or cardiovascular symptoms, or other signs or symptoms of anaphylaxis, immediate intramuscular epinephrine is the treatment of choice.”).

<sup>15</sup> 85 Fed. Reg. at 35,101.

designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, *or cure a serious or life-threatening disease or condition caused by such a drug, biological product, or device.*<sup>16</sup>

Under the Third Amendment, ACIP-recommended vaccines are “covered countermeasures.” Epinephrine mitigates or treats a serious or life-threatening condition that, in some rare instances, may be a side effect of vaccine administration. Furthermore, the Third Amendment requires qualified pharmacists and pharmacy interns to, among other things, have sufficient training on “recognition and treatment of emergency reactions to vaccines.”<sup>17</sup> Therefore, epinephrine is a “covered countermeasure” and the PREP Act covers its use as set forth in the Third Amendment to address such severe acute vaccine reactions. The PREP Act would not cover the administration of epinephrine to address unrelated respiratory or cardiovascular symptoms.

## II. Limitations

This Advisory Opinion may be supplemented or modified. It is intended to minimize the need for individual advisory opinions. This Advisory Opinion sets forth the current views of the Office of the General Counsel.<sup>18</sup> It is not a final agency action or a final order. Nor does it bind the Department of Health and Human Services or the federal courts. It does not have the force or effect of law.

Persons seeking PREP Act immunity are responsible for determining whether their products are “covered countermeasures,” whether a person or entity is a “covered person,” whether reasonable precautions have been taken to facilitate the safe use of covered countermeasures, and in general, whether immunity applies to them and their activities. In order to obtain PREP Act coverage, persons must meet all requirements set forth in the PREP Act and the Declaration.

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<sup>16</sup> *Id.* (emphasis added); *see also* 42 U.S.C. 247d-6d(i)(7)(A)(ii).

<sup>17</sup> 85 Fed. Reg. at 52,139.

<sup>18</sup> See *Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 647-48 (6th Cir. 2004) (holding that the Chief Counsel of the National Highway Traffic Safety Administration had delegated authority to issue advisory opinions to regulated entities in fulfillment of a congressional directive to promote regulatory compliance); 5 U.S.C. § 301 (“The head of an executive department ... may prescribe regulations for the government of his department, the conduct of its employees, [and] the distribution and performance of its business[.]”); Statement of Organization, Functions, and Delegations of Authority, 85 Fed. Reg. 54,581 54,583 (Sept. 2, 2020).