(Slip Opinion)

Preemption of State and Local Requirements Under a PREP Act Declaration

The Public Readiness and Emergency Preparedness Act and the COVID-19 declaration issued by the Secretary of Health and Human Services under that Act preempt state or local requirements, such as state licensing laws, that would prohibit or effectively prohibit qualifying state-licensed pharmacists from ordering and administering FDA-approved COVID-19 tests and FDA-authorized or FDA-licensed COVID-19 vaccines.

January 19, 2021

MEMORANDUM OPINION FOR THE GENERAL COUNSEL
DEPARTMENT OF HEALTH AND HUMAN SERVICES

As the international pandemic coronavirus disease 2019 ("COVID-19") reached the United States early last year, the Secretary of Health and Human Services (the "Secretary") issued an emergency declaration triggering the availability of emergency public health resources.[1] Shortly thereafter, the President declared that "the COVID-19 outbreak in the United States constitutes a national emergency." Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak, Proclamation No. 9994, 85 Fed. Reg. 15,337 (Mar. 13, 2020). That spring, the Food and Drug Administration ("FDA") authorized the use of numerous diagnostic tests for COVID-19, and health professionals have administered millions of tests since.[2] In December 2020, FDA granted two emergency use authorizations for vaccines developed to treat the disease.[3]

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[1] *See* U.S. Department of Health and Human Services ("HHS"), Determination that a Public Health Emergency Exists (Jan. 31, 2020), https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx (relying on HHS authority under 42 U.S.C. § 247d).

[2] *See* Johns Hopkins University & Medicine, *Daily State-by-State Testing Trends,* https://coronavirus.jhu.edu/testing/individual-states (last visited Jan. 19, 2021); FDA, *In Vitro Diagnostics EUAs*, https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas (last visited Jan. 19, 2021) (displaying tables that list FDA emergency use authorizations for COVID-19 diagnostic tests granted as early as March 2020).

[3] *See, e.g.*, FDA, *FDA Takes Additional Action in Fight Against COVID-19 by Issuing Emergency Use Authorization for Second COVID-19 Vaccine* (Dec. 18, 2020), https://

On March 10, 2020, the Secretary invoked his authority under the Public Readiness and Emergency Preparedness Act (the "PREP Act" or the "Act") to provide immunity to certain health care professionals tasked with responding to the crisis. 42 U.S.C. §§ 247d-6d, 247d-6e. The Act authorizes the Secretary, in response to what he determines to be a "public health emergency," to "make a declaration . . . recommending" the use of certain "covered countermeasures." *Id.* § 247d-6d(b)(1). That declaration triggers immunity from suit or liability for "covered person[s]," such as manufacturers and health care professionals, for "claims for loss" arising from administration or use of the declaration's recommended countermeasures. *Id.* § 247d-6d(a)(1), (d)(1), (i)(2).[4] The PREP Act also preempts "any provision of law or legal requirement that . . . is different from, or is in conflict with, any requirement applicable under this section" and that is "relate[d] to" those countermeasures. *Id.* § 247d-6d(b)(8).

The Secretary's declaration, as amended, identifies properly trained and certified state-licensed pharmacists who order or administer COVID-19 tests and vaccines authorized for emergency use as "covered persons." *See* Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, § V, 85 Fed. Reg. 15,198, 15,201–02 (Mar. 17, 2020) ("March Declaration"); Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration, § V(a), (d)(2), 85 Fed. Reg. 79,190, 79,195–96 & n.20 (Dec. 9, 2020) ("Fourth Amendment to the Declaration"). It designates FDA-approved COVID-19 tests and FDA-authorized or FDA-licensed COVID-19 vaccines as "covered countermeasures." *See* March Declaration § VI, 85 Fed. Reg. at 15,202; Second Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, § VI, 85 Fed. Reg. 35,100, 35,102 (June 8, 2020).

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www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid.

[4] The Act contains an exception to immunity, creating an exclusive federal cause of action for willful misconduct that results in death or serious physical injury, 42 U.S.C. § 247d-6d(d)(1), and establishes an alternative federal compensation system for targeted claims, *id.* § 247d-6e.

In May 2020, you asked for our advice about whether the PREP Act, in conjunction with the Secretary's declaration, preempts state and local requirements that would prohibit or effectively prohibit state-licensed pharmacists from ordering and administering COVID-19 tests that the FDA has authorized.[5] We advised that the PREP Act preempts such laws and regulations, and you subsequently issued an advisory opinion reaching that conclusion.[6] You have now asked us to formalize our conclusion in an opinion and, in addition, asked whether the same conclusion holds for state-licensed pharmacists who administer COVID-19 vaccines.[7] Consistent with our earlier advice, we conclude that the PREP Act preempts state and local requirements that would prohibit or effectively prohibit qualifying state-licensed pharmacists covered by a declaration from ordering or administering COVID-19 tests or vaccines.

I.

Preemption is rooted in the Constitution's Supremacy Clause, which provides that federal statutes "shall be the supreme Law of the Land." U.S. Const. art. VI, cl. 2. The Clause acts as "a rule of decision," establishing that federal law prevails over state law when the two conflict, meaning that every preemption question is a question of statutory construction. *Murphy v. Nat'l Collegiate Athletic Ass'n*, 138 S. Ct. 1461, 1479 (2018) (quotation marks omitted); *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383 (1992) ("The question, at bottom, is one of statutory intent, and we accordingly begin with the language employed by

[5] Although state-licensed pharmacists are generally "licensed health professionals" who would be qualified persons under section 247d-6d(i)(8)(A), certain state laws or regulations prohibit pharmacists from administering diagnostic tests or treatments such as vaccinations in at least some circumstances. *See, e.g.*, Fla. Stat. § 465.189 (2015) (restricting pharmacists to administration of vaccines to adults and to administration of specific listed vaccines); N.C. Gen. Stat. § 90-85.15B(a) (2019) (generally restricting pharmacists to administration of vaccines to adults pursuant to a specific prescription order).

[6] *See* HHS, *Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration Under the Act* (May 19, 2020), https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf.

[7] *See* Letter for Steven A. Engel, Assistant Attorney General, Office of Legal Counsel, from Robert P. Charrow, General Counsel, HHS (Dec. 1, 2020); E-mail for Jennifer Mascott, Deputy Assistant Attorney General, Office of Legal Counsel, from Jonah Hecht, Deputy General Counsel, HHS (Jan. 4, 2021, 4:47 PM).

Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose." (quotation marks omitted)).

The Court has recognized three categories of preemption—express, conflict, and field preemption. *See Kansas v. Garcia*, 140 S. Ct. 791, 801 (2020); *The Federalism Accountability Act*, 23 Op. O.L.C. 172, 172–73 (1999). Express preemption—the category relevant here—occurs when a federal statute explicitly states that it preempts certain state or local laws or requirements and the particular state or local law or requirement falls within those terms. *See Morales*, 504 U.S. at 383–90; *see also Coventry Health Care of Mo., Inc. v. Nevils*, 137 S. Ct. 1190, 1196–98 (2017). Where, as here, a statute "contains an express pre-emption clause," we "focus on the plain wording of the clause, which necessarily contains the best evidence of Congress'[s] pre-emptive intent." *Puerto Rico v. Franklin Cal. Tax-Free Trust*, 136 S. Ct. 1938, 1946 (2016) (quotation marks omitted). We conclude that the Act expressly preempts state and local requirements to the extent that they would effectively prohibit qualifying pharmacists from ordering and administering COVID-19 tests and vaccines authorized by the Secretary's declaration.

II.

The PREP Act's preemption provision states in full:

> During the effective period of a declaration under subsection (b), or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—
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> (A) is different from, or is in conflict with, any requirement applicable under this section; and
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> (B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any oth-

> er provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act.

42 U.S.C. § 247d-6d(b)(8).

In determining whether this section preempts state and local requirements that would effectively prohibit qualifying state-licensed pharmacists from administering COVID-19 tests and vaccines, we must consider whether such a state or local requirement "(A) is different from, or is in conflict with, any requirement applicable under" section 247d-6d, and whether the requirement "(B) relates to . . . administration by qualified persons of the covered countermeasure." *Id.* We conclude that those state or local limits on state-licensed pharmacists "relate[] to" the administration of COVID-19 diagnostic tests and vaccines, and that the requirements would "differ[] from" and "conflict with" an authorization granted to the pharmacists as "qualified persons" who may administer those countermeasures.[8]

We think the first conclusion is straightforward. State or local requirements that would effectively prohibit licensed pharmacists from ordering and administering COVID-19 tests or vaccines "relate[] to" the "administration by qualified persons of [a] covered countermeasure[]." The phrase "relates to" sweeps widely, covering anything that has "a connection with, or reference to" the particular topic. *Nevils*, 137 S. Ct. at 1197 (quotation marks omitted). Under the Act and the Secretary's declaration, state-licensed pharmacists are "qualified persons," and FDA-approved COVID-19 tests and vaccines are "covered countermeasures." *See* March Declaration § VI, 85 Fed. Reg. at 15,202; Fourth Amendment to the Declaration § V(a), (d), 85 Fed. Reg. at 79,195–96 & n.20; *see also* 42

[8] The analysis in this memorandum also applies to (1) pharmacist-supervised pharmacy technicians, (2) pharmacist-supervised state-licensed or registered pharmacy interns, and (3) National Guardsmen, whom the Secretary has identified as qualified persons to administer COVID-19 tests or vaccines, subject to certain parameters. *See* Office of the Assistant Secretary for Health ("OASH"), HHS, *Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing* at 2–5 (Oct. 20, 2020), https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf; Fourth Amendment to the Declaration § V(a), (d), 85 Fed. Reg. at 79,195–96 & nn.20–21; OASH, HHS, *Guidance for National Guard Personnel Regarding COVID-19 Vaccines and Immunity under the PREP Act* (Dec. 18, 2020), https://www.hhs.gov/about/news/2020/12/18/guidance-for-national-guard-personnel-regarding-covid-19-vaccines-immunity-under-prep-act.html.

U.S.C. § 247d-6d(i)(1), (8)(B). State or local requirements that address the ordering and administering of COVID-19 tests and vaccines unquestionably "relate[] to" administering COVID-19 tests and vaccines and thus fall within the terms of this mandatory element for PREP Act preemption. *See Northwest, Inc. v. Ginsberg*, 572 U.S. 273, 284 (2014) (finding the term "relate[] to" in a federal express preemption clause to reach all claims that have "a connection with, or reference to" the regulated object (quotation marks omitted)); *see also Rutledge v. Pharm. Care Mgmt. Ass'n*, 141 S. Ct. 474, 479 (2020) (reaching the same conclusion when interpreting the preemptive effect of the term "relate to" in the Employee Retirement Income Security Act of 1974).

The second determination presents a more difficult question. Although the Secretary's declaration affirmatively authorizes action and provides immunity for those actions to covered persons, it is less clear that the conditions within the declaration would naturally be described as "*requirement[s]* applicable under" section 247d-6d. *See* 42 U.S.C. § 247d-6d(b)(8)(A) (emphasis added). Although Congress perhaps could have chosen a better word than "requirement" in this context, we conclude that the phrase does refer to the terms and conditions of the Secretary's declaration. The requirements "applicable under" this section include not only obligations flowing directly from the PREP Act itself, such as immunity from "claims for loss," but also the terms and conditions contained within the declarations issued by the Secretary under the Act that define the metes and bounds of immunity and provide authorization to covered persons to administer the required countermeasures. Although the immunity itself would be unlikely to extend to actions to enforce state licensing requirements—because the immunity applies only to "claims for loss"—we think that state and local laws that prohibit or effectively prohibit state-licensed pharmacists from ordering or administering the tests or vaccines authorized by the PREP Act would be "in conflict with" and "differ[] from" these "requirement[s] applicable under" section 247d-6d.

In using the word "requirement" in section 247d-6d(b)(8)(A), Congress adopted language paralleling the express preemption instructions in other statutes where the phrase would more naturally apply to the terms of the federal action, which plainly impose obligations on regulated parties. *Compare, e.g.*, 7 U.S.C. § 136v(b) ("Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to

or different from those required under this subchapter."), *with id.* § 136a (prohibiting the sale of unregistered pesticides); *compare also* 21 U.S.C. § 360k(a) (preempting certain state and local "requirement[s]" that are "different from, or in addition to, any requirement applicable under this chapter"), *with id.* §§ 351–352 (specifying circumstances under which drugs and devices "shall be deemed to be" adulterated or misbranded). Although the term "any requirement," standing alone, may not be the most natural way to describe the terms and conditions within the Secretary's declaration, the statutory context makes clear that those terms reflect the "requirement[s] applicable under this [Act]." In interpreting other statutory preemption provisions that reference "requirements," the Supreme Court has construed the term to mean "a rule of law that must be obeyed." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 444–45 (2005) (using the term "rule of law" to describe "requirements" that include state common-law duties); *see also Webster's Third New International Dictionary* 1929 (2002) (defining "requirement" as, among other things, "something called for or demanded"). The declaration will not ordinarily impose an affirmative obligation on covered persons, but it is necessary that those persons meet those terms and conditions to rely upon the immunity. We think that the terms and conditions of the declaration therefore establish "requirement[s]" by setting forth the terms and conditions under which PREP Act immunity shields the actions of state-licensed pharmacists in administering covered countermeasures, which must be followed by anyone seeking to raise the immunity as a defense to liability in a civil action.

The Act authorizes the Secretary to issue a declaration that "recommend[s]" the use of countermeasures and "stat[es]" that the PREP Act's immunity "is in effect" for those measures. 42 U.S.C. § 247d-6d(b)(1). The "covered person[s]" include "qualified person[s] who prescribe[], administer[], or dispense[]" those countermeasures. *Id.* §§ 247d-6d(a)(1), 247d-6d(i)(2). The statutory category of "qualified person" in turn consists of two key groups: "licensed health professional[s]" or other individuals authorized to administer countermeasures under state law, *or* "person[s] within a category of persons so identified in a declaration by the Secretary under subsection (b)." *Id.* § 247d-6d(i)(8)(A)–(B). By including two categories of "qualified person[s]"—both those professionals who are licensed or otherwise "authorized to"

dispense countermeasures under state law, and those whom the Secretary identifies as "qualified"—the PREP Act specifically contemplates that a declaration may authorize non-licensed persons to administer countermeasures free from liability. The Secretary may identify someone as a "qualified person" for purposes of "the administration or use of a covered countermeasure" even if that person is *not already authorized* by state law to perform those tasks.

Here, the Secretary's declaration identifies as "qualified persons," among others, licensed pharmacists who order and administer FDA-approved, FDA-authorized, or FDA-licensed COVID-19 tests and vaccines. *See* Fourth Amendment to the Declaration § V(a), (d), 85 Fed. Reg. at 79,195–96 & n.20. Consequently, the Secretary's declaration extends PREP Act immunity to individuals licensed as pharmacists whether or not they have authority under relevant state law to administer such tests and vaccines. And although the PREP Act describes the Secretary's declaration as just "*recommending*" the administration or use of countermeasures, the operative effect of that declaration makes clear that its terms and conditions have a direct legal effect on those who do so. 42 U.S.C. § 247d-6d(b)(1) (emphasis added) (authorizing a declaration to state that immunity protections are "in effect" for the activities covered by the declaration).

We think that state or local requirements, such as licensing laws, that prohibit or effectively prohibit qualifying pharmacists from ordering or administering COVID-19 tests or vaccines therefore would conflict with, or at least be different from, the terms and conditions of the Secretary's authorizing designation. *See Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 154–56 (1982) (applying the conflict preemption doctrine to find that federal regulation permitting due-on-sale clauses in certain instances preempted a state law forbidding such clauses). The Secretary's designation of certain state-licensed pharmacists as "qualified persons" to order and administer COVID-19 tests and vaccines—thereby facilitating such action free from liability from claims for loss—is at the very least a requirement that is different from a state law that would stop the pharmacists from so acting. *See Bates*, 544 U.S. at 447 (concluding that state requirements that are not "equivalent to, and fully consistent with" federal requirements "differ[]" from them for express preemption purposes under the relevant statute).

Other language of the PREP Act supports this conclusion. The preemption provision applies "with respect to conduct undertaken *in accordance with*" the Secretary's declaration, suggesting that certain behavior is consistent with the declaration and that the States may not "establish, enforce, or continue in effect" requirements inconsistent with it. 42 U.S.C. § 247d-6d(b)(8) (emphasis added). Further, in issuing a PREP Act declaration, the Secretary must "consider the desirability of encouraging the . . . administration, licensing, and use of such countermeasure[s]"—expressly indicating that a declaration is to encourage the covered behavior. *Id.* § 247d-6d(b)(6). A state-law requirement that, in contrast, discourages such action by imposing prohibitive licensing requirements, or sanctions, or liability for enforcement actions is "different from" or in "conflict with" the declaration's textually indicated intended impact. *Id.* § 247d-6d(b)(8).

The statutory context further confirms this interpretation. Elsewhere in the statute, Congress evidently knew how to refer to a requirement imposed by the statute, such as immunity, rather than the terms and conditions of the Secretary's declaration, when it so desired. In section 247d-6d(d)(1), it listed willful misconduct claims as "the sole exception to the immunity from suit and liability of covered persons set forth in subsection (a)." *Id.* § 247d-6d(d)(1). Had Congress wanted to similarly tie the preemption provision solely to requirements explicitly stated in the statute, such as the provision of immunity, it could have preempted only state or local requirements that differ from or conflict with "the immunity from suit and liability of covered persons set forth in subsection (a)." The provision instead broadly preempts all state or local legal requirements that differ from the requirements applicable under section 247d-6d as a whole. *See Henson v. Santander Consumer USA Inc.*, 137 S. Ct. 1718, 1723 (2017) (noting that typically, "differences in language . . . convey differences in meaning"). The difference here suggests that the section's "requirement[s]" are broader than the immunity granted in subsection (a). *Cf. Wis. Cent. Ltd. v. United States*, 138 S. Ct. 2067, 2071–72 (2018) (finding that a reference to the more specific phrase "*money* remuneration" in one statute conveyed a distinct meaning from the reference to "*all* remuneration" in another).

This result is also consistent with the structure of the statutory scheme, because the opposite conclusion would effectively nullify the Secretary's

authority to designate qualified persons other than those already authorized under state law to administer diagnostic tests and vaccines. *See Garcia*, 140 S. Ct. at 803 (endorsing, in an express preemption analysis, one view of a statute in part because "strange consequences would ensue" under the alternative view). The Act plainly allows the Secretary to grant immunity from suit and liability to people administering countermeasures who are not already authorized under state law. We think that it would be incongruous for Congress to grant the Secretary the authority to immunize those persons from suit in connection with a public health emergency, while nonetheless permitting the States, through licensing requirements, to take the very action that the Secretary's declaration identified as necessary to respond to a public health emergency. *Cf. County of Maui v. Haw. Wildlife Fund*, 140 S. Ct. 1462, 1473 (2020) (interpreting a statute to avoid a reading that would allow a key piece of the law to be easily circumvented by others in part because it was implausible that "Congress . . . intended to create such a large and obvious loophole"); *McQuiggin v. Perkins*, 569 U.S. 383, 393–94 (2013) (noting that it would be "passing strange" to read the Antiterrorism and Effective Death Penalty Act of 1996 to require "stricter enforcement of federal procedural rules than procedural rules established and enforced by the *States*" given the statute's aim "to promote federalism and comity"). Pharmacists, who would be immune under the Secretary's declaration, could hardly order and administer COVID-19 tests or vaccines if the States could impose penalties for the same activity by revoking their licenses. Such state or local requirements would threaten to make the Secretary's authorizing identification a practical nullity.

We therefore conclude that the Secretary's decision to identify licensed pharmacists as "qualified persons" allowed to order and administer FDA-approved COVID-19 tests and FDA-authorized or FDA-licensed vaccines constitutes a requirement with preemptive effect under the terms of section 247d-6d.

III.

We have considered two potential objections to this conclusion. Neither overcomes the meaning evident from the preemption provision's text and the structure and context of the Act.

A.

First, it might be argued that the Secretary's declaration does not itself establish a "requirement," because the declaration elements are not "requirement[s]" listed in the statute itself. And the Act specifically describes a Secretary's declaration as "recommending" measures—in contrast to requiring them. *Compare* 42 U.S.C. § 247d-6d(b)(1), *with id.* § 247d-6d(a)(1) ("a covered person *shall be* immune from suit and liability" (emphasis added)); *see also id.* § 247d-6d(b)(1) (describing the "activities so recommended" in a declaration); *id.* § 247d-6d(b)(2)(A) (specifying how the Secretary is to specify the categories of threats to health for which he "*recommends* the administration or use of [a] countermeasure" (emphasis added)).

But the statutory phrase here, "requirement[s] applicable under this section," is not limited to rules established by statutes. *Cf. Riegel v. Medtronic, Inc.*, 552 U.S. 312, 319, 322–23 (2008) (finding that the "requirements" included in an express preemption provision included pre-market approval for drugs authorized by federal regulation); *Bates*, 544 U.S. at 443 (concluding that "requirements" reaches "to embrace common-law duties"); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 497–98 (1996) (recognizing that federal labeling regulations are federal "requirement[s]" under the terms of an express preemption provision); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992) ("The phrase '[n]o requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law[.]"). Moreover, the Secretary's declaration was naturally promulgated "under" the PREP Act, as the Act authorized its issuance. *See, e.g.*, *Nat'l Ass'n of Mfrs. v. Dep't of Def.*, 138 S. Ct. 617, 630 (2018) (interpreting "limitation under" to mean "pursuant to" or "by reason of the authority of" (quotation marks omitted)); *In re Hechinger Inv. Co. of Del.*, 335 F.3d 243, 252 (3d Cir. 2003) (Alito, J.) ("When an action is said to be taken 'under' a provision of law . . . , what is generally meant is that the action is 'authorized' by the provision of law[.]"). The terms within the Secretary's declaration also plainly have a direct legal effect on regulated parties. *See, e.g.*, 42 U.S.C. § 247d-6d(b)(8) (relating the time period "[d]uring" which the Act's preemptive effect is operative to the "effective period of a declaration").

Moreover, the text of the Act describes a PREP Act declaration as containing both "directions" or certain derivative "requirements"; they are not just "recommend[ations]." For example, section 247d-6d(c)(4) establishes a defense for "qualified person[s]" who have "acted consistent with applicable directions, guidelines, or recommendations" by the Secretary related to authorized countermeasures. And the statute defines "program planner[s]" eligible for immunity to include persons "who ha[ve] established requirements . . . in accordance with a declaration." *Id.* § 247d-6d(i)(6). The statutory scheme thus supports the conclusion that the remaining terms and conditions of the declaration themselves have mandatory operative effect for purpose of the PREP Act's preemption provision.

That inference is reinforced by the description of those state laws that the PREP Act preempts, which the statute specifies to include "any provision of law *or legal requirement*."[9] *Id.* § 247d-6d(b)(8) (emphasis added). The fact that Congress here distinguished a "provision of law" from a "legal requirement" suggests that Congress intended the latter term to include even action by a state that falls short of itself having the force of law independent from its authorization in a statute. The term "requirement" that appears in the very next clause, section 247d-6d(b)(8)(A)—and without the narrowing qualifier legal "requirement"—presumptively should be afforded at least the same reach. *See Powerex Corp. v. Reliant Energy Servs., Inc.*, 551 U.S. 224, 232 (2007) ("A standard principle of statutory construction provides that identical words and phrases within the same statute should normally be given the same meaning."). And that identity, in turn, suggests that the term includes administrative or other non-statutory mandates that establish terms and conditions even beyond those set forth in the PREP Act itself, like the Secretary's declaration.

B.

Second, one might argue that our reading of the statute gives the Secretary authority to preempt an unduly great extent of state and local laws in

[9] The only judicial decision of which we are aware to squarely address PREP Act preemption of a state tort-law claim also notes that the Act's broad preemption provision applies to state common-law claims as well as regulations. *See Parker v. St. Lawrence County Pub. Health Dep't*, 102 A.D.3d 140, 143–44 (N.Y. App. Div. 2012) (applying the Act's "sweeping" immunity protection to a common-law tort claim challenging the administration of a vaccine without parental consent).

response to a public health emergency. But our interpretation must be guided by the breadth of the statute itself. *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2380 (2020) (giving force to broad statutory language while noting that "Congress could have limited . . . discretion in any number of ways" in the Act "but it chose not to do so"). And it is routine, and in keeping with numerous provisions in the federal code, for Congress to confer broad statutory authority to respond to emergencies. *See, e.g.*, Defense Production Act of 1950, 50 U.S.C. § 4501 *et seq.*; Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. §§ 5121–5207; Memorandum for the Attorney General from Karl R. Thompson, Principal Deputy Assistant Attorney General, Office of Legal Counsel, *Re: Summary of Legal Authorities for Use in Response to an Outbreak of Ebola in the United States* at 1 (Oct. 16, 2014) (noting the "substantial authorities" that the Executive Branch has to respond to the outbreak of disease in the United States).

In any event, the scope of declarations with preemptive effect under the Act must be tailored to the scope of critical needs during a public health emergency. The PREP Act requires that the Secretary first make a threshold determination that a "public health emergency" exists, and that he then specify the time period, covered populations, and geographic areas within which the declaration will apply, consider the desirability of countermeasures, and submit a report to congressional committees explaining his determinations within 30 days. *See* 42 U.S.C. § 247d-6d(b)(1), (2), (6), (9). The Secretary's declaration thus must satisfy these requirements in order to provide for the covered immunity and to preempt conflicting state and local requirements. *See id.* § 247d-6d(b)(1) (authorizing a Secretary to make declarations "[s]ubject to" the requirement that the Secretary identify the relevant health threats or diseases and the population, geographic regions, and time periods for which the declaration is in effect). The preemptive effect of a PREP Act declaration must thus be directly tailored to the public health emergency that it seeks to address, and it is consistent with the congressional power to equip the Executive Branch to respond to national emergencies. *Cf. Regan v. Wald*, 468 U.S. 222, 227–28 (1984) (discussing additional federal statutes authorizing the use of emergency authority, only subject to certain conditions); *Dames & Moore v. Regan*, 453 U.S. 654, 662–63 & n.1, 672 (1981) (describing

congressional authorization of increased executive authority to respond to national security, foreign policy, and economic threats during a national emergency). In view of the magnitude of the COVID-19 pandemic here, we think it evident under the statute that the Secretary had the authority to act quickly to expand the number of covered persons who may administer necessary countermeasures to deal with that crisis, and Congress specified that state or local health officials lack authority to take measures that would conflict with such an action.

IV.

For these reasons, we conclude that the PREP Act and the Secretary's declaration preempt state or local requirements, such as state licensing laws, that would prohibit or effectively prohibit qualifying state-licensed pharmacists from ordering and administering FDA-approved COVID-19 tests and FDA-authorized or FDA-licensed COVID-19 vaccines.

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