



April 16, 2020

Neil Romano
Chairman
National Council on Disability
1331 F Street, N.W.
Suite 850
Washington, D.C. 20004

Dear Mr. Romano:

Thank you for your letter of March 31, 2020, to Secretary Azar concerning the March 28 "Bulletin: Civil Rights, HIPAA, and the Coronavirus Disease 2019 (COVID-19)," issued by the Department's Office for Civil Rights ("OCR"). I am responding on behalf of the Department.

You expressed concern that reference in the Bulletin to "PREP Act" immunity could be confusing. We apologize for any confusion, but the law in this area is difficult to explain in a short Bulletin, and the Bulletin would have been potentially misleading if reference to the PREP Act were not included. Given that dynamic, OCR properly directed all legal questions, as it must, to the Office of the General Counsel ("OGC").

The Public Readiness and Emergency Preparedness Act ("PREP Act"), Pub. L. No. 109-148, Public Health Service Act § 319F-3, 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e, authorizes the Secretary of Health and Human Services ("Secretary") to issue a Declaration to provide liability immunity from private and State rights of action to certain individuals and entities ("Covered Persons") against any claim of loss caused by, arising out of, relating to, or resulting from, the manufacture, distribution, administration, or use of medical countermeasures ("Covered Countermeasures").

The PREP Act provides that a "[C]overed [P]erson shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure." *Id.* at § 247d-6d(a)(1). The PREP Act also expressly preempts State and local laws that "establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that . . . is different from, or is in conflict with, any requirement applicable under this section[.]" *Id.* at § 247d-6d(b)(8).

On March 10, 2020, the Secretary issued the declaration under subsection (b) providing liability immunity for Covered Persons with respect to the administration or use of Covered Countermeasures that are any

Neil Romano
April 16, 2020
Page 2

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, and all components and constituent materials of any such product.

85 Fed. Reg. 15,198, 15,202 (March 17, 2020).

A couple of significant caveats about the PREP Act that are often overlooked. First, the PREP Act does not immunize anyone from federal enforcement action, whether under the civil rights laws or otherwise. Thus, OCR has full authority, notwithstanding the PREP Act, to undertake its normal activities and take enforcement action in consultation with OGC. Second, the PREP Act replaces rights of action in court regarding claims for loss with a no-fault compensation system outlined at 42 C.F.R. pt. 110 for certain injuries. In addition, anyone whose civil rights have been violated may bring an action in federal court for injunctive relief, as may authorized by the pertinent federal civil rights statute. The PREP Act neither bars such an action nor provides immunity to the putative defendant.

As noted in the Bulletin, OGC is happy to respond to legal questions about the scope of the PREP Act and other pertinent laws. You may find OGC's recently issued general Advisory Opinion on the scope of the PREP Act helpful. See <https://www.hhs.gov/sites/default/files/prep-act-advisory-opinion-april-14-2020.pdf> (April 14, 2020).

Sincerely yours,

Robert P. Charrow

Robert Charrow
General Counsel