KEN PAXTON
ATTORNEY GENERAL OF TEXAS

August 11, 2021

The Honorable James White
Chair, House Committee on Homeland Security & Public Safety
Texas House of Representatives
Post Office Box 2910
Austin, Texas 78768-2910

Opinion No. KP-0379

Re: Whether access to a government facility can be conditioned upon obtaining a vaccine issued under emergency usage authorization (RQ-0402-KP)

Dear Representative White:

You ask whether a "government jurisdiction" may "legally condition access to a government facility on a vaccine issued under Emergency Usage Authorization" in light of the Governor's executive orders.[1] You ask your question amidst the ongoing COVID-19 pandemic and the rapid development of vaccines in an attempt to reduce the spread of the disease.

I. The Food and Drug Administration has issued emergency use authorization for COVID-19 vaccines in the United States but has not yet granted full approval for any COVID-19 vaccine.

Congress established a comprehensive regulatory framework, administered by the U.S. Food and Drug Administration ("FDA"), to control the development and distribution of vaccines to ensure their safety, effectiveness, and quality for use in the United States. *See generally* 21 U.S.C. §§ 301–399i. A vaccine manufacturer must satisfy a number of steps before obtaining FDA approval for use, including clinical trials conducted on human populations.[2] Human population testing involves three stages, with each phase increasing the number of individuals given the vaccine, and testing first for safety, then dosage, and then efficacy in preventing the disease. When the manufacturer completes the clinical trials, the vaccine maker develops a

[1] *See* Letter from Honorable James White, Chair, House Comm. on Homeland Sec. & Pub. Safety, to Honorable Ken Paxton, Tex. Att'y Gen. at 1 (Apr. 1, 2021), https://www2.texasattorneygeneral.gov/opinions/opinions/51paxton/rq/2021/pdf/RQ0402KP.pdf ("Request Letter").

[2] *See* U.S. FOOD & DRUG ADMIN., VACCINE DEVELOPMENT – 101 (2020), https://www fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101.

manufacturing process to ensure the vaccine is produced reliably. Only then does the manufacturer seek FDA approval to distribute and market the vaccine in the United States.

In instances of a public health emergency, federal law authorizes the Secretary of the Department of Health and Human Services ("Secretary") to declare an emergency that justifies emergency use of a product, including a vaccine. 21 U.S.C. § 360bbb-3(b)(1)(C). To authorize the emergency use of a specific product, the Secretary must conclude, "based on the totality of scientific evidence available . . . , including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe" that: (1) "the product may be effective in diagnosing, treating, or preventing [a] disease or condition"; (2) "the known and potential benefits of the product . . . outweigh the known and potential risks of the product"; and (3) "there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition." *Id*. § 360bbb-3(c)(2)–(3). By granting emergency use authorization to vaccine manufacturers, the FDA authorizes unapproved medical products to be used in an emergency to diagnose, treat, or prevent, serious or life-threatening diseases.[3] Individuals to whom the product is administered must be informed that they have "the option to accept or refuse administration of the product." *Id*. § 360bbb-3(e)(1)(A)(ii)(III).[4] While vaccine manufacturers receiving emergency use authorization have conducted extensive clinical trials to investigate the safety and efficacy of their vaccines, those trials are expedited, and the data on which the FDA grants emergency use authorization is less than that required for full FDA approval.[5]

Pursuant to this emergency authority, on February 4, 2020, the Secretary determined that a public health emergency existed due to COVID-19. Determination of Public Health Emergency, 85 Fed. Reg. 7316, 7316–17 (Feb. 7, 2020). Based on that determination, the Secretary, on March 27, 2020, declared that circumstances existed justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic. Emergency Use Authorization Declaration, 85 Fed. Reg. 18250, 18250–51 (Apr. 1, 2020). The FDA issued emergency use authorization for the Pfizer-BioNTech COVID-19 vaccine on December 11, 2020, the Moderna COVID-19 vaccine on December 18, 2020, and the Johnson & Johnson/Janssen vaccine on

[3]*See* U.S. FOOD & DRUG ADMIN., EMERGENCY USE AUTHORIZATION FOR VACCINES EXPLAINED (2020), https://www fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained.

[4]Recent federal guidance has advised that "the option to accept or refuse" a product granted emergency use authorization does not prohibit entities from imposing vaccination requirements while the only available vaccines for COVID-19 remain subject to emergency use authorization. U.S. Dep't of Justice, Memorandum Opinion for the Deputy Counsel to the President, *Whether Section 564 of the Food, Drug, and Cosmetic Act Prohibits Entities from Requiring the Use of a Vaccine Subject to an Emergency Use Authorization* (July 6, 2021), https://www.justice.gov/olc/file/1415446/download.

[5]A vaccine manufacturer may submit a request for emergency use authorization based on an interim analysis of phase 3 clinical trials, "i.e., an analysis performed before the planned end of the trial once the data have met the pre-specified success criteria for the study's primary efficacy endpoint." U.S. FOOD & DRUG ADMIN., EMERGENCY USE AUTHORIZATION FOR VACCINES EXPLAINED (2020), https://www fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained.

February 27, 2021.[6] Although two manufacturers have requested full approval of a COVID-19 vaccine, the FDA has not, to date, granted full approval for any COVID-19 vaccine for use in the United States.[7]

II. Executive Order GA-38 prohibits state agencies and political subdivisions from conditioning an individual's access to a government facility on receipt of a vaccine issued under emergency use authorization.

The Governor declared a state of disaster in Texas due to COVID-19 on March 13, 2020, and that declaration is ongoing.[8] Office of the Governor, Proclamation 41-3730, 45 Tex. Reg. 2094 (2020). The Legislature authorized the Governor, upon declaring a disaster, "to issue executive orders, proclamations, and regulations and amend or rescind them." TEX. GOV'T CODE § 418.012. The Governor's executive orders issued pursuant to his emergency powers under chapter 418 of the Government Code "have the force and effect of law." *Id*. Pursuant to that authority, the Governor has issued multiple executive orders, proclamations, and other statements, relating to the COVID-19 disaster declaration.

Relevant to your question, the Governor has issued orders in response to concerns that governmental bodies might compel disclosure of an individual's COVID-19 vaccination status by mandating a so-called "vaccine passport" or otherwise condition receipt of services on an individual's COVID-19 vaccination status.[9] Most recently, on July 29, 2021, Governor Abbott issued Executive Order GA-38.[10] That order expressly prohibits state agencies and political

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[6]*See* Letter from FDA to Pfizer Inc. (May 10, 2021), https://www.fda.gov/media/144412/download; Letter from FDA to ModernaTX, Inc. (Feb. 25, 2021), https://www fda.gov/media/144636/download; Letter from FDA to Janssen Biotech, Inc. (Feb. 27, 2021), https://www.fda.gov/media/146303/download.

[7]On May 7, 2021, Pfizer began the process of filing a biologics license application for approval of its COVID-19 vaccine. *See* https://investors.pfizer.com/investor-news/press-release-details/2021/Pfizer-and-BioNTech-Initiate-Rolling-Submission-of-Biologics-License-Application-for-U.S.-FDA-Approval-of-Their-COVID-19-Vaccine/default.aspx. On June 1, 2021, Moderna did the same. *See* https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-initiation-rolling-submission-biologics.

[8]*See* GOVERNOR OF THE STATE OF TEXAS, DISASTER PROCLAMATION (Mar. 13, 2020), https://gov.texas.gov/uploads/files/press/DISASTER_covid19_disaster_proclamation_IMAGE_03-13-2020.pdf. The Governor renewed the disaster declaration most recently on July 30, 2021. *See* GOVERNOR OF THE STATE OF TEXAS, DISASTER PROCLAMATION (July 30, 2021), https://gov.texas.gov/news/post/governor-abbott-renews-covid-19-disaster-declaration-for-august-2021.

[9]On April 5, 2021, Governor Abbott issued Executive Order GA-35, prohibiting state agencies and political subdivisions from conditioning access to a government facility on receipt of a vaccine issued under emergency usage authorization. Office of the Governor, Executive Order GA-35, 46 Tex. Reg. 2515 (2021). *See* GOVERNOR OF THE STATE OF TEXAS, EXECUTIVE ORDER 35 (Apr. 5, 2021), https://gov.texas.gov/uploads/files/press/EO-GA-35_private_health_information_protection_vaccines.pdf.

[10]*See* GOVERNOR OF THE STATE OF TEXAS, EXECUTIVE ORDER 38 (July 29, 2021), https://gov.texas.gov/uploads/files/press/EO-GA-38_continued_response_to_the_COVID-19_disaster_IMAGE_07-29-2021.pdf. Executive Order GA-38 superseded most pre-existing COVID-19-related executive orders, including Executive Order GA-35, about which you specifically ask. But the prohibitions on vaccine passports in Executive Order GA-38 are analogous to those in GA-35 and we address your question accordingly.

subdivisions from conditioning access to a government facility on receipt of a vaccine issued under emergency usage authorization:

> State agencies and political subdivisions shall not adopt or enforce any order, ordinance, policy, regulation, rule, or similar measure that requires an individual to provide, as a condition of receiving any service or entering any place, documentation regarding the individual's vaccination status for any COVID-19 vaccine administered under an emergency use authorization.

Office of the Governor, Executive Order GA-38 (2021). Thus, under the Governor's order, a state agency or political subdivision is prohibited from conditioning an individual's access to a government facility on receipt of a vaccine issued under emergency usage authorization.

You also ask whether a local government may enforce a policy conditioning access to a governmental facility on an individual's receipt of a vaccine in light of the Governor's executive orders. Request Letter at 1. Because executive orders have the force and effect of law, they supersede inconsistent orders made on a local level. *State v. El Paso Cnty.*, 618 S.W.3d 812, 821–22 (Tex. App.—El Paso 2020, no pet.). Executive Order GA-38 expressly provides that a political subdivision may not *enforce* "any order, ordinance, policy, regulation, rule or similar measure" requiring individuals to provide documentation regarding vaccination status for any COVID-19 vaccine administered under an emergency use authorization, and any attempt to do so would be in violation of state law. Office of the Governor, Executive Order GA-38 (2021).

III. Senate Bill 968 restricts businesses from requiring customers to provide proof of vaccination to enter, gain access to, or receive services from the business.

Although you ask specifically about the Governor's executive orders, also pertinent to your question is Senate Bill 968, passed by the Eighty-seventh Legislature. Senate Bill 968 added section 161.0085 to the Health and Safety Code to restrict governmental entities from issuing, and businesses from requiring the use of, COVID-19 vaccine passports in most circumstances, providing in relevant part:

> (b) A governmental entity in this state may not issue a vaccine passport, vaccine pass, or other standardized documentation to certify an individual's COVID-19 vaccination status to a third party for a purpose other than health care or otherwise publish or share any individual's COVID-19 immunization record or similar health information for a purpose other than health care.
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> (c) A business in this state may not require a customer to provide any documentation certifying the customer's COVID-19 vaccination or post-transmission recovery on entry to, to gain access to, or to receive service from the business. A business that fails to comply with this subsection is not eligible to receive a grant or enter into a contract payable with state funds.

TEX. HEALTH & SAFETY CODE § 161.0085(b)–(c).[11] Thus, pursuant to Senate Bill 968, a governmental entity in Texas may not issue a COVID-19 vaccine passport or any other documentation certifying COVID-19 vaccination status for any purpose other than health care. Implicit in this prohibition is that a governmental entity may not issue a COVID-19 vaccine passport and condition entry to a governmental facility on possession of it. This prohibition is not limited to vaccines issued under emergency use authorization and therefore will also apply to COVID-19 vaccines with full FDA approval.

[11]Senate Bill 968 took effect on May 30, 2021. *See* Tex. S.B. 968, § 23, 87th Leg., R.S. (2021) ("This Act takes effect immediately if it receives a vote of two-thirds of all the members elected to each house, as provided by Section 39, Article III, Texas Constitution."); TEX. CONST. art. III, § 39 ("No law passed by the Legislature, except the general appropriations act, shall take effect or go into force until ninety days after the adjournment of the session at which it was enacted, unless the Legislature shall, by a vote of two-thirds of all the members elected to each House, otherwise direct; said vote to be taken by yeas and nays, and entered upon the journals."). The Senate passed S.B. 968 on April 21, 2021 with a vote of "Yeas 31; Nays 0." S.J. of Tex., 87th Leg., R.S. 891 (2021). The House passed S.B. 968 on May 26, 2021 with a vote of "146 Yeas, 2 Nays, 1 Present, not voting." H.J. of Tex., 87th Leg., R.S. 4112 (2021). The Senate concurred in the House amendments to S.B. 968 on May 30, 2021, by a vote of "28 Yeas, 3 Nays." *Id*. at 5471. Because S.B. 968 was passed by two-thirds of all the members of each house, it became effective immediately upon passage.

S U M M A R Y

Pursuant to Executive Order GA-38, Texas state agencies and political subdivisions may not condition an individual's access to a government facility on receipt of a vaccine administered under emergency use authorization and not yet approved by the Food and Drug Administration.

Furthermore, pursuant to Senate Bill 968, passed by the Eighty-seventh Legislature, a governmental entity in Texas may not issue a COVID-19 vaccine passport or any other documentation certifying COVID-19 vaccination status for any purpose other than health care. Implicit in this prohibition is that a governmental entity may not issue a COVID-19 vaccine passport and condition entry to a governmental facility on possession of it. This prohibition is not limited to vaccines issued under emergency use authorization and therefore will also apply to COVID-19 vaccines with full FDA approval.

Very truly yours,

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