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MEMORANDUM

TO: Rebecca Curtiss, IDPH Bureau Chief

FROM: Heather Adams, Assistant Attorney General

DATE: December 14, 2020, updated March 15, 2021

RE: Public Readiness and Emergency Preparedness (PREP) Act and
Emergency Use Authorizations (EAUs) for COVID-19 Vaccine

You have asked me to outline the relevant provisions of the PREP Act and recent EUAs as they relate to providing legal immunity to persons who distribute and administer COVID-19 vaccine, as well as to address other laws which may provide legal immunity to those involved in the provision of COVID-19 vaccine.

PREP ACT

The Public Readiness and Emergency Preparedness Act or PREP Act is a federal law which authorizes the Secretary of Health and Human Services (HHS) to provide tort liability immunity to individuals and organizations involved in the development, manufacture, distribution, administration and use of “covered countermeasures” against pandemics, epidemics and diseases and health threats. The purpose for issuing a PREP Act declaration is to provide immunity from tort liability; a PREP Act declaration is different and independent from other emergency or disaster declarations.

On February 4, 2020, HHS through declaration invoked PREP Act immunity for covered persons who manufacture, distribute, and administer medical covered countermeasures against COVID-19, including covered vaccines. The immunities provided by the PREP Act are sweeping and broad and cover a range of legal

claims.¹ See Division C of P.L. 109-148 (2005), 42 USCA 247d; HHS “Advisory Opinion” dated April 14, 2020. The February 4th declaration has been amended seven times to further broaden the scope of the PREP Act immunities, including a December 3, 2020, amendment which further clarifies and expands the scope of PREP Act immunity, and a March 12, 2021, amendment which broadens the pool of health care providers who can administer vaccines to include providers who may not typically administer vaccines in their scope of practice or who have recently expired licenses, and students of certain professions.

Taken together, the PREP Act declaration and amendments grant broad immunity protections to all “covered persons” in the COVID-19 vaccine distribution chain - from those who manufacture the vaccine to the person who administers the vaccine, including:

Qualified Persons. The declaration and amendments provide tort liability immunity to “qualified persons,” including healthcare professionals or others authorized under state law or the PREP Act to prescribe, administer, and dispense COVID-19 vaccine either approved by the FDA or authorized under an Emergency Use Authorization (EUA) as part of the emergency response.

Under Iowa law, the following licensed/certified healthcare professionals are authorized to administer vaccines and hence would be considered “qualified persons” under the declaration: physicians; nurses, including LPNs, RNs, and ARNPs; physician assistants; paramedics; AEMTs; and pharmacists (authorized to administer vaccine via prescription order or to adults via written protocol).

The PREP Act and its amendments have expanded the definition of qualified persons to include the following additional providers:

-Pharmacists, pharmacy interns, and pharmacy technicians;

¹ The declaration prevents tort liability claims under federal and state law, excluding willful misconduct, for losses caused by or relating to administration or use of the COVID-19 vaccine, including any claim with a causal relationship to any stage of development, distribution, dispensing, prescribing, administration or use of the vaccine. In addition, by defining “administration” broadly the declaration clarifies that the immunity covers claims related to the management and operation of a vaccine program or site, such as “slip and fall” types of claims, and not just injuries and illnesses arising from actually receiving the vaccine.

- Respiratory therapists; dentists; podiatrists; optometrists; and veterinarians;*

- Inactive licensees: physicians, ARNPs, RNs, LPNs, pharmacists, pharmacy interns, midwives, paramedics, AEMTs, respiratory therapists, dentists, PAs, podiatrists, optometrists, and veterinarians who have held an active license or certification under the law of any State within the last five years which is inactive, expired or lapsed, so long as the license or certification was active and in good standing;*

- Students: medical, nursing, pharmacy, pharmacy intern, midwife, paramedic, AEMT, physician assistant, respiratory therapy, dental, podiatry, optometry or veterinary students with appropriate training in administering vaccines as determined by their school or training program and supervision by a currently practicing healthcare professional experienced in administering intramuscular injections;*

*provided such health care providers and students: (1) document completion of the CDC COVID-19 Vaccine Training Modules [[see https://www2.cdc.gov/vaccines/ed/covid19/index.asp](https://www2.cdc.gov/vaccines/ed/covid19/index.asp)] and, if applicable, such additional training as may be required by their state licensing board or jurisdiction in which they are administering vaccinations; (2) document an observation period by a currently practicing healthcare professional experienced in administering intramuscular injections, and for whom administering intramuscular injections is in their ordinary scope of practice, who confirms competency of the healthcare provider or student in preparation and administration of the COVID-19 vaccines; and (3) have a current certificate in basic cardiopulmonary resuscitation.

Healthcare providers and students must comply with applicable provisions of the PREP Act and the CDC COVID–19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID– 19 vaccines. *See* “Expanding the COVID-19 Vaccination Workforce”, www.phe.gov, for a current summary of providers qualified to administer COVID-19 vaccine and accompanying requirements.

The declaration also provides tort liability immunity to individuals and organizations that assist public officials with vaccination programs. Qualified persons also include individuals or organizations (including their officials,

agents, employees, contractors and volunteers) that are part of the Iowa Department of Public Health’s emergency response through prescribing, administering, delivering, distributing, or dispensing COVID-19 vaccine. These qualified persons can include any public or private person, entity, or organization – such as local businesses, community groups and volunteer groups -- and their officials, agents, employees, contractors and volunteers, assisting in carrying out COVID-19 vaccinations under agreements, plans, protocols, procedures, policies or other arrangements with any State or county public health agency.

Program Planners. The Act protects “program planners” – a group which expressly includes state and local government officials that supervise or administer a program with respect to the administration, dispensing, distribution, provision, or use of COVID-19 vaccine; or provide policy guidance, supply technical or medical advice. This definition extends PREP Act immunity coverage to the State Medical Director and county board of health physicians who issue standing orders to authorize the administration of the COVID-19 vaccine.

Others. The declaration also provides tort liability immunity to the United States, to vaccine manufacturers, and vaccine distributors. Officials, agents, and employees of program planners, qualified persons, the United States, manufacturers, and distributors are also immune from tort liability.

Countermeasures Injury Compensation Program (CICP). The Act authorizes the CICP to provide benefits to persons who sustain a covered injury as a direct result of COVID-19 vaccine administration. The CICP is administered by DHHS, and information about the program is available at <http://www.hrsa.gov/cicp/>

EMERGENCY USE AUTHORIZATIONS

The FDA may grant an EUA pursuant to a separate declaration under Section 564 of the Federal Food, Drug and Cosmetic Act. The FDA utilizes EUAs solely during times of declared emergency to authorize unapproved medical products to assist patients if there are no adequate, FDA-approved alternatives available. The FDA has issued dozens of EUAs throughout the COVID-19 pandemic, including EUAs related to testing, medical devices such as ventilators, and other medical equipment. A comprehensive listing of COVID-related EUAs can be found at

<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

On December 11, 2020, the FDA issued an EUA to permit the emergency use of the Pfizer-BioNTech COVID-19 Vaccine for individuals 16 years of age and older. On December 18, 2020, the FDA issued an EUA to permit the emergency use of Moderna COVID-19 Vaccine for use in individuals 18 and older. On February 27, 2021, the FDA issued an EUA to permit the emergency use of Janssen COVID-19 Vaccine for use in individuals 18 and older. The EUA's dictate a number of terms and conditions for vaccine administration, including that providers who administer the vaccine shall do so in accordance with the EUA; comply with the terms and training required by CDC's COVID-19 Vaccination Program; provide the Fact Sheet for Recipients and Caregivers to each individual receiving vaccination; report administration errors and serious adverse events; and monitor and comply with vaccine management and administration requirements. Additional EUA's for COVID-19 vaccine are expected to be issued in the coming months.

OTHER IMMUNITY LAWS

Because there is some question about the extent to which the PREP Act covers the refusal or failure to administer COVID-19 vaccine, or more generally the medical care provided by health care providers and facilities to COVID-19 patients, other immunity laws may play an important role in providing legal protections to those involved with the provision of medical care during this pandemic.² Specifically, persons and entities involved with the distribution or administration of COVID-19 vaccine may - in addition to the federal protections discussed above - also be protected by state laws which may extend immunities to their actions, including but not limited to the following:

² For example, some courts have held that the PREP Act does not cover health care received more generally by patients in health care facilities. See *Estate of Maglioli v. Andover SubAcute Rehab Center I*, WL 4671091 (D.N.J. August 12, 2020); *Lutz v. Big Blue Healthcare*, WL 4815100 (D. Kan. Aug. 19, 2020). In addition, courts have held that the PREP Act does not cover a decision *not* to administer a vaccine. See *Casabianca v. Mt. Sinai Medical Center*, WL 10413521 (N.Y. Sup. Dec. 12, 2014). I note, however, that the recent fourth amendment to the Act declaration on December 3, 2020, attempts to address this issue by extending liability protection to certain decisions not to provide a vaccine if made in connection with public health prioritization guidance. See Fourth Amendment, Section IX.

Iowa Code § 135.147 - Immunity for Persons, Businesses, and Others Providing Disaster Aid. “A person, corporation, or other legal entity, or an employee or agent of such person, corporation, or entity, who, during a public health disaster, in good faith and at the request of or under the direction of the department or the department of public defense renders emergency care or assistance to a victim of a public health disaster shall not be liable for civil damages for causing the death of or injury to a person, or for damage to property, unless such acts or omissions constitute recklessness.”

Note: IDPH has issued a number of Orders and guidance documents during the COVID-19 public health disaster which extend this immunity to persons or other legal entities which comply with such Order or guidance, including a Hospital Mandatory Reporting Order issued April 3, 2020, as amended July 27, 2020; PPE Shortage Order issued April 9, 2020, and modified on April 25, 2020; Statewide Standing Order for COVID-19 Testing issued May 12, 2020; Distribution Order for Remdesivir issued May 11, 2020; and a Statewide Standing Order for COVID-19 Vaccination issued December 14, 2020.

Iowa Code § 139A.8A - Immunity for Compliance with a Vaccine Shortage Order. “A health care provider, hospital, clinic, pharmacy, health care facility, local board of health, public health agency, or other person or entity that distributes or administers vaccines shall not be civilly liable in any action based on a failure or refusal to distribute or administer a vaccine to any person if the failure or refusal to distribute or administer the vaccine was consistent with a department order issued pursuant to” chapter 139A.

Note: IDPH issued a Vaccine Shortage Order on December 14, 2020, which has been modified as supply increases.

SF 2338 - COVID-19 Response and Back to Business Limited Liability Act. This recently passed law limits the liability of individuals, premises owners, health care providers, and persons involved with certain types of products in civil actions related to COVID-19 exposure, including the following relevant provisions:

Civil actions alleging exposure to COVID-19 when the accused has been following applicable federal or state law related to COVID-19. “A person in this state shall not be held liable for civil damages for any injuries sustained from exposure to COVID-19 if the act or omission alleged to

violate a duty of care was in substantial compliance or was consistent with any federal or state statute, regulation, order, or public health guidance related to COVID-19 that was applicable to the person or activity at issue at the time of the alleged exposure or potential exposure.” (Iowa Code § 686D.5).

Civil actions alleging death or injury as a result of a health care provider’s acts or omissions while providing or arranging health care in support of the state’s response to COVID-19. So long as a health care provider’s acts or omissions do not constitute reckless or willful misconduct, a provider “shall not be held liable for civil damages for causing or contributing, directly or indirectly, to the death or injury of an individual as a result of the health care provider’s acts or omissions while providing or arranging health care in support of the state’s response to COVID-19.” (Iowa Code § 686D.6). The Act provides detailed descriptions of the acts or omissions for which liability has been limited.

Civil actions alleging personal injury, death, or property damage caused by or resulting from the design, manufacturing, labeling, selling, distributing, or donating of household disinfecting or cleaning supplies, PPE, or other specified products. “Any person that designs, manufactures, labels, sells, distributes, or donates household disinfecting or cleaning supplies, personal protective equipment, or a qualified product in response to COVID-19 shall not be liable in a civil action alleging personal injury, death, or property damage caused by or resulting from the design, manufacturing, labeling, selling, distributing, or donating of household disinfecting or cleaning supplies, personal protective equipment, or a qualified product.” (Iowa Code § 686D.7(1)). Similarly, such a person shall not be liable for a failure to provide proper instructions or sufficient warnings with the product. (Iowa Code § 686D.7(2)). However, liability is not limited when such a person has recklessly disregarded a substantial and unnecessary risk that the product would cause serious personal injury, death, or serious property damage, or when such a person has acted with actual malice. (Iowa Code § 686D.7(3)).

The Act applies retroactively to January 1, 2020, meaning that liability is limited for any events relating to the above described circumstances that occurred on or after January 1, 2020. For events that occurred prior to that date, the usual liability rules and standards apply.

Please note that this memorandum is not a formal opinion of the Attorney General.