John Bel Edwards
GOVERNOR

Dr. Courtney N. Phillips
SECRETARY

State of Louisiana

Louisiana Department of Health
Office of Public Health

EMERGENCY ORDER

PROTOCOL FOR ADMINISTRATION OF CERTAIN COVID-19 VACCINES

FROM: Joseph Kanter, MD, MPH, State Health Officer

SUBJECT: EMERGENCY ORDER

PURPOSE/APPLICABILITY: To authorize certain medical professionals to administer the Pfizer and Moderna COVID-19 vaccines by protocol in lieu of a patient-specific order from a physician or prescribing practitioner.

POLICY STATEMENT: The protocol authorized herein is intended to ensure the safety, efficacy, and increased provision of COVID-19 immunizations to meet the needs of the public welfare.

EFFECTIVE DATES: This Emergency Order will be initially effective only until May 1, 2021, but may be further extended by subsequent order of the State Health Officer. However, termination of the Public Health Emergency concerning COVID-19 originally declared by Governor John Bel Edwards in Proclamation Number 25 JBE 2020 will result in the automatic termination of this Emergency Order.

RATIONALE AND LEGAL AUTHORITY:

WHEREAS, on January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization declared the COVID-19 outbreak a "public health emergency of international concern" (PHEIC). On January 31, 2020, Health and Human Services Secretary Alex M. Azar II declared a public health emergency (PHE) for the United States. Pursuant to the Louisiana Health Emergency Powers Act, R.S. 29:760, et seq., a state of public health emergency resulting from the outbreak of "coronavirus disease 2019" ("COVID-19") was initially declared to exist in the entire State of Louisiana by Proclamation Number 25 JBE 2020, and was extended to the present date by subsequent declarations.

WHEREAS, a COVID-19 vaccine developed by Pfizer-BioNTech (hereinafter the "Pfizer vaccine") received Emergency Use Authorization ("EUA") from the U.S. Food

and Drug Administration ("FDA") on December 11, 2020. A COVID-19 vaccine developed by Moderna (hereinafter the "Moderna vaccine") received an EUA from the FDA on December 18, 2020.

WHEREAS, the White House's Operation Warp Speed ("OWS") began sending limited shipments of both the Pfizer and Moderna vaccines to Louisiana in late December, 2020, and the number of shipments is expected to drastically increase in the coming months as Pfizer and Moderna increase their output of the vaccines.

WHEREAS, administering COVID vaccinations to as many Louisiana residents as possible as quickly as possible is vitally important. However, because the currently available vaccines require administration of two separate doses at two separate times, and because so many health professionals in the state are already overwhelmed dealing with COVID patients (in addition to dealing with everyday non-COVID issues), the state may experience a shortage in the number of authorized health professionals needed to quickly administer all doses of the vaccines as they are received from OWS. This is particularly true in the more rural parts of the state. As the number of OWS vaccine shipments increases in the coming months, this shortage may be expected to increase.

WHEREAS, allowing registered nurses (RNs), licensed practical nurses (LPNs), and pharmacists to administer the Pfizer and Moderna vaccines pursuant to a Protocol will help reduce the above-described shortage and will free-up other medical resources.

WHEREAS, the SHO has determined that the any risks associated with allowing registered nurses (RNs), licensed practical nurses (LPNs), and pharmacists to administer the Pfizer and Moderna vaccines as set forth herein is outweighed by the benefits of expanded timely administration of as many doses as possible.

NOW THEREFORE, pursuant to the powers vested in me by La. R.S. 40:1 *et seq.*, particularly La. R.S. 40:4(A)(13) and La. R.S. 40:5(A)(1) and (2), I, Joseph Kanter, MD, MPH, State Health Officer, do hereby issue the following emergency order:

Registered nurses (RNs), licensed practical nurses (LPNs), and pharmacists licensed in Louisiana (or licensed in another jurisdiction but allowed to practice in Louisiana pursuant to Executive Order or Proclamation of the Governor, temporary approval by the appropriate Louisiana licensing board, or similar authority) are hereby authorized to administer the Pfizer and Moderna COVID-19 vaccines pursuant to the respective Protocols for each attached to this EMERGENCY ORDER, without the need for an individualized patient-specific prescription or order from a physician or other prescribing practitioner.

The authorization granted herein applies only to RNs, LPNs, and pharmacists who are competent by virtue of education and/or clinical training to safely and effectively administer intramuscular deltoid injections.

Signed this 5th day of February, 2021.

Joseph Kanter, MD, MPH
State Health Officer

Concurrence:

2/9/21

Dr. Courtney N. Phillips DATE
Secretary, Louisiana Department of Health

Moderna COVID-19 Vaccine

Protocol for Administering Vaccine to Persons 18 Years of Age and Older

LOUISIANA DEPARTMENT OF HEALTH

CDC

Note: For more information/guidance, please contact the immunization program at your state or local health department or the appropriate state body (e.g., state board of medical/nursing/pharmacy practice).

Purpose

- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

Procedure

Assess persons 18 years of age and older for vaccination with Moderna COVID-19 Vaccine based on the following criteria:

- No complete 2-dose COVID-19 vaccination history, regardless of brand. If 2 doses of a same-brand or mixed-brand series have been administered, no additional doses are recommended.
  - If the recipient has received 1 previous dose of Moderna COVID-19 Vaccine, a second dose of the same brand should be administered.
  - This vaccine is administered in a 2-dose series. Separate doses by at least 28 days.*
- Moderna COVID-19 Vaccine should not be administered at the same time as other vaccines. Separate Moderna COVID-19 Vaccine from other vaccines by 14 days before or after the administration of Moderna COVID-19 Vaccine.
- Moderna COVID-19 Vaccine should be deferred for at least 90 days for persons who received passive antibody therapy (monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment.
- Screen for contraindications and precautions.
  - Contraindications
    - » Severe allergic reaction (e.g., anaphylaxis) to a previous dose or component of either mRNA COVID-19 vaccine
    - » Immediate allergic reaction† of any severity to a previous dose or component of an mRNA COVID-19 vaccine (including polyethylene glycol [PEG]. See Table 1 of vaccine components on page 3.
    - » Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)
  - Precautions
    - » History of an immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbate)
    - » Moderate to severe acute illness
- Provide all recipients with a copy of the current federal Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers.
- Prepare to administer the vaccine.
  - Choose the correct needle gauge, needle length, and injection site for persons:
    - » 18 years of age: 1-inch needle is recommended.
    - » 19 years of age and older: See table below.
  - Follow the manufacturer's guidance for storing/handling punctured vaccine vials.

Sex and Weight of Patient	Needle Gauge	Needle Length	Injection Site‡
Female or male fewer than 130 lbs	22–25	5/8§–1"	Deltoid muscle of arm
Female or male 130–152 lbs	22–25	1"	Deltoid muscle of arm
Female 152–200 lbs	22–25	1–11/2"	Deltoid muscle of arm
Male 153–260 lbs	22–25	1–11/2"	Deltoid muscle of arm
Female 200+ lbs	22–25	11/2"	Deltoid muscle of arm
Male 260+ lbs	22–25	11/2"	Deltoid muscle of arm

*Vaccine doses administered at/after day 24 are considered valid. The 4-day grace period should not routinely be used to schedule doses.

†For the purpose of this guidance, an immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.

‡Alternatively, the anterolateral thigh also can be used.

§Some experts recommend a 5/8-inch needle for men and women who weigh less 130 pounds. If used, skin must be stretched tightly (do not bunch subcutaneous tissue).

- Administer 0.5 mL Moderna COVID-19 Vaccine by intramuscular (IM) injection.

- Document vaccination.
  - COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the Louisiana LINKS Immunization Registry as soon as practicable and no later than 72 hours after administration.
  - Document each recipient's vaccine administration information:
    - » Medical record: The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
    - » Vaccination record card: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.
    - » Immunization information system (IIS): Report the vaccination to Louisiana LINKS as soon as possible, and no later than 72 hours after vaccination.

- Additional preparation and administration information is available on the manufacturer's website at https://www.modernatx.com/.

- Be prepared to manage medical emergencies.
  - Vaccination providers should observe patients aftervaccination to monitor for the occurrence of immediate adverse reactions:
    - » **30 minutes:** Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause
    - » **15 minutes:** All other persons.
  - Have a written protocol to manage medical emergencies following vaccination, as well as equipment and medications, including at least 3 epinephrine prefilled syringes or autoinjectors, H1 antihistamine, blood pressure cuff, and stethoscope and timing device to assess pulse.
  - For more information, please see:
    - » **Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites at https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html**
    - » **CDC's *General Best Practice Guidelines for Immunization*, "Preventing and Managing Adverse Reactions," at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html**
    - » **Immunization Action Coalition's "Medical Management of Vaccine Reactions in Adults in a Community Setting" at https://www.immunize.org/catg.d/p3082.pdf**

- Report adverse events to the Vaccine AdverseEvent Reporting System (VAERS).
  - While this vaccine is under Emergency Use Authorization (EUA), healthcare professionals are required to report to VAERS:
    - » Vaccine administration errors (whether associated with an adverse event [AE] or not)
    - » Serious AEs (irrespective of attribution to vaccination)
    - » Multisystem inflammatory syndrome (MIS) in adults or children
    - » Cases of COVID-19 that result in hospitalization or death
    - » Any additional AEs and revised safety requirements per the Food and Drug Administration's conditions for use of an authorized vaccine throughout the duration of the EUA
  - Healthcare professionals are encouraged to report to VAERS:
    - » Clinically important adverse events that occur after vaccination, even if you are not sure whether the vaccine caused the adverse event

Table 1: Ingredients included in Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines

An immediate allergic reaction to any component or previous dose of an mRNA COVID-19 vaccine is a contraindication to vaccination with both the Pfizer-BioNTech and Moderna vaccines. The following is a list of ingredients for the Pfizer-BioNTech and Moderna COVID-19 vaccines, as reported in the prescribing information for each vaccine.

Description	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine
mRNA	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2
Lipids	2[(polyethylene glycol)-2000]-N, N-ditetradecylacetamide	PEG2000-DMG: 1, 2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	Cholesterol	Cholesterol
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl) bis(2-hexyldecanoate)	SM-102: heptadecane-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate
Salts, sugars, buffers	Potassium chloride	Tromethamine
	Monobasic potassium phosphate	Tromethamine hydrochloride
	Sodium chloride	Acetic acid
	Dibasic sodium phosphate dihydrate	Sodium acetate
	Sucrose	Sucrose

*Neither vaccine contains eggs, gelatin, latex, or preservatives.

Note: Both the Pfizer-BioNTech and Moderna COVID-19 vaccines contain polyethylene glycol (PEG). PEG is a primary ingredient in osmotic laxatives and oral bowel preparations for colonoscopy procedures, an inactive ingredient or excipient in many medications, and is used in a process called "pegylation" to improve the therapeutic activity of some medications (including certain chemotherapeutics). Additionally, cross-reactive hypersensitivity between PEG and polysorbates (included as an excipient in some vaccines and other therapeutic agents) can occur.

Information on whether a medication contains PEG, a PEG derivative, or polysorbates as either active or inactive ingredients can be found in the package insert. The National Institutes of Health DailyMed database (https://dailymed.nlm.nih.gov/dailymed/index.cfm) may also be used as a resource. Medications that contain PEG and/or polysorbate are also described in the supplementary materials of Stone CA, et al. "Immediate hypersensitivity to polyethylene glycols and polysorbates: more common than we have recognized." *The Journal of Allergy and Clinical Immunology: In Practice* 7.5 (2019): 1533–1540. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6706272/pdf/nihms-1019221.pdf

Pfizer-BioNTech COVID-19 Vaccine

Protocol for Administering Vaccine to Persons 16 Years of Age and Older

LOUISIANA DEPARTMENT OF HEALTH

CDC

Purpose

- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

Procedure

- Assess persons 16 years of age and older for vaccination with Pfizer-BioNTech COVID-19 Vaccine based on the following criteria:
  - No complete 2-dose COVID-19 vaccination history, regardless of brand. If 2 doses of a same-brand or mixed-brand series have been administered, no additional doses are recommended.
  - If the recipient has received 1 previous dose of Pfizer-BioNTech COVID-19 Vaccine, the second dose of the same brand should be administered.
  - This vaccine is administered in a **2-dose** series. Separate doses by at least 21 days.*
- Pfizer-BioNTech COVID-19 Vaccine should not be administered at the same time as other vaccines. Separate Pfizer-BioNTech COVID-19 Vaccine from other vaccines by 14 days before or after the administration of Pfizer-BioNTech COVID-19 Vaccine.
- Pfizer-BioNTech COVID-19 Vaccine should be deferred for at least 90 days for persons who received passive antibody therapy (monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment.
- Screen for contraindications and precautions.
  - Contraindications:
    - Severe allergic reaction (e.g., anaphylaxis) to a previous dose or component of either mRNA COVID-19 vaccine
    - Immediate allergic reaction† of any severity to a previous dose or component of an mRNA COVID-19 vaccine (including polyethylene glycol [PEG]. See Table 1 of vaccine components on page 3.
    - Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)
  - Precautions:
    - History of an immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbate)
    - Moderate to severe acute illness
- Provide all recipients with a copy of the current federal Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers.
- Prepare to administer the vaccine.
  - Choose the correct needle gauge, needle length, and injection site for persons:
    - 16 through 18 years of age: 1-inch needle is recommended.
    - 19 years of age and older: See table below.

Sex and Weight of Patient	Needle Gauge	Needle Length	Injection Site‡
Female or male fewer than 130 lbs	22–25	5/8 §–1"	Deltoid muscle of arm
Female or male 130–152 lbs	22–25	1"	Deltoid muscle of arm
Female 152–200 lbs	22–25	1–11/2"	Deltoid muscle of arm
Male 153–260 lbs	22–25	1–11/2"	Deltoid muscle of arm
Female 200+ lbs	22–25	11/2"	Deltoid muscle of arm
Male 260+ lbs	22–25	11/2"	Deltoid muscle of arm

*If the second dose Pfizer-BioNTech COVID-19 Vaccine was given as early as 17 days after the first dose, then do not repeat a second dose.

†For the purpose of this guidance, an immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.

‡Alternatively, the anterolateral thigh also can be used.

§Some experts recommend a 5/8-inch needle for men and women who weigh less 130 pounds. If used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

- Mix Pfizer-BioNTech COVID-19 Vaccine with 0.9% sodium chloride (normal saline, preservative-free) diluent according to the manufacturer's instructions. Follow manufacturer's guidance for storing/handling mixed vaccine.

- Administer 0.3 mL Pfizer-BioNTech COVID-19 Vaccine by intramuscular (IM) injection.
- Document vaccination.
  - COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration to the Louisiana LINKS Immunization registry as soon as practicable and no later than 72 hours after administration.
  - Document each recipient's vaccine administration information:
    - » Medical record: The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
    - » Vaccination record card: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.
    - » Immunization information system (IIS): Report the vaccination to the Louisiana LINKS system.
- Additional preparation and administration information is available on the manufacturer's website at www.cvdvaccine.com.
- Be prepared to manage medical emergencies.
  - Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions:
    - » **30 minutes:** Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause
    - » **15 minutes:** All other persons
  - Have a written protocol to manage medical emergencies following vaccination, as well as equipment and medications, including at least 3 epinephrine prefilled syringes or autoinjectors, H1 antihistamine, blood pressure cuff, and stethoscope and timing device to assess pulse. For more information, please see:
    - » **Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination at https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html**
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    - » **Immunization Action Coalition's "Medical Management of Vaccine Reactions in Adults in a Community Setting" at https://www.immunize.org/catg.d/p3082.pdf**
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    - » Cases of COVID-19 that result in hospitalization or death
    - » Any additional AEs and revised safety requirements per the Food and Drug Administration's conditions for use of an authorized vaccine throughout the duration of the EUA
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Lipids	2[(polyethylene glycol)-2000]-N, N-ditetradecylacetamide	PEG2000-DMG: 1, 2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	Cholesterol	Cholesterol
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl) bis(2-hexyldecanoate)	SM-102: heptadecane-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate
Salts, sugars, buffers	Potassium chloride	Tromethamine
	Monobasic potassium phosphate	Tromethamine hydrochloride
	Sodium chloride	Acetic acid
	Dibasic sodium phosphate dihydrate	Sodium acetate
	Sucrose	Sucrose

*Neither vaccine contains eggs, gelatin, latex, or preservatives.

Note: Both the Pfizer-BioNTech and Moderna COVID-19 vaccines contain polyethylene glycol (PEG). PEG is a primary ingredient in osmotic laxatives and oral bowel preparations for colonoscopy procedures, an inactive ingredient or excipient in many medications, and is used in a process called "pegylation" to improve the therapeutic activity of some medications (including certain chemotherapeutics). Additionally, cross-reactive hypersensitivity between PEG and polysorbates (included as an excipient in some vaccines and other therapeutic agents) can occur.

Information on whether a medication contains PEG, a PEG derivative, or polysorbates as either active or inactive ingredients can be found in the package insert. The National Institutes of Health DailyMed database (https://dailymed.nlm.nih.gov/dailymed/index.cfm) may also be used as a resource. Medications that contain PEG and/or polysorbate are also described in the supplementary materials of Stone CA, et al. "Immediate hypersensitivity to polyethylene glycols and polysorbates: more common than we have recognized." *The Journal of Allergy and Clinical Immunology: In Practice* 7.5 (2019): 1533–1540. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6706272/pdf/nihms-1019221.pdf