

OVERVIEW OF PREP ACT¹

<u>Authority of HHS Secretary</u>	<u>Covered Persons and Covered Countermeasures</u>	<u>Preemption of State Law</u>
<p>The PREP Act, generally, grants authority to the Secretary of HHS to issue declarations regarding the administration of “covered countermeasures” in response to a public health emergency.</p> <p>“[If] the Secretary makes a determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency, the Secretary may make a declaration, through publication in the Federal Register, recommending, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures [. . .].” 42 U.S.C.A. § 247d-6d(b).</p> <p>“The Secretary may through publication in the Federal Register amend any portion of a declaration [. . .].” 42 U.S.C.A. § 247d-6d(b)(4).</p>	<p>For purposes of this summary, the PREP Act relates to the administration of “covered countermeasures” by “covered persons.” 42 U.S.C.A. § 247d-6d(i).</p> <p>“Covered persons” include a “qualified person,” which includes, “a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed;” and “[a] person within a category of persons so identified in a declaration by the Secretary.” 42 U.S.C.A. § 247d-6d(i)(8).</p> <p>“Covered countermeasures” include, for purposes of this summary, COVID-19 vaccinations that FDA-approved, or for which the FDA has granted an Emergency Use Authorization, certain COVID-19 tests, as well as certain other vaccinations.</p>	<p>The PREP Act generally preempts state law to the extent state law is in conflict with actions taken pursuant to the Act that relate to the administration of covered countermeasures by covered persons. “During the effective period of a declaration [. . .], 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 [. . .]is different from, or is in conflict with, any requirement applicable under this section; and relates to 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 [. . .].” 42 U.S.C.A. § 247d-6d(b)</p>

¹ Federal law on this matter is quite broad. It consists of statutes, regulations, declarations by the Secretary of the Department of Health and Human Services (“HHS”), opinions by the Office of General Counsel for HHS, and Guidance Documents published by HHS. This table is intended only to serve as a brief overview of general matters as they apply to scopes of practice issues for LLR licensees, only. For complete guidance, the reader is encouraged to the complete text of the PREP Act at 42 U.S.C. §§ 247d-6d, 247d-6e (2006), as well as the Declarations and Amendments published in the Federal Register. Finally, the reader should consider HHS Guidance and Advisory Opinions of the General Counsel. These documents are available on the federal Public Health Emergency website at: <https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx>.

DECLARATIONS, GUIDANCE DOCUMENTS, AND ADVISORY OPINIONS ISSUED BY HHS		
<u>Date</u>²	<u>Document</u>	<u>Effect</u>
March 17, 2020	Declaration for Public Readiness and Emergency Preparedness Act Coverage for medical countermeasures against COVID-19. 85 FR 15198	For purposes of this Summary, the primary effect of the Declaration was to declare a public health emergency and establish its scope. The Declaration also identified certain covered countermeasures, including any antiviral, any other drug, any biologic, any diagnostic, any other device, any respiratory protective 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.
April 8, 2020	Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act	This Guidance authorized licensed pharmacists to order and administer COVID-19 tests, including serology tests, that the Food and Drug Administration (FDA) has authorized and identified them as covered persons under the PREP Act when performing this function.
April 15, 2020	First Amendment to Declaration under the PREP Act for Medical Countermeasures Against COVID-19. 85 FR 35100	In his First Amendment to Declaration, the Secretary determined that the use of any respiratory protective device approved by NIOSH is a priority for use during the public health emergency. As such, he designated such respiratory protective devices as covered countermeasures.
April 17, 2020, as Modified on May 19, 2020	Advisory Opinion on the Public Readiness and Emergency Preparedness Act and The March 10, 2020 Declaration Under the Act	In this Advisory Opinion, General Counsel: <ul style="list-style-type: none"> • Provided a list of covered countermeasures subject to an Emergency Use Authorization (EUA); • Advised that an entity or individual who complies with all other requirements of the PREP Act and the conditions of the Secretary’s declaration will not lose PREP Act immunity—even if the medical product at issue is not a covered countermeasure—if that entity or individual reasonably could have believed that the product was a covered countermeasure; • Advised that a person who complies with all other requirements of the PREP Act and the conditions of the Secretary’s declaration will not lose PREP Act immunity—even if the person at issue is not a covered person—if the entity or

² For the Declaration and Amendments thereto made by the Secretary, the date refers to the date of publication in the Federal Register.

		<p>individual reasonably could have believed that the person was a covered person; and</p> <ul style="list-style-type: none"> • Set forth HHS’s view that covered persons should take, and document, reasonable precautions under the current emergent circumstances to facilitate the safe use or administration of covered countermeasures and to make those documents publicly and easily available.
May 19, 2020	Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary’s Declaration Under the Act	In this Advisory Opinion, the General Counsel opined that “the Public Readiness and Emergency Preparedness (PREP) Act preempts state licensing laws that restrict the ability of pharmacists to order and administer COVID-19 diagnostic tests where the Department of Health and Human Services (HHS) has expressly authorized pharmacists, under the PREP Act, to order and administer those tests.”
June 8, 2020	Second Amendment to Declaration under the PREP Act for Medical Countermeasures Against COVID-19 85 FR 35100	The Second Amendment to Declaration clarified that covered countermeasures under the original Declaration include qualified products that limit the harm such a pandemic or epidemic might otherwise cause.
August 24, 2020	Third Amendment to Declaration under the PREP Act for Medical Countermeasures Against COVID-19. 85 FR 52136	The Third Amendment to Declaration identified State-licensed pharmacists (and pharmacy interns acting under their supervision if the pharmacy intern is licensed or registered by his or her State board of pharmacy) as qualified persons under when the pharmacist orders and either the pharmacist or the supervised pharmacy intern administers vaccines to individuals ages three through 18, subject to certain requirements as set forth more fully in the Third Amendment to Declaration.
August 31, 2020	Guidance for PREP Act Coverage for COVID-19 Screening Tests at Nursing Homes, Assisted-Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities,	<p>This Guidance:</p> <ul style="list-style-type: none"> • Extended coverage under the PREP Act to licensed health-care practitioners prescribing or administering point-of-care COVID-19 tests, using anterior nares specimen collection or self-collection, for screening in congregate facilities across the Nation. Such tests must be authorized, approved, or cleared by the FDA (collectively, FDA-authorized COVID-19 tests); • Declared that PREP Act coverage encompasses licensed health-care practitioners prescribing or administering FDA-authorized COVID-19 tests, including for off-label (outside the authorization) use to screen asymptomatic individuals in congregate facilities;

		<ul style="list-style-type: none"> • Required that licensed health-care practitioners comply with the requirements of the PREP Act and the conditions of the Secretary’s declaration under the PREP Act in order to receive PREP Act coverage; and • Stated that this PREP Act coverage preempts any State or local provision of law or legal requirement that prohibits or effectively prohibits such licensed health-care practitioners from administering or prescribing FDA-authorized COVID-19 tests to symptomatic or asymptomatic individuals at congregate facilities.
September 3, 2020	Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act	This Guidance, subject to satisfaction of certain requirements, authorized State-licensed pharmacists to order and administer, and State-licensed or registered pharmacy interns acting under the supervision of the qualified pharmacist to administer, to persons ages three or older COVID-19 vaccinations that have been authorized or licensed by the Food and Drug Administration (FDA). Such pharmacists and pharmacy interns will qualify as “covered persons” under the PREP Act, subject to certain requirements. Requirements referenced in this section are set forth in full in the September 3, 2020 Guidance. Other applicable requirements of the Act and the requirements discussed below. They may also receive immunity under the PREP Act with respect to all claims for loss caused by, arising out of, relating to, or resulting from, the administration or use of FDA-authorized or FDA-licensed COVID-19 vaccines. 42 U.S.C. § 247d-6d(a)(1).
October 20, 2020	Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing	<p>This Guidance clarified that pharmacy interns administering vaccines must be authorized by the state or board of pharmacy in the state in which the practical pharmacy internship occurs, but this authorization need not take the form of a license from, or registration with, the State board of pharmacy.</p> <p>Further, subject to satisfaction of certain requirements set forth in full in the Guidance Document, the Guidance authorized both qualified pharmacy technicians and State-authorized pharmacy interns acting under the supervision of a qualified pharmacist to administer FDA-authorized or FDA-licensed COVID-19 vaccines to persons ages three or older and to administer FDA-authorized or FDA-licensed ACIP-recommended vaccines to persons ages three through 18 according to ACIP’s standard immunization schedule. It further authorized them to administer COVID-19 tests.</p>
October 22, 2020, as modified on October 23, 2020	Advisory Opinion 20-03 on the Public Readiness and Emergency Preparedness Act and The Secretary’s Declaration Under the Act	<p>This Opinion offered answers to three vaccine-related questions. In considering these questions, General Counsel opined that:</p> <ul style="list-style-type: none"> • Pharmacists in states with less stringent training requirements than those set forth in the Third Amendment to Declaration, could be considered qualified persons under certain circumstances; • During the effective period of the PREP Act declaration, states cannot use any protocol or CPA to prohibit or effectively prohibit “qualified persons” from ordering and

		<p>administering ACIP-recommended childhood vaccines in a manner consistent with that specified in the Third Amendment; and</p> <ul style="list-style-type: none"> • Epinephrine is a “covered countermeasure” and the PREP Act covers its use as set forth in the Third Amendment to address such severe acute vaccine reactions.
October 22, 2020, as modified On October 23, 2020	Advisory Opinion 20-04 on the Public Readiness and Emergency Preparedness Act and the Secretary’s Declaration Under the Act	This Opinion related to jurisdictional issues not relevant to the subject of this summary.
October 29, 2020	PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures	This Guidance clarified that pharmacies are also qualified persons when their staff pharmacists order and administer, or their pharmacy interns and pharmacy technicians administer, covered countermeasures consistent with the terms and conditions of the Secretary’s Declaration and guidance, as of the date that these staff pharmacists, pharmacy interns, and pharmacy technicians were authorized to order or administer these covered countermeasures. Such pharmacies qualify as “covered persons” under the PREP Act, provided they meet certain requirements set forth more fully in the Guidance document.
December 9, 2020	<p>Fourth Amendment to Declaration under the PREP Act for Medical Countermeasures Against COVID-19.</p> <p>85 FR 79190</p>	<p>In the Fourth Amendment to Declaration, the Secretary:</p> <ul style="list-style-type: none"> • Clarified that the Declaration must be construed in accordance with the Advisory Opinions and expressly incorporated the Advisory Opinions for that purpose; • Added as an additional category of qualified persons healthcare personnel who are permitted to order and administer a Covered Countermeasure through telehealth in a state may do so for patients in another state so long as the healthcare personnel comply with the legal requirements of the state in which the healthcare personnel are permitted to order and administer the Covered Countermeasure by means of telehealth subject to certain requirements as set forth more fully in the Fourth Amendment to Declaration; • Made explicit that the requirement in that section for certain qualified persons to have a current certificate in basic cardiopulmonary resuscitation is satisfied by, among other things, a certification in basic cardiopulmonary resuscitation by an online program that has received accreditation from the American Nurses

		<p>Credentialing Center, the Accreditation Council for Pharmacy Education (ACPE), or the Accreditation Council for Continuing Medical Education;</p> <ul style="list-style-type: none"> • Amended the training requirements for licensed pharmacists to order and administer certain childhood or COVID-19 vaccines. To order and administer vaccines, the licensed pharmacist must have completed the immunization training that the licensing State requires in order for pharmacists to administer vaccines; and • Made such other amendments as set forth more fully in the Fourth Amendment to Declaration under the PREP Act for Medical Countermeasures Against COVID-19.
December 18, 2020	Guidance for National Guard Personnel Regarding COVID-19 Vaccines and Immunity under the PREP Act	This Guidance extended coverage under the Public Readiness and Emergency Preparedness Act (PREP Act) to qualified National Guardsmen administering COVID-19 vaccinations that have been authorized or licensed by the Food and Drug Administration (FDA).
January 8, 2021	Advisory Opinion 21-01 on the Public Readiness And Emergency Preparedness Act Scope of Preemption Provision	In this Advisory Opinion, General Counsel responded to the question of whether the PREP Act applies where a covered person declines to use a covered countermeasure when it arguably ought to have been used. General Counsel determined that it does, unless the failure to provide to provide the covered countermeasure was willful or wanton. Where a facility has been allocated a scarce therapeutic purchased by the federal government and that facility fails to administer that therapeutic to an individual who meets the requirements of the FDA's authorization, approval, or license, and whose physician prescribes that therapeutic, then the facility's refusal to administer that therapeutic could still trigger the PREP Act assuming the non-use of the therapeutic was the result of conscious decision-making. However, the facility may still be liable under the PREP Act, if the plaintiff alleges that the decision to deny him or her the therapeutic was wanton and willful and resulted in death or serious injury.
January 12, 2021	Advisory Opinion 21-02 on the Public Readiness And Emergency Preparedness Act Scope of Preemption Provision	In this Advisory Opinion, General Counsel offers the opinion that satisfying the Advisory Committee on Immunization Practices' (ACIP) allocation recommendations is not a precondition to PREP Act coverage. The reference in the Declarations to order and administer according to ACIP's COVID-19 vaccine recommendations simply means that the vaccine must be one that ACIP recommends for the prevention of COVID-19; it does not mean that the vaccine will be administered pursuant to any particular allocation guidance or recommendation.
February 2, 2021	Fifth Amendment to Declaration under the PREP Act for Medical Countermeasures Against COVID-19.	<p>In the Fifth Amendment to Declaration, the Acting Secretary added additional categories of Qualified Persons authorized to prescribe, dispense, and administer COVID-19 vaccines. More specifically, it added:</p> <ul style="list-style-type: none"> • Any healthcare professional or other individual who holds an active license or certification permitting the person to prescribe, dispense, or administer vaccines under the law of any State [. . .];

		<ul style="list-style-type: none">• Who prescribes, dispenses, or administers COVID–19 vaccines that are Covered Countermeasures [. . .];• in any jurisdiction where the PREP Act applies, other than the State in which the license or certification is held,• in association with a COVID–19 vaccination effort by a federal, State, local, Tribal, or territorial authority or by an institution in the State in which the COVID–19 vaccine covered countermeasure is administered;• so long as the license or certification of the healthcare professional has not been suspended or restricted by any licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General;• subject to:<ul style="list-style-type: none">○ Documentation of completion of the Centers for Disease Control and Prevention COVID–19 (CDC) Vaccine Training Modules 1 and, for healthcare providers who are not currently practicing, documentation of an observation period by a currently practicing healthcare professional adequately experienced in vaccination who confirms competency of the healthcare provider in preparation and administration of the particular COVID– 19 vaccine(s) to be administered; and (g) Any physician, advanced practice registered nurse, registered nurse, or practical nurse who has held an active license or certification to prescribe, dispense, or administer vaccines under the law of any State within the last five years, which is inactive, expired or lapsed, who prescribes, dispenses, or administers COVID–19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID–19 vaccination effort by a federal, State, local, tribal or territorial authority or by an institution in which the COVID–19 vaccine covered countermeasure is administered, so long as the license or certification was active and in good standing prior to the date it went inactive, expired or lapsed and was not revoked by the licensing authority, surrendered while under suspension, discipline, or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General, subject to (i) documentation of completion of the Centers for Disease Control and Prevention COVID–19 Vaccine Training Modules; and
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February 2, 2021	Guidance for Department of Defense Personnel, Contractors, and Volunteers Regarding COVID-19 Vaccines and Immunity under the PREP Act	The Guidance authorizes qualified DOD personnel, contractors, and volunteers as “covered persons” to administer COVID-19 vaccinations that have been authorized or licensed by the Food and Drug Administration (FDA), subject to certain conditions.
February 16, 2021	Sixth Amendment to Declaration under the PREP Act for Medical Countermeasures Against COVID-19.	In the Sixth Amendment to Declaration, the Acting Secretary added as qualified persons certain federal government employees, contractors, or volunteers who prescribe, administer, distribute, or dispense a covered countermeasure.
February 22, 2021	Technical Correction to Fifth and Sixth Amendments to Declaration under the PREP Act for Medical Countermeasures Against COVID-19.	The only amendment of substance for our purposes in this document is that it adds “any member of a uniformed service (including members of the National Guard in a Title 32 status) to the list of federal government employees, etc.
March 11, 2021	Seventh Amendment to Declaration under the PREP Act for Medical Countermeasures Against COVID-19.	<p>In the Seventh Amendment, the Acting Secretary again expands the number of individuals considered qualified persons for purposes of administering the COVID-19 vaccine to include:</p> <ul style="list-style-type: none"> • Any midwife, paramedic, advanced or intermediate emergency medical technician (EMT), physician assistant, respiratory therapist, dentist, podiatrist, optometrist or veterinarian licensed or certified to practice under the law of any state who prescribes, dispenses, or administers COVID-19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID-19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID-19 vaccine covered countermeasure is administered; • Any physician, advanced practice registered nurse, registered nurse, practical nurse, pharmacist, pharmacy intern, midwife, paramedic, advanced or intermediate EMT, respiratory therapist, dentist, physician assistant, podiatrist, optometrist, or veterinarian who has held an active license or certification under the law of any State within the last five years, which is inactive, expired or lapsed, who prescribes, dispenses, or administers COVID-19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID-19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID-19 vaccine covered countermeasure is administered, so long as the license or certification was active and in good standing prior to the date it went inactive, expired or lapsed and was not revoked by the licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General;

		<ul style="list-style-type: none">• Any medical, nursing, pharmacy, pharmacy intern, midwife, paramedic, advanced or intermediate EMT, physician assistant, respiratory therapy, dental, podiatry, optometry or veterinary student with appropriate training in administering vaccines as determined by his or her school or training program and supervision by a currently practicing healthcare professional experienced in administering intramuscular injections who administers COVID-19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID-19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID-19 vaccine covered countermeasure is administered; Subject to the following requirements:<ul style="list-style-type: none">○ The vaccine must be authorized, approved, or licensed by the FDA;○ Vaccination must be ordered and administered according to ACIP's COVID-19 vaccine recommendation(s);○ The healthcare professionals and students must have documentation of completion of the Centers for Disease Control and Prevention COVID-19 Vaccine Training Modules and, if applicable, such additional training as may be required by the State, territory, locality, or Tribal area in which they are prescribing, dispensing, or administering COVID-19 vaccines;○ The healthcare professionals and students must have documentation of 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 vaccine(s) to be administered and, if applicable, such additional training as may be required by the State, territory, locality, or Tribal area in which they are prescribing, dispensing, or administering COVID-19 vaccines;○ The healthcare professionals and students must have a current certificate in basic cardiopulmonary resuscitation;○ The healthcare professionals and students must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine
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		<p>must review the vaccine registry or other vaccination records prior to administering a vaccine; and</p> <ul style="list-style-type: none"> ○ The healthcare professionals and students comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention (CDC) COVID- 19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID- 19 vaccine(s).
August 4, 2021	Eighth Amendment to Declaration under the PREP Act for Medical Countermeasures Against COVID-19.	In the Eight Amendment to Declaration, the Secretary clarifies that qualified pharmacy technicians are Qualified Persons covered by the Declaration, and expands the scope of authority for qualified pharmacy technicians to administer seasonal influenza vaccines to adults within the state where they are authorized to practice and for interns to administer seasonal influenza vaccines to adults consistent with other terms and conditions of the Declaration.
September 14, 2021	Ninth Amendment to Declaration under the PREP Act for Medical Countermeasures Against COVID-19.	<p>In the Ninth Amendment, the Secretary expands the scope of authority for licensed pharmacists to order and administer and qualified pharmacy technicians and pharmacy interns to administer COVID-19 therapeutics subcutaneously, intramuscularly, or orally as authorized, approved, or licensed by the U.S. Food and Drug Administration (FDA).</p> <p>More specifically, it provides that a State-licensed pharmacist who orders and administers, and pharmacy interns and qualified pharmacy technicians who administer (if the pharmacy intern or technician acts under the supervision of such pharmacist and the pharmacy intern or technician is licensed or registered by his or her State board of pharmacy) FDA authorized, approved, or licensed COVID-19 therapeutics. Such State-licensed pharmacists and the State-licensed or registered interns or technicians under their supervision are qualified persons only if the following requirements are met:</p> <ul style="list-style-type: none"> • The COVID-19 therapeutic must be authorized, approved, or licensed by the FDA; • In the case of a licensed pharmacist ordering a COVID-19 therapeutic, the therapeutic must be ordered for subcutaneous, intramuscular, or oral administration and in accordance with the FDA approval, authorization, or licensing; • In the case of licensed pharmacists, qualified pharmacy technicians, and licensed or registered pharmacy interns administering the COVID-19 therapeutic, the therapeutic must be administered subcutaneously, intramuscularly, or orally in accordance with the FDA approval, authorization, or licensing; • In the case of qualified pharmacy technicians, the supervising pharmacist must be readily and immediately available to the qualified pharmacy technician;

		<ul style="list-style-type: none">• In the case of COVID-19 therapeutics administered through intramuscular or subcutaneous injections, the licensed pharmacist, licensed or registered pharmacy intern and qualified pharmacy technician must complete a practical training program that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of COVID-19 therapeutics, the recognition and treatment of emergency reactions to COVID-19 therapeutics, and any additional training required in the FDA approval, authorization, or licensing;• The licensed pharmacist, licensed or registered pharmacy intern and qualified pharmacy technician must have a current certificate in basic cardiopulmonary resuscitation;• The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers COVID-19 therapeutics, including informing the patient's primary-care provider when available and complying with requirements with respect to reporting adverse events;• The licensed pharmacist, the licensed or registered pharmacy intern and the qualified pharmacy technician must comply with any applicable requirements (or conditions of use) that apply to the administration of COVID-19 therapeutics.
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