Shots in Arms: Overview of Legal Authority Governing The Ordering and Administration of Vaccines by Pharmacists, Pharmacy Interns, and Pharmacy Technicians

The South Carolina Board of Pharmacy January 27, 2021

It may seem as though the rules governing administration of vaccines by pharmacists have become more complex than the Tax Code. This article is offered to help clarify these rules and highlight recent changes to state law, as well as actions taken at the federal level. While South Carolina law is relatively straight-forward, the body of federal law relating to these issues is more complex. It consists of statutes, regulations, declarations by the Secretary of the Department of Health and Human Services, Guidance Documents, and opinions by the Office of General Counsel for the Department of Health and Human Services. In addition to authorizing certain pharmacy personnel to administer certain vaccines, the body of federal law involves matters relating to liability protections and payment issues, among many Such matters are outside the Board's others. jurisdiction, so the scope of this article is limited solely to laws authorizing pharmacy personnel to order and/or administer vaccines. The article will cover the basic issues of 1) who may administer and/or order vaccines; 2) the requirements for ordering and/or administering vaccines; and 3) what vaccines may be ordered and/or administered and to whom. Finally, this article is not intended to serve as legal advice. Should you have any questions about the items covered in this article, or the full scope of federal law, you are encouraged to contact your legal counsel.

1. SOUTH CAROLINA LAW

As a general rule, the administration of vaccines by pharmacists is a matter of state law. While the Federal Government regulates certain third-party payors and other matters incidental to the practice of pharmacy, the regulation of the practice of pharmacy is left to the individual states. Under

¹ See S.C. Code Ann. §§ 40-43-190 and 40-43-200 for a full overview of the current law governing the administration of vaccines by pharmacists.

South Carolina law, pharmacists meeting certain criteria have been authorized to administer certain vaccines since 2010.¹ In 2010, the General Assembly added S.C. Code Ann. §§ 40-43-190 (2010) and 40-43-200 (2010) to the Pharmacy Practice Act. These additions authorized pharmacists who meet certain criteria to administer the influenza vaccine to individuals 18 years of age and older pursuant to a written protocol developed by the Joint Pharmacist Administered Influenza Vaccines Committee and approved by the Board of Medical Examiners.

In 2015, the General Assembly amended S.C. Code Ann. §§ 40-43-190 and 40-43-200 to allow pharmacists and pharmacy interns working under the direct supervision of a pharmacist who meet certain conditions to administer additional vaccines to individuals 18 and older pursuant to a written protocol ("Protocol") developed by the renamed Joint Pharmacist Administered Vaccines Committee ("Committee")² and approved by the Board of Medical Examiners. The 2015 amendments also authorized pharmacists and pharmacy interns working under the direct supervision of a pharmacist who meet certain conditions to administer the influenza vaccine to individuals 12 years of age and older pursuant to the Protocol.

In September of 2020, the General Assembly again amended S.C. Code Ann. §§ 40-43-190 and 40-43-200 to authorize pharmacists and pharmacy interns working under the direct supervision of a pharmacist who meet certain conditions to administer the influenza vaccine to individuals under the age of 12 pursuant to the Protocol. The Protocol was revised on December 10, 2020 in accordance with the new amendments. ^{3, 4} Pursuant to this

² The Committee consists of members appointed by the Board of Pharmacy, Board of Nursing, Board of Medical Examiners, and one member from the Department of Health and Environmental Control.

³ A copy of the Protocol revised on December 10, 2020, is available on the Board's website at: https://llr.sc.gov/bop/pforms/vaccines.pdf.

⁴ Licensees and registrants should review the latest Protocol in its entirety, paying special attention to the additional required supplies and equipment listed in Appendix B. Additional required supplies and equipment include a scale capable of weighing children and

revised Protocol, pharmacists, and pharmacy interns working under the direct supervision of a pharmacist, who meet certain conditions may administer the influenza vaccine to individuals age 3 and older.

The following table represents the evolution of South Carolina law regarding administration of vaccines by pharmacists and pharmacy interns:

		Vaccines		
<u>Year</u>	<u>Licensee</u> /Registrant	Influenza Vaccine pursuant to Protocol	Addt'l. Vaccines included in, and pursuant to, Protocol	Vaccines ordered or prescribed by practitioner for patient of practitioner
2010	Pharmacists	Individuals 18 and older	N/A	N/A
2015	Pharmacists Pharmacy Interns	Individuals 12 and older	Individuals 18 and older	Any Age
2020 (current law)	Pharmacists Pharmacy Interns	Individuals 3 and older	Individuals 18 and older	Any Age

The Protocol does <u>not</u> yet allow for the administration of any vaccines for COVID-19; however, the Committee met on January 25, 2021 and voted to recommend the inclusion of COVID-19 vaccines in the Protocol.⁵ This recommendation will go to the Board of Medical Examiners for approval on February 1, 2021. It is important to note, though, that any COVID-19 vaccines could only be administered to individuals 18 and older pursuant to the Protocol.⁶ As discussed

hydroxyzine tablets. Additionally, licenses and registrants are also encouraged to pay special attention to updates to Appendix H (HPV) and Appendix I (Pneumococcal Vaccines).

above, S.C. Code Ann. § 40-43-190 only allows for the administration of the influenza vaccine to individuals under 18 pursuant to the Protocol.

2. FEDERAL LAW

a. Overview of the PREP Act

Having reviewed current state law on vaccinations by pharmacists and pharmacy interns, we will now consider recent federal actions. As set forth above, the regulation of the practice of pharmacy is generally left to the states. In 2005, however, Congress passed the Public Readiness and Emergency Preparedness (PREP) Act. The PREP Act, as amended by the 2020 Coronavirus Aid, Relief, and Economic Security (CARES) Act,8 generally authorizes the Secretary of Health and Human Services (HHS) to issue declarations authorizing the administration of "covered countermeasures" in response to a public health emergency.9 It provides that if the Secretary "makes a determination that a disease or other health condition or other threat to health constitutes a public health emergency [. . .] the Secretary may make a declaration [. . .] recommending, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures [. . .]."10,11 For purposes of this article, "covered countermeasures" include: 1) COVID-19 tests, including serology tests, that the Food and Drug Administration (FDA) has authorized;¹² 2) ACIP-recommended childhood vaccinations;13 and 3) COVID-19 vaccinations that have been authorized or licensed by the Food and Drug Administration (FDA).14

https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf.

⁵ Federal law currently allows for the administration of COVID-19 vaccines by pharmacists and other pharmacy personnel, subject to certain conditions described in more detail below.

⁶ Again, federal law currently allows for the administration of the COVID-19 vaccine to individuals ages three through 18, should such a vaccine ever be so indicated.

⁷ 42 U.S.C. §§ 247d-6d, 247d-6e(2006).

⁸ Pub.L. 116-136.

⁹ See 42 U.S.C.A. § 247d-6d(b)(1).

¹⁰ 42 U.S.C.A. § 247d-6d(b)(1).

¹¹ The PREP Act also contains certain liability protections that are beyond the scope of this article.

¹² April 8, 2020 HHS *Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act.* Available

¹³ 85 FR 52136-01.

¹⁴ September 3, 2020 HHS *Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act*. Available at: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/licensed-pharmacists-and-

The Act allows for the administration of covered countermeasures by "covered persons." 15 purposes of administering a covered countermeasure, "covered person" is defined to include, "a qualified person who prescribed, administered, or dispensed such countermeasure."16 A "qualified person" is either: 1) "a licensed health professional or other individual who is authorized to prescribe, administer, or dispense countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed;" or 2) a "person within a category of persons so identified in a declaration by the Secretary [. . .]."17 In other words, a "qualified person" (and thus, a "covered person") is an individual who could, for example, order and administer a COVID-19 vaccine under state law; or a class of individuals identified in a declaration by the Secretary as being authorized to order and administer a COVID-19 vaccine. As there are differences between the two, preemption becomes important.

The Act provides that during the effective period of a declaration by the Secretary, no 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 [the Act]."18 In other words, federal action taken pursuant to the PREP Act preempts, or overrides, state law to the contrary. Because state law is preempted, some pharmacists, pharmacy interns, and pharmacy technicians may find themselves performing certain acts under the authority granted to them under federal law that may not be authorized by the Pharmacy Practice Act. Because federal law preempts state law in this situation, such acts would not result in discipline by the Board of Pharmacy.

pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf.

Finally, it is important to note that only the federal agency charged with administering the law (in this case, HHS) or a court could offer a binding interpretation of federal law as it relates to actions taken by the Secretary pursuant to the PREP Act. Likewise, the Board of Pharmacy is charged with interpreting and administering the South Carolina Pharmacy Practice Act and, apart from a court, would be the only authority that could offer an interpretation of the Practice Act. Just as HHS is not in a position to interpret or otherwise offer opinions on the requirements contained in the Pharmacy Practice Act, the Board is not in a position to interpret or otherwise offer opinions on to actions taken by the Secretary pursuant to the PREP Act.

Pharmacy personnel seeking information on how the PREP Act applies to a specific set of facts will likely need to consult legal counsel. HHS has stated:

> [...] Persons seeking PREP Act immunity are responsible for determining whether their products covered are countermeasures, whether a person or entity is a covered person, whether reasonable precautions have been taken to facilitate the safe use of covered countermeasures, and in general, whether immunity applies to them and their activities. In order to obtain PREP Act coverage, persons must meet all requirements set forth in the PREP Act and the Declaration. 19, 20

To this end, coverage under the PREP Act is likely something that would be determined after the fact.

b. Actions Taken by HHS and its Secretary Pursuant to the PREP Act

As set forth above, the Secretary of HHS is authorized to make certain declarations regarding the

sites/default/files/hhs-guidance-documents/AO-21-02-PREP-Act 1-12-2021 FINAL SIGNED.pdf

¹⁵ See 42 U.S.C.A. § 247d-6d(i).

¹⁶ 42 U.S.C.A. § 247d-6d(i)(2)(B)(iv).

¹⁷ 42 U.S.C.A. § 247d-6d(i)(8).

¹⁸ 42 U.S.C.A. § 247d-6d(b)(8)(a).

¹⁹ Advisory Opinion 21-02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration Under The Act dated January 12, 2021. Available at: https://www.hhs.gov/guidance/

²⁰ It is worth noting that federal law creates, essentially, a safe harbor that allows pharmacy personnel to practice outside their usual scopes of practice in certain situations. If pharmacy personnel do not meet all of the requirements to fit within this safe harbor, it is possible that they would lose its protection and their actions would be viewed under existing state law.

administration of covered countermeasures by covered persons.²¹ On March 17, 2020, the Secretary published his first Declaration under the PREP ACT for Countermeasures Against ("Declaration").²² In this Declaration, he determined that "[. . .] the spread of SARS-CoV-2 or a virus mutating therefrom and the resulting disease, COVID-19, constitutes a public health emergency for purposes of this Declaration under the PREP Act."23 The Declaration has undergone a number of amendments since it was first published. Additionally, HHS has issued Guidance Documents, and its Office of General Counsel has issued Advisory The relevant Amendments, Guidance Documents, and Advisory Opinions are discussed below.

i. <u>Third Amendment to</u> Declaration

On August 24, 2020 the Secretary published his Third Amendment to Declaration.²⁴ The Secretary amended the Declaration to "clarify that the category of disease, health condition, or threat for which he recommends the administration or use of the Covered Countermeasures includes not only COVID-19 caused by SARS-CoV-2 or a virus mutating therefrom, but also other diseases, health conditions, or threats that may have been caused by COVID-19, SARS-CoV-2, or a virus mutating therefrom, including the decrease in the rate of childhood immunizations, which will lead to an increase in the rate of infectious diseases."²⁵

The Secretary noted that "[p]harmacists are well-positioned to increase access to vaccinations, particularly in certain areas or for certain populations that have too few pediatricians and other primary-care providers, or that are otherwise medically underserved." Further, he stated that "[p]harmacists are trusted healthcare professionals with established relationships with their patients [and] have strong relationships with local medical providers and hospitals to refer patients as appropriate." ²⁷

Based on the above, the Secretary authorized, "certain State-licensed pharmacists to order and administer, and pharmacy interns (who are licensed or registered by their State board of pharmacy and acting under the supervision of a State-licensed pharmacist) to administer, any vaccine that the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through 18 according to ACIP's standard immunization schedule (ACIP-recommended vaccines)."²⁸

The Third Amendment also set forth the following requirements for the ordering and/or administering of vaccines:²⁹

- The vaccine must be FDAauthorized or FDA-approved.
- The vaccination must be ordered and administered according to ACIP's standard immunization schedule.
- The licensed pharmacist must complete a practical training program of at least 20 hours 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 vaccines, and the recognition and treatment of emergency reactions to vaccines.
- The licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.

²¹ See 42 U.S.C.A. § 247d-6d(b)(1)

²² 85 FR 15198-01.

²³ Id.

²⁴ 85 FR 52136.

²⁵ Id.

²⁶ Id.

²⁷ Id.

²⁸ Id.

²⁹ Id.

- The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.
- The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period.
- The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primarycare provider when available, submitting required the 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 administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine.
- The licensed pharmacist must inform his or her childhoodvaccination patients and the adult caregivers accompanying the children of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and refer patients as appropriate.

The Third Amendment did not expressly include an authorization for the ordering and administering of COVID-19 vaccines.

ii. <u>September 3, 2020 and October</u> 20, 2020 Guidance

On September 3, 2020, the Secretary issued Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act.³⁰ This guidance authorized "[s]tate-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)."³¹

Notably, the Third Amendment did not address the administration of vaccines by pharmacy technicians. On October 20, 2020, the Secretary issued Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing.³² This Guidance authorized certain pharmacy technicians 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 ACIPrecommended vaccines to persons ages three ACIP's standard through 18 according to immunization schedule."33 The Guidance further

³⁰September 3, 2020 HHS *Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act*. Available at: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf

³¹ *Id*.

³² October 20, 2020 HHS *Guidance for PREP Act Coverage* for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing. Available at: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-

documents//prep-act-guidance.pdf ³³ *Id.*

outlines the requirements for administration by pharmacy technicians and pharmacy interns.³⁴

The requirements are as follows:35

- The vaccination must be ordered by the supervising qualified pharmacist.
- The supervising qualified pharmacist must be readily and immediately available to the immunizing qualified pharmacy technicians.
- The vaccine must be FDAauthorized or FDA-licensed.
- In the case of a COVID-19 vaccine, the vaccination must be ordered and administered according to ACIP's COVID-19 vaccine recommendation(s).
- In the case of a childhood vaccine, the vaccination must be ordered and administered according to ACIP's standard immunization schedule.
- The qualified pharmacy technician or State-authorized pharmacy intern 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 and the recognition and treatment of emergency reactions to vaccines.
- The qualified pharmacy technician or State-authorized pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.
- The qualified pharmacy technician must complete a

- minimum of two hours of ACPEapproved, immunization-related continuing pharmacy education during the relevant State licensing period(s).
- The supervising qualified pharmacist 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 and submitting required immunization the information to the state or local immunization information system (vaccine registry). The supervising qualified pharmacist is responsible for complying with requirements related reporting adverse events.
- The supervising qualified pharmacist must review the vaccine registry or other vaccination records prior to ordering the vaccination to be administered by the qualified pharmacy technician or Stateauthorized pharmacy intern.
- The qualified pharmacy technician and State-authorized pharmacy intern must, if the patient is 18 years of age or younger, inform the patient and adult caregiver accompanying the patient of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and refer patients appropriate.
- The supervising qualified pharmacist must comply with

³⁴ Though not relevant to pharmacy interns in South Carolina, the Guidance recognized that some states do not require pharmacy interns to be licensed or registered by their boards. Thus, it clarified that pharmacy interns not required to be licensed or registered need only be "authorized" by their state boards of pharmacy.

³⁵ October 20, 2020 HHS *Guidance for PREP Act Coverage* for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing. Available at: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf

any applicable requirements (or conditions of use) as set forth in the CDC's COVID-19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s).

Thus, at present, the Secretary has authorized certain pharmacists, pharmacy interns, and pharmacy technicians to administer certain vaccines as shown in the following table:

<u>Authorization</u>	<u>Licensee</u> /Registrant	ACIP Vaccines ³⁶	COVID-19 Vaccines ³⁷
Third Amendment to Declaration under PREP Act ³⁸ (ACIP Vaccines); September 3, 2020 Guidance ³⁹ (COVID- 19 Vaccines)	Pharmacists	May Order and Administer to Individuals ages 3 through 18.	May Order and Administer to Individuals Ages 3 and Older
Third Amendment to Declaration under PREP Act ⁴⁰ (ACIP Vaccines); September 3, 2020 Guidance ⁴¹ (COVID- 19 Vaccines)	Registered Pharmacy Interns Acting under the Supervision of a Pharmacist	May Administer to Individuals ages 3 through 18.	May Administer to Individuals Ages 3 and Older
October 20, 2020 Guidance ⁴²	Registered Pharmacy Technicians Acting under the Supervision of a Pharmacist	May Administer to Individuals ages 3 through 18.	May Administer to Individuals Ages 3 and Older

iii. <u>Fourth Amendment to</u> Declaration

On December 9, 2020, the Secretary published his Fourth Amendment to the Declaration Under the PREP Act ("Fourth Amendment").⁴³ This Amendment, *inter alia*, "[m]odifie[d] and clarifie[d] the training requirements for certain licensed pharmacists and pharmacy interns to administer certain routine childhood or COVID-19 vaccinations."^{44,45} The modifications are set forth below:⁴⁶

- The requirement that the vaccine must be FDA-authorized or FDAapproved was changed to state that the "vaccine must be authorized, approved, or licensed by the FDA."
- The provision regarding the necessary training for pharmacists, only, was changed to state that "the licensed pharmacist must have completed the immunization training that the licensing State requires in order for pharmacists to order and administer vaccines." Only if a state does not specify requirements for pharmacists to order and administer vaccines must a pharmacist complete the 20-hour ACPE vaccination training program.

Vaccines and Immunity under the PREP Act. Available at: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/

licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf

³⁶ Vaccines that the Advisory Committee on Immunization Practices (ACIP) Recommends to Persons Ages Three Through 18 According to ACIP's Standard Immunization Schedule.

 $^{^{\}rm 37}$ COVID-19 Vaccinations that Have Been Authorized or Licensed by the Food and Drug Administration

^{38 85} FR 52136

³⁹ September 3, 2020 HHS *Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act*. Available at: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf.

⁴⁰ 85 FR 52136

⁴¹ September 3, 2020 HHS Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19

⁴² October 20, 2020 HHS *Guidance for PREP Act Coverage* for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing. Available at: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf

⁴³ 85 FR 79190

⁴⁴ Id.

⁴⁵ The Fourth Amendment does not amend the requirements for pharmacy technicians to administer vaccines.

⁴⁶ 85 FR 79190

The following requirement was added: "The licensed pharmacist and the licensed or registered pharmacy intern must 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)."

Thus, as of the date of publication of the Fourth Amendment on December 9, 2020, the requirements for administration of vaccines by pharmacy personnel are set forth in the table below:

<u>Pharmacists</u>	Pharmacy Interns	<u>Pharmacy</u> Technicians	
	Vaccination must be	Vaccination must be	
	Ordered by	Ordered by	
	supervising	supervising	
	pharmacist.	pharmacist.	
	Supervising	Supervising	
	pharmacist must be	pharmacist must be	
	readily and	readily and	
	immediately	immediately	
	available ⁴⁷	available	
Vaccine must be	Vaccine must be	Vaccine must be	
authorized,	FDA-authorized or	FDA-authorized or	
approved, or	FDA-licensed.	FDA-licensed.	
licensed by the FDA.			
Childhood vaccine	Childhood vaccine	Childhood vaccine	
must be ordered and	must be ordered and	must be ordered and	
administered per	administered per	administered per	
ACIP's standard	ACIP's standard	ACIP's standard	
immunization	immunization	immunization	
schedule.	schedule.	schedule.	
COVID-19 vaccine	COVID-19 vaccine	COVID-19 vaccine	
must be ordered and	must be ordered and	must be ordered and	
administered	administered	administered	
according to ACIP's	according to ACIP's	according to ACIP's	
COVID-19 vaccine	COVID-19 vaccine	COVID-19 vaccine	
recommendation(s).	recommendation(s).	recommendation(s).	
Must have	Must complete ACPE	Must complete ACPE	
completed	practical training	practical training	
immunization	program (including	program (including	
training to order and	injection technique,	injection technique,	
administer vaccines.	recognition/Tx of	recognition/Tx of	
	emergency	emergency	
	reactions, etc.).	reactions, etc.).	

⁴⁷ The Guidance only lists this requirement for pharmacy technicians. Presumably this was an oversight, and the requirement applies equally to pharmacy interns.

Pharmacists	Pharmacy Interns	Pharmacy	
<u> </u>	Thatmacy meeris	Technicians	
Must have a current	Must have a current	Must have a current	
certificate in basic	certificate in basic	certificate in basic	
cardiopulmonary	cardiopulmonary	cardiopulmonary	
resuscitation.	resuscitation.	resuscitation.	
Must complete minimum of 2 hours		Must complete minimum of 2 hours	
of ACPE-approved,		of ACPE-approved,	
immunization-		immunization-	
related CE per licensing period.		related CE per licensing period.	
Must comply with SC	Supervising	Supervising	
recordkeeping/repor	<u>pharmacist</u>	<u>pharmacist</u>	
ting requirements	responsible for	responsible for	
(notice to PCP,	compliance with SC	compliance with SC	
vaccine registry,	recordkeeping/repor	recordkeeping/repor	
adverse events,	ting requirements.	ting requirements.	
review of vaccine			
registry prior to			
administering, etc.).			
Must inform	Must inform patients	Must inform patients	
childhood patients	18 and under and	18 and under and	
and adult caregiver	adult caregiver of	adult caregiver of	
of the importance of	the importance of a	the importance of a	
a well-child visit with	well-child visit with a	well-child visit with a	
a pediatrician/other	pediatrician/other	pediatrician/other	
PCP and refer as	PCP and refer as	PCP and refer as	
appropriate	appropriate	appropriate	
Must comply with	Supervising	Supervising	
any applicable	pharmacist must	pharmacist must	
requirements (or	comply with	comply with	
conditions of use) in (CDC) COVID-19	provider agreement and any other	provider agreement and anv other	
(CDC) COVID-19 vaccination provider	and any other federal law.	and any other federal law.	
agreement and any	ieueidi idw.	reuerdi idw.	
other federal			
requirements that			
apply to			
administration of			
administration of			

Individuals who satisfy these requirements may order (pharmacists) and administer (pharmacists, pharmacy interns, and pharmacy technicians) certain vaccines to certain patients as set forth above.

4. **CONCLUSION**

COVID-19 vaccine(s).

Hopefully, this article has offered some clarity as to the state of the law on vaccinations by pharmacy personnel at the state and federal levels. Readers should keep in mind that the requirements for administration under the PREP Act are a matter of federal law. The Board cannot opine as to how a federal agency, or a court, would interpret these requirements. Also, it is important to recognize that as a new administration has taken office, the federal

Declaration and its Amendments could change significantly, or not at all. Therefore, it is especially important to regularly monitor actions taken by the new HHS Secretary and the Office of General Counsel. Furthermore, the General Assembly will consider multiple COVID-related items this legislative session. These items could, of course, modify South Carolina law. The Board will monitor relevant legislation that may be filed in the General Assembly and provide updates, as appropriate.

Additionally, the Board would encourage all licensees and registrants to make sure they have upto-date medications, supplies, and equipment required to respond to an adverse reaction. The Board would also encourage all licensees and registrants to review the December 10, 2020 Revised Protocol, as it includes a requirement to stock an additional required medication, as well as additional required supplies and equipment, to administer vaccines pursuant to the Protocol.

Finally, the Board would like to recognize and thank its licensees and registrants. They are often the tip of the spear when it comes to frontline healthcare workers. They have displayed outstanding professionalism and have worked tirelessly to offer continued care for their patients in the midst of a global pandemic. Now, they have an opportunity to help lead the way when it comes to administering the vaccination that will hopefully end it. Again, the Board offers its thanks and support for its licensees and registrants.