AN ONGOING CE PROGRAM
of the University of Connecticut
School of Pharmacy

EDUCATIONAL OBJECTIVES

After completing the continuing education activity, pharmacists and pharmacy technicians will be able to

- Describe the history and extension of the PREP Act and what the 12th Amendment of the PREP ACT authorizes pharmacists, pharmacy interns, and pharmacy technicians to do.
- Explain why pharmacy personnel are essential for providing immunization and testing for COVID-19.
- Review techniques for COVID-19 testing and inactivated immunization of those 3 years and older.

The University of Connecticut School of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Pharmacists and pharmacy technicians are eligible to participate in this application-based activity and will receive up to 0.125 CEU (1.25) contact hours) for completing the activity, passing the post-test with a grade of 70% or better, and completing an online evaluation. Statements of credit are available via the CPE Monitor online system and your participation will be recorded with CPE Monitor within 72 hours of submission

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To obtain CPE credit, visit the UConn Online CE Center https://pharmacyce.uconn.edu/login.php. Use your NABP E-profile ID and the **session code 25YC05-ABC23 for pharmacists or 25YC05-CAB48 for pharmacy technicians** to access the online quiz and evaluation. First-time users must pre-register in the Online CE Center. Test results will be displayed immediately and your participation will be recorded with CPE Monitor within 72 hours of completing the requirements.

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TO REGISTER and PAY FOR THIS CE, go to: https://pharmacyce.uconn.edu/program_register.php

You Asked for It! CE

LAW: The Pharmacy Implications of the PREP Act Extension

TARGET AUDIENCE: Pharmacists and pharmacy technicians who want or need to know the specific of the federal PREP Act extension through 2029.

ABSTRACT: Vaccines are a very important public health measure to prevent disease and/or severe disease and death, depending on the vaccine. Pharmacies are becoming more recognized as the optimal place patients receive vaccines. Recent estimates suggest that pharmacy staff administers 64% of adult influenza vaccines and almost 90% of all COVID-19 vaccines. As illnesses and deaths from COVID-19 continue to occur as do concerns over strain of the healthcare system during COVID-19 waves, the Secretary of the Health and Human Services has extended the duration of the 12th Amendment of the Public Health and Readiness (PREP) Act to December 31, 2029. The Act provides liability immunity to covered persons (pharmacists, interns, technicians) against claims of loss related to the administration or use of designated medical countermeasures. This authorization covers pharmacists to order and administer, and pharmacy interns and qualified pharmacy technicians to administer under the supervision of a pharmacist, COVID-19 and seasonal influenza vaccines and COVID-19 tests. The authorization also covers pharmacists to prescribe nirmatrelvir/ritonavir tablets (Paxlovid).

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FACULTY DISCLOSURE: The faculty have no financial relationships with an ineligible company.

DISCLOSURE OF DISCUSSIONS of OFF-LABEL and INVESTIGATIONAL DRUG USE: This activity may contain discussion of off label/unapproved use of drugs. The content and views presented in this educational program are those of the faculty and do not necessarily represent those of the University of Connecticut School of Pharmacy. Please refer to the official prescribing information for each product for discussion of approved indications, contraindications, and warnings.

INTRODUCTION

If you've heard it once, you've probably heard it a dozen or more times: pharmacists are the most accessible healthcare resource. Most people live close to a pharmacy. A 2022 study reported 89% of persons in the United States (U.S.) live within five miles of a pharmacy and all but 3% are within 10 miles.[1] Despite being this accessible, pharmacies are closing in record numbers.[2,3] These closures are creating pharmacy deserts—communities in which residents must travel farther to access the nearest pharmacy to fill prescriptions—in communities in urban

centers or with Black and Latine (see **SIDEBAR** to the right) populations most at risk.[2,3]

Vaccines are one of the most successful interventions in public health in our generation. Worldwide, vaccines have prevented 154 million deaths since 1974.[4] In the U.S., routine childhood vaccinations provided to children born between 1994 and 2023 have had an impressive impact. Within this population, they have saved $540 billion in direct costs and prevented more than 500 million illnesses, 32 million hospitalizations, and 1.1 million deaths.[5]

Immunizing for Influenza and COVID-19

Influenza and coronavirus disease 2019 (COVID-19) vaccines are examples of vaccines whose primary goal is to prevent severe disease and death. Influenza vaccine specifically has shown to decrease risk of intensive care admission (odds ratio [OR] = 0.74 (95% confidence interval [CI]: 0.58-0.93)) and death (OR = 0.69 (95% CI 0.52-0.92) among adults hospitalized with influenza disease.[6] An odds ratio less than 1.0 indicates a protective effect; therefore an OR of 0.74 indicates the influenza vaccine reduces the risk of an intensive care admission by 26%, and an OR of 0.69 indicates 31% less risk of death when hospitalized with influenza disease. The CI reflects there is 95% confidence the true risk of an intensive care admission is reduced by 7% to 42%, and the risk of death is reduced by 8% to 48%. In the first year of use, primary COVID-19 vaccination prevented 14.4 million deaths.[7] The 2023-2024 booster vaccines provided 51% and 36% effectiveness against hospitalization for the seven to 79 days post-vaccination in healthy non-immunocompromised and immunocompromised patients. Unfortunately, vaccine efficacy wanes significantly by four to six months in all people, but especially in the immunocompromised, explaining the recommendations for boosters.[8]

Pharmacists, pharmacy technicians and interns, and pharmacies have become the most relied-upon resources for obtaining recommended vaccines, especially the COVID-19 and influenza vaccines. Sixty-eight percent of COVID-19 vaccines from September 2022 to September 2023 were administered in a pharmacy.[9] More recently, these numbers have risen, with data showing that pharmacists provided 90% (23.5 million doses) of the 26.1 million doses of COVID-19 vaccines from August 31 through November 30, 2024.[10] Data shows similar trends for adult influenza vaccinations at pharmacies, with growth from 49% in 2019 through 2020 steadily increasing each year; initial estimates (through November 2024) indicate that for the 2024-2025 season report, pharmacies have administered 64% of influenza vaccines.[11]

Pharmacy's response to the COVID-19 pandemic has amplified the pharmacist's and pharmacy technician's value and accessibility to providers, policymakers, and the public. Expanding the pharmacist's clinical functions will only become more critical as the physician workforce continues to shrink through the coming decades. According to the Association of American Medical Colleges (AAMC), the U.S. is projected to face a physician shortage of up to 86,000 physicians by 2036, with the most significant shortage expected in primary care specialties.[12]

SIDEBAR: Latine or Latinx?

Americans have used many terms to describe individuals or groups who live in the United States and have Latin American roots. Traditionally, the word "Latino" has been used to describe males or males and females, and sometimes "Latina" has been used for females. The most widely used term, however, was "Hispanic" and included people of Spanish origin (i.e., from Spain). Several years ago, the term Latinx emerged as a gender-neutral, more inclusive term. Language, however, evolves, and some people with Latin American origins objected to the inclusion of the letter X. Older languages in Latin America did not include the letter X. Colonists forced indigenous people to add X into languages during the conquest. Its pronunciation is odd or unnatural in many dialects.

While Latinx is currently used more frequently in the academic literature, the term Latine is becoming more commonly accepted in the community. For the purposes of this continuing education activity, they are interchangeable.

More than Immunizations

Beyond immunizing, the pandemic revealed the pharmacist's valuable contributions involving point-of-care testing and follow-up care through treatments not only for COVID-19, but also for influenza, urinary tract infections, HIV, and contraceptives. The Centers for Disease Control and Prevention (CDC) recognized pharmacy's contributions during the COVID-19 pandemic by stating, "The COVID-19 pandemic has demonstrated needed roles for the community pharmacist in an emergency, including continuity of provision of medications, providing preventive services, and ensuring health equity. Along with medication management, pharmacists provide infectious disease mitigation, point-of-care testing, and vaccinations."[13]

The COVID-19 pandemic resulted in an excess burden of mortality in at-risk populations, precipitated by racial and ethnic disparities in health care access and use. While, as stated, 89% of Americans live within five miles of a pharmacy, heightened awareness of newly emerging pharmacy deserts in Black and Latine communities resulting in higher risk of morbidity and mortality disparities is needed.[1,3] Health Affairs published a pharmacy closure study in December 2024. It revealed that independent pharmacies were at greater risk for closure than chain pharmacies across all neighborhood and market characteristics. The authors hypothesized that independent pharmacies in predominantly Black and Latine neighborhoods would be at greatest risk for closure because they are more likely than chain pharmacies to serve populations insured through Medicaid or Medicare. The reason is that Medicaid and Medicare incentivize patients to use preferred pharmacy networks managed by phar-

macy benefit managers. Because preferred networks often exclude independent pharmacies, this policy limits patient volumes and profits of independent (nonpreferred) pharmacies, thus potentially increasing their risk for closure. This may have created previous health disparities and may potentially exacerbate future disparities by worsening access and lowering adherence rates to medications and other therapies.[2,3]

PUBLIC READINESS AND EMERGENCY PREPAREDNESS (PREP) ACT

The Public Readiness and Emergency Preparedness (PREP) Act is not new. Initially approved by Congress in 2005 and signed by then-President George W. Bush in 2005. The PREP Act authorizes the Secretary of Health and Human Services (HHS) to limit legal liability for losses relating to the administration of medical countermeasures such as diagnostics, treatments, and vaccines. In a declaration effective February 4, 2020, the Secretary of HHS invoked the PREP Act and declared COVID-19 to be a public health emergency warranting liability protections for covered countermeasures. The PREP Act is currently on its 12th amendment.[14] The PREP Act defines a "covered person" to include licensed health professionals and other individuals authorized to prescribe, administer, or dispense covered countermeasures under state law, and other categories of persons identified by the Secretary in a PREP Act declaration.[14-16]

The April 2020 amendment to the Act provided pharmacists federal authority to order and administer FDA-authorized COVID-19 tests. The August 2020 Amendment to the PREP Act (the amendment process is discussed below) expanded the definitions of covered diseases and covered persons. It expanded the categories of disease representing a public health emergency to include diseases resulting from "the decrease in the rate of childhood immunizations, which will lead to an increase in the rate of infectious diseases." This allowed pharmacists to prescribe and administer, and interns to administer vaccines in accordance with the Advisory Committee for Immunization Practices (ACIP) to children 3 through 18 years old.[14-16]

In the fall of 2020, the Secretary of HHS modified the Act twice more. In August, it added COVID-19 vaccines to the vaccines pharmacists and interns were permitted to administer. In September, notably, for the first time it included pharmacy technicians in the authority provisions, allowing them to administer childhood and COVID-19 vaccines to those aged 3 years and older. A year later, in August and September of 2021, the Act extended authorization covering pharmacy interns and technicians to administer seasonal influenza vaccination for those 19 years and older as recommended by ACIP. It also authorized pharmacists to prescribe and administer specific COVID-19 therapeutics, such as monoclonal antibodies, and interns and technicians to administer these products.[14-16] In July 2022, another amendment added the authority for pharmacists to prescribe nirmatrelvir/ritonavir tablets (Paxlovid).[14,16]

As a public health crisis resolves, the PREP Act is amended to eliminate provisions no longer deemed necessary. HHS declared the Public Health Emergency was no longer in effect as of May 11, 2023, however COVID-19 was deemed to still present a "credible risk of a future public health emergency." As the COVID-19 emergency was no longer at its peak, the 11th Amendment in May 2023 began to decrease the authority of pharmacists, interns, and technicians. Specifically, the 11th Amendment of the PREP Act extended authority through December 31, 2024, but the authorization would only allow pharmacists to order and administer, and pharmacy interns and technicians to administer COVID-19 and seasonal influenza vaccines to age 3 and over and COVID-19 tests. The authorization no longer covers all childhood vaccines but continues to allow pharmacists to prescribe nirmatrelvir/ritonavir tablets.[15]

Is the PREP Act Still Needed?

COVID-19 continues to cause significant illness and death and considered to present a credible risk of a future public health emergency. In 2024, the CDC's COVID Data Tracker reported between 300 and 2500 deaths from COVID-19 each week.[17] Congress delegated the ability to amend the PREP Act to the HHS Secretary. This motivated Xavier Becerra, the then HHS Secretary, to issue the 12th amendment to the PREP Act in December 2024.[14] Effective January 1, 2025, it was amended to continue PREP Act coverage through December 31, 2029, barring any change from the HHS Secretary. This extension granted by the 12th amendment to the PREP act allows pharmacists, pharmacy interns, and technicians to continue providing essential services for seasonal influenza and COVID-19.[14] These services include allowing pharmacists to prescribe and administer seasonal influenza and COVID-19 vaccines for those as young as 3 years of age (see **SIDEBAR** on the next page) in line with the ACIP recommendations (see **Table 1** on page 5). They still have the authority to prescribe nirmatrelvir/ritonavir tablets.[18] Pharmacy interns and pharmacy technicians are also authorized under the Act to provide these two immunizations to these patients under the pharmacist's supervision.

SIDEBAR: What's Magic about Age 3?[20,21]

The PREP Act authorized administration of inactivated vaccines in children as young as 3 years of age. The minimum age of 3 years old was chosen because that is the age at which the vaccine administration process is the same as that employed for adults. Before age 3, the thigh is the preferred site because of the greater muscle mass.

Specifically, as these shots are all inactivated vaccines, the preferred site of administration, beginning at age 3 years, is the deltoid muscle. When administering inactivated vaccines, immunizers should inject them at a 90-degree angle into the deltoid muscle, avoiding the top 1/3 of the muscle and staying above the armpit. It is important to landmark the deltoid and use the recommended vaccine needle size to ensure efficacy and prevent shoulder injury related to vaccine administration (SIRVA).

The HHS Secretary decides to amend or declare the PREP Act based on a variety of factors. HHS gathers expert advice and public health data and assesses legal considerations by consulting with relevant stakeholders before issuing a declaration or amendment. The HHS Secretary must consider the many variables involved encouraging the use of countermeasures (interventions that help prevent or slow the spread of disease). These include the design, clinical testing, manufacturing, labeling, marketing, purchase, donation, dispensing, licensing, prescribing, and administering of the countermeasure. A determination of a public health emergency is different than a PREP Act declaration. If HHS determines a public health emergency exists, HHS can waive certain Medicaid, Medicare, State Children's Health Insurance Program (CHIP), and Health Insurance Portability and Accountability Act (HIPPA) requirements. A PREP Act declaration may be made in advance of a public health emergency and may provide liability immunity for activities both before and after a declared public health emergency.

Public Health Emergencies vs PREP Act Declarations

A public health emergency determination or other emergency declaration is only required for immunity under the PREP Act if this is explicity stated in the declaration.[18] Therefore, when it is determined that there is no longer concern for significant COVID-19 related illnesses, it is likely that the Secretary of HHS will sunset this provision as well. Thus, it is important that pharmacists, pharmacy interns, and pharmacy technicians continue to advocate for expansion of their immunization authority. This advocacy, specifically in states where full immunization authority is absent, will enhance immunization care to patients in need.

PAUSE AND PONDER: What vaccines does your state authorize pharmacists, pharmacy interns, and pharmacy technicians to provide and are there vaccine or age restrictions?

In addition to the vaccination authority, the Act continues to allow pharmacists to prescribe and administer, and for interns, and technicians to administer under the pharmacist supervision, COVID-19 tests.[14] Multiple types of COVID-19 tests are able to be used in the pharmacy. It is important for all immunizers and support staff to review the instructions on the specific tests carried in the pharmacy. Many tests (e.g., antigen, nucleic acid amplification tests [NAATs]) require nasal or nasopharyngeal sampling, but some NAAT tests may require oropharyngeal, sputum, or saliva sampling.[19] Importantly, the Act continues to provide liability protection for those who provide these services (i.e. vaccines, tests) per the recommendations.[14]

ADULT VACCINATION UPTAKE POOR, PEDIATRIC RATES DECREASING

Although the 11th amendment of the PREP Act in May 2023 removed federal authority for pharmacists to provide routine childhood vaccines (other than seasonal influenza or COVID-19), many states have worked to expand their state laws to provide these authorities. As of January 2025, only one state, Delaware, does not authorize pharmacists to provide any vaccines to children under its state laws.[15,22-24] Currently, 42 states provide pharmacists authority to administer routine vaccines beyond influenza and COVID-19 to children younger than 12 years old. At this time, 36 states allow vaccines other than COVID-19 and influenza to be administered by a pharmacist to children 7 years of age or younger.[22-30] Many states currently have no minimum age for pharmacists to provide childhood vaccines. Further, pharmacists in most states can provide many routine vaccines to adults. It is important that pharmacists continue to educate and advocate for timely vaccination of children and adults and provide an accessible way for patients to easily obtain these vaccines, when authorized.

PAUSE AND PONDER: How do you routinely advocate and provide immunizations to patients? How could you improve?

Many adults do not know that they should receive any vaccines. Data from 2022 demonstrates that only 22.8% of adults received appropriate immunizations for age including influenza. Further concerning is that Black and Latine populations reported lower rates at 12.1% and 17%, respectively.[31] When rates associated with individual vaccines were analyzed, tetanus vaccination in the past 10 years (59.2% of all adults) and pneumococcal vaccination in those 65 years and older (64%) were the highlights, having the best coverage. Some significant deficits included pneumococcal vaccination for high-risk adults (23%) and a single dose of recombinant zoster vaccination of individuals 50 years and older (25.6%).[31] These data provide yet another reason to continue efforts to educate adult patients within your practice that they may need vaccines.

(Text continues on the bottom of page 5)

Table 1. PREP Act Requirements for Pharmacists, Pharmacy Interns, and Pharmacy Technicians[14,18]

Provider Type	Pharmacists	Pharmacy Interns	Pharmacy Technicians
Vaccine authorization	Order and administer an FDA* authorized or approved COVID-19 or seasonal influenza vaccine to those 3 years of age and older that aligns with ACIP/CDC recommendations	Administer an FDA* authorized or approved COVID-19 or seasonal influenza vaccine to those 3 years of age and older that aligns with ACIP/CDC recommendations and under the pharmacist's supervision	Administer an FDA* authorized or approved COVID-19 or seasonal influenza vaccine to those 3 years of age and older that aligns with ACIP/CDC recommendations, and under the supervision of a pharmacist who is immediately available
Training required	Completed an immunization training course (i.e., injection techniques, application of vaccine indications and contraindications, recognition and management of vaccine reactions) that is at least 20 hours and approved by ACPE	Complete a practical immunization training course (i.e., injection techniques, application of vaccine indications and contraindications, recognition and management of vaccine reactions)	
License and CPR requirements	Must be and maintain license or registration by their state board of pharmacy. Must have current CPR certification		
COVID-19 additional requirements	Comply with conditions of use in the COVID-19 provider agreements and other COVID-19 vaccine requirements		
Education requirements	Two-hours of immunization related continuing education (ACPE accredited) in each state licensing period	N/R	N/R
	Follow record keeping, reporting, and documentation requirements per local/state/federal Requirements	N/R	N/R
Parental / caregiver information required	Educate parents/caregivers of the children being vaccinated of importance of well-child visit with their primary healthcare provider	N/R	N/R

ABBREVIATIONS: ACIP = Advisory Committee on Immunization Practices; ACPE = Accreditation Council for Pharmacy Education; CDC = Centers for Disease Control and Prevention; CPR = cardiopulmonary resuscitation; FDA = Food & Drug Administration; N/R = None required

*FDA authorized COVID-19 vaccines: Novavax for those 12 years and older, Moderna and Pfizer BioNTech for those 6 months through 11 years. FDA approved COVID-19 vaccines: Moderna and Pfizer BioNTech for those 12 years of age and older.

PAUSE AND PONDER: What can you do in your pharmacy to provide education to adult individuals about their needs for vaccinations?

Unfortunately, vaccine misinformation is rampant and has led to many children not receiving the vaccines they need. Survey data from those entering kindergarten suggests that overall immunization rates have dropped from 95% just a few years ago to overall 93%.[32] Some parents are either avoiding some or all vaccinations or spacing them beyond what is recommended. This has been noted by a large increase in vaccine exemptions for children.[32-34] States and localities generally establish vaccination requirements for school attendance. They also develop conditions and procedures for exemptions from vaccine requirements, timeframes for submitting documentation, and conditional registration for students who need more time to be vaccinated. In the

2023-2024 academic year, 3.3% of children who prepared to enroll in kindergarten had at least one vaccine exemption. Thirty states had exemption rates higher than this with Idaho reporting 14.3% of children with at least one vaccine exemption. Of note, 93% of these exemptions were nonmedical in nature.[32] Readers can find the exemption rates for their own states here in Figure 1: https://pmc.ncbi.nlm.nih.gov/articles/PMC11486350/

It is a problem when many individuals decide not to be vaccinated or to not have their children vaccinated, because when a community no longer maintains a high percent of a population protected (generally considered at least 90%), the population loses herd immunity.[35] Without herd immunity protecting a community population, the community will be susceptible to outbreaks of these vaccine preventable diseases.

Measles is a prime example of this phenomenon. Measles is a very contagious infection that requires about 95% of a population to be vaccinated to prevent spread in a community.[36] Recent data suggests that the percent of children entering kindergarten receiving two doses of MMR vaccination dropped below 95% (at 93.9%) in 2021-2022 and further decreased to 92.7% in 2023-2024.[32,34] We have begun seeing increases in measles cases again, with 284 cases (40% requiring hospitalization) reported in 2024.[35,37]

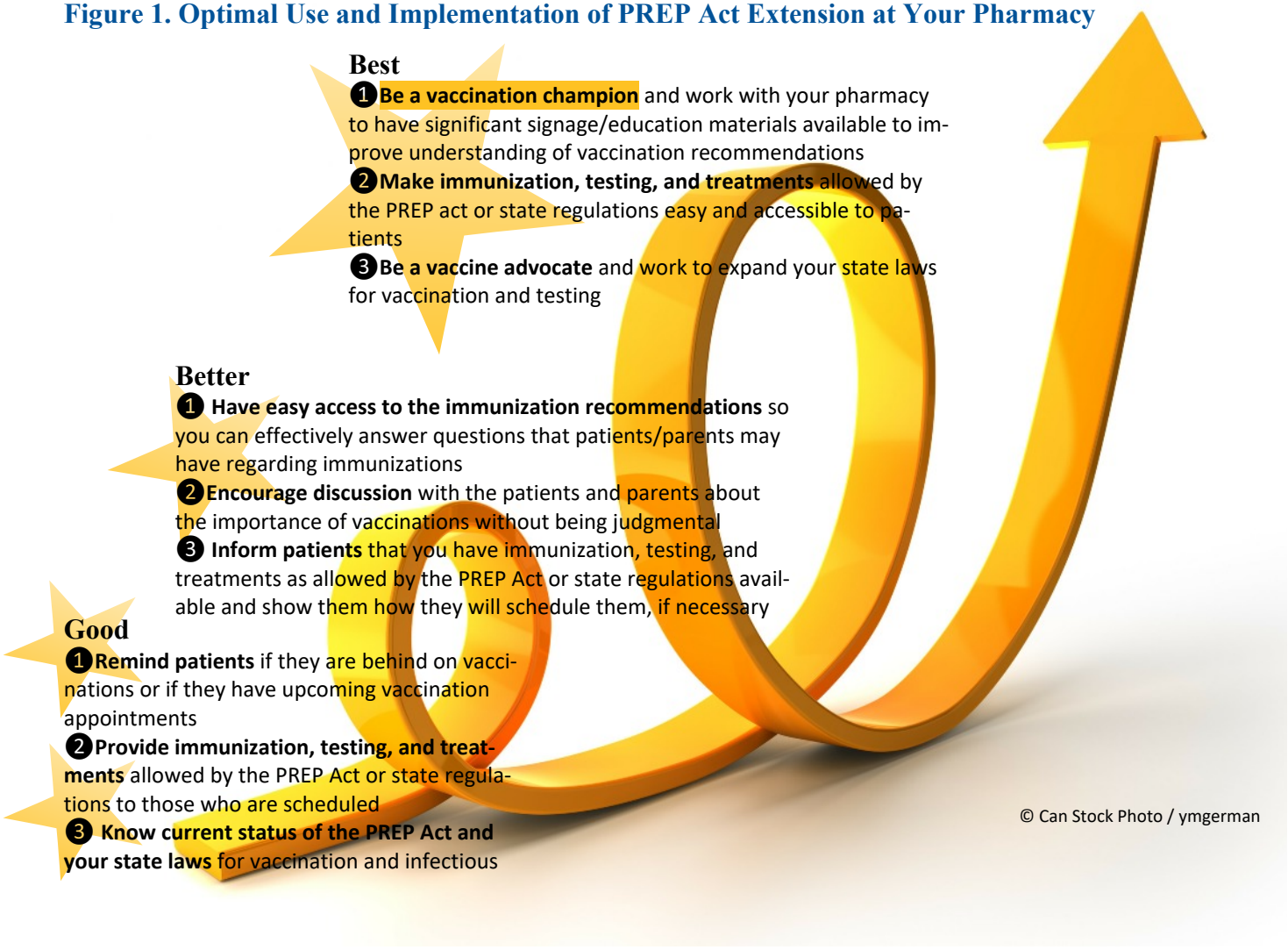
The percentage of the population that needs to be vaccinated to achieve herd immunity depends on the disease, and is often at or above 90%. While herd immunity for measles requires about 95% of the population to be vaccinated, for polio the threshold is about 80%. It may take several years to determine herd immunity for a specific disease, and it will likely vary according to the community, the vaccine, the populations prioritized for vaccination, and other factors.

CONCLUSION

The December 2024 12th amendment of the PREP Act provided liability immunity for pharmacists, pharmacy interns, and pharmacy technicians to continue to provide COVID-19 and influenza vaccination and testing and treatment for COVID-19. The age at which these two immunizations have been expanded by the Act is for those 3 years and older. This age was chosen for these inactivated vaccines as the administration route is the same as it is for adults (i.e., intramuscular in the deltoid). Effective January 1, 2025, the 12th Amendment of the PREP Act Declaration was extended to continue coverage through December 31, 2029.

It is essential to have pharmacy personnel continue to advocate and provide easily accessible vaccines as pharmacists are the most accessible healthcare providers, as a pharmacy is within five miles of nearly 90% of the population. However, a potentially significant health disparity is developing as decreasing access is occurring due to pharmacy closures, especially independent pharmacies and those in Black and Latine communities. Policy makers should consider strategies to increase the participation of independent pharmacies in Medicare and Medicaid preferred networks managed by pharmacy benefit managers and to increase public insurance reimbursement rates for pharmacies that are at the highest risk for closure.

Figure 1. Optimal Use and Implementation of PREP Act Extension at Your Pharmacy



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