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WYOMING STATE BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Expanding Role of Pharmacy Technicians

By Kristina Zaharas, PharmD Candidate

During the past year, pharmacists, interns, and technicians have truly stepped up to the meaning of the phrase, "pharmacists are the most accessible health care providers." They have been on the front lines of the pandemic providing relief with education and vaccinations, helping communities navigate these trying times and begin returning to a sense of normalcy.

Guidance for technicians being able to vaccinate was issued under the Public Readiness and Emergency Preparedness Act (PREP Act) for the coronavirus disease 2019 (COVID-19) public health emergency in the United States. This guidance authorizes qualified pharmacy technicians, under the supervision of a pharmacist, to administer Food and Drug Administration (FDA)-authorized or FDA-licensed COVID-19 vaccinations to persons ages three or older, and to administer FDA-authorized or FDA-licensed Advisory Committee on Immunization Practices-recommended vaccines to persons ages three through 18, according to the standard childhood immunization schedule.

The Office of the Assistant Secretary for Health requires pharmacy technicians to satisfy several requirements before being considered a qualified person to vaccinate, as defined under 42 US Code §247d-6d(i)(8)(B). Requirements for technicians to vaccinate are as follows:

- The technician must have an active CPR certification
- The technician must complete a practical training program that is approved by the Accreditation Council for Pharmacy Education (ACPE)
- The technician must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during the state licensing period

Although COVID-19 vaccination rates in Wyoming have slowed down over the past few months, it is not too late for technicians to become authorized to vaccinate and further help their pharmacy

and community. Options for practical training programs that are ACPE accredited include the American Pharmacists Association's Pharmacy-Based Immunization Administration by Pharmacy Technicians and the National Pharmacy Technician Association's Immunization Administration Training Program. The training program chosen "must include hands-on injection technique and recognition and treatment of emergency reactions to vaccines."

In March 2021, the US Department of Health and Human Services made a seventh amendment to the Declaration under the PREP Act, stating that qualified individuals, which include pharmacy technicians, are approved to administer COVID-19 and childhood vaccinations until October 1, 2024, unless the Declaration of Emergency gets terminated sooner. The latest PREP Act amendment in early August allows technicians to administer flu vaccines. The Wyoming State Board of Pharmacy is in the process of working with the legislature about the possibility of permanently allowing technicians in the state of Wyoming to administer vaccinations and expanding the scope of the vaccines they can give. Adopting this change would improve the workflow in pharmacies and further improve the accessibility of vaccines to the public, as allowing technicians to administer limited vaccines has already proven invaluable to pharmacies around the state during these unprecedented times.

Vaccine Hesitancy

By Aaron Lawson, PharmD Candidate

The COVID-19 pandemic has caused significant disruption to our personal and professional lives. While we initially knew very little about the virus, as time has passed, much more complete and useful information has become available. Despite the information that we now know about the virus, there are many people who remain hesitant about obtaining a COVID-19 vaccine.

There are many reasons for this hesitancy, ranging from concerns about the completeness of trial data to the spread of misinformation. While the data behind the vaccines shows that they are largely safe and effective, the fact remains that they are currently being administered under an emergency use authorization (EUA). An EUA is used during public health crises to facilitate the availability of potentially lifesaving therapies. To grant an EUA, FDA requires data to show that a product **may** be safe and effective, but for full approval, the data need to show that the product **is** safe and effective. In August 2021, Pfizer's COVID-19 vaccine was granted full FDA approval. As of press time, Moderna has applied for and is seeking full FDA approval of its vaccine, and Johnson & Johnson is expected to apply later in 2021.

Full approval of these vaccines would mark the first time that a vaccine with this mechanism of action has been approved for use in humans. The Moderna and Pfizer COVID-19 vaccines employ a different mechanism of action than most other vaccines. They encapsulate mRNA within lipid particles, allowing the mRNA to be delivered into the cell. Once inside the cell, the mRNA is used to produce a protein, and is then destroyed. The Johnson & Johnson vaccine works differently, by inserting a replication-incapable viral particle into the cell to produce the protein. The proteins

produced by the vaccines are then expressed on the outside of the cell, where the immune system can recognize and destroy it.

The immune system is also capable of remembering the specific proteins that the vaccines cause to be expressed. This means that getting vaccinated is associated with a lower likelihood of getting an infection, as well as better outcomes if an infection does occur. A severe case of COVID-19 can result in significant morbidity as well as death. Heart and lung scarring, blood clots, and neurological problems are common consequences of severe infection. While immunity is gained from having an infection, vaccine-generated immunity is not associated with the same morbidity.

Despite the clear benefits of getting vaccinated, it can sometimes be difficult to assure patients and their guardians that the COVID-19 vaccines are safe and effective ways to prevent a potentially devastating disease. It is important to build good relationships with your patients and listen to the concerns that they raise. Once you understand their concerns, you can address them using the available evidence. It may also be beneficial to explain the vaccine's EUA to your patients, and to assure them that the vaccines being administered have been held to very high standards. Inform your patients that these vaccines have been shown to be safe and effective at preventing infection and severe cases of disease, and that side effects are typically mild. Keep in mind that there will still be some patients who do not wish to get vaccinated, but every person vaccinated means fewer severe cases and deaths.

New Sterile Compounding Inspection Process

A new sterile compounding inspection process will be implemented starting this current fiscal year (July 1, 2021-June 30, 2022). All sterile compounding inspections will now be completed in two phases. The first phase will consist of a virtual pre-inspection, and the second phase will include an unannounced on-site inspection.

The virtual pre-inspection will consist of a comprehensive review of policies, records, and documentation. All pharmacists-in-charge (PICs) will be notified of the virtual pre-inspection and provided 30 days to compile and submit all required information. The intent of the virtual pre-inspection is to prevent interruptions in daily operations that typically occur while reviewing such records on site.

Once the virtual pre-inspection is complete and reviewed with the designated person, inspectors will follow up with a random, unannounced on-site inspection. This second phase will consist of completing the associated retail or institutional inspection checklists and observation of processes, techniques, and adherence to procedures. Please be advised that staff must be observed performing compounding activities in order to complete the second phase of the inspection process. If compounding is not being performed on that day, inspectors will request staff to simulate sterile compounding activities.

As a reminder, effective May 13, 2021, Governor Mark Gordon approved Wyoming Pharmacy Act Rules and Regulations, Chapter 17: Sterile Compounding. All designated persons should review and become familiar with the Board's rules on sterile compounding. PICs may request a self-inspection checklist that inspectors will utilize for the pre-virtual and on-site inspection. The Board strongly encourages licensees to complete the self-inspection checklist and fix any noted discrepancies beforehand to facilitate a smooth inspection process.

PICs will also have the option to submit additional information in order to complete the retail/institutional portion of the inspection in the two-phase approach outlined above.

Compliance Corner: Focus of Inspections

The focus of inspections during fiscal year 2021-2022 includes, but is not limited to, the following:

- auditing controlled substance (CS) prescriptions for compliance with Wyoming Statute 35-7-1030 and the Wyoming Controlled Substances Act Rules Chapter 10;
- promoting self-inspections as a best practice;
- physical inspection of prescription files, including non-CS;
- checking for outdated medications, vaccines, and compounding components;
- review of immunization protocol and comparison to emergency kit configuration;
- documentation of training and compounding competencies for compounding staff (sterile and nonsterile); and
- compliance with compounding record-keeping and labeling requirements (sterile and nonsterile).

For retail pharmacies, the inspectors will be moving toward a system that allows discretion as to how often pharmacies are inspected. Inspections will be no more than two years in between compliant pharmacies and a minimum of once yearly for noncompliant pharmacies.

NCDQS QAS Accreditation Recognized by the Board

At the June 16-17, 2021 Board meeting, the Board recognized the National Coalition for Drug Quality & Security (NCDQS) Quality and Security (QAS) Accreditation Program.

Rutledge v. Pharmaceutical Care Management Association

By Jerry Withers III, PharmD Candidate

It is no secret that community pharmacies cannot survive indefinitely solely on the filling and dispensing of prescriptions. Pharmacy benefit managers (PBMs) set maximum allowable cost (MAC) lists for drugs that they base their insurance reimbursements on. The MAC can often be less than what it costs the pharmacy to acquire the drug, making the pharmacy lose money each time it is dispensed.

In 2015, Arkansas passed Act 900 to address the trade practices of PBMs that were contributing to pharmacy closures. The act required PBMs to allow pharmacies to access MAC lists, update the lists in a timely manner, create an appeal process for unfair MACs, and decline services if a PBM's reimbursement is less than the acquisition cost. PBMs immediately fought the act. Their argument was that low reimbursement rates meant there would be additional savings that could be passed down to the individual insurance beneficiaries.

The Pharmaceutical Care Management Association (PCMA) represents the 11 largest PBMs in the US and insurers including Humana, Express Scripts, OptumRx, and more. In an attempt to overturn the statute, PCMA filed a lawsuit claiming that the act was preempted by the Employee Retirement Income Security Act of 1974 (ERISA). PCMA's argument was that states are preempted from passing laws that potentially affect employee-sponsored benefit plans due to ERISA.

The US District Court for the Eastern District of Arkansas found that ERISA preempted some portions of the act, making the act invalid. The US Court of Appeals for the Eighth Circuit affirmed that ERISA preempted Act 900 and that Medicare Part D also preempted it. PCMA had argued that ERISA preempts "any and all state laws insofar as they may now or hereafter relate to any employee benefit plan."

The lawsuit was ultimately brought before the US Supreme Court and, in December 2020, the Supreme Court unanimously agreed that ERISA did not preempt Arkansas Act 900 and overturned the previous decision made by the court of appeals. Act 900 does not have impermissible relationships with ERISA, nor does it apply exclusively to ERISA plans. Act 900 works by cost regulation as opposed to decreased benefits for patients. The decision by the Supreme Court validated Act 900 and allowed it to be enforced within the state of Arkansas.

This helps create a fairer and more transparent environment for community pharmacies in Arkansas, but time will tell how this will affect the long-term operation of these community pharmacies. Opponents of the act, mainly PBMs, claim that higher reimbursement rates will lead to higher costs for drug plans, employers, and beneficiaries. Proponents claim that the trade practices of PBMs are unfair due to higher reimbursement rates for PBM-affiliated pharmacies than independent pharmacies.

Arguably, this act is more of a win for independent local pharmacies than it is for the large corporate pharmacies. While this act is limited to the state of Arkansas and does not affect pharmacies in the state of Wyoming, Wyoming has many small communities that rely on the services of small local pharmacies. Other states are considering similar legislation and the Wyoming Legislature's Joint Labor, Health and Social Services Committee has formed a working group to look more into this issue.

Recent Disciplinary Action

M.A., Pharmacist License #3363: As PIC, allowed a technician-in-training to work on an expired permit. Required to pay an administrative penalty of $1,000, to submit a plan for preventing unlicensed practice in the future, and complete three hours of continuing education on the topic of pharmacy law, in addition to the annual requirement. (Total earned in 2021 must be 15 hours.)

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