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"Legal Considerations: Technician Supervision"

February 2014

Each year we present at least one lesson relevant to some sort of legal consideration & its impact on pharmacy practice. It is speculated that technician responsibilities will increase in the coming years. This is a good thing. At the same time, liability may increase—both to the pharmacist & to the technician. In this lesson it is our goal to take a look at this issue. This lesson provides 3.0 hours (0.3 CEUs) of credit, and is intended for pharmacists in all practice settings.

The objectives of this lesson are such that upon completion the participant will be able to:

- 1. List functions permitted for technicians.
- 2. Discuss practice system design.
- 3. Comment upon regulatory hazards.
- 4. Relate appropriate technician use for judgment.
- 5. Describe the increased responsibilities that technicians will be taking in the future.



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INTRODUCTION

Pharmacist responsibilities are expanding into new areas of clinical care, and the recent passage in some states of legislation that authorizes provider status for pharmacists will underscore the importance of this expansion of patient-oriented practice. At the same time, pharmacists remain responsible for the distribution of pharmaceutical products, and there is no suggestion from anyone that this traditional and important product-oriented role will be in any way diminished. Future pharmacists will split their time between responsibilities for products and responsibilities for patients. Pharmacists will have more responsibilities in the future, and they will be challenged to address the problem of how to manage a profession for which there are greater expectations. This is a disheartening reality to face, but it is one that must be accepted, and solutions must be found.

Expecting pharmacists to simply work harder is not necessarily a realistic solution. Working smarter is the key. Pharmacists are already working as hard as they can, and there is no question that pharmacists are highly qualified and highly motivated to produce excellent results from their existing efforts. System improvement is a better alternative to rhetoric urging pharmacists to be more efficient in the management of their time. The "fat" that may have existed in pharmacy work schedules at one time has already been eliminated. There is not much more productivity to be squeezed from pharmacists without a change in the way things are done within pharmacy practice systems.

One suggestion for system change is the expanded use of pharmacy technicians to occupy some of the professional space that pharmacists have traditionally accepted as their own responsibility. This suggestion has the potential to relieve pharmacists from some of the technical aspects of the profession that do not require the judgment of a person who has been trained at the doctoral level. On the other hand, this is a suggestion that has the potential to expose pharmacists to legal consequences for the errors made by their supportive pharmacy technicians. It is important for pharmacists that they allow pharmacy technicians to control only those aspects of medication distribution that the pharmacist knows the technician not be attributed to a supervising pharmacist who could not have prevented the error.

THE UNCOMFORTABLE LANDSCAPE OF CHANGE

The potential for expansion of pharmacy practice was highlighted in an article published in the prestigious journal *Health Affairs* in November, 2013. The authors, all pharmacists, are Lucinda Maine, Katherine Knapp, and Douglas Scheckelhoff. They emphasize the need to fully utilize pharmacy technicians in a meaningful supportive role if pharmacists are to fulfill their potential as patient-oriented health care professionals.

In a pertinent section the article notes that: "Today technicians routinely assist in outpatient and inpatient prescription dispensing, enter medication orders into information systems, compound sterile and nonsterile preparations, and manage pharmacies' inventory. To a growing extent, technicians are also taking on other roles, such as medication safety and quality assurance; optimizing the use of technology; checking the work of other pharmacy technicians; and participating in medication reconciliation, including compiling medication lists, collecting other information, and scheduling patients' clinic visits. These services free pharmacists from administrative tasks, giving them more time for direct patient care."

Yet there is a note of caution amidst the enthusiasm the authors are expressing toward the

future of pharmacy. That caution relates to the inconsistency with which pharmacy technicians are trained, and the inability of pharmacists to rely on pharmacy technician credentialing to provide a level of certainty that any particular technician is capable of providing the level of competent service that is needed in a specific situation on any given day.

By way of contrast with inconsistent technician training, the training of pharmacists is standardized. A person who works with a pharmacist can know that a pharmacist colleague has demonstrated knowledge and skill in areas of pharmacology, pharmaceutics, medicinal chemistry, clinical pharmacy, social/behavioral pharmacy, and pharmacy law. The accreditation standards for pharmacy education require that these subjects be learned. Examinations are administered to applicants for licensure, and a person cannot become a pharmacist without showing competence in these areas. While some pharmacists are better than others, and some pharmacists are specialists while others are generalists, their basic training is the same. The competence of a licensed pharmacist is assured from state to state across the country.

Regarding the challenge of pharmacy technician qualifications, the article notes:

"Regulatory requirements for pharmacy technicians' training, certification, and registration or licensure are established by each state and vary widely. Most states require that technicians be certified, which requires passing an examination. However, other states have minimal or no requirements. In these states technicians are often trained on the job by their employer. Still other states require that technicians complete an accredited training program and demonstrate their competence before they can work with medicines."

"In addition, the duties that certified technicians can perform vary across states. So does the required pharmacist-technician ratio, which means that in some states technicians need less supervision than in other states."

"There are limited data on how current pharmacy technicians were trained. However, surveys have consistently indicated that fewer than 15 percent of the technicians working in hospitals have completed an accredited training program and that most were trained on the job. There continues to be a need for a single standard for education, training, certification, and registration or licensure for technicians."

GOVERNMENT APPROACHES TO CREDENTIALING

The people within a society, through their government representatives, have the power to legally designate some members of that society as persons who are authorized to perform particular functions, and to forbid others to perform those functions. This is an expression of public trust that grants a monopoly to designated occupations and professions, with the expectation that those occupations and professions will serve the public honestly and competently. For example, pharmacists have traditionally been given the authority to distribute medications, to monitor medication use, and to conduct patient counseling aimed at improving the therapeutic value of medications. A person who does these things without the legal authority to do them has committed a crime. There are various ways in which a government may designate a person as qualified for an occupation, and these ways include licensure, registration, and certification.

Pharmacists are among those who are granted a license to practice their profession by the state in which they practice. A license is given to a person who has completed a prescribed

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course of education and has demonstrated knowledge and skill by passing a licensure exam. In most states, a license may be renewed only if the completion of continuing education requirements can be demonstrated. A licensed person who commits an act that is inconsistent with the public interest can be disciplined by the licensing agency, to include the possible revocation of the person's license if the violation is severe. Licensure is the most robust of the credentials awarded by government to specially trained individuals.

Registration is a government credential that may have very few criteria, if any. Unfortunately, the designation "Registered Pharmacist" is misleading in that pharmacists are not registered; they are licensed. The purpose of registration is to identify and track an individual from one place to another through a government maintained "paper trail" of employment. When the government requires registration for a particular occupation, employers may only employ registered individuals, and the requirement of registration creates the possibility for a subsequent employer to identify and contact a previous employer. If a registrant has engaged in inappropriate behavior during previous employment, future employment can be denied. A registrant who engages in illegal behavior can also be de-registered and cannot be employed again within that occupation.

Certification is a non-governmental credential that is usually based on minimal criteria (such as age and residency) and the successful completion of an exam and/or experiential training. This credential can be confusing, because some state governments defer to non-government certification groups, requiring that an occupation be practiced only by one who is privately certified by the group. In this way, the government escapes the need to create a separate bureaucracy to administer the credentialing process, but the government is dependent on the private certification group to develop and maintain standards that will adequately protect the public from incompetent or dishonest practitioners.

The status quo for pharmacy technician credentialing is a combination of the unregulated open market, registration, certification, and licensure. This may be a difficult situation for pharmacists who must increasingly rely on technicians to meet critical responsibilities under a pharmacist's supervision. The reality that pharmacists may be held legally liable for a technician error increases the frustration felt by pharmacists who necessarily must relinquish control over activities they cannot possibly supervise due to time constraints, yet are required to account for the performance of others who engage in those activities. Since the government is not consistently assuring the competence of pharmacy technicians at present, supervising pharmacists must accept responsibility for technician oversight.

LESSONS LEARNED FROM CHALLENGES IN PRACTICE

It is now well recognized that dispensing errors are usually the result of system deficiencies that set up pharmacists to fail. If you put a good pharmacist into a bad system, the system will cause errors.

On the other hand, pharmacists are part of the system and they have the responsibility to improve the system when that can be done, and perhaps to remove themselves from the system if the system is so flawed that patient safety is a major concern. This is an important lesson that can be taken from the case of Ohio Pharmacist Eric Cropp, whose widely publicized error led to enactment in Ohio of a law that establishes expanded qualifications for pharmacy technicians. According to reports of the incident, Pharmacist Cropp failed to detect a pharmacy technician error that led to the death of a patient who was administered a chemotherapy solution that was supposed to contain 0.9% sodium chloride but in fact contained over 20%.

Here is how Michael Cohen of the Institute for Safe Medication Practices described the incident: "When Eric Cropp came to work on the day of the event, he learned that the pharmacy computer system was down and his assistant in the preparation area for intravenous (IV) solutions was a pharmacy technician who, according to press reports, was also planning her wedding on the day of the event and, thus, distracted while working. With the pharmacy computer system down, a backlog of physician orders had developed, creating incredible time pressures for Eric. A nurse had also called requesting the chemotherapy solution (for the young child who died) immediately, which ultimately may not have been warranted. This added more time pressures to Eric's workload. According to a witness at the state board hearing, the chemotherapy was not needed until much later that afternoon. Testimony at the board hearing also uncovered that Eric was working short-staffed that day and had no time for normal work breaks."

"Eric did not make the error himself. Still, he did not notice that the technician made the error when he checked her work. Such an error is crucial, but we have no knowledge of how Eric missed the technician's preparation error other than the fact that he is human and thus prone to human fallibility. I have no doubt that the work pressures and working conditions mentioned above played a significant role. But the price of that error was ever so costly: a little girl named Emily Jerry received an incredibly high amount of sodium chloride. After receiving the chemotherapy later that day, she suffered a terrible headache and thirst, and she soon lapsed into a coma and died."

What makes this case particularly problematic from a pharmacy perspective is that Pharmacist Cropp was criminally indicted, despite no evidence that he intended any harm to the patient. He pled guilty and was sentenced to 6 months in jail. Not only did he lose his pharmacy license, he lost his freedom. And the basis of these losses was the failure to detect a pharmacy technician error within a dysfunctional system that set up the pharmacist for failure.

THE PHARMACIST'S SUPERVISORY RESPONSIBILITY

Unfortunately, the legal requirements for pharmacist supervision of pharmacy technicians reflect the practice environments of years ago, when prescription volume was significantly less than it is today and job stress was manageable. In the busy pharmacies of contemporary practice, it is difficult to supervise pharmacy technicians at the level that state laws appear to require. It is impractical for pharmacists to look over the shoulder of a pharmacy technician every minute of every workday.

An example of a legal standard for pharmacist supervision of pharmacy technicians is found within the Florida Pharmacy Act. Most states have similar language in their laws. The Florida law states: "A person other than a licensed pharmacist or pharmacy intern may not engage in the practice of the profession of pharmacy, except that a licensed pharmacist may delegate to pharmacy technicians who are registered pursuant to this section those duties, tasks, and functions that do not fall within the purview of [the practice of the profession of pharmacy]. All such delegated acts shall be performed under the direct supervision of a licensed pharmacist who shall be responsible for all such acts performed by persons under his or her supervision."

There are three very important aspects of this typical state law. First, it is each pharmacist's

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responsibility to decide what tasks to delegate to technicians. If a pharmacist does not feel confident that a technician can perform any particular task safely, in the best interest of patients, then the task should not be delegated to that technician. Second, "direct supervision" is required of all delegated tasks performed by pharmacists. While this requirement does not mean standing by the technician's side and reviewing all work done while it is being done, the requirement does require physical presence in the place where the technician is working, and the ability to answer questions asked by the technician. It also requires that pharmacists perform a final check of all work done by a technician. Third, the law apparently imputes responsibility for technician error to the supervising pharmacist. This is the most challenging aspect of the law. Under one possible interpretation of the language of the law, pharmacists share with technicians the responsibility for technician error, even if a pharmacist has no way to discover that an error has been made.

Under the law, pharmacy technicians are expected to support the professional activities of pharmacists, but not to infringe on those professional activities. The limits of what a pharmacy technician may do are not always clearly defined in state laws. New Jersey law is typical of state restrictions imposed on the activities of pharmacy technicians. The New Jersey law states: "Pharmacy technician means an individual working in a pharmacy practice site who, under the immediate supervision of a pharmacist, assists in pharmacy activities as permitted by this act and the rules and regulations of the board that do not require the professional judgment of a pharmacist."

This typical state law (most other states have similar language to that contained in New Jersey law) begs the question: "What acts require the professional judgment of a pharmacist?" It requires judgment to distinguish between a tablet and a capsule, but is this "professional" judgment? The same question can be asked about the distinction between two drugs with look-alike and sound-alike names, recognizing that a patient is a child rather than an adult, and reading on the computer screen that only two days ago the patient received a 30-day refill of a drug that has been newly prescribed today. These are important matters that require human decision-making skills, but they do not necessarily require a pharmacist's judgmental expertise. So the challenge for pharmacists in the interpretation of such a law is to determine how to allow technicians to use human judgment, but preserve for pharmacists the exercise of professional judgment.

It is not surprising that many pharmacists express a high level of frustration with the ambiguity of laws regarding pharmacy technician supervision. Equally frustrating are the legal consequences of being held responsible for a technician error after a regulatory agency concludes that a pharmacist did not supervise technicians appropriately. State laws challenge pharmacists to develop a systematic approach to pharmacy technician supervision, within the constraints imposed by the state laws and the realities of often hectic pharmacy practice sites.

FROM FRUSTRATIONS TO SOLUTIONS

To address frustrations found in ambiguous state laws, and to find solutions that will better meet the needs of patients, pharmacists may wish to reconsider how to best utilize pharmacy technicians. Under some circumstances, within allowable limits established by state laws, pharmacists may be in a position to handoff to technicians some responsibilities that require human judgment, but do not require the professional judgment of a pharmacist. A solution of this sort would be found through collaboration with management and with support of the state board of pharmacy. A review of pharmacist legal mandates provides insight on how this might happen.

- <u>The Accuracy Mandate</u>. The foundational legal responsibility of pharmacists is to accurately process prescriptions. Patients must receive the right drug, in the right strength, in the right dosage form, with the right directions for use. Technicians contribute significantly to this role already. In most states, pharmacists must perform the final check of every prescription to assure the accuracy of the technician who processed the prescription. But studies suggest that a technician performing the final check may be equally as accurate. It may be possible to adopt so-called "tech-check-tech" practices in some states, with permission of the state board of pharmacy. If this were done, the pharmacy, and not the pharmacist, would be held responsible for any error that did not involve pharmacist review.
- <u>The Efficiency Mandate</u>. The health care system is under considerable pressure to reduce costs while maintaining quality. One area in which cost reduction is stressed is in the use of less expensive generic products rather than more expensive branded products. Traditionally it has been the pharmacist to whom the law has assigned responsibility for decisions about generic substitution, but this may now be an appropriate role for pharmacy technicians. Since the FDA publishes an easy-to-use reference list of therapeutically equivalent generic drug products, it may be time to shift responsibility for generic substitution to pharmacy technicians, and relieve pharmacists of liability for errors made in this relatively simple role.
- <u>The Accessibility Mandate</u>. One of the strengths of the pharmacy profession is that pharmacists are easily available to the public. The law requires that pharmacists be readily identifiable in community practice, with their names and licenses posted for public information. The hours that pharmacists work are not confined to the eight-to-five block that most clinics are open. Unfortunately, pharmacists are sometimes too accessible to the public. Distractions caused by patients who want attention from a pharmacist can lead to errors if the pharmacist is in the middle of a professional task that requires concentration. Technicians can play a critical role by being the first contact for patients in a busy practice setting, answering questions that do not require a pharmacist's attention, and politely explaining that the pharmacist will be available when other responsibilities have been met.
- <u>The Individuality Mandate</u>. Each patient is unique. In recognition of the special needs of every patient, pharmacists have been given the responsibility to provide patient counseling when it is appropriate to do so. Yet there are some elements of counseling that are relevant for all patients receiving a medication, despite the recognized differences between patients. For broadly applicable information that should be told to everyone receiving a medication, pharmacy technicians may be appropriate patient educators. For example, telling a patient that a medication may cause drowsiness, or that a medication should be taken before mealtime with a full glass of water, does not necessarily require the professional judgment of a pharmacist. When a patient requires individualized counseling, a pharmacist can be made available on request of a technician. But it may not be necessary for a pharmacist to provide all counseling at all times for all patients. Technicians can provide general patient counseling information when patient individuality is not an issue.
- The Safety Mandate. When prescribers make mistakes, the pharmacist's responsibility is to

contact the prescriber for consultation and correction. This is a relatively new safety role for pharmacists. It has developed over the past 25 years. Prior to that time, pharmacists were responsible only for accurate order processing, even if the order contained a prescriber's error. Sometimes errors are so obvious that it is not necessary for a pharmacist to make the contact with a prescriber. The contact person at the prescriber's office may have little or no medical training, and a pharmacy technician may be the most appropriate person to initiate contact with the prescriber's office. For example, consider a patient who has been prescribed a drug for many years with directions to take one tablet daily. If the prescriber's office sends to the pharmacy a new prescription that suddenly increases the dose to four times daily, this dramatic change suggests that a clerical error has occurred. A pharmacy technician can quickly clarify the intent of the prescriber's office. A pharmacist should be available for more extensive discussion if the circumstances require it, but there is no need for a pharmacist to initiate every call to a prescriber's office.

The Quality Mandate. As pharmacists move into roles that focus on improving the quality of patients' drug therapy, they will need assistance from pharmacy technicians in gathering information necessary to provide high quality care. Technicians can ask basic screening questions and administer brief surveys to patients who seek clinical care from pharmacists. This assistance could be appropriate for immunizations, medication therapy management, and primary pharmacist care. All decisions about patient care must be made by a pharmacist, but activities such as HIPAA compliance, the maintenance of patient care records, and scheduling for appropriate follow-up care can be done by a pharmacy technician.

PRACTICE SYSTEM DESIGN

The complexity of modern pharmacotherapy, combined with the volume of patients to take care of in every pharmacy, have led to obsolescence of the pharmacy practice model in which a pharmacist can accept responsibility for personally participating in all activities that occur within each pharmacy. The successful pharmacist of the future will be responsible for designing a practice system that works for that pharmacist at the pharmacist's practice site, and for assuring that the activities done by all people within the system are done as well as they can be done, given the enormous challenges of the medication use process.

Pharmacy technicians are a critical component of any pharmacy practice system, and the successful pharmacist must be able to understand when technicians are competent and when they are not. This includes detecting situations in which pharmacy technicians lack the skills necessary to provide adequate support of the pharmacist. Establishing a culture of learning and collaboration in a pharmacy can encourage technicians with skill deficiencies to request assistance and perhaps additional training. Just as is the case with pharmacists, learning is a lifelong pursuit for pharmacy technicians. Supervising pharmacists must be prepared to provide just-in-time training on the job. When a deficiency is detected, there is no time like the present to conduct a friendly and productive educational correction. Pharmacy technicians should clearly understand that there is no such thing as a "stupid question." Any pharmacist who embarrasses or disparages a technician for asking a question will discover that mistakes have increased because inquiries have been discouraged.

The job duties of pharmacy technicians are usually well delineated in a pharmacy practice

system. What pharmacists must do is discover whether technicians possess the skills necessary to appropriately perform those duties. These are some of the technician skills that should be measured by a pharmacist who is designing a practice system for success:

- Vision. Can the pharmacy technician see at close range and at a distance, sufficient to interpret prescription orders and distinguish one patient from another?
- Listening. Can the pharmacy technician understand the spoken word and recognize the important aspects of what is being spoken?
- Speaking. Can the pharmacy technician convey information and ideas effectively?
- Writing. Can the pharmacy technician use the written word to communicate accurately?
- *Reasoning.* Can the pharmacy technician identify potential problems, evaluate those problems, and bring them to the attention of a person who is qualified to address them?
- Reading Comprehension. Can the pharmacy technician understand the significance of what she or he has read?
- Learning. Does the pharmacy technician welcome opportunities to learn, and can the pharmacy technician apply lessons taught?
- Social Skills. Does the pharmacy technician relate well to other people and treat them with dignity and respect?
- *Time Management*. Does the pharmacy technician prioritize efforts with a primary focus on those activities that are of greatest importance?
- Selflessness. Does the pharmacy technician understand that the purpose of pharmacy practice is to serve the needs of others to the best of one's ability?

A PRACTICE CHECKLIST

The pharmacist's responsibility for technician supervision is ongoing. Every time a pharmacist begins to serve patients, it is important to assure that support personnel at the practice site are adequate to promote satisfactory outcomes for patients. Particularly for pharmacists who are practicing within a relatively unfamiliar setting, it can be useful to review a brief checklist to assure a level of comfort with the support staff that has been provided. This checklist is in many ways similar to the specifications used by the captain of an airplane prior to deciding that it is safe for a commercial flight to takeoff.

Items that could be included in a pharmacist's checklist are:

- Do I have sufficient numbers of pharmacy technicians to meet the needs of my practice setting?
- Are the pharmacy technicians made available to me adequately trained and experienced to provide competent support?
- Do the pharmacy technicians have a sense of the high level of responsibility they have to perform at the highest level of ability?

- Do the pharmacy technicians appreciate the importance of their role and the limits of their responsibilities?
- Does the work environment stress the importance of teamwork and collaboration?

CONCLUSION AND CAUTION

The expansion of pharmacy practice into new areas of patient care will necessitate the elevation of pharmacy technician roles. Pharmacists can't do everything. They need support from technicians, not only with order processing but with patient care as well. Pharmacists who find they can't let go of traditional responsibilities and become effective supervisors of technicians who fulfill traditional pharmacist roles, will be at a disadvantage as compared with pharmacists who embrace the supervisory function.

On the other hand, pharmacists will discover that as they expand their responsibilities, coordination with management and regulatory agencies will be critical. Many new roles that seem appropriate for pharmacy technicians are already authorized under state laws but are being resisted by some pharmacists. Other new roles must be validated by boards of pharmacy as being within the framework of pharmacy technician authority. Still others will require new legislation. The boards of pharmacy will find themselves in a difficult predicament if they increase expectations of pharmacists without also increasing the responsibility of pharmacy technicians. This is a challenge that can only be met through close collaboration between practicing pharmacists, pharmacy management, and pharmacy regulators. It is important to realize that it is not a matter of criticizing, but an opportunity to embrace technicians with increased training & responsibilities.

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2.	In the article by Lucinda Maine et.al., what roles ar described as technician roles to a growing extent? A. Medication safety B. Quality assurance C. Check work of other technicians D. All of these		 7. According to the Lucinda Maine et.al. article, surveys have consistently indicated that fewer than 15% of the technicians working in hospitals have completed an accredited training program. A. True B. False
3.	In the Lucinda Maine article, how do the authors characterize regulatory requirements for technicia training, certification, & registration or licensure? A. Established by each state & vary widely B. Established by each state & there is little variation C. Established by a federal agency & there is little variation D. Established by colleges of pharmacy & vary widely	IN	 8. Under New Jersey law, what type of judgment may not be delegated to a technician by a pharmacist? A. "Professional" judgment B. "Human" judgment C. "Personal" judgment D. "Scientific" judgment 9. The foundational responsibility of pharmacists is to assure that patients receive the right drug, in the right strength, in the right dosage form, with the right directions. These responsibilities represent the legal
4.	Under Florida law, direct supervision is required by pharmacist of a pharmacy technician. A. True B. False		arections. These responsibilities represent the legal mandate of "accuracy."? A. True B. False 0. Which of these pharmacy technician skills should
5.	What error did Pharmacist Eric Cropp personally make that led to his being held criminally liable for harm to a patient? A. He diluted chemotherapy B. He "over-anticoagulated" a patient C. He overdosed a patient D. None. Technician made the error.		a pharmacist measure in designing a pharmacy practice system for success? A. Listening B. Reasoning C. Learning D. All of these

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