



EMILY'S LAW: OHIO PHARMACY TECHNICIANS AND THEIR EMPLOYERS FACE NEW STATE REGULATIONS

Ohio Senate Bill 203, known as Emily's Law, imposes new regulations on Ohio pharmacy technicians and their employers. Emily's Law was signed into law by Governor Strickland on January 7, 2009. Emily's Law is named in memory of Emily Jerry, a child who died as a result of a dosing error made by a pharmacy technician that was not detected by her supervising pharmacist (who was recently sentenced to six months in prison for his mistake). The law specifies criteria for the qualification of pharmacy technicians and establishes criminal penalties for "unauthorized" pharmacy-related activities unless a person is a pharmacist, pharmacy intern, or qualified pharmacy technician. Emily's Law also establishes criminal penalties for managers and employers of nonqualified pharmacy technicians.

REGULATED ACTIVITIES

Ohio law previously did not license pharmacy technicians or regulate the activities of pharmacy workers

other than pharmacists. Emily's Law, which went into effect on April 8, 2009, mandates that only pharmacists, pharmacy interns, or qualified pharmacy technicians who are working in a pharmacy may compound drugs, package or label drugs, or prepare intravenous drugs. Certain health professionals who are authorized to engage in the above pharmacy-related activities in the course of their professional practice (e.g., physicians) and students in a pharmacy technician training program are exempted from compliance with Emily's Law.

QUALIFICATION CRITERIA FOR PHARMACY TECHNICIANS

Emily's Law defines a "qualified pharmacy technician" as someone who:

- is at least 18 years old;
- has a high school diploma or a certificate of high school equivalence, or was employed prior to the effective date of this section as a pharmacy

- technician without a high school diploma or a certificate of high school equivalence;
- has passed a competency examination approved by Ohio's State Board of Pharmacy; and
- has submitted to a criminal background check that indicates that the person does not have a felony on record.

Emily's Law does not, however, require that qualified pharmacy technicians be certified, registered, or licensed by Ohio's State Board of Pharmacy (the "Board").

PHARMACY TECHNICIAN RULES

The Board has recently published final Pharmacy Technician Rules (the "Rules"). The Rules provide for two types of Board-approved examinations for qualified pharmacy technicians, define the requirements for a qualified pharmacy technician training program, and describe the process for the criminal background check. The Board is still in the process of establishing the procedure for the criminal background check procedure. To this end, the Board has proposed a new regulation for the Ohio Administrative Code (*i.e.*, OAC 4729-4-04: Criminal Records Check for Qualified Pharmacy Technicians). Until the proposed regulation is adopted by the Board, applicants are instructed to follow the criminal background check procedure summary and the proposed new regulation language provided by the Board on its web site (<http://pharmacy.ohio.gov/whatsnew.htm>).

Examinations. The first type of Board-approved examination is an examination provided by a national pharmacy technician certification program that is accredited by the National Commission for Certifying Agencies, which at present are the Pharmacy Technician Certification Board and the Institute for the Certification of Pharmacy Technicians. The other type of Board-approved examination is an examination that is created by an employer that meets the Board's requirements and standards for acceptable examinations. The Board lists the minimum competencies that an employer examination must address, including:

- Applicable employer practice areas;
- Pharmacy terminology;
- Basic drug information;

- Basic calculations;
- Quality control procedures; and
- State and federal laws, rules, and regulations regarding (i) qualified pharmacy technician duties; (ii) pharmacist duties; (iii) pharmacy intern duties; (iv) prescription or drug order processing procedures; (v) drug record-keeping requirements; (vi) patient confidentiality; (vii) security requirements; and (viii) storage requirements.

A minimum score of 75 percent is required to pass an employer examination. Further, upon the Board's request, an employer must submit the examination procedures, materials, and results for the Board's review and approval. The Board's approval of an employer-created examination applies to that employer only.

Training Programs. Under the Rules, the minimum competencies that must be addressed by a pharmacy technician training program are identical to those required by an employer examination. The Rules also provide that a criminal background check shall be performed by the Ohio Bureau of Criminal Identification and Investigation ("BCI&I") and shall consist of both a BCI&I criminal records check and a Federal Bureau of Investigation ("FBI") criminal records check. Under proposed regulation OAC 4729-4-04, applicants for the background check must provide electronic fingerprint impressions at a designated WebCheck (BCI&I and FBI) provider located within the state of Ohio.

TIMEFRAME FOR COMPLIANCE

Pharmacy technicians who were employed as of April 8, 2009, have until April 7, 2010, to pass an approved examination. Pharmacy technicians employed after April 8, 2009, have 210 days following the initial date of employment to pass an approved competency examination, provided that the person (i) is participating in or has completed a pharmacy technician training program that meets the Board of Pharmacy's standards, (ii) is preparing to take an approved competency examination, and (iii) does not have a felony on record. If a pharmacy technician has already completed a pharmacy technician training program at a vocational school district or joint vocational school district, the person is not required to undergo further training during the 210-day

period. Emily's Law allows multiple attempts to pass the examination throughout the 210-day time period, but the criminal background check results are final and immediate, and any person who fails to clear the criminal background check is immediately prohibited from working as a pharmacy technician.

“GRANDFATHERING” PROVISIONS

Any person employed as a pharmacy technician as of April 8, 2009, may continue to work as a pharmacy technician until he or she passes an approved competency examination by April 7, 2010, or fails the requisite criminal background check, which should be initiated immediately. If a pharmacy technician has been with the same employer for more than five years, he or she will have to pass an approved examination by April 7, 2010, but is not required to submit to the criminal background check.

PENALTIES AND FINES

Under Emily's Law, a pharmacy technician who engages in unauthorized pharmacy-related activities without becoming a qualified pharmacy technician is guilty of “pharmacy-related drug conduct,” which is a second degree misdemeanor. A second offense involving unauthorized pharmacy-related drug conduct is a misdemeanor of the first degree, and a third or subsequent offense is a felony of the fifth degree.

Any pharmacist or person who owns, manages, or conducts a pharmacy who allows any person employed or otherwise under the control of the pharmacist to violate Emily's Law is guilty of permitting unauthorized pharmacy-related drug conduct, which is a misdemeanor of the second degree. Permitting unauthorized pharmacy-related drug conduct is a misdemeanor of the first degree on a second offense and a felony of the fifth degree on a third or subsequent offense.

Finally, Emily's Law allows the Board to impose fines commensurate with the criminal offense on violators of the law. For example, under Ohio Revised Code § 2929.28 and §2929.18, a second degree misdemeanor may carry a fine

of up to \$750, and a fifth degree felony may carry a fine of up to \$2,500. Any fines that are collected will be used to subsidize the Board's law enforcement efforts that pertain to drug offenses.

UNRESOLVED COMPLIANCE ISSUES

Until Emily's Law is enforced, there remain a number of unresolved issues regarding compliance and enforcement of the law. For example, if an unauthorized practice occurs in a hospital pharmacy, it is unclear whether liability extends beyond the pharmacist on duty to the director of pharmacy or even to the hospital itself. In a chain drug store, it is unclear whether the liability rests with the pharmacist on duty, the individual store manager, or the entire corporation (or a combination thereof). Further, unanswered questions remain regarding escalating penalties for repeat violations. For example, do multiple people engaged in unauthorized practices in the same pharmacy constitute a second offense or two separate first offenses? Similarly, if there are unauthorized practices in different stores of the same chain, is that a second offense or two separate first offenses? Culpability appears to be based upon knowledge of the unauthorized practice, meaning that the courts will need to resolve alleged violations based upon the facts of a particular case. Therefore, many of these questions regarding compliance with Emily's Law may not be resolved until the law is enforced.

PRACTICAL TIPS

Given the serious nature of the fines and penalties, all persons who practice in the field of pharmacy in the state of Ohio need to undertake steps to ensure compliance with the requirements of Emily's Law and its related regulations. Employers of pharmacy technicians should establish and implement policies and procedures aimed at complying with such requirements, including ensuring that all pharmacy technicians are appropriately qualified, documenting evidence of such qualification, creating or adopting examinations for pharmacy technicians, creating or adopting training programs for pharmacy technicians, and establishing procedures for ensuring appropriate criminal background checks

are performed on pharmacy technicians. Employers who choose to provide examinations must establish procedures that ensure the security and integrity of the examination materials, describe the testing format, and define the successful completion of an examination. The law also requires employers to maintain examinations and scores of all pharmacy technicians who successfully passed an examination for a minimum of three years following the termination of employment. Most employers will likely want to roll their Emily's Law compliance efforts into their existing compliance programs.

LAWYER CONTACTS

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