SB3336

LRB09916220MLM40549b

99TH GENERAL ASSEMBLY

State of Illinois

2015 and 2016

SB3336

Introduced 2/19/2016, by Sen. Dale A. Righter

SYNOPSIS AS INTRODUCED:

225 ILCS 85/18a new

Amends the Pharmacy Practice Act. Requires pharmacies to establish and maintain a quality assurance program designed to prevent dispensing errors as well as a process designed to detect and identify dispensing errors. Requires pharmacies to commence an investigation into any detected dispensing errors within 2 days after the date the dispensing error is discovered. Requires that if an investigation into a dispensing error indicates that the dispensing error is attributable, in whole or in part, to the pharmacy or its personnel, that a quality assurance review be performed. Provides requirements for the quality assurance review and its records. Provides that the records of the quality assurance review shall not be subject to discovery in any arbitration, civil, or other proceeding, except in certain circumstances. Effective 12 months after becoming law.

LRB099 16220 MLM 40549 b

A BILL FOR

AN ACT concerning regulation.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 5. The Pharmacy Practice Act is amended by adding Section 18a as follows:

(225 ILCS 85/18a new)

Sec. 18a. Quality assurance program.

(a) For purposes of this Section:

"Dispensing error" means any preventable event that may cause or lead to inappropriate medication use or patient harm. Such events may be related to professional practice, health care products, procedures, and systems, including: prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. "Dispensing error" does not include any act or omission that is corrected prior to furnishing the drug to the patient or the patient's agent.

"Essential cause examination" means a process for identifying the basic or causal factors that underlie the occurrence or possible occurrence of a dispensing error. An essential cause examination focuses primarily on systems and processes, not individual performance. It progresses from

special causes in the dispensing process to common causes in organizational processes and identifies potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future or determines, after analysis, that no such opportunities for improvement exist.

(b) Each pharmacy shall establish and maintain a quality assurance program designed to prevent dispensing errors.

(c) Each quality assurance program shall be described in written policies and procedures maintained in the pharmacy and shall be reviewed by the licensee and revised, if necessary, prior to application for renewal of the pharmacy's license. The policies and procedures shall include directions for communicating the details of the dispensing error to the patient, caregiver, prescriber, and other members of the health care team as appropriate. This communication shall also describe methods for correcting the dispensing error and reducing its negative impact on the patient.

(d) Each quality assurance program shall include a process designed to detect and identify dispensing errors. An investigation of each dispensing error shall commence as soon as is reasonably possible, but no later than 2 business days after the date the dispensing error is discovered. If the investigation indicates that the dispensing error is attributable, in whole or in part, to the pharmacy or its personnel, a quality assurance review shall be performed.

(e) The quality assurance review shall include

investigation of the dispensing error and completion of an essential cause examination of the dispensing error. A written record of the quality assurance review shall be retained in the pharmacy. The written record shall contain at least the following:

(1) the date of, location of, and participants in the quality assurance review conducted;

(2) the record of the facts relating to the dispensing error;

(3) the essential cause examination;

(4) the findings and determinations generated by the quality assurance review;

(5) changes to pharmacy policy or procedure made pursuant to the quality assurance review, if any; and

(6) activities undertaken with the patient or health care providers to mitigate the dispensing error.

The pharmacy shall inform all pharmacy personnel of any changes in pharmacy policy or procedure made pursuant to a quality assurance review.

(f) Records relating to activities undertaken as part of a quality assurance review for dispensing errors that occurred in the pharmacy, including, but not limited to, investigation or confirmation of a dispensing error, shall be maintained and immediately accessible in the pharmacy for at least 5 years from the date those records were created. The Department may review quality assurance records in an individual pharmacy as

necessary to protect the public health and safety, as determined by the Department, or if fraud is alleged by a government agency with jurisdiction over the pharmacy.

(g) Neither the proceedings nor records of a pharmacy's quality assurance program shall be subject to discovery in any arbitration, civil, or other proceeding, except as provided in subsection (f) of this Section. No person in attendance at a meeting of a pharmacy's quality assurance committee shall be required to testify in any arbitration, civil, or other proceeding, except as provided in subsection (f) of this Section, as to what transpired at that meeting.

(h) The pharmacy's compliance with this Section may be considered by the Department as a mitigating factor in the investigation and evaluation of a dispensing error.

(i) Nothing in this Section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources by a third party or administrative offices with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this Section.

Section 99. Effective date. This Act takes effect 12 months after becoming law.