



99TH GENERAL ASSEMBLY

State of Illinois

2015 and 2016

HB6180

Introduced 2/11/2016, by Rep. Michael P. McAuliffe

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 15999 MLM 40316 b

1 AN ACT concerning regulation.

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

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

6 (225 ILCS 85/18a new)

7 Sec. 18a. Quality assurance program.

8 (a) For purposes of this Section:

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

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

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

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

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

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

26 (e) The quality assurance review shall include

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

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

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

10 (3) the essential cause examination;

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

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

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

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

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

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

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

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

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

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