

House Amendment 1432

PAG LIN

1 1 Amend House File 833 as follows:
1 2 #1. Page 1, by inserting before line 1 the
1 3 following:
1 4 <Section 1. Section 22.7, Code 2005, is amended by
1 5 adding the following new subsection:
1 6 NEW SUBSECTION. 51. The information contained in
1 7 the electronic drug database established in section
1 8 124.510A, except to the extent that disclosure is
1 9 authorized pursuant to section 124.510C.
1 10 Sec. 2. NEW SECTION. 124.510A ELECTRONIC DRUG
1 11 DATABASE ESTABLISHED.
1 12 The board shall establish and maintain an
1 13 electronic drug database. The board shall use the
1 14 electronic drug database to monitor the misuse, abuse,
1 15 and diversion of selected controlled substances and
1 16 other drugs the board includes in the database
1 17 pursuant to section 124.510E, subsection 1, paragraph
1 18 "i". The board shall electronically collect and
1 19 disseminate information pursuant to sections 124.510C
1 20 and 124.510D and rules adopted pursuant to this
1 21 division. The board may contract with a third=
1 22 party/private vendor to administer the electronic drug
1 23 database.
1 24 Sec. 3. NEW SECTION. 124.510B DATA REPORTING.
1 25 1. Each licensed pharmacy that dispenses selected
1 26 drugs identified by the board by rule to patients in
1 27 the state, and each licensed pharmacy located in the
1 28 state that dispenses such selected drugs to patients
1 29 inside or outside the state, unless specifically
1 30 excepted in this section or by rule, shall submit the
1 31 following prescription information to the board or its
1 32 designee:
1 33 a. Pharmacy identification.
1 34 b. Patient identification.
1 35 c. Prescriber identification.
1 36 d. The date the prescription was issued by the
1 37 prescriber.
1 38 e. The date the prescription was dispensed.
1 39 f. An indication of whether the prescription
1 40 dispensed is new or a refill.
1 41 g. Identification of the drug dispensed.
1 42 h. Quantity of the drug dispensed.
1 43 i. The number of days' supply of the drug
1 44 dispensed.
1 45 j. Serial or prescription number assigned by the
1 46 pharmacy.
1 47 k. Source of payment for the prescription.
1 48 2. Information shall be submitted electronically
1 49 in the format specified by the board unless the board
1 50 has granted a waiver and approved an alternate format.
2 1 3. Information shall be timely transmitted as
2 2 designated by the board by rule, unless the board
2 3 grants an extension. The board may grant an extension
2 4 if either of the following occurs:
2 5 a. The pharmacy suffers a mechanical or electronic
2 6 failure, or cannot meet the deadline established by
2 7 the board for other reasons beyond the pharmacy's
2 8 control.
2 9 b. The board or its designee is unable to receive
2 10 electronic submissions.
2 11 4. This section shall not apply to a prescriber
2 12 furnishing, dispensing, supplying, or administering
2 13 drugs to the prescriber's patient, or to dispensing by
2 14 a licensed pharmacy for the purposes of inpatient
2 15 hospital care, inpatient hospice care, or long-term
2 16 residential facility patient care.
2 17 Sec. 4. NEW SECTION. 124.510C DATA ACCESS.
2 18 1. The board or its designee may provide
2 19 information from the electronic drug database to all
2 20 of the following:
2 21 a. A person who is a designated representative of
2 22 a governmental entity responsible for the licensure,
2 23 regulation, or discipline of licensed health care
2 24 professionals authorized to prescribe or dispense

2 25 drugs, who is involved in an investigation of a person
2 26 licensed, regulated, or subject to discipline by the
2 27 entity, and who is seeking access to information in
2 28 the database that is relevant to the subject matter of
2 29 the investigation and pursuant to a written probable
2 30 cause determination.

2 31 b. A federal, state, county, township, or
2 32 municipal officer of this or any other state, or the
2 33 United States, whose duty it is to enforce the laws
2 34 relating to prescription drugs and who is actively
2 35 engaged in a specific investigation of a specific
2 36 person and is seeking access to information in the
2 37 database pursuant to a written probable cause
2 38 determination or warrant.

2 39 c. A properly convened grand jury pursuant to a
2 40 subpoena properly issued.

2 41 d. A pharmacist or prescriber who requests the
2 42 information and certifies in a form specified by the
2 43 board that it is for the purpose of providing medical
2 44 or pharmaceutical care to a patient of the pharmacist
2 45 or prescriber.

2 46 e. An individual who requests the individual's own
2 47 database information in accordance with the procedure
2 48 established in rules of the board adopted under
2 49 section 124.510E.

2 50 2. The board or its designee shall maintain a
3 1 record of each person that requests information from
3 2 the database. Pursuant to rules adopted by the board
3 3 under section 124.510E, the board may use the records
3 4 to document and report statistics and law enforcement
3 5 outcomes and to identify inappropriate access or other
3 6 prohibited acts. The board or its designee may
3 7 provide records of a person's requests for database
3 8 information to the following persons:

3 9 a. Pursuant to a written probable cause
3 10 determination, a designated representative of a
3 11 governmental entity that is responsible for the
3 12 licensure, regulation, or discipline of licensed
3 13 health care professionals authorized to prescribe or
3 14 dispense drugs who is involved in a specific
3 15 investigation of the individual who submitted the
3 16 request.

3 17 b. Pursuant to a written probable cause
3 18 determination or warrant, a federal, state, county,
3 19 township, or municipal officer of this or any other
3 20 state or the United States, whose duty is to enforce
3 21 the laws relating to prescription drugs, and who is
3 22 actively engaged in a specific investigation of the
3 23 specific person who submitted the request.

3 24 3. Information contained in the database and any
3 25 information obtained from it is strictly confidential
3 26 medical information, is not a public record pursuant
3 27 to chapter 22, and is not subject to discovery,
3 28 subpoena, or other means of legal compulsion for
3 29 release except as provided in this division.

3 30 Information contained in the records of requests for
3 31 information from the database is privileged and
3 32 confidential, is not a public record, and is not
3 33 subject to discovery, subpoena, or other means of
3 34 legal compulsion for release except as provided in
3 35 this division. Information from the database shall
3 36 not be released, shared with an agency or institution,
3 37 or made public except as provided in this division.

3 38 4. Information collected for the database shall be
3 39 retained in the database for four years. The
3 40 information shall then be destroyed unless a law
3 41 enforcement agency or a governmental entity
3 42 responsible for the licensure, regulation, or
3 43 discipline of licensed health care professionals
3 44 authorized to prescribe or dispense drugs has
3 45 submitted a written request to the board or its
3 46 designee for retention of specific information in
3 47 accordance with rules adopted by the board under
3 48 section 124.510E.

3 49 5. A pharmacist or other dispenser making a report
3 50 to the database in good faith pursuant to this
4 1 division is immune from any liability, civil,
4 2 criminal, or administrative, which might otherwise be
4 3 incurred or imposed as a result of the report.

4 4 6. Nothing in this section shall require a
4 5 pharmacist or prescriber to obtain information about a

4 6 patient from the database. A pharmacist or prescriber
4 7 does not have a duty and shall not be held liable in
4 8 damages to any person in any civil or derivative
4 9 criminal or administrative action for injury, death,
4 10 or loss to person or property on the basis that the
4 11 pharmacist or prescriber did or did not seek or obtain
4 12 information from the database. A pharmacist or
4 13 prescriber acting in good faith is immune from any
4 14 civil, criminal, or administrative liability that
4 15 might otherwise be incurred or imposed for requesting
4 16 or receiving information from the database.

4 17 7. The board shall not charge a fee to a pharmacy,
4 18 pharmacist, or prescriber for the establishment,
4 19 maintenance, or administration of the database. The
4 20 board shall not charge a fee for the transmission of
4 21 data to the database nor for the receipt of
4 22 information from the database, except that the board
4 23 may charge a reasonable fee to an individual who
4 24 requests the individual's own database information or
4 25 to a person requesting statistical, aggregate, or
4 26 nonpersonally identified information from the
4 27 database. A fee charged pursuant to this subsection
4 28 shall not exceed the cost of providing the requested
4 29 information and shall be considered a repayment
4 30 receipt as defined in section 8.2.

4 31 Sec. 5. NEW SECTION. 124.510D DATA REVIEW AND
4 32 REFERRAL.

4 33 The board or its designee shall review the
4 34 information in the electronic drug database. If the
4 35 board determines, consistent with the board's
4 36 authority under this chapter or chapter 155A, that
4 37 there is probable cause to believe that drug diversion
4 38 or another violation of law may have occurred, the
4 39 board shall notify the appropriate law enforcement
4 40 agency or the governmental entity responsible for the
4 41 licensure, regulation, or discipline of the licensed
4 42 health care professional, and shall supply information
4 43 from the database supporting the probable cause
4 44 determination. The board shall not refer information
4 45 relating to an individual for further investigation
4 46 except upon a probable cause determination. A
4 47 probable cause determination shall be consistent with
4 48 guidelines developed by the advisory council
4 49 established under section 124.510F.

4 50 Sec. 6. NEW SECTION. 124.510E RULES AND
5 1 REPORTING.

5 2 1. The board shall adopt rules in accordance with
5 3 chapter 17A to carry out the purposes of, and to
5 4 enforce the provisions of, this division. The rules
5 5 shall include but not be limited to the development of
5 6 procedures relating to:

5 7 a. Identifying each patient about whom information
5 8 is entered into the electronic drug database.

5 9 b. An electronic format for the submission of
5 10 information from pharmacies.

5 11 c. A waiver to submit information in another
5 12 format for a pharmacy unable to submit information
5 13 electronically.

5 14 d. Granting by the board of a request from a law
5 15 enforcement agency or a governmental entity
5 16 responsible for the licensure, regulation, or
5 17 discipline of licensed health care professionals
5 18 authorized to prescribe or dispense drugs for the
5 19 retention of information scheduled for deletion from
5 20 the database after four years when the information
5 21 pertains to an open investigation being conducted by
5 22 the agency or entity.

5 23 e. An application for an extension of time by a
5 24 pharmacy regarding information to be transmitted to
5 25 the board or its designee.

5 26 f. The submission by a person or governmental
5 27 entity to which the board is authorized to provide
5 28 information of a request for the information and a
5 29 procedure for the verification of the identity of the
5 30 requestor.

5 31 g. Use by the board of the database request
5 32 records required by section 124.510C, subsection 2, to
5 33 document and report statistics and law enforcement
5 34 outcomes and to identify inappropriate access or other
5 35 prohibited acts.

5 36 h. Submission of a request by an individual for

5 37 the individual's own database information and
5 38 verification of the identity of the requestor.
5 39 i. The development of a list of controlled
5 40 substances and other drugs that shall be included in
5 41 the database.
5 42 j. Access by a pharmacist or prescriber to
5 43 information in the database pursuant to a written
5 44 agreement with the board.

5 45 k. Terms and conditions of the contract, if the
5 46 board contracts for database administration with a
5 47 third-party or private vendor.
5 48 1. The correction or deletion of erroneous
5 49 information from the database.

5 50 2. No later than January 1, 2008, and every two
6 1 years thereafter, the board shall present to the
6 2 general assembly and the governor a report of the
6 3 following:

6 4 a. The cost to the state of implementing and
6 5 maintaining the database.

6 6 b. Information from pharmacies, prescribers, the
6 7 board, and others regarding the usefulness of the
6 8 database.

6 9 c. Information from pharmacies, prescribers, the
6 10 board, and others regarding the board's effectiveness
6 11 in providing information from the database.

6 12 d. Information documenting the timely transmission
6 13 of information from the electronic drug database to
6 14 authorized requestors.

6 15 Sec. 7. NEW SECTION. 124.510F ADVISORY COUNCIL
6 16 ESTABLISHED.

6 17 The board shall establish an advisory council to
6 18 provide oversight to the electronic drug database
6 19 program. The board shall adopt rules specifying the
6 20 duties and activities of the advisory council and
6 21 related matters.

6 22 1. The council shall consist of three licensed
6 23 pharmacists, three licensed physicians, two licensed
6 24 prescribers who are not physicians, and two members of
6 25 the general public. The board shall solicit
6 26 recommendations for health professional council
6 27 members from Iowa health professional licensing
6 28 boards, associations, and societies. The license of
6 29 each health professional appointed to and serving on
6 30 the advisory council shall be current and in good
6 31 standing with the professional's licensing board.

6 32 2. The council may make recommendations to advance
6 33 the goals of the database, which include
6 34 identification of misuse and diversion of identified
6 35 controlled substances and other drugs and enhancement
6 36 of the quality of health care delivery in this state.

6 37 3. Among other things, the council shall:

6 38 a. Assist the board in developing criteria for
6 39 granting requests by researchers and other persons for
6 40 statistical, aggregate, or nonpersonally identified
6 41 information using database information, developed
6 42 consistent with the goals of the database.

6 43 b. Assist the board in ensuring patient
6 44 confidentiality and the integrity of the patient's
6 45 treatment relationship with the patient's health care
6 46 provider.

6 47 c. Make recommendations regarding the continued
6 48 benefits of maintaining the electronic drug database
6 49 in relationship to cost and other burdens to the
6 50 board. The council's recommendations shall be
7 1 included in reports required by section 124.510E,
7 2 subsection 2.

7 3 4. Members of the advisory council shall be
7 4 eligible to request and receive actual expenses for
7 5 their duties as members of the advisory council,
7 6 subject to reimbursement limits imposed by the
7 7 department of administrative services, and shall also
7 8 be eligible to receive a per diem compensation as
7 9 provided in section 7E.6, subsection 1.

7 10 Sec. 8. NEW SECTION. 124.510G PROHIBITED ACTS
7 11 AND PENALTIES.

7 12 The failure of a licensed pharmacist or licensed
7 13 prescriber to comply with the requirements of this
7 14 division, or the performance or causing the
7 15 performance of, or the aiding and abetting of another
7 16 person in the performance of, any of the prohibited
7 17 acts identified in this section shall constitute

7 18 grounds for disciplinary action against the pharmacist
7 19 or prescriber by the appropriate professional
7 20 licensing board. Each licensing board that licenses
7 21 prescribers and drug dispensers subject to the
7 22 provisions of this division may adopt rules in
7 23 accordance with chapter 17A to implement the
7 24 provisions of this section and may impose penalty as
7 25 allowed under section 272C.3. In addition, a civil
7 26 penalty not to exceed twenty-five thousand dollars for
7 27 each violation may be imposed.

7 28 1. A pharmacist who willfully and knowingly fails
7 29 to submit prescription information to the board or its
7 30 designee as required by this division, or who
7 31 knowingly and intentionally submits prescription
7 32 information known to the pharmacist to be false or
7 33 fraudulent, may be subject to disciplinary action by
7 34 the board.

7 35 2. A person authorized to access or receive
7 36 prescription information pursuant to this division who
7 37 willfully and knowingly discloses or attempts to
7 38 disclose such information with the intent to cause
7 39 harm to another person in violation of this division
7 40 is guilty of a class "D" felony.

7 41 3. A person who willfully and knowingly uses,
7 42 releases, publishes, or otherwise makes available to
7 43 another person any personally identifiable information
7 44 obtained from or contained in the database is guilty
7 45 of a serious misdemeanor.

7 46 4. A person without lawful authority who obtains
7 47 or attempts to obtain information, obtains or attempts
7 48 to obtain unauthorized access to, or who willfully and
7 49 knowingly alters or destroys valid information
7 50 contained in the database is guilty of a class "D"
8 1 felony.

8 2 5. A person authorized to access or receive
8 3 prescription information pursuant to this division who
8 4 knowingly and intentionally discloses confidential
8 5 information to a person who is not authorized to
8 6 receive the information pursuant to this division is
8 7 guilty of a serious misdemeanor.

8 8 6. This section shall not preclude a pharmacist or
8 9 prescriber who requests and receives information from
8 10 the database consistent with the requirements of this
8 11 chapter from otherwise lawfully providing that
8 12 information to any other person for medical or
8 13 pharmaceutical care purposes.>

8 14 #2. Page 12, by inserting after line 12 the
8 15 following:

8 16 <Sec. _____. EFFECTIVE DATE. The sections of this
8 17 Act relating to and establishing an electronic drug
8 18 database, being deemed of immediate importance, take
8 19 effect upon enactment.>

8 20 #3. Title page, by striking line 2, and inserting
8 21 the following: <providing for the creation of an
8 22 electronic drug database, establishing and
8 23 appropriating fees, providing penalties, and providing
8 24 an effective date.>

8 25 #4. By renumbering as necessary.

8 26

8 27

8 28

8 29 _____
8 29 UPMEYER of Hancock

8 30

8 31

8 32

8 33 _____
8 33 SMITH of Marshall

8 34 HF 833.302 81

8 35 rn/cf/2107