MAR 1 1 2005
Place On Calendar

HOUSE FILE 722
BY COMMITTEE ON HUMAN RESOURCES

(SUCCESSOR TO HSB 226)

Passed House, Date 3-22-05 Passed Senate, Date _____
Vote: Ayes 98 Nays 0 Vote: Ayes _____ Nays _____
Approved _____

A BILL FOR

An Act providing for the creation of an electronic drug database, establishing fees, providing penalties, and providing an effective date.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

HF 722

TLSB 1293HV 81
rn/sh/8

S.F. _____ H.F. 722

Section 1. Section 22.7, Code 2005, is amended by adding the following new subsection:

NEW SUBSECTION. 51. The information contained in the electronic drug database established in section 124.510A, except to the extent that disclosure is authorized pursuant to section 124.510C.

Sec. 2. NEW SECTION. 124.510A ELECTRONIC DRUG DATABASE ESTABLISHED.

The board shall establish and maintain an electronic drug database. The board shall use the electronic drug database to monitor the misuse, abuse, and diversion of selected controlled substances and other drugs the board includes in the database pursuant to section 124.510E, subsection 1, paragraph "i". The board shall electronically collect and disseminate information pursuant to sections 124.510C and 124.510D and rules adopted pursuant to this division. The board may contract with a third-party/private vendor to administer the electronic drug database.

Sec. 3. NEW SECTION. 124.510B DATA REPORTING.

1. Each licensed pharmacy that dispenses selected drugs identified by the board by rule to patients in the state, and each licensed pharmacy located in the state that dispenses such selected drugs to patients inside or outside the state, unless specifically excepted in this section or by rule, shall submit the following prescription information to the board or its designee:

a. Pharmacy identification.

b. Patient identification.

c. Prescriber identification.

d. The date the prescription was issued by the prescriber.

e. The date the prescription was dispensed.

f. An indication of whether the prescription dispensed is new or a refill.

g. Identification of the drug dispensed.

h. Quantity of the drug dispensed.

i. The number of days' supply of the drug dispensed.

j. Serial or prescription number assigned by the pharmacy.

k. Source of payment for the prescription.

2. Information shall be submitted electronically in the format specified by the board unless the board has granted a waiver and approved an alternate format.

3. Information shall be timely transmitted as designated by the board by rule, unless the board grants an extension. The board may grant an extension if either of the following occurs:

a. The pharmacy suffers a mechanical or electronic failure, or cannot meet the deadline established by the board for other reasons beyond the pharmacy's control.

b. The board or its designee is unable to receive electronic submissions.

4. This section shall not apply to a prescriber furnishing, dispensing, supplying, or administering drugs to the prescriber's patient, or to dispensing by a licensed pharmacy for the purposes of inpatient hospital care, inpatient hospice care, or long-term residential facility patient care.

Sec. 4. NEW SECTION. 124.510C DATA ACCESS.

1. The board or its designee may provide information from the electronic drug database to all of the following:

a. A person who is a designated representative of a governmental entity responsible for the licensure, regulation, or discipline of licensed health care professionals authorized to prescribe or dispense drugs, who is involved in an investigation of a person licensed, regulated, or subject to discipline by the entity, and who is seeking access to information in the database that is relevant to the subject matter of the investigation and pursuant to a written probable cause determination.

b. A federal, state, county, township, or municipal officer of this or any other state, or the United States,

whose duty it is to enforce the laws relating to prescription drugs and who is actively engaged in a specific investigation of a specific person and is seeking access to information in the database pursuant to a probable cause determination or warrant.

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

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

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

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

a. Pursuant to a probable cause determination, a designated representative of a governmental entity that is responsible for the licensure, regulation, or discipline of licensed health care professionals authorized to prescribe or dispense drugs who is involved in a specific investigation of the individual who submitted the request.

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

3. Information contained in the database and any information obtained from it is strictly confidential medical information, is not a public record pursuant to chapter 22, and is not subject to discovery, subpoena, or other means of legal compulsion for release except as provided in this division. Information contained in the records of requests for information from the database is privileged and confidential, is not a public record, and is not subject to discovery, subpoena, or other means of legal compulsion for release except as provided in this division. Information from the database shall not be released, shared with an agency or institution, or made public except as provided in this division.

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

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

6. Nothing in this section shall require a pharmacist or prescriber to obtain information about a patient from the database. A pharmacist or prescriber does not have a duty and shall not be held liable in damages to any person in any civil or derivative criminal or administrative action for injury, death, or loss to person or property on the basis that the pharmacist or prescriber did or did not seek or obtain information from the database. A pharmacist or prescriber

acting in good faith is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for requesting or receiving information from the database.

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

Sec. 5. NEW SECTION. 124.510D DATA REVIEW AND REFERRAL.

The board or its designee shall review the information in the electronic drug database. If the board determines, consistent with the board's authority under this chapter or chapter 155A, that there is probable cause to believe that drug diversion or another violation of law may have occurred, the board shall notify the appropriate law enforcement agency or the governmental entity responsible for the licensure, regulation, or discipline of the licensed health care professional, and shall supply information required to initiate an investigation. The board shall not refer information relating to an individual for further investigation except upon a probable cause determination. A probable cause determination shall be consistent with guidelines developed by the advisory council established under section 124.510F.

Sec. 6. NEW SECTION. 124.510E RULES AND REPORTING.

1. The board shall adopt rules in accordance with chapter 17A to carry out the purposes of, and to enforce the

provisions of, this division. The rules shall include but not be limited to the development of procedures relating to:

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

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

c. A waiver to submit information in another format for a pharmacy unable to submit information electronically.

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

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

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

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

h. Submission of a request by an individual for the individual's own database information and verification of the identity of the requestor.

i. The development of a list of controlled substances and other drugs that shall be included in the database.

j. Access by a pharmacist or prescriber to information in the database pursuant to a written agreement with the board.

k. Terms and conditions of the contract, if the board contracts for database administration with a third-party or

private vendor.

1. The correction or deletion of erroneous information from the database.

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

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

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

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

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

Sec. 7. NEW SECTION. 124.510F ADVISORY COUNCIL ESTABLISHED.

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

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

2. The council may make recommendations to advance the goals of the database, which include identification of misuse and diversion of identified controlled substances and other drugs and enhancement of the quality of health care delivery

in this state.

3. Among other things, the council shall:

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

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

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

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

Sec. 8. NEW SECTION. 124.510G PROHIBITED ACTS AND PENALTIES.

The failure of a licensed pharmacist or licensed prescriber to comply with the requirements of this division, or the performance or causing the performance of, or the aiding and abetting of another person in the performance of, any of the prohibited acts identified in this section shall constitute grounds for disciplinary action against the pharmacist or prescriber by the appropriate professional licensing board. Each licensing board that licenses prescribers and drug dispensers subject to the provisions of this division may adopt rules in accordance with chapter 17A to implement the provisions of this section and may impose penalty as allowed under section 272C.3. In addition, a civil penalty not to

exceed twenty-five thousand dollars for each violation may be imposed.

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

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

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

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

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

Sec. 9. EFFECTIVE DATE. This Act, being deemed of immediate importance, takes effect upon enactment.

EXPLANATION

This bill authorizes the board of pharmacy examiners to establish and administer a prescription drug database containing a record of the dispensing of prescriptions for identified controlled substances and prescription drugs. The bill provides that the goals of the database program include

identification of misuse and diversion of prescription drugs and enhancement of the quality of health care delivery in Iowa.

The bill identifies minimum data requirements to be reported by pharmacies dispensing to patients in Iowa, and for pharmacies located in Iowa and dispensing to patients outside the state, for the format and timeliness of data submissions, for the exemption of specified entities from data submission requirements, and for the adoption of rules by the board regarding implementation of the database program.

The bill provides for the identification of persons authorized to request information from the database program, places limitations on access by certain authorized persons, and requires that a record be made and maintained of any request for database information. The bill provides that information contained in the database or derived from the database is confidential information, and provides protection from liability for pharmacists and prescribers whether or not they choose to utilize information from the database in the medical treatment of patients.

The bill provides for the establishment of an advisory council to provide oversight to the database program and provides for the payment of per diem and council member expenses. The bill additionally identifies actions and information uses which are prohibited under the program and the establishment of criminal, administrative, and civil penalties for prohibited acts.

The bill provides for the addition of information contained in the database to the list of confidential records in Code section 22.7.

The bill takes effect upon enactment.

H-1121 **HOUSE FILE 722**

Amend House File 722 as follows:

1. Page 9, by inserting after line 27 the following:

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

By SMITH of Marshall

H-1121 FILED MARCH 21, 2005

HOUSE FILE 722
BY COMMITTEE ON HUMAN RESOURCES

(SUCCESSOR TO HSB 226)

(As Amended and Passed by the House March 22, 2005)

Re- Passed House, Date 4-6-06 Passed Senate, Date 3-29-06
Vote: Ayes 99 Nays 0 Vote: Ayes 48 Nays 0
Approved _____

A BILL FOR

An Act providing for the creation of an electronic drug database, establishing fees, providing penalties, and providing an effective date.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

House Amendments _____

TLSB 1293HV 81
rn/sh/8

S.F. _____ H.F. 722

Section 1. Section 22.7, Code 2005, is amended by adding the following new subsection:

NEW SUBSECTION. 51. The information contained in the electronic drug database established in section 124.510A, except to the extent that disclosure is authorized pursuant to section 124.510C.

Sec. 2. NEW SECTION. 124.510A ELECTRONIC DRUG DATABASE ESTABLISHED.

The board shall establish and maintain an electronic drug database. The board shall use the electronic drug database to monitor the misuse, abuse, and diversion of selected controlled substances and other drugs the board includes in the database pursuant to section 124.510E, subsection 1, paragraph "i". The board shall electronically collect and disseminate information pursuant to sections 124.510C and 124.510D and rules adopted pursuant to this division. The board may contract with a third-party/private vendor to administer the electronic drug database.

Sec. 3. NEW SECTION. 124.510B DATA REPORTING.

1. Each licensed pharmacy that dispenses selected drugs identified by the board by rule to patients in the state, and each licensed pharmacy located in the state that dispenses such selected drugs to patients inside or outside the state, unless specifically excepted in this section or by rule, shall submit the following prescription information to the board or its designee:

a. Pharmacy identification.

b. Patient identification.

c. Prescriber identification.

d. The date the prescription was issued by the prescriber.

e. The date the prescription was dispensed.

f. An indication of whether the prescription dispensed is new or a refill.

g. Identification of the drug dispensed.

h. Quantity of the drug dispensed.

whose duty it is to enforce the laws relating to prescription drugs and who is actively engaged in a specific investigation of a specific person and is seeking access to information in the database pursuant to a probable cause determination or warrant.

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

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

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

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

a. Pursuant to a probable cause determination, a designated representative of a governmental entity that is responsible for the licensure, regulation, or discipline of licensed health care professionals authorized to prescribe or dispense drugs who is involved in a specific investigation of the individual who submitted the request.

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

i. The number of days' supply of the drug dispensed.

j. Serial or prescription number assigned by the pharmacy.

k. Source of payment for the prescription.

2. Information shall be submitted electronically in the format specified by the board unless the board has granted a waiver and approved an alternate format.

3. Information shall be timely transmitted as designated by the board by rule, unless the board grants an extension. The board may grant an extension if either of the following occurs:

a. The pharmacy suffers a mechanical or electronic failure, or cannot meet the deadline established by the board for other reasons beyond the pharmacy's control.

b. The board or its designee is unable to receive electronic submissions.

4. This section shall not apply to a prescriber furnishing, dispensing, supplying, or administering drugs to the prescriber's patient, or to dispensing by a licensed pharmacy for the purposes of inpatient hospital care, inpatient hospice care, or long-term residential facility patient care.

Sec. 4. NEW SECTION. 124.510C DATA ACCESS.

1. The board or its designee may provide information from the electronic drug database to all of the following:

a. A person who is a designated representative of a governmental entity responsible for the licensure, regulation, or discipline of licensed health care professionals authorized to prescribe or dispense drugs, who is involved in an investigation of a person licensed, regulated, or subject to discipline by the entity, and who is seeking access to information in the database that is relevant to the subject matter of the investigation and pursuant to a written probable cause determination.

b. A federal, state, county, township, or municipal officer of this or any other state, or the United States,

3. Information contained in the database and any information obtained from it is strictly confidential medical information, is not a public record pursuant to chapter 22, and is not subject to discovery, subpoena, or other means of legal compulsion for release except as provided in this division. Information contained in the records of requests for information from the database is privileged and confidential, is not a public record, and is not subject to discovery, subpoena, or other means of legal compulsion for release except as provided in this division. Information from the database shall not be released, shared with an agency or institution, or made public except as provided in this division.

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

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

6. Nothing in this section shall require a pharmacist or prescriber to obtain information about a patient from the database. A pharmacist or prescriber does not have a duty and shall not be held liable in damages to any person in any civil or derivative criminal or administrative action for injury, death, or loss to person or property on the basis that the pharmacist or prescriber did or did not seek or obtain information from the database. A pharmacist or prescriber

acting in good faith is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for requesting or receiving information from the database.

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

Sec. 5. NEW SECTION. 124.510D DATA REVIEW AND REFERRAL.

The board or its designee shall review the information in the electronic drug database. If the board determines, consistent with the board's authority under this chapter or chapter 155A, that there is probable cause to believe that drug diversion or another violation of law may have occurred, the board shall notify the appropriate law enforcement agency or the governmental entity responsible for the licensure, regulation, or discipline of the licensed health care professional, and shall supply information required to initiate an investigation. The board shall not refer information relating to an individual for further investigation except upon a probable cause determination. A probable cause determination shall be consistent with guidelines developed by the advisory council established under section 124.510F.

Sec. 6. NEW SECTION. 124.510E RULES AND REPORTING.

1. The board shall adopt rules in accordance with chapter 17A to carry out the purposes of, and to enforce the

provisions of, this division. The rules shall include but not be limited to the development of procedures relating to:

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

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

c. A waiver to submit information in another format for a pharmacy unable to submit information electronically.

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

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

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

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

h. Submission of a request by an individual for the individual's own database information and verification of the identity of the requestor.

i. The development of a list of controlled substances and other drugs that shall be included in the database.

j. Access by a pharmacist or prescriber to information in the database pursuant to a written agreement with the board.

k. Terms and conditions of the contract, if the board contracts for database administration with a third-party or

private vendor.

1. The correction or deletion of erroneous information from the database.

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

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

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

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

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

Sec. 7. NEW SECTION. 124.510F ADVISORY COUNCIL ESTABLISHED.

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

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

2. The council may make recommendations to advance the goals of the database, which include identification of misuse and diversion of identified controlled substances and other drugs and enhancement of the quality of health care delivery

in this state.

3. Among other things, the council shall:

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

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

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

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

Sec. 8. NEW SECTION. 124.510G PROHIBITED ACTS AND PENALTIES.

The failure of a licensed pharmacist or licensed prescriber to comply with the requirements of this division, or the performance or causing the performance of, or the aiding and abetting of another person in the performance of, any of the prohibited acts identified in this section shall constitute grounds for disciplinary action against the pharmacist or prescriber by the appropriate professional licensing board. Each licensing board that licenses prescribers and drug dispensers subject to the provisions of this division may adopt rules in accordance with chapter 17A to implement the provisions of this section and may impose penalty as allowed under section 272C.3. In addition, a civil penalty not to

exceed twenty-five thousand dollars for each violation may be imposed.

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

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

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

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

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

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

Sec. 9. EFFECTIVE DATE. This Act, being deemed of immediate importance, takes effect upon enactment.

EIGHTY FIRST GENERAL ASSEMBLY
2006 REGULAR SESSION
DAILY

SENATE CLIP SHEET

MARCH 28, 2006

HOUSE FILE 722

S-5126

Amend House File 722, as passed by the House, as follows:

1. By striking everything after the enacting clause and inserting the following:

"Section 1. Section 22.7, Code Supplement 2005, is amended by adding the following new subsection:

NEW SUBSECTION. 52. The information contained in the information program established in section 124.510A, except to the extent that disclosure is authorized pursuant to section 124.510C.

Sec. 2. NEW SECTION. 124.510A INFORMATION PROGRAM FOR DRUG PRESCRIBING AND DISPENSING.

Contingent upon the receipt of funds pursuant to section 124.510G sufficient to carry out the purposes of this division, the board, in conjunction with the advisory council created in section 124.510E, shall establish and maintain an information program for drug prescribing and dispensing. The program shall collect from pharmacies dispensing information for controlled substances identified pursuant to section 124.510D, subsection 1, paragraph "g". The information collected shall be used by prescribing practitioners and dispensing pharmacists on a need-to-know basis for purposes of improving patient health care by facilitating early identification of patients who may be at risk for addiction, or who may be using, abusing, or diverting drugs for unlawful or otherwise unauthorized purposes at risk to themselves and others, or who may be appropriately using controlled substances lawfully prescribed for them but unknown to the practitioner. The board shall collect, store, and disseminate program information consistent with security criteria established by rule, including use of appropriate encryption or other industry-recognized security technology. The board shall seek any federal waiver necessary to implement the provisions of the program.

Sec. 3. NEW SECTION. 124.510B INFORMATION REPORTING.

1. Each licensed pharmacy that dispenses controlled substances identified pursuant to section 124.510D, subsection 1, paragraph "g", to patients in the state, and each licensed pharmacy located in the state that dispenses such controlled substances identified pursuant to section 124.510D, subsection 1, paragraph "g", to patients inside or outside the state, unless specifically excepted in this section or by rule, shall submit the following prescription information to the program:

a. Pharmacy identification.

b. Patient identification.
c. Prescriber identification.
d. The date the prescription was issued by the prescriber.
e. The date the prescription was dispensed.
f. An indication of whether the prescription dispensed is new or a refill.
g. Identification of the drug dispensed.
h. Quantity of the drug dispensed.
i. The number of days' supply of the drug dispensed.
j. Serial or prescription number assigned by the pharmacy.
k. Type of payment for the prescription.
l. Other information identified by the board and advisory council by rule.

2. Information shall be submitted electronically in a secure format specified by the board unless the board has granted a waiver and approved an alternate secure format.

3. Information shall be timely transmitted as designated by the board and advisory council by rule, unless the board grants an extension. The board may grant an extension if either of the following occurs:
a. The pharmacy suffers a mechanical or electronic failure, or cannot meet the deadline established by the board for other reasons beyond the pharmacy's control.
b. The board is unable to receive electronic submissions.

4. This section shall not apply to a prescriber furnishing, dispensing, supplying, or administering drugs to the prescriber's patient, or to dispensing by a licensed pharmacy for the purposes of inpatient hospital care, inpatient hospice care, or long-term residential facility patient care.

Sec. 4. NEW SECTION. 124.510C INFORMATION ACCESS.

1. The board may provide information from the program to the following:
a. A pharmacist or prescriber who requests the information and certifies in a form specified by the board that it is for the purpose of providing medical or pharmaceutical care to a patient of the pharmacist or prescriber. Neither a pharmacist nor a prescriber may delegate program information access to another individual.
b. An individual who requests the individual's own program information in accordance with the procedure established in rules of the board and advisory council

adopted under section 124.510D.

c. Pursuant to an order, subpoena, or other means of legal compulsion for access to or release of program information that is issued based upon a determination of probable cause in the course of a specific investigation of a specific individual.

2. The board shall maintain a record of each person that requests information from the program. Pursuant to rules adopted by the board and advisory council under section 124.510D, the board may use the records to document and report statistical information.

3. Information contained in the program and any information obtained from it, and information contained in the records of requests for information from the program, is privileged and strictly confidential information. Such information is not a public record pursuant to chapter 22, and is not subject to discovery, subpoena, or other means of legal compulsion for release except as provided in this division. Information from the program shall not be released, shared with an agency or institution, or made public except as provided in this division.

4. Information collected for the program shall be retained in the program for four years from the date of dispensing. The information shall then be destroyed.

5. A pharmacist or other dispenser making a report to the program reasonably and in good faith pursuant to this division is immune from any liability, civil, criminal, or administrative, which might otherwise be incurred or imposed as a result of the report.

6. Nothing in this section shall require a pharmacist or prescriber to obtain information about a patient from the program. A pharmacist or prescriber does not have a duty and shall not be held liable in damages to any person in any civil or derivative criminal or administrative action for injury, death, or loss to person or property on the basis that the pharmacist or prescriber did or did not seek or obtain or use information from the program. A pharmacist or prescriber acting reasonably and in good faith is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for requesting or receiving or using information from the program.

7. The board shall not charge a fee to a pharmacy, pharmacist, or prescriber for the establishment, maintenance, or administration of the program, including costs for forms required to submit

information to or access information from the program, except that the board may charge a fee to an individual who requests the individual's own program information. A fee charged pursuant to this subsection shall not exceed the actual cost of providing the requested information and shall be considered a repayment receipt as defined in section 8.2.

Sec. 5. NEW SECTION. 124.510D RULES AND REPORTING.

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

a. Identifying each patient about whom information is entered into the program.

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

c. A waiver to submit information in another format for a pharmacy unable to submit information electronically.

d. An application by a pharmacy for an extension of time for transmitting information to the program.

e. The submission by an authorized requestor of a request for information and a procedure for the verification of the identity of the requestor.

f. Use by the board or advisory council of the program request records required by section 124.510C, subsection 2, to document and report statistical information.

g. Including all Schedule II controlled substances and those substances in Schedules III and IV that the advisory council and board determine can be addictive or fatal if not taken under the proper care and direction of a prescriber.

h. Access by a pharmacist or prescriber to information in the program pursuant to a written agreement with the board and advisory council.

i. The correction or deletion of erroneous information in the program.

2. Beginning January 1, 2007, and annually by January 1 thereafter, the board and advisory council shall present to the general assembly and the governor a report prepared consistent with section 124.510E, subsection 3, paragraph "d", which shall include but not be limited to the following:

a. The cost to the state of implementing and maintaining the program.

b. Information from pharmacies, prescribers, the

board, the advisory council, and others regarding the benefits or detriments of the program.

c. Information from pharmacies, prescribers, the board, the advisory council, and others regarding the board's effectiveness in providing information from the program.

Sec. 6. NEW SECTION. 124.510E ADVISORY COUNCIL ESTABLISHED.

An advisory council shall be established to provide oversight to the board and the program and to comanage program activities. The board and advisory council shall jointly adopt rules specifying the duties and activities of the advisory council and related matters.

1. The council shall consist of eight members appointed by the governor. The members shall include three licensed pharmacists, four physicians licensed under chapter 148, 150, or 150A, and one licensed prescriber who is not a physician. The governor shall solicit recommendations for council members from Iowa health professional licensing boards, associations, and societies. The license of each member appointed to and serving on the advisory council shall be current and in good standing with the professional's licensing board.

2. The council shall advance the goals of the program, which include identification of misuse and diversion of controlled substances identified pursuant to section 124.510D, subsection 1, paragraph "g", and enhancement of the quality of health care delivery in this state.

3. Duties of the council shall include but not be limited to the following:

a. Ensuring the confidentiality of the patient, prescriber, and dispensing pharmacist and pharmacy.

b. Respecting and preserving the integrity of the patient's treatment relationship with the patient's health care providers.

c. Encouraging and facilitating cooperative efforts among health care practitioners and other interested and knowledgeable persons in developing best practices for prescribing and dispensing controlled substances and in educating health care practitioners and patients regarding controlled substance use and abuse.

d. Making recommendations regarding the continued benefits of maintaining the program in relationship to cost and other burdens to the patient, prescriber, pharmacist, and the board. The council's recommendations shall be included in reports required

by section 124.510D, subsection 2.

e. One physician and one pharmacist member of the council shall include in their duties the responsibility for monitoring and ensuring that patient confidentiality, best interests, and civil liberties are at all times protected and preserved during the existence of the program.

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

Sec. 7. NEW SECTION. 124.510F EDUCATION AND TREATMENT.

The program for drug prescribing and dispensing shall include education initiatives and outreach to consumers, prescribers, and pharmacists, and shall also include assistance for identifying substance abuse treatment programs and providers. The board and advisory council shall adopt rules, as provided under section 124.510D, to implement this section.

Sec. 8. NEW SECTION. 124.510G DRUG INFORMATION PROGRAM FUND.

The drug information program fund is established to be used by the board to fund or assist in funding the program. The board may make deposits into the fund from any source, public or private, including grants or contributions of money or other items of value, which it determines necessary to carry out the purposes of this division. Moneys received by the board to establish and maintain the program must be used for the expenses of administering this division. Notwithstanding section 8.33, amounts contained in the fund that remain unencumbered or unobligated at the close of the fiscal year shall not revert but shall remain available for expenditure for the purposes designated in future years.

Sec. 9. NEW SECTION. 124.510H PROHIBITED ACTS -- PENALTIES.

1. FAILURE TO COMPLY WITH REQUIREMENTS. A pharmacist, pharmacy, or prescriber who knowingly fails to comply with the confidentiality requirements of this division or who delegates program information access to another individual is subject to disciplinary action by the appropriate professional licensing board. A pharmacist or pharmacy that knowingly fails to comply with other requirements of this division is subject to disciplinary action by the

board. Each licensing board may adopt rules in accordance with chapter 17A to implement the provisions of this section.

2. UNLAWFUL ACCESS, DISCLOSURE, OR USE OF INFORMATION. A person who intentionally or knowingly accesses, uses, or discloses program information in violation of this division, unless otherwise authorized by law, is guilty of a class "D" felony. This section shall not preclude a pharmacist or prescriber who requests and receives information from the program consistent with the requirements of this chapter from otherwise lawfully providing that information to any other person for medical or pharmaceutical care purposes.

Sec. 10. Sections 124.510A through 124.510H are repealed June 30, 2009.

Sec. 11. EFFECTIVE DATE. This Act, being deemed of immediate importance, takes effect upon enactment."

2. Title page, by striking lines 1 through 3 and inserting the following: "An Act providing for the establishment of an information program for drug prescribing and dispensing, providing penalties, and providing an effective date."

3. By renumbering as necessary.

COMMITTEE ON HUMAN RESOURCES
AMANDA RAGAN, CO-CHAIRPERSON
JAMES SEYMOUR, CO-CHAIRPERSON

S-5126 FILED MARCH 27, 2006

EIGHTY FIRST GENERAL ASSEMBLY
2006 REGULAR SESSION
DAILY
SENATE CLIP SHEET

MARCH 30, 2006

HOUSE FILE 722

S-5137

Amend the Senate amendment, S-5126, to House File 722, as amended, passed, and reprinted by the House, as follows:

1. Page 2, line 41, by inserting after the word "a." the following: "(1)".

2. Page 2, by inserting after line 47 the following:

"(2) Notwithstanding subparagraph (1), a prescriber may delegate program information access to another licensed health care professional only in emergency situations where the patient would be placed in greater jeopardy if the precriber was required to access the information personally.".

By JACK HATCH
JAMES SEYMOUR

S-5137 FILED MARCH 29, 2006
ADOPTED

HOUSE FILE 722

S-5139

Amend the Senate amendment, S-5126, to House File 722, as amended, passed, and reprinted by the House, as follows:

1. Page 1, line 23, by striking the word "dispensing".

2. Page 1, line 31, by inserting after the word "practitioner." the following: "For purposes of this division, "prescribing practitioner" means a practitioner who has prescribed or is contemplating the authorization of a prescription for the patient about whom information is requested, and "pharmacist" means a practicing pharmacist who is actively engaged in and responsible for the pharmaceutical care of the patient about whom information is requested."

By JAMES SEYMOUR
JACK HATCH

S-5139 FILED MARCH 29, 2006
ADOPTED

SENATE AMENDMENT TO
HOUSE FILE 722

H-8438

Amend House File 722, as passed by the House, as follows:

1. By striking everything after the enacting clause and inserting the following:

"Section 1. Section 22.7, Code Supplement 2005, is amended by adding the following new subsection:

NEW SUBSECTION. 52. The information contained in the information program established in section 124.510A, except to the extent that disclosure is authorized pursuant to section 124.510C.

Sec. 2. NEW SECTION. 124.510A INFORMATION PROGRAM FOR DRUG PRESCRIBING AND DISPENSING.

Contingent upon the receipt of funds pursuant to section 124.510G sufficient to carry out the purposes of this division, the board, in conjunction with the advisory council created in section 124.510E, shall establish and maintain an information program for drug prescribing and dispensing. The program shall collect from pharmacies dispensing information for controlled substances identified pursuant to section 124.510D, subsection 1, paragraph "g". The information collected shall be used by prescribing practitioners and pharmacists on a need-to-know basis for purposes of improving patient health care by facilitating early identification of patients who may be at risk for addiction, or who may be using, abusing, or diverting drugs for unlawful or otherwise unauthorized purposes at risk to themselves and others, or who may be appropriately using controlled substances lawfully prescribed for them but unknown to the practitioner. For purposes of this division, "prescribing practitioner" means a practitioner who has prescribed or is contemplating the authorization of a prescription for the patient about whom information is requested, and "pharmacist" means a practicing pharmacist who is actively engaged in and responsible for the pharmaceutical care of the patient about whom information is requested. The board shall collect, store, and disseminate program information consistent with security criteria established by rule, including use of appropriate encryption or other industry-recognized security technology. The board shall seek any federal waiver necessary to implement the provisions of the program.

Sec. 3. NEW SECTION. 124.510B INFORMATION REPORTING.

1. Each licensed pharmacy that dispenses controlled substances identified pursuant to section 124.510D, subsection 1, paragraph "g", to patients in the state, and each licensed pharmacy located in the

state that dispenses such controlled substances identified pursuant to section 124.510D, subsection 1, paragraph "g", to patients inside or outside the state, unless specifically excepted in this section or by rule, shall submit the following prescription information to the program:

a. Pharmacy identification.

b. Patient identification.

c. Prescriber identification.

d. The date the prescription was issued by the prescriber.

e. The date the prescription was dispensed.

f. An indication of whether the prescription dispensed is new or a refill.

g. Identification of the drug dispensed.

h. Quantity of the drug dispensed.

i. The number of days' supply of the drug dispensed.

j. Serial or prescription number assigned by the pharmacy.

k. Type of payment for the prescription.

l. Other information identified by the board and advisory council by rule.

2. Information shall be submitted electronically in a secure format specified by the board unless the board has granted a waiver and approved an alternate secure format.

3. Information shall be timely transmitted as designated by the board and advisory council by rule, unless the board grants an extension. The board may grant an extension if either of the following occurs:

a. The pharmacy suffers a mechanical or electronic failure, or cannot meet the deadline established by the board for other reasons beyond the pharmacy's control.

b. The board is unable to receive electronic submissions.

4. This section shall not apply to a prescriber furnishing, dispensing, supplying, or administering drugs to the prescriber's patient, or to dispensing by a licensed pharmacy for the purposes of inpatient hospital care, inpatient hospice care, or long-term residential facility patient care.

Sec. 4. NEW SECTION. 124.510C INFORMATION ACCESS.

1. The board may provide information from the program to the following:

a. (1) A pharmacist or prescriber who requests the information and certifies in a form specified by the board that it is for the purpose of providing

medical or pharmaceutical care to a patient of the pharmacist or prescriber. Neither a pharmacist nor a prescriber may delegate program information access to another individual.

(2) Notwithstanding subparagraph (1), a prescriber may delegate program information access to another licensed health care professional only in emergency situations where the patient would be placed in greater jeopardy if the precriber was required to access the information personally.

b. An individual who requests the individual's own program information in accordance with the procedure established in rules of the board and advisory council adopted under section 124.510D.

c. Pursuant to an order, subpoena, or other means of legal compulsion for access to or release of program information that is issued based upon a determination of probable cause in the course of a specific investigation of a specific individual.

2. The board shall maintain a record of each person that requests information from the program. Pursuant to rules adopted by the board and advisory council under section 124.510D, the board may use the records to document and report statistical information.

3. Information contained in the program and any information obtained from it, and information contained in the records of requests for information from the program, is privileged and strictly confidential information. Such information is not a public record pursuant to chapter 22, and is not subject to discovery, subpoena, or other means of legal compulsion for release except as provided in this division. Information from the program shall not be released, shared with an agency or institution, or made public except as provided in this division.

4. Information collected for the program shall be retained in the program for four years from the date of dispensing. The information shall then be destroyed.

5. A pharmacist or other dispenser making a report to the program reasonably and in good faith pursuant to this division is immune from any liability, civil, criminal, or administrative, which might otherwise be incurred or imposed as a result of the report.

6. Nothing in this section shall require a pharmacist or prescriber to obtain information about a patient from the program. A pharmacist or prescriber does not have a duty and shall not be held liable in damages to any person in any civil or derivative

criminal or administrative action for injury, death, or loss to person or property on the basis that the pharmacist or prescriber did or did not seek or obtain or use information from the program. A pharmacist or prescriber acting reasonably and in good faith is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for requesting or receiving or using information from the program.

7. The board shall not charge a fee to a pharmacy, pharmacist, or prescriber for the establishment, maintenance, or administration of the program, including costs for forms required to submit information to or access information from the program, except that the board may charge a fee to an individual who requests the individual's own program information. A fee charged pursuant to this subsection shall not exceed the actual cost of providing the requested information and shall be considered a repayment receipt as defined in section 8.2.

Sec. 5. NEW SECTION. 124.510D RULES AND REPORTING.

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

a. Identifying each patient about whom information is entered into the program.

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

c. A waiver to submit information in another format for a pharmacy unable to submit information electronically.

d. An application by a pharmacy for an extension of time for transmitting information to the program.

e. The submission by an authorized requestor of a request for information and a procedure for the verification of the identity of the requestor.

f. Use by the board or advisory council of the program request records required by section 124.510C, subsection 2, to document and report statistical information.

g. Including all Schedule II controlled substances and those substances in Schedules III and IV that the advisory council and board determine can be addictive or fatal if not taken under the proper care and direction of a prescriber.

h. Access by a pharmacist or prescriber to

information in the program pursuant to a written agreement with the board and advisory council.

i. The correction or deletion of erroneous information in the program.

2. Beginning January 1, 2007, and annually by January 1 thereafter, the board and advisory council shall present to the general assembly and the governor a report prepared consistent with section 124.510E, subsection 3, paragraph "d", which shall include but not be limited to the following:

a. The cost to the state of implementing and maintaining the program.

b. Information from pharmacies, prescribers, the board, the advisory council, and others regarding the benefits or detriments of the program.

c. Information from pharmacies, prescribers, the board, the advisory council, and others regarding the board's effectiveness in providing information from the program.

Sec. 6. NEW SECTION. 124.510E ADVISORY COUNCIL ESTABLISHED.

An advisory council shall be established to provide oversight to the board and the program and to comanage program activities. The board and advisory council shall jointly adopt rules specifying the duties and activities of the advisory council and related matters.

1. The council shall consist of eight members appointed by the governor. The members shall include three licensed pharmacists, four physicians licensed under chapter 148, 150, or 150A, and one licensed prescriber who is not a physician. The governor shall solicit recommendations for council members from Iowa health professional licensing boards, associations, and societies. The license of each member appointed to and serving on the advisory council shall be current and in good standing with the professional's licensing board.

2. The council shall advance the goals of the program, which include identification of misuse and diversion of controlled substances identified pursuant to section 124.510D, subsection 1, paragraph "g", and enhancement of the quality of health care delivery in this state.

3. Duties of the council shall include but not be limited to the following:

a. Ensuring the confidentiality of the patient, prescriber, and dispensing pharmacist and pharmacy.

b. Respecting and preserving the integrity of the patient's treatment relationship with the patient's

health care providers.

c. Encouraging and facilitating cooperative efforts among health care practitioners and other interested and knowledgeable persons in developing best practices for prescribing and dispensing controlled substances and in educating health care practitioners and patients regarding controlled substance use and abuse.

d. Making recommendations regarding the continued benefits of maintaining the program in relationship to cost and other burdens to the patient, prescriber, pharmacist, and the board. The council's recommendations shall be included in reports required by section 124.510D, subsection 2.

e. One physician and one pharmacist member of the council shall include in their duties the responsibility for monitoring and ensuring that patient confidentiality, best interests, and civil liberties are at all times protected and preserved during the existence of the program.

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

Sec. 7. NEW SECTION. 124.510F EDUCATION AND TREATMENT.

The program for drug prescribing and dispensing shall include education initiatives and outreach to consumers, prescribers, and pharmacists, and shall also include assistance for identifying substance abuse treatment programs and providers. The board and advisory council shall adopt rules, as provided under section 124.510D, to implement this section.

Sec. 8. NEW SECTION. 124.510G DRUG INFORMATION PROGRAM FUND.

The drug information program fund is established to be used by the board to fund or assist in funding the program. The board may make deposits into the fund from any source, public or private, including grants or contributions of money or other items of value, which it determines necessary to carry out the purposes of this division. Moneys received by the board to establish and maintain the program must be used for the expenses of administering this division. Notwithstanding section 8.33, amounts contained in the fund that remain unencumbered or unobligated at the close of the fiscal year shall not revert but shall

remain available for expenditure for the purposes designated in future years.

Sec. 9. NEW SECTION. 124.510H PROHIBITED ACTS -- PENALTIES.

1. FAILURE TO COMPLY WITH REQUIREMENTS. A pharmacist, pharmacy, or prescriber who knowingly fails to comply with the confidentiality requirements of this division or who delegates program information access to another individual is subject to disciplinary action by the appropriate professional licensing board. A pharmacist or pharmacy that knowingly fails to comply with other requirements of this division is subject to disciplinary action by the board. Each licensing board may adopt rules in accordance with chapter 17A to implement the provisions of this section.

2. UNLAWFUL ACCESS, DISCLOSURE, OR USE OF INFORMATION. A person who intentionally or knowingly accesses, uses, or discloses program information in violation of this division, unless otherwise authorized by law, is guilty of a class "D" felony. This section shall not preclude a pharmacist or prescriber who requests and receives information from the program consistent with the requirements of this chapter from otherwise lawfully providing that information to any other person for medical or pharmaceutical care purposes.

Sec. 10. Sections 124.510A through 124.510H are repealed June 30, 2009.

Sec. 11. EFFECTIVE DATE. This Act, being deemed of immediate importance, takes effect upon enactment."

2. Title page, by striking lines 1 through 3 and inserting the following: "An Act providing for the establishment of an information program for drug prescribing and dispensing, providing penalties, and providing an effective date."

3. By renumbering as necessary.

RECEIVED FROM THE SENATE

H-8438 FILED MARCH 29, 2006

Tomenga
Hutter
Smith

SF 0722

HSB 226
HUMAN RESOURCES

SENATE/HOUSE FILE _____
BY (PROPOSED DEPARTMENT OF PUBLIC HEALTH/BOARD OF PHARMACY EXAMINERS BILL)

Passed Senate, Date _____ Passed House, Date _____
Vote: Ayes _____ Nays _____ Vote: Ayes _____ Nays _____
Approved _____

A BILL FOR

An Act providing for the creation of an electronic drug database, establishing fees, providing penalties, and providing an effective date.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

TLSB 1293DP 81
rn/sh/8

S.F. _____ H.F. _____

Section 1. Section 22.7, Code 2005, is amended by adding the following new subsection:

NEW SUBSECTION. 51. The information contained in the electronic drug database established in section 124.510A, except to the extent that disclosure is authorized pursuant to section 124.510C.

Sec. 2. NEW SECTION. 124.510A ELECTRONIC DRUG DATABASE ESTABLISHED.

The board shall establish and maintain an electronic drug database. The board shall use the electronic drug database to monitor the misuse, abuse, and diversion of selected controlled substances and other drugs the board includes in the database pursuant to section 124.510E, subsection 1, paragraph "i". The board shall electronically collect and disseminate information pursuant to sections 124.510C and 124.510D and rules adopted pursuant to this division. The board may contract with a third-party/private vendor to administer the electronic drug database.

Sec. 3. NEW SECTION. 124.510B DATA REPORTING.

1. Each licensed pharmacy that dispenses selected drugs identified by the board by rule to patients in the state, and each licensed pharmacy located in the state that dispenses such selected drugs to patients inside or outside the state, unless specifically excepted in this section or by rule, shall submit the following prescription information to the board or its designee:

a. Pharmacy identification.

b. Patient identification.

c. Prescriber identification.

d. The date the prescription was issued by the prescriber.

e. The date the prescription was dispensed.

f. An indication of whether the prescription dispensed is new or a refill.

g. Identification of the drug dispensed.

h. Quantity of the drug dispensed.

i. The number of days' supply of the drug dispensed.

j. Serial or prescription number assigned by the pharmacy.

k. Source of payment for the prescription.

2. Information shall be submitted electronically in the format specified by the board unless the board has granted a waiver and approved an alternate format.

3. Information shall be timely transmitted as designated by the board by rule, unless the board grants an extension. The board may grant an extension if either of the following occurs:

a. The pharmacy suffers a mechanical or electronic failure, or cannot meet the deadline established by the board for other reasons beyond the pharmacy's control.

b. The board or its designee is unable to receive electronic submissions.

4. This section shall not apply to a prescriber furnishing, dispensing, supplying, or administering drugs to the prescriber's patient, or to dispensing by a licensed pharmacy for the purposes of inpatient hospital care, inpatient hospice care, or long-term residential facility patient care.

Sec. 4. NEW SECTION. 124.510C DATA ACCESS.

1. The board or its designee may provide information from the electronic drug database to all of the following:

a. A person who is a designated representative of a governmental entity responsible for the licensure, regulation, or discipline of licensed health care professionals authorized to prescribe or dispense drugs, who is involved in an investigation of a person licensed, regulated, or subject to discipline by the entity, and who is seeking access to information in the database that is relevant to the subject matter of the investigation and pursuant to a written probable cause determination.

b. A federal, state, county, township, or municipal officer of this or any other state, or the United States,

whose duty it is to enforce the laws relating to prescription drugs and who is actively engaged in a specific investigation of a specific person and is seeking access to information in the database pursuant to a probable cause determination or warrant.

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

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

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

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

a. Pursuant to a probable cause determination, a designated representative of a governmental entity that is responsible for the licensure, regulation, or discipline of licensed health care professionals authorized to prescribe or dispense drugs who is involved in a specific investigation of the individual who submitted the request.

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

3. Information contained in the database and any information obtained from it is strictly confidential medical information, is not a public record pursuant to chapter 22, and is not subject to discovery, subpoena, or other means of legal compulsion for release except as provided in this division. Information contained in the records of requests for information from the database is privileged and confidential, is not a public record, and is not subject to discovery, subpoena, or other means of legal compulsion for release except as provided in this division. Information from the database shall not be released, shared with an agency or institution, or made public except as provided in this division.

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

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

6. Nothing in this section shall require a pharmacist or prescriber to obtain information about a patient from the database. A pharmacist or prescriber does not have a duty and shall not be held liable in damages to any person in any civil or derivative criminal or administrative action for injury, death, or loss to person or property on the basis that the pharmacist or prescriber did or did not seek or obtain information from the database. A pharmacist or prescriber

acting in good faith is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for requesting or receiving information from the database.

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

Sec. 5. NEW SECTION. 124.510D DATA REVIEW AND REFERRAL.

The board or its designee shall review the information in the electronic drug database. If the board determines, consistent with the board's authority under this chapter or chapter 155A, that there is probable cause to believe that drug diversion or another violation of law may have occurred, the board shall notify the appropriate law enforcement agency or the governmental entity responsible for the licensure, regulation, or discipline of the licensed health care professional, and shall supply information required to initiate an investigation. The board shall not refer information relating to an individual for further investigation except upon a probable cause determination. A probable cause determination shall be consistent with guidelines developed by the advisory council established under section 124.510F.

Sec. 6. NEW SECTION. 124.510E RULES AND REPORTING.

1. The board shall adopt rules in accordance with chapter 17A to carry out the purposes of, and to enforce the

provisions of, this division. The rules shall include but not be limited to the development of procedures relating to:

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

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

c. A waiver to submit information in another format for a pharmacy unable to submit information electronically.

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

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

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

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

h. Submission of a request by an individual for the individual's own database information and verification of the identity of the requestor.

i. The development of a list of controlled substances and other drugs that shall be included in the database.

j. Access by a pharmacist or prescriber to information in the database pursuant to a written agreement with the board.

k. Terms and conditions of the contract, if the board contracts for database administration with a third-party or

private vendor.

1. The correction or deletion of erroneous information from the database.

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

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

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

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

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

Sec. 7. NEW SECTION. 124.510F ADVISORY COUNCIL ESTABLISHED.

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

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

2. The council may make recommendations to advance the goals of the database, which include identification of misuse and diversion of identified controlled substances and other drugs and enhancement of the quality of health care delivery

in this state.

3. Among other things, the council shall:

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

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

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

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

Sec. 8. NEW SECTION. 124.510G PROHIBITED ACTS AND PENALTIES.

The failure of a licensed pharmacist or licensed prescriber to comply with the requirements of this division, or the performance or causing the performance of, or the aiding and abetting of another person in the performance of, any of the prohibited acts identified in this section shall constitute grounds for disciplinary action against the pharmacist or prescriber by the appropriate professional licensing board. Each licensing board that licenses prescribers and drug dispensers subject to the provisions of this division may adopt rules in accordance with chapter 17A to implement the provisions of this section and may impose penalty as allowed under section 272C.3. In addition, a civil penalty not to

exceed twenty-five thousand dollars for each violation may be imposed.

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

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

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

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

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

Sec. 9. EFFECTIVE DATE. This Act, being deemed of immediate importance, takes effect upon enactment.

EXPLANATION

This bill authorizes the board of pharmacy examiners to establish and administer a prescription drug database containing a record of the dispensing of prescriptions for identified controlled substances and prescription drugs. The bill provides that the goals of the database program include

identification of misuse and diversion of prescription drugs and enhancement of the quality of health care delivery in Iowa.

The bill identifies minimum data requirements to be reported by pharmacies dispensing to patients in Iowa, and for pharmacies located in Iowa and dispensing to patients outside the state, for the format and timeliness of data submissions, for the exemption of specified entities from data submission requirements, and for the adoption of rules by the board regarding implementation of the database program.

The bill provides for the identification of persons authorized to request information from the database program, places limitations on access by certain authorized persons, and requires that a record be made and maintained of any request for database information. The bill provides that information contained in the database or derived from the database is confidential information, and provides protection from liability for pharmacists and prescribers whether or not they choose to utilize information from the database in the medical treatment of patients.

The bill provides for the establishment of an advisory council to provide oversight to the database program and provides for the payment of per diem and council member expenses. The bill additionally identifies actions and information uses which are prohibited under the program and the establishment of criminal, administrative, and civil penalties for prohibited acts.

The bill provides for the addition of information contained in the database to the list of confidential records in Code section 22.7.

The bill takes effect upon enactment.

IOWA BOARD OF PHARMACY EXAMINERS

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Des Moines, IA 50309-4688
515/281-5944 Voice **Website: www.state.ia.us/ibpe** **515/281-4609 Fax**

M E M O R A N D U M

DATE: November 29, 2004

TO: Members of the 80th Iowa General Assembly

FROM: Lloyd K. Jessen
Executive Secretary/Director

SUBJECT: Requested Legislative Amendment – Revise Iowa Code Chapter 124

The Board of Pharmacy Examiners respectfully requests that the proposed amendment be made to Iowa Code Chapter 124.

This bill proposes the adoption of new division in Iowa Code chapter 124 to be known as the Division VI, Electronic Drug Database. The division establishes an electronic drug database for the collection of information for all prescriptions issued for select controlled substances and other drugs having a potential for abuse.

The electronic drug database makes it possible to collect and analyze prescription data much more efficiently than without such a program, where the collection of prescription information requires the manual review of pharmacy files. The increased efficiency of an electronic drug database allows for the early detection of trends in abuse and possible sources of diversion. Prescribers and pharmacists could access the database information to review a patient's prescription drug usage, permitting identification of patients in need of counseling or treatment for abuse or excessive use. Information review would also identify patients involved in doctor or pharmacy shopping, a common scheme used to divert drugs of abuse to the illicit market.

Analyzing the collected data also allows for the identification of outmoded prescribing practices, which may result in the development of new educational programs for medical professionals. States with electronic drug databases have found that the programs are an effective tool for enforcement, education, and prevention that does not interfere with legitimate prescribing and dispensing of pharmaceuticals. Nearly one-half of all U.S. states have established, or are in the process of establishing, an electronic drug database program and there is legislation pending in the U.S. Senate that would require each state to establish and maintain an electronic drug database for all prescriptions dispensing controlled substances.

The new division identifies minimum data elements regarding each prescription that are to be reported and, unless a dispenser is granted a waiver for good cause by the board, data is to be submitted electronically. Provisions of the new division ensure the privacy and confidentiality of information collected by the electronic drug database and specifically identify the persons and agencies to which information may be released and the circumstances dictating such release. Information that is maintained in the database and any information derived from

database information is identified as confidential medical information and records requests for information from the database is confidential. Individual patients are specifically permitted access to their own prescription information.

The new division requires that electronic drug database information be reviewed to determine if there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, in which case the appropriate law enforcement or professional licensing agency will be notified and given necessary information. The Board of Pharmacy Examiners is authorized to adopt rules necessary to implement the electronic drug database and to contract with another state agency or with a private vendor to assist with the implementation and operation of the database. The contracting agency or vendor would be subject to the confidentiality provisions of the division, as would any health care practitioner accessing database information. The new division provides penalties for violation of confidentiality requirements and for a knowing failure to submit accurate or required information to the electronic drug database. Provisions of the new division protect prescribers and pharmacists from liability in any civil or derivative criminal or administrative action based on the practitioner's decision whether or not to utilize database information in the treatment of a patient.

Representatives from Iowa's health professions licensing boards, associations, societies, pharmacies, and prescriber practices participated in the drafting and development of this proposed amendment to the Iowa Controlled Substances Act.

Tomenga
Hutter
Smith

HSB 226
HUMAN RESOURCES

SENATE/HOUSE FILE _____
BY (PROPOSED DEPARTMENT OF PUBLIC HEALTH/BOARD OF PHARMACY EXAMINERS BILL)

Passed Senate, Date _____ Passed House, Date _____
Vote: Ayes _____ Nays _____ Vote: Ayes _____ Nays _____
Approved _____

A BILL FOR

An Act providing for the creation of an electronic drug database, establishing fees, providing penalties, and providing an effective date.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

TLSB 1293DP 81
rn/sh/8

S.F. _____ H.F. _____

Section 1. Section 22.7, Code 2005, is amended by adding the following new subsection:

NEW SUBSECTION. 51. The information contained in the electronic drug database established in section 124.510A, except to the extent that disclosure is authorized pursuant to section 124.510C.

Sec. 2. NEW SECTION. 124.510A ELECTRONIC DRUG DATABASE ESTABLISHED.

The board shall establish and maintain an electronic drug database. The board shall use the electronic drug database to monitor the misuse, abuse, and diversion of selected controlled substances and other drugs the board includes in the database pursuant to section 124.510E, subsection 1, paragraph "i". The board shall electronically collect and disseminate information pursuant to sections 124.510C and 124.510D and rules adopted pursuant to this division. The board may contract with a third-party/private vendor to administer the electronic drug database.

Sec. 3. NEW SECTION. 124.510B DATA REPORTING.

1. Each licensed pharmacy that dispenses selected drugs identified by the board by rule to patients in the state, and each licensed pharmacy located in the state that dispenses such selected drugs to patients inside or outside the state, unless specifically excepted in this section or by rule, shall submit the following prescription information to the board or its designee:

a. Pharmacy identification.

b. Patient identification.

c. Prescriber identification.

d. The date the prescription was issued by the prescriber.

e. The date the prescription was dispensed.

f. An indication of whether the prescription dispensed is new or a refill.

g. Identification of the drug dispensed.

h. Quantity of the drug dispensed.

i. The number of days' supply of the drug dispensed.

j. Serial or prescription number assigned by the pharmacy.

k. Source of payment for the prescription.

2. Information shall be submitted electronically in the format specified by the board unless the board has granted a waiver and approved an alternate format.

3. Information shall be timely transmitted as designated by the board by rule, unless the board grants an extension. The board may grant an extension if either of the following occurs:

a. The pharmacy suffers a mechanical or electronic failure, or cannot meet the deadline established by the board for other reasons beyond the pharmacy's control.

b. The board or its designee is unable to receive electronic submissions.

4. This section shall not apply to a prescriber furnishing, dispensing, supplying, or administering drugs to the prescriber's patient, or to dispensing by a licensed pharmacy for the purposes of inpatient hospital care, inpatient hospice care, or long-term residential facility patient care.

Sec. 4. NEW SECTION. 124.510C DATA ACCESS.

1. The board or its designee may provide information from the electronic drug database to all of the following:

a. A person who is a designated representative of a governmental entity responsible for the licensure, regulation, or discipline of licensed health care professionals authorized to prescribe or dispense drugs, who is involved in an investigation of a person licensed, regulated, or subject to discipline by the entity, and who is seeking access to information in the database that is relevant to the subject matter of the investigation and pursuant to a written probable cause determination.

b. A federal, state, county, township, or municipal officer of this or any other state, or the United States,

whose duty it is to enforce the laws relating to prescription drugs and who is actively engaged in a specific investigation of a specific person and is seeking access to information in the database pursuant to a probable cause determination or warrant.

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

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

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

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

a. Pursuant to a probable cause determination, a designated representative of a governmental entity that is responsible for the licensure, regulation, or discipline of licensed health care professionals authorized to prescribe or dispense drugs who is involved in a specific investigation of the individual who submitted the request.

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

3. Information contained in the database and any information obtained from it is strictly confidential medical information, is not a public record pursuant to chapter 22, and is not subject to discovery, subpoena, or other means of legal compulsion for release except as provided in this division. Information contained in the records of requests for information from the database is privileged and confidential, is not a public record, and is not subject to discovery, subpoena, or other means of legal compulsion for release except as provided in this division. Information from the database shall not be released, shared with an agency or institution, or made public except as provided in this division.

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

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

6. Nothing in this section shall require a pharmacist or prescriber to obtain information about a patient from the database. A pharmacist or prescriber does not have a duty and shall not be held liable in damages to any person in any civil or derivative criminal or administrative action for injury, death, or loss to person or property on the basis that the pharmacist or prescriber did or did not seek or obtain information from the database. A pharmacist or prescriber

acting in good faith is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for requesting or receiving information from the database.

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

Sec. 5. NEW SECTION. 124.510D DATA REVIEW AND REFERRAL.

The board or its designee shall review the information in the electronic drug database. If the board determines, consistent with the board's authority under this chapter or chapter 155A, that there is probable cause to believe that drug diversion or another violation of law may have occurred, the board shall notify the appropriate law enforcement agency or the governmental entity responsible for the licensure, regulation, or discipline of the licensed health care professional, and shall supply information required to initiate an investigation. The board shall not refer information relating to an individual for further investigation except upon a probable cause determination. A probable cause determination shall be consistent with guidelines developed by the advisory council established under section 124.510F.

Sec. 6. NEW SECTION. 124.510E RULES AND REPORTING.

1. The board shall adopt rules in accordance with chapter 17A to carry out the purposes of, and to enforce the

provisions of, this division. The rules shall include but not be limited to the development of procedures relating to:

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

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

c. A waiver to submit information in another format for a pharmacy unable to submit information electronically.

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

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

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

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

h. Submission of a request by an individual for the individual's own database information and verification of the identity of the requestor.

i. The development of a list of controlled substances and other drugs that shall be included in the database.

j. Access by a pharmacist or prescriber to information in the database pursuant to a written agreement with the board.

k. Terms and conditions of the contract, if the board contracts for database administration with a third-party or

private vendor.

1. The correction or deletion of erroneous information from the database.

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

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

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

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

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

Sec. 7. NEW SECTION. 124.510F ADVISORY COUNCIL ESTABLISHED.

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

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

2. The council may make recommendations to advance the goals of the database, which include identification of misuse and diversion of identified controlled substances and other drugs and enhancement of the quality of health care delivery

in this state.

3. Among other things, the council shall:

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

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

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

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

Sec. 8. NEW SECTION. 124.510G PROHIBITED ACTS AND PENALTIES.

The failure of a licensed pharmacist or licensed prescriber to comply with the requirements of this division, or the performance or causing the performance of, or the aiding and abetting of another person in the performance of, any of the prohibited acts identified in this section shall constitute grounds for disciplinary action against the pharmacist or prescriber by the appropriate professional licensing board. Each licensing board that licenses prescribers and drug dispensers subject to the provisions of this division may adopt rules in accordance with chapter 17A to implement the provisions of this section and may impose penalty as allowed under section 272C.3. In addition, a civil penalty not to

exceed twenty-five thousand dollars for each violation may be imposed.

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

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

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

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

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

Sec. 9. EFFECTIVE DATE. This Act, being deemed of immediate importance, takes effect upon enactment.

EXPLANATION

This bill authorizes the board of pharmacy examiners to establish and administer a prescription drug database containing a record of the dispensing of prescriptions for identified controlled substances and prescription drugs. The bill provides that the goals of the database program include

identification of misuse and diversion of prescription drugs and enhancement of the quality of health care delivery in Iowa.

The bill identifies minimum data requirements to be reported by pharmacies dispensing to patients in Iowa, and for pharmacies located in Iowa and dispensing to patients outside the state, for the format and timeliness of data submissions, for the exemption of specified entities from data submission requirements, and for the adoption of rules by the board regarding implementation of the database program.

The bill provides for the identification of persons authorized to request information from the database program, places limitations on access by certain authorized persons, and requires that a record be made and maintained of any request for database information. The bill provides that information contained in the database or derived from the database is confidential information, and provides protection from liability for pharmacists and prescribers whether or not they choose to utilize information from the database in the medical treatment of patients.

The bill provides for the establishment of an advisory council to provide oversight to the database program and provides for the payment of per diem and council member expenses. The bill additionally identifies actions and information uses which are prohibited under the program and the establishment of criminal, administrative, and civil penalties for prohibited acts.

The bill provides for the addition of information contained in the database to the list of confidential records in Code section 22.7.

The bill takes effect upon enactment.

IOWA BOARD OF PHARMACY EXAMINERS

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M E M O R A N D U M

DATE: November 29, 2004

TO: Members of the 80th Iowa General Assembly

FROM: Lloyd K. Jessen
Executive Secretary/Director

SUBJECT: Requested Legislative Amendment – Revise Iowa Code Chapter 124

The Board of Pharmacy Examiners respectfully requests that the proposed amendment be made to Iowa Code Chapter 124.

This bill proposes the adoption of new division in Iowa Code chapter 124 to be known as the Division VI, Electronic Drug Database. The division establishes an electronic drug database for the collection of information for all prescriptions issued for select controlled substances and other drugs having a potential for abuse.

The electronic drug database makes it possible to collect and analyze prescription data much more efficiently than without such a program, where the collection of prescription information requires the manual review of pharmacy files. The increased efficiency of an electronic drug database allows for the early detection of trends in abuse and possible sources of diversion. Prescribers and pharmacists could access the database information to review a patient's prescription drug usage, permitting identification of patients in need of counseling or treatment for abuse or excessive use. Information review would also identify patients involved in doctor or pharmacy shopping, a common scheme used to divert drugs of abuse to the illicit market.

Analyzing the collected data also allows for the identification of outmoded prescribing practices, which may result in the development of new educational programs for medical professionals. States with electronic drug databases have found that the programs are an effective tool for enforcement, education, and prevention that does not interfere with legitimate prescribing and dispensing of pharmaceuticals. Nearly one-half of all U.S. states have established, or are in the process of establishing, an electronic drug database program and there is legislation pending in the U.S. Senate that would require each state to establish and maintain an electronic drug database for all prescriptions dispensing controlled substances.

The new division identifies minimum data elements regarding each prescription that are to be reported and, unless a dispenser is granted a waiver for good cause by the board, data is to be submitted electronically. Provisions of the new division ensure the privacy and confidentiality of information collected by the electronic drug database and specifically identify the persons and agencies to which information may be released and the circumstances dictating such release. Information that is maintained in the database and any information derived from

database information is identified as confidential medical information and records requests for information from the database is confidential. Individual patients are specifically permitted access to their own prescription information.

The new division requires that electronic drug database information be reviewed to determine if there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, in which case the appropriate law enforcement or professional licensing agency will be notified and given necessary information. The Board of Pharmacy Examiners is authorized to adopt rules necessary to implement the electronic drug database and to contract with another state agency or with a private vendor to assist with the implementation and operation of the database. The contracting agency or vendor would be subject to the confidentiality provisions of the division, as would any health care practitioner accessing database information. The new division provides penalties for violation of confidentiality requirements and for a knowing failure to submit accurate or required information to the electronic drug database. Provisions of the new division protect prescribers and pharmacists from liability in any civil or derivative criminal or administrative action based on the practitioner's decision whether or not to utilize database information in the treatment of a patient.

Representatives from Iowa's health professions licensing boards, associations, societies, pharmacies, and prescriber practices participated in the drafting and development of this proposed amendment to the Iowa Controlled Substances Act.

HOUSE FILE 722

AN ACT

PROVIDING FOR THE ESTABLISHMENT OF AN INFORMATION PROGRAM FOR DRUG PRESCRIBING AND DISPENSING, PROVIDING PENALTIES, AND PROVIDING AN EFFECTIVE DATE.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. Section 22.7, Code Supplement 2005, is amended by adding the following new subsection:

NEW SUBSECTION. 52. The information contained in the information program established in section 124.510A, except to the extent that disclosure is authorized pursuant to section 124.510C.

Sec. 2. NEW SECTION. 124.510A INFORMATION PROGRAM FOR DRUG PRESCRIBING AND DISPENSING.

Contingent upon the receipt of funds pursuant to section 124.510G sufficient to carry out the purposes of this division, the board, in conjunction with the advisory council created in section 124.510E, shall establish and maintain an information program for drug prescribing and dispensing. The program shall collect from pharmacies dispensing information for controlled substances identified pursuant to section 124.510D, subsection 1, paragraph "g". The information collected shall be used by prescribing practitioners and pharmacists on a need-to-know basis for purposes of improving patient health care by facilitating early identification of patients who may be at risk for addiction, or who may be using, abusing, or diverting drugs for unlawful or otherwise unauthorized purposes at risk to themselves and others, or who may be appropriately using controlled substances lawfully

prescribed for them but unknown to the practitioner. For purposes of this division, "prescribing practitioner" means a practitioner who has prescribed or is contemplating the authorization of a prescription for the patient about whom information is requested, and "pharmacist" means a practicing pharmacist who is actively engaged in and responsible for the pharmaceutical care of the patient about whom information is requested. The board shall collect, store, and disseminate program information consistent with security criteria established by rule, including use of appropriate encryption or other industry-recognized security technology. The board shall seek any federal waiver necessary to implement the provisions of the program.

Sec. 3. NEW SECTION. 124.510B INFORMATION REPORTING.

1. Each licensed pharmacy that dispenses controlled substances identified pursuant to section 124.510D, subsection 1, paragraph "g", to patients in the state, and each licensed pharmacy located in the state that dispenses such controlled substances identified pursuant to section 124.510D, subsection 1, paragraph "g", to patients inside or outside the state, unless specifically excepted in this section or by rule, shall submit the following prescription information to the program:

a. Pharmacy identification.

b. Patient identification.

c. Prescriber identification.

d. The date the prescription was issued by the prescriber.

e. The date the prescription was dispensed.

f. An indication of whether the prescription dispensed is new or a refill.

g. Identification of the drug dispensed.

h. Quantity of the drug dispensed.

i. The number of days' supply of the drug dispensed.

j. Serial or prescription number assigned by the pharmacy.

k. Type of payment for the prescription.

l. Other information identified by the board and advisory council by rule.

2. Information shall be submitted electronically in a secure format specified by the board unless the board has granted a waiver and approved an alternate secure format.

3. Information shall be timely transmitted as designated by the board and advisory council by rule, unless the board grants an extension. The board may grant an extension if either of the following occurs:

a. The pharmacy suffers a mechanical or electronic failure, or cannot meet the deadline established by the board for other reasons beyond the pharmacy's control.

b. The board is unable to receive electronic submissions.

4. This section shall not apply to a prescriber furnishing, dispensing, supplying, or administering drugs to the prescriber's patient, or to dispensing by a licensed pharmacy for the purposes of inpatient hospital care, inpatient hospice care, or long-term residential facility patient care.

Sec. 4. NEW SECTION. 124.510C INFORMATION ACCESS.

1. The board may provide information from the program to the following:

a. (1) A pharmacist or prescriber who requests the information and certifies in a form specified by the board that it is for the purpose of providing medical or pharmaceutical care to a patient of the pharmacist or prescriber. Neither a pharmacist nor a prescriber may delegate program information access to another individual.

(2) Notwithstanding subparagraph (1), a prescriber may delegate program information access to another licensed health care professional only in emergency situations where the patient would be placed in greater jeopardy if the prescriber was required to access the information personally.

b. An individual who requests the individual's own program information in accordance with the procedure established in rules of the board and advisory council adopted under section 124.510D.

c. Pursuant to an order, subpoena, or other means of legal compulsion for access to or release of program information that is issued based upon a determination of probable cause in the course of a specific investigation of a specific individual.

2. The board shall maintain a record of each person that requests information from the program. Pursuant to rules adopted by the board and advisory council under section 124.510D, the board may use the records to document and report statistical information.

3. Information contained in the program and any information obtained from it, and information contained in the records of requests for information from the program, is privileged and strictly confidential information. Such information is not a public record pursuant to chapter 22, and is not subject to discovery, subpoena, or other means of legal compulsion for release except as provided in this division. Information from the program shall not be released, shared with an agency or institution, or made public except as provided in this division.

4. Information collected for the program shall be retained in the program for four years from the date of dispensing. The information shall then be destroyed.

5. A pharmacist or other dispenser making a report to the program reasonably and in good faith pursuant to this division is immune from any liability, civil, criminal, or administrative, which might otherwise be incurred or imposed as a result of the report.

6. Nothing in this section shall require a pharmacist or prescriber to obtain information about a patient from the program. A pharmacist or prescriber does not have a duty and shall not be held liable in damages to any person in any civil or derivative criminal or administrative action for injury, death, or loss to person or property on the basis that the pharmacist or prescriber did or did not seek or obtain or use information from the program. A pharmacist or prescriber

acting reasonably and in good faith is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for requesting or receiving or using information from the program.

7. The board shall not charge a fee to a pharmacy, pharmacist, or prescriber for the establishment, maintenance, or administration of the program, including costs for forms required to submit information to or access information from the program, except that the board may charge a fee to an individual who requests the individual's own program information. A fee charged pursuant to this subsection shall not exceed the actual cost of providing the requested information and shall be considered a repayment receipt as defined in section 8.2.

Sec. 5. NEW SECTION. 124.510D RULES AND REPORTING.

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

a. Identifying each patient about whom information is entered into the program.

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

c. A waiver to submit information in another format for a pharmacy unable to submit information electronically.

d. An application by a pharmacy for an extension of time for transmitting information to the program.

e. The submission by an authorized requestor of a request for information and a procedure for the verification of the identity of the requestor.

f. Use by the board or advisory council of the program request records required by section 124.510C, subsection 2, to document and report statistical information.

g. Including all Schedule II controlled substances and those substances in Schedules III and IV that the advisory

council and board determine can be addictive or fatal if not taken under the proper care and direction of a prescriber.

h. Access by a pharmacist or prescriber to information in the program pursuant to a written agreement with the board and advisory council.

i. The correction or deletion of erroneous information in the program.

2. Beginning January 1, 2007, and annually by January 1 thereafter, the board and advisory council shall present to the general assembly and the governor a report prepared consistent with section 124.510E, subsection 3, paragraph "d", which shall include but not be limited to the following:

a. The cost to the state of implementing and maintaining the program.

b. Information from pharmacies, prescribers, the board, the advisory council, and others regarding the benefits or detriments of the program.

c. Information from pharmacies, prescribers, the board, the advisory council, and others regarding the board's effectiveness in providing information from the program.

Sec. 6. NEW SECTION. 124.510E ADVISORY COUNCIL ESTABLISHED.

An advisory council shall be established to provide oversight to the board and the program and to comanage program activities. The board and advisory council shall jointly adopt rules specifying the duties and activities of the advisory council and related matters.

1. The council shall consist of eight members appointed by the governor. The members shall include three licensed pharmacists, four physicians licensed under chapter 148, 150, or 150A, and one licensed prescriber who is not a physician. The governor shall solicit recommendations for council members from Iowa health professional licensing boards, associations, and societies. The license of each member appointed to and serving on the advisory council shall be current and in good standing with the professional's licensing board.

2. The council shall advance the goals of the program, which include identification of misuse and diversion of controlled substances identified pursuant to section 124.510D, subsection 1, paragraph "g", and enhancement of the quality of health care delivery in this state.

3. Duties of the council shall include but not be limited to the following:

a. Ensuring the confidentiality of the patient, prescriber, and dispensing pharmacist and pharmacy.

b. Respecting and preserving the integrity of the patient's treatment relationship with the patient's health care providers.

c. Encouraging and facilitating cooperative efforts among health care practitioners and other interested and knowledgeable persons in developing best practices for prescribing and dispensing controlled substances and in educating health care practitioners and patients regarding controlled substance use and abuse.

d. Making recommendations regarding the continued benefits of maintaining the program in relationship to cost and other burdens to the patient, prescriber, pharmacist, and the board. The council's recommendations shall be included in reports required by section 124.510D, subsection 2.

e. One physician and one pharmacist member of the council shall include in their duties the responsibility for monitoring and ensuring that patient confidentiality, best interests, and civil liberties are at all times protected and preserved during the existence of the program.

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

Sec. 7. NEW SECTION. 124.510F EDUCATION AND TREATMENT.

The program for drug prescribing and dispensing shall include education initiatives and outreach to consumers, prescribers, and pharmacists, and shall also include assistance for identifying substance abuse treatment programs and providers. The board and advisory council shall adopt rules, as provided under section 124.510D, to implement this section.

Sec. 8. NEW SECTION. 124.510G DRUG INFORMATION PROGRAM FUND.

The drug information program fund is established to be used by the board to fund or assist in funding the program. The board may make deposits into the fund from any source, public or private, including grants or contributions of money or other items of value, which it determines necessary to carry out the purposes of this division. Moneys received by the board to establish and maintain the program must be used for the expenses of administering this division. Notwithstanding section 8.33, amounts contained in the fund that remain unencumbered or unobligated at the close of the fiscal year shall not revert but shall remain available for expenditure for the purposes designated in future years.

Sec. 9. NEW SECTION. 124.510H PROHIBITED ACTS -- PENALTIES.

1. FAILURE TO COMPLY WITH REQUIREMENTS. A pharmacist, pharmacy, or prescriber who knowingly fails to comply with the confidentiality requirements of this division or who delegates program information access to another individual is subject to disciplinary action by the appropriate professional licensing board. A pharmacist or pharmacy that knowingly fails to comply with other requirements of this division is subject to disciplinary action by the board. Each licensing board may adopt rules in accordance with chapter 17A to implement the provisions of this section.

2. UNLAWFUL ACCESS, DISCLOSURE, OR USE OF INFORMATION. A person who intentionally or knowingly accesses, uses, or discloses program information in violation of this division,

unless otherwise authorized by law, is guilty of a class "D" felony. This section shall not preclude a pharmacist or prescriber who requests and receives information from the program consistent with the requirements of this chapter from otherwise lawfully providing that information to any other person for medical or pharmaceutical care purposes.

Sec. 10. Sections 124.510A through 124.510H are repealed June 30, 2009.

Sec. 11. EFFECTIVE DATE. This Act, being deemed of immediate importance, takes effect upon enactment.

CHRISTOPHER C. RANTS
Speaker of the House

JEFFREY M. LAMBERTI
President of the Senate

I hereby certify that this bill originated in the House and is known as House File 722, Eighty-first General Assembly.

MARGARET THOMSON
Chief Clerk of the House

Approved _____, 2006

THOMAS J. VILSACK
Governor