

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

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

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

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HF 722

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

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

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

9 The board shall establish and maintain an electronic drug
10 database. The board shall use the electronic drug database to
11 monitor the misuse, abuse, and diversion of selected
12 controlled substances and other drugs the board includes in
13 the database pursuant to section 124.510E, subsection 1,
14 paragraph "i". The board shall electronically collect and
15 disseminate information pursuant to sections 124.510C and
16 124.510D and rules adopted pursuant to this division. The
17 board may contract with a third-party/private vendor to
18 administer the electronic drug database.

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

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

- 27 a. Pharmacy identification.
- 28 b. Patient identification.
- 29 c. Prescriber identification.
- 30 d. The date the prescription was issued by the prescriber.
- 31 e. The date the prescription was dispensed.
- 32 f. An indication of whether the prescription dispensed is
33 new or a refill.
- 34 g. Identification of the drug dispensed.
- 35 h. Quantity of the drug dispensed.

- 1 i. The number of days' supply of the drug dispensed.
- 2 j. Serial or prescription number assigned by the pharmacy.
- 3 k. Source of payment for the prescription.

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

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

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

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

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

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

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

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

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

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

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

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

12 e. An individual who requests the individual's own
13 database information in accordance with the procedure
14 established in rules of the board adopted under section
15 124.510E.

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

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

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

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

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

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

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

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

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

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

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

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

34 1. The board shall adopt rules in accordance with chapter
35 17A to carry out the purposes of, and to enforce the

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

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

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

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

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

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

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

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

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

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

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

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

1 private vendor.

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

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

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

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

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

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

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

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

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

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

1 in this state.

2 3. Among other things, the council shall:

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

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

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

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

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

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

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

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

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

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

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

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

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

30 EXPLANATION

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

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

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

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

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

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

31 The bill takes effect upon enactment.

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HOUSE FILE 722

H-1121

1 Amend House File 722 as follows:

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

4 "6. This section shall not preclude a pharmacist
5 or prescriber who requests and receives information
6 from the database consistent with the requirements of
7 this chapter from otherwise lawfully providing that
8 information to any other person for medical or
9 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

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

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

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House Amendments _____

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

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

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

9 The board shall establish and maintain an electronic drug
10 database. The board shall use the electronic drug database to
11 monitor the misuse, abuse, and diversion of selected
12 controlled substances and other drugs the board includes in
13 the database pursuant to section 124.510E, subsection 1,
14 paragraph "i". The board shall electronically collect and
15 disseminate information pursuant to sections 124.510C and
16 124.510D and rules adopted pursuant to this division. The
17 board may contract with a third-party/private vendor to
18 administer the electronic drug database.

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

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

- 27 a. Pharmacy identification.
- 28 b. Patient identification.
- 29 c. Prescriber identification.
- 30 d. The date the prescription was issued by the prescriber.
- 31 e. The date the prescription was dispensed.
- 32 f. An indication of whether the prescription dispensed is
33 new or a refill.
- 34 g. Identification of the drug dispensed.
- 35 h. Quantity of the drug dispensed.

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

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

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

12 e. An individual who requests the individual's own
13 database information in accordance with the procedure
14 established in rules of the board adopted under section
15 124.510E.

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

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

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

- 1 i. The number of days' supply of the drug dispensed.
- 2 j. Serial or prescription number assigned by the pharmacy.
- 3 k. Source of payment for the prescription.

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

7 3. Information shall be timely transmitted as designated
8 by the board by rule, unless the board grants an extension.

9 The board may grant an extension if either of the following
10 occurs:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

34 1. The board shall adopt rules in accordance with chapter
35 17A to carry out the purposes of, and to enforce the

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

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

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

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

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17 regarding information to be transmitted to the board or its
18 designee.

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20 which the board is authorized to provide information of a
21 request for the information and a procedure for the
22 verification of the identity of the requestor.

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28 individual's own database information and verification of the
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31 other drugs that shall be included in the database.

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33 the database pursuant to a written agreement with the board.

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35 contracts for database administration with a third-party or

1 private vendor.

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3 from the database.

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5 thereafter, the board shall present to the general assembly
6 and the governor a report of the following:

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8 the database.

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

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12 and others regarding the board's effectiveness in providing
13 information from the database.

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15 information from the electronic drug database to authorized
16 requestors.

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4 requests by researchers and other persons for statistical,
5 aggregate, or nonpersonally identified information using
6 database information, developed consistent with the goals of
7 the database.

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

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

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

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

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

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

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

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

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

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

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

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

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

35

**EIGHTY FIRST GENERAL ASSEMBLY
2006 REGULAR SESSION
DAILY
SENATE CLIP SHEET**

MARCH 28, 2006

HOUSE FILE 722

S-5126

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

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

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

7 NEW SUBSECTION. 52. The information contained in
8 the information program established in section
9 124.510A, except to the extent that disclosure is
10 authorized pursuant to section 124.510C.

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

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

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

40 1. Each licensed pharmacy that dispenses
41 controlled substances identified pursuant to section
42 124.510D, subsection 1, paragraph "g", to patients in
43 the state, and each licensed pharmacy located in the
44 state that dispenses such controlled substances
45 identified pursuant to section 124.510D, subsection 1,
46 paragraph "g", to patients inside or outside the
47 state, unless specifically excepted in this section or
48 by rule, shall submit the following prescription
49 information to the program:

50 a. Pharmacy identification.

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- 1 b. Patient identification.
- 2 c. Prescriber identification.
- 3 d. The date the prescription was issued by the
- 4 prescriber.
- 5 e. The date the prescription was dispensed.
- 6 f. An indication of whether the prescription
- 7 dispensed is new or a refill.
- 8 g. Identification of the drug dispensed.
- 9 h. Quantity of the drug dispensed.
- 10 i. The number of days' supply of the drug
- 11 dispensed.
- 12 j. Serial or prescription number assigned by the
- 13 pharmacy.
- 14 k. Type of payment for the prescription.
- 15 1. Other information identified by the board and
- 16 advisory council by rule.
- 17 2. Information shall be submitted electronically
- 18 in a secure format specified by the board unless the
- 19 board has granted a waiver and approved an alternate
- 20 secure format.
- 21 3. Information shall be timely transmitted as
- 22 designated by the board and advisory council by rule,
- 23 unless the board grants an extension. The board may
- 24 grant an extension if either of the following occurs:
- 25 a. The pharmacy suffers a mechanical or electronic
- 26 failure, or cannot meet the deadline established by
- 27 the board for other reasons beyond the pharmacy's
- 28 control.
- 29 b. The board is unable to receive electronic
- 30 submissions.
- 31 4. This section shall not apply to a prescriber
- 32 furnishing, dispensing, supplying, or administering
- 33 drugs to the prescriber's patient, or to dispensing by
- 34 a licensed pharmacy for the purposes of inpatient
- 35 hospital care, inpatient hospice care, or long-term
- 36 residential facility patient care.

37 Sec. 4. NEW SECTION. 124.510C INFORMATION

38 ACCESS.

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

1 adopted under section 124.510D.

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

7 2. The board shall maintain a record of each
8 person that requests information from the program.

9 Pursuant to rules adopted by the board and advisory
10 council under section 124.510D, the board may use the
11 records to document and report statistical
12 information.

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

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

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

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

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

1 information to or access information from the program,
2 except that the board may charge a fee to an
3 individual who requests the individual's own program
4 information. A fee charged pursuant to this
5 subsection shall not exceed the actual cost of
6 providing the requested information and shall be
7 considered a repayment receipt as defined in section
8 8.2.

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

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

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

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

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

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

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

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

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

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

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

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

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

50 b. Information from pharmacies, prescribers, the

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

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

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

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

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

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

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

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

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

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

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

1 by section 124.510D, subsection 2.

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

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

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

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

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

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

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

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

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

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

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

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

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

24 3. By renumbering as necessary.

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

**EIGHTY FIRST GENERAL ASSEMBLY
2006 REGULAR SESSION
DAILY
SENATE CLIP SHEET**

MARCH 30, 2006

HOUSE FILE 722

S-5137

1 Amend the Senate amendment, S-5126, to House File
2 722, as amended, passed, and reprinted by the House,
3 as follows:

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

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

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

By JACK HATCH
JAMES SEYMOUR

S-5137 FILED MARCH 29, 2006
ADOPTED

HOUSE FILE 722

S-5139

1 Amend the Senate amendment, S-5126, to House File
2 722, as amended, passed, and reprinted by the House,
3 as follows:

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

6 2. Page 1, line 31, by inserting after the word
7 "practitioner." the following: "For purposes of this
8 division, "prescribing practitioner" means a
9 practitioner who has prescribed or is contemplating
10 the authorization of a prescription for the patient
11 about whom information is requested, and "pharmacist"
12 means a practicing pharmacist who is actively engaged
13 in and responsible for the pharmaceutical care of the
14 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

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

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

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

7 NEW SUBSECTION. 52. The information contained in
8 the information program established in section
9 124.510A, except to the extent that disclosure is
10 authorized pursuant to section 124.510C.

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

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

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

47 1. Each licensed pharmacy that dispenses
48 controlled substances identified pursuant to section
49 124.510D, subsection 1, paragraph "g", to patients in
50 the state, and each licensed pharmacy located in the

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

- 7 a. Pharmacy identification.
- 8 b. Patient identification.
- 9 c. Prescriber identification.
- 10 d. The date the prescription was issued by the
11 prescriber.
- 12 e. The date the prescription was dispensed.
- 13 f. An indication of whether the prescription
14 dispensed is new or a refill.
- 15 g. Identification of the drug dispensed.
- 16 h. Quantity of the drug dispensed.
- 17 i. The number of days' supply of the drug
18 dispensed.
- 19 j. Serial or prescription number assigned by the
20 pharmacy.
- 21 k. Type of payment for the prescription.
- 22 1. Other information identified by the board and
23 advisory council by rule.
- 24 2. Information shall be submitted electronically
25 in a secure format specified by the board unless the
26 board has granted a waiver and approved an alternate
27 secure format.
- 28 3. Information shall be timely transmitted as
29 designated by the board and advisory council by rule,
30 unless the board grants an extension. The board may
31 grant an extension if either of the following occurs:
32 a. The pharmacy suffers a mechanical or electronic
33 failure, or cannot meet the deadline established by
34 the board for other reasons beyond the pharmacy's
35 control.
- 36 b. The board is unable to receive electronic
37 submissions.
- 38 4. This section shall not apply to a prescriber
39 furnishing, dispensing, supplying, or administering
40 drugs to the prescriber's patient, or to dispensing by
41 a licensed pharmacy for the purposes of inpatient
42 hospital care, inpatient hospice care, or long-term
43 residential facility patient care.

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

- 46 1. The board may provide information from the
47 program to the following:
 - 48 a. (1) A pharmacist or prescriber who requests
49 the information and certifies in a form specified by
50 the board that it is for the purpose of providing

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

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

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

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

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

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

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

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

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

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

10 7. The board shall not charge a fee to a pharmacy,
11 pharmacist, or prescriber for the establishment,
12 maintenance, or administration of the program,
13 including costs for forms required to submit
14 information to or access information from the program,
15 except that the board may charge a fee to an
16 individual who requests the individual's own program
17 information. A fee charged pursuant to this
18 subsection shall not exceed the actual cost of
19 providing the requested information and shall be
20 considered a repayment receipt as defined in section
21 8.2.

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

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

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

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

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

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

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

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

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

50 h. Access by a pharmacist or prescriber to

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

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

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

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

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

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

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

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

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

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

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

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

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

1 health care providers.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

37 3. By renumbering as necessary.

RECEIVED FROM THE SENATE

*Tomenga
Hutter
Smith*

SU 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

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

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

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

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

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

9 The board shall establish and maintain an electronic drug
10 database. The board shall use the electronic drug database to
11 monitor the misuse, abuse, and diversion of selected
12 controlled substances and other drugs the board includes in
13 the database pursuant to section 124.510E, subsection 1,
14 paragraph "i". The board shall electronically collect and
15 disseminate information pursuant to sections 124.510C and
16 124.510D and rules adopted pursuant to this division. The
17 board may contract with a third-party/private vendor to
18 administer the electronic drug database.

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

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

- 27 a. Pharmacy identification.
- 28 b. Patient identification.
- 29 c. Prescriber identification.
- 30 d. The date the prescription was issued by the prescriber.
- 31 e. The date the prescription was dispensed.
- 32 f. An indication of whether the prescription dispensed is
33 new or a refill.
- 34 g. Identification of the drug dispensed.
- 35 h. Quantity of the drug dispensed.

- 1 i. The number of days' supply of the drug dispensed.
- 2 j. Serial or prescription number assigned by the pharmacy.
- 3 k. Source of payment for the prescription.

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

7 3. Information shall be timely transmitted as designated
8 by the board by rule, unless the board grants an extension.

9 The board may grant an extension if either of the following
10 occurs:

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

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

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

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

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

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

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

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

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

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

12 e. An individual who requests the individual's own
13 database information in accordance with the procedure
14 established in rules of the board adopted under section
15 124.510E.

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

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

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

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

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

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

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

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

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

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

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

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

34 1. The board shall adopt rules in accordance with chapter
35 17A to carry out the purposes of, and to enforce the

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

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

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

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

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

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

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

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

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

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

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

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

1 private vendor.

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

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

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

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

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

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

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

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

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

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

1 in this state.

2 3. Among other things, the council shall:

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

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

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

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

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

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

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

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

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

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

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

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

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

30 EXPLANATION

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

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

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

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

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

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

31 The bill takes effect upon enactment.

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IOWA BOARD OF PHARMACY EXAMINERS

400 S.W. Eighth Street, Suite E

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

BOARD OF PHARMACY EXAMINERS

MEMORANDUM

November 29, 2004

Page 2

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

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

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

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

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

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

9 The board shall establish and maintain an electronic drug
10 database. The board shall use the electronic drug database to
11 monitor the misuse, abuse, and diversion of selected
12 controlled substances and other drugs the board includes in
13 the database pursuant to section 124.510E, subsection 1,
14 paragraph "i". The board shall electronically collect and
15 disseminate information pursuant to sections 124.510C and
16 124.510D and rules adopted pursuant to this division. The
17 board may contract with a third-party/private vendor to
18 administer the electronic drug database.

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

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

- 27 a. Pharmacy identification.
- 28 b. Patient identification.
- 29 c. Prescriber identification.
- 30 d. The date the prescription was issued by the prescriber.
- 31 e. The date the prescription was dispensed.
- 32 f. An indication of whether the prescription dispensed is
33 new or a refill.
- 34 g. Identification of the drug dispensed.
- 35 h. Quantity of the drug dispensed.

- 1 i. The number of days' supply of the drug dispensed.
- 2 j. Serial or prescription number assigned by the pharmacy.
- 3 k. Source of payment for the prescription.

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

7 3. Information shall be timely transmitted as designated
8 by the board by rule, unless the board grants an extension.

9 The board may grant an extension if either of the following
10 occurs:

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

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

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

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

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

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

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

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

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

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

12 e. An individual who requests the individual's own
13 database information in accordance with the procedure
14 established in rules of the board adopted under section
15 124.510E.

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

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

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

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

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

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

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

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

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

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

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

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

34 1. The board shall adopt rules in accordance with chapter
35 17A to carry out the purposes of, and to enforce the

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

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

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

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

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

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

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

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

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

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

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

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

1 private vendor.

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

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

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

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

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

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

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

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

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

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

1 in this state.

2 3. Among other things, the council shall:

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

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

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

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

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

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

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

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

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

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

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

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

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

30 EXPLANATION

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

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

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

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

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

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

31 The bill takes effect upon enactment.

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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

BOARD OF PHARMACY EXAMINERS

MEMORANDUM

November 29, 2004

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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