House Amendment 8438

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Amend House File 722, as passed by the House, as
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   2 follows:
    3 #1. By striking everything after the enacting
    4 clause and inserting the following:
          <Section 1. Section 22.7, Code Supplement 2005, is
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   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.
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          Sec. 2. <u>NEW SECTION</u>. 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
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  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.
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          Sec. 3. <u>NEW SECTION</u>.
                                       124.510B INFORMATION
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  46 REPORTING.
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               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 1 state that dispenses such controlled substances
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   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
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   6 information to the program:
          a. Pharmacy identification.b. Patient identification.
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          b.
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          c. Prescriber identification.
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          d.
               The date the prescription was issued by the
  11 prescriber.
          e.
               The date the prescription was dispensed.
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               An indication of whether the prescription
  14 dispensed is new or a refill.
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              Identification of the drug dispensed.
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               Quantity of the drug dispensed.
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          i.
               The number of days' supply of the drug
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  18 dispensed.
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         j. Serial or prescription number assigned by the
  20 pharmacy.
               Type of payment for the prescription.
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              Other information identified by the board and
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  23 advisory council by rule.
          2. Information shall be submitted electronically
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2 25 in a secure format specified by the board unless the 2 26 board has granted a waiver and approved an alternate 2 27 secure format.

- 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.
- b. The board is unable to receive electronic 37 submissions.

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- 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.
- Sec. 4. <u>NEW SECTION</u>. 124.510C INFORMATION 45 ACCESS.
- The board may provide information from the 1. 47 program to the following:
- 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.
- (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 precriber was required to 10 access the information personally.
- 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.
- 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.
- 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.
- 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.
- Information collected for the program shall be 38 retained in the program for four years from the date The information shall then be 39 of dispensing. 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.
- 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.

4 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 4 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.

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

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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:

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

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

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.

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.

f. Use by the board or advisory council of the 4 42 program request records required by section 124.510C, 43 subsection 2, to document and report statistical 4 44 information.

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.

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.

i. The correction or deletion of erroneous

4 information in the program.

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.

Sec. 6. <u>NEW SECTION</u>. 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, 5 35 and societies. The license of each member appointed 5 36 to and serving on the advisory council shall be

37 current and in good standing with the professional's 5 38 licensing board.

The council shall advance the goals of the 2. 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.

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

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

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b. Respecting and preserving the integrity of the 50 patient's treatment relationship with the patient's 1 health care providers.

Encouraging and facilitating cooperative 3 efforts among health care practitioners and other 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.

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 15

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.

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. <u>NEW SECTION</u>. 124.510F EDU

124.510F EDUCATION AND 29 TREATMENT.

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. <u>NEW SECTION</u>. 38 PROGRAM FUND. 124.510G DRUG INFORMATION

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.

Sec. 9. NEW SECTION. 124.510H PROHIBITED ACTS == 4 PENALTIES.

FAILURE TO COMPLY WITH REQUIREMENTS. 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.

2. UNLAWFUL ACCESS, DISCLOSURE, OR USE OF

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7 18 INFORMATION. A person who intentionally or knowingly
7 19 accesses, uses, or discloses program information in
7 20 violation of this division, unless otherwise
7 21 authorized by law, is guilty of a class "D" felony.
7 22 This section shall not preclude a pharmacist or
7 23 prescriber who requests and receives information from
7 24 the program consistent with the requirements of this
7 25 chapter from otherwise lawfully providing that
7 26 information to any other person for medical or
7 27 pharmaceutical care purposes.
8 28 Sec. 10. Sections 124.510A through 124.510H are
7 29 repealed June 30, 2009.
8 30 Sec. 11. EFFECTIVE DATE. This Act, being deemed
8 31 of immediate importance, takes effect upon enactment.
8 32 #2. Title page, by striking lines 1 through 3 and
8 inserting the following: <An Act providing for the
9 34 establishment of an information program for drug
9 prescribing and dispensing, providing penalties, and
9 and
9 37 #3. By renumbering as necessary.
9 38 HF 722.S
9 39 rn/cc/26
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