

By Senator Fasano

11-693-04

1 A bill to be entitled
2 An act relating to controlled substances;
3 creating s. 831.311, F.S.; prohibiting the
4 sale, manufacture, alteration, delivery,
5 uttering, or possession of
6 counterfeit-resistant prescription blanks for
7 controlled substances; providing penalties;
8 amending s. 893.04, F.S.; providing additional
9 requirements for the dispensing of a controlled
10 substance listed in Schedule II, Schedule III,
11 or Schedule IV; providing rulemaking authority
12 to the Board of Pharmacy; creating s. 893.055,
13 F.S.; requiring the Department of Health to
14 establish an electronic system to monitor the
15 prescribing of controlled substances listed in
16 Schedules II, III, and IV; requiring the
17 dispensing of such controlled substances to be
18 reported through the system; providing
19 exceptions; providing reporting requirements;
20 providing penalties; requiring the department
21 and regulatory boards to adopt rules; requiring
22 the department to cover all costs for the
23 system; providing for an appropriation, subject
24 to availability of funds; providing that a
25 certain trust fund may not be used to fund the
26 program; creating s. 893.065, F.S.; requiring
27 the department to develop and adopt by rule the
28 form and content for a counterfeit-proof
29 prescription blank for voluntary use by
30 physicians to prescribe a controlled substance
31 listed in Schedule II, Schedule III, or

1 Schedule IV; providing an appropriation and
2 authorizing positions; providing contingent
3 applicability of penalties; providing
4 contingent effective dates.

5
6 Be It Enacted by the Legislature of the State of Florida:

7
8 Section 1. Section 831.311, Florida Statutes, is
9 created to read:

10 831.311 Unlawful sale, manufacture, alteration,
11 delivery, uttering, or possession of counterfeit-resistant
12 prescription blanks for controlled substances listed in
13 Schedules II, III, and IV.--

14 (1) It is unlawful for any person with the intent to
15 injure or defraud any person or to facilitate any violation of
16 s. 893.13 to sell, manufacture, alter, deliver, utter, or
17 possess any counterfeit-resistant prescription blanks for
18 controlled substances adopted by rule of the Department of
19 Health pursuant to s. 893.065.

20 (2) Any person who violates this section commits a
21 felony of the third degree, punishable as provided in s.
22 775.082, s. 775.083, or s. 775.084.

23 Section 2. Section 893.04, Florida Statutes, is
24 amended to read:

25 893.04 Pharmacist and practitioner.--

26 (1) A pharmacist, in good faith and in the course of
27 professional practice only, may dispense controlled substances
28 upon a written or oral prescription of a practitioner, under
29 the following conditions:

30
31

1 (a) Oral prescriptions must be promptly reduced to
2 writing by the pharmacist or recorded electronically if
3 permitted by federal law.

4 (b) The written prescription must be dated and signed
5 by the prescribing practitioner on the day when issued.

6 (c) There shall appear on the face of the prescription
7 or written record thereof for the controlled substance the
8 following information:

9 1. The full name and address of the person for whom,
10 or the owner of the animal for which, the controlled substance
11 is dispensed.

12 2. The full name and address of the prescribing
13 practitioner and the practitioner's federal controlled
14 substance registry number shall be printed thereon.

15 3. If the prescription is for an animal, the species
16 of animal for which the controlled substance is prescribed.

17 4. The name of the controlled substance prescribed and
18 the strength, quantity, and directions for use thereof.

19 5. The number of the prescription, as recorded in the
20 prescription files of the pharmacy in which it is filled.

21 6. The initials of the pharmacist filling the
22 prescription and the date filled.

23 (d) The prescription shall be retained on file by the
24 proprietor of the pharmacy in which it is filled for a period
25 of 2 years.

26 (e) Affixed to the original container in which a
27 controlled substance is delivered upon a prescription or
28 authorized refill thereof, as hereinafter provided, there
29 shall be a label bearing the following information:

30 1. The name and address of the pharmacy from which
31 such controlled substance was dispensed.

1 2. The date on which the prescription for such
2 controlled substance was filled.

3 3. The number of such prescription, as recorded in the
4 prescription files of the pharmacy in which it is filled.

5 4. The name of the prescribing practitioner.

6 5. The name of the patient for whom, or of the owner
7 and species of the animal for which, the controlled substance
8 is prescribed.

9 6. The directions for the use of the controlled
10 substance prescribed in the prescription.

11 7. A clear, concise warning that it is a crime to
12 transfer the controlled substance to any person other than the
13 patient for whom prescribed.

14 (f) A prescription for a controlled substance listed
15 in Schedule II may be dispensed only upon a written
16 prescription of a practitioner, except that in an emergency
17 situation, as defined by regulation of the Department of
18 Health, such controlled substance may be dispensed upon oral
19 prescription but is limited to a 72-hour supply. No
20 prescription for a controlled substance listed in Schedule II
21 may be refilled.

22 (g) No prescription for a controlled substance listed
23 in Schedule ~~Schedules~~ III, Schedule IV, or Schedule V may be
24 filled or refilled more than five times within a period of 6
25 months after the date on which the prescription was written
26 unless the prescription is renewed by a practitioner.

27 (2)(a) A pharmacist may not dispense a controlled
28 substance listed in Schedule II, Schedule III, or Schedule IV
29 to any patient or patient's agent without first determining,
30 in the exercise of her or his professional judgment, that the
31 order is valid. The pharmacist or pharmacist's agent must

1 also obtain the patient or patient's agent identification
2 information, in writing, electronic format, or other approved
3 manner prior to dispensing any controlled substance. If the
4 patient or patient's agent does not have appropriate
5 identification, the pharmacist may dispense the controlled
6 substance only when the pharmacist determines, in the exercise
7 of her or his professional judgment, that the order is valid
8 and includes such information in the patient's record. The
9 Board of Pharmacy may adopt, by rule, required patient
10 identification information for controlled substances and
11 procedures for a pharmacist to verify the validity of a
12 prescription for controlled substances for circumstances in
13 which the pharmacist was not provided required identification
14 information.

15 (b) Any pharmacist that dispenses by mail a controlled
16 substance listed in Schedule II, Schedule III, or Schedule IV
17 shall be exempt from the requirement to obtain suitable
18 identification for the prescription dispensed by mail.

19 (c) Any controlled substance listed in Schedule III or
20 Schedule IV may be dispensed by a pharmacist upon an oral
21 prescription if, before filling the prescription, the
22 pharmacist reduces it to writing or records the prescription
23 electronically if permitted by federal law. Such prescriptions
24 must contain the date of the oral authorization.

25 (d) Each written prescription prescribed by a
26 practitioner in this state for a controlled substance listed
27 in Schedule II, Schedule III, or Schedule IV must include both
28 a written and a numerical notation of the quantity on the face
29 of the prescription and a notation of the date with the
30 abbreviated month written out on the face of the prescription.
31 A pharmacist shall be permitted, upon verification by the

1 prescriber, to document any information required by this
2 paragraph.

3 (e) A pharmacist may not dispense more than a 30-day
4 supply of a controlled substance listed in Schedule III upon
5 an oral prescription issued in this state.

6 (f) A pharmacist may not knowingly fill a prescription
7 that has been forged for a controlled substance listed in
8 Schedule II, Schedule III, or Schedule IV.

9 (3)(2) Notwithstanding the provisions of subsection
10 (1), a pharmacist may dispense a one-time emergency refill of
11 up to a 72-hour supply of the prescribed medication for any
12 medicinal drug other than a medicinal drug listed in Schedule
13 II, in compliance with the provisions of s. 465.0275.

14 (4)(3) The legal owner of any stock of controlled
15 substances in a pharmacy, upon discontinuance of dealing in
16 controlled substances, may sell said stock to a manufacturer,
17 wholesaler, or pharmacy. Such controlled substances may be
18 sold only upon an order form, when such an order form is
19 required for sale by the drug abuse laws of the United States
20 or this state, or regulations pursuant thereto.

21 Section 3. Section 893.055, Florida Statutes, is
22 created to read:

23 893.055 Electronic monitoring system for prescription
24 of controlled substances listed in Schedules II, III, and
25 IV.--

26 (1) By June 30, 2005, the Department of Health shall
27 design and establish an electronic system consistent with the
28 American Society for Automation in Pharmacy (ASAP) standards
29 to monitor the prescribing and dispensing of controlled
30 substances listed in Schedules II, III, and IV by health care
31 practitioners within the state and the dispensing of such

1 controlled substances to an individual at a specific address
2 within the state by a pharmacy permitted or registered by the
3 Board of Pharmacy.

4 (2) Any controlled substance listed in Schedule II,
5 Schedule III, or Schedule IV which is dispensed to an
6 individual in this state must be reported to the Department of
7 Health through the system, as soon thereafter as possible but
8 not more than 35 days after the date the controlled substance
9 is dispensed, each time the controlled substance is dispensed.
10 A pharmacy may meet the reporting requirements of this section
11 by providing the Department of Health an exchangeable
12 electronic disc or tape of each controlled substance listed in
13 Schedules II, III, and IV which it dispenses.

14 (3) This section does not apply to controlled
15 substances:

16 (a) Administered by a health care practitioner
17 directly to a patient.

18 (b) Dispensed by a health care practitioner authorized
19 to prescribe controlled substances directly to a patient and
20 limited to an amount adequate to treat the patient for a
21 period of no more than 72 hours.

22 (c) Dispensed by a health care practitioner or a
23 pharmacist to an inpatient of a facility with an institutional
24 pharmacy permit.

25 (d) Ordered from an institutional pharmacy permitted
26 under s. 465.019 in accordance with the institutional policy
27 for such controlled substances or drugs.

28 (e) Either dispensed by a pharmacist or administered
29 by a health care practitioner to a patient or resident
30 receiving care from a hospital, nursing home, assisted living
31 facility, home health agency, hospice, or intermediate care

1 facility for the developmentally disabled which is licensed in
2 this state.

3 (f) Prescribed by a health care practitioner for a
4 patient younger than 16 years of age.

5 (4) The data required to be reported under this
6 section shall be determined by the Department of Health by
7 rule but may include any data required under s. 893.04.

8 (5) A practitioner or pharmacist who dispenses a
9 controlled substance under this section must submit the
10 information required by this section in an electronic or other
11 format approved by rule of the Department of Health. The cost
12 to the dispenser in submitting the information required by
13 this subsection may not be material or extraordinary. Costs
14 not considered to be material or extraordinary include, but
15 are not limited to, regular postage, compact discs, zip drive
16 storage, regular electronic mail, magnetic tapes, diskettes,
17 and facsimile charges. The information submitted to the
18 Department of Health under this section may be transmitted to
19 any person or agency authorized to receive it pursuant to
20 section 2 of Senate Bill _____, or similar legislation, and
21 that person or agency may maintain the information received
22 for up to 24 months before purging it from its records. All
23 transmissions required by this paragraph must comply with
24 relevant federal and state privacy and security laws. However,
25 any authorized agency receiving such information may maintain
26 it longer than 24 months if the information is pertinent to an
27 ongoing investigation or prosecution.

28 (6) Any person who knowingly fails to report the
29 dispensing of a controlled substance listed in Schedule II,
30 Schedule III, or Schedule IV as required by this section
31

1 commits a misdemeanor of the first degree, punishable as
2 provided in s. 775.082 or s. 775.083.

3 (7) The Department of Health and the regulatory boards
4 for the health care practitioners subject to this section
5 shall adopt rules pursuant to ss. 120.536(1) and 120.54
6 necessary to implement and administer this section.

7 (8) All costs incurred by the Department of Health in
8 implementing the prescription monitoring system shall be borne
9 by the department, and there is appropriated annually, subject
10 to the availability of funds, from the Grants and Donations
11 Trust Fund an amount necessary to cover such costs. The
12 Medical Quality Assurance Trust Fund may not be used to
13 implement or otherwise fund this program.

14 Section 4. Section 893.065, Florida Statutes, is
15 created to read:

16 893.065 Counterfeit-resistant prescription blanks for
17 controlled substances listed in Schedules II, III, and
18 IV.--The Department of Health shall develop and adopt by rule
19 the form and content for a counterfeit-resistant prescription
20 blank which may be used by practitioners to prescribe a
21 controlled substance listed in Schedule II, Schedule III, or
22 Schedule IV. The Department of Health may require the
23 prescription blanks to be printed on distinctive, watermarked
24 paper and to bear the preprinted name, address, and category
25 of professional licensure of the practitioner and that
26 practitioner's federal registry number for controlled
27 substances. The prescription blanks may not be transferred.

28 Section 5. There is appropriated \$2,196,352 from the
29 Grants and Donations Trust Fund to the Department of Health,
30 and three full-time equivalent positions are authorized for
31

