

By Senator Burt

16-516A-02

1 A bill to be entitled
2 An act relating to controlled substances;
3 providing for specified licensing boards to
4 adopt rules governing the prescribing of
5 controlled substances; requiring certain health
6 care providers to complete education courses
7 relating to the prescription of controlled
8 substances; providing penalties and requiring a
9 report; providing for the emergency suspension
10 of certain licenses for prescribing violations;
11 requiring the Department of Health and the
12 Department of Law Enforcement to share certain
13 information regarding health care
14 practitioners; requiring a report; requiring
15 the Department of Legal Affairs to establish an
16 electronic system to monitor the prescribing of
17 certain controlled substances; establishing an
18 advisory council and providing for its
19 membership, duties, staff, and compensation;
20 amending s. 456.033, F.S.; eliminating certain
21 requirements for HIV and AIDS education
22 courses; amending s. 456.072, F.S.; requiring a
23 fine for certain violations involving excessive
24 prescribing of controlled substances; amending
25 s. 458.345, F.S.; requiring certain resident
26 physicians, interns, and fellows to complete an
27 educational course in prescribing controlled
28 substances; amending s. 461.013, F.S.;
29 prohibiting the presigning of blank
30 prescription forms and providing penalties;
31 amending s. 893.04, F.S.; providing additional

1 requirements for pharmacists regarding the
2 identification of persons to whom controlled
3 substances are dispensed; prohibiting certain
4 prescribing practitioners from possessing,
5 administering, dispensing, or prescribing
6 controlled substances; creating s. 893.065,
7 F.S.; establishing protocols requiring
8 prescriptions for certain controlled substances
9 to be issued on special forms developed by the
10 Department of Legal Affairs; establishing
11 requirements for the design, issuance, and
12 control of such forms; providing record-keeping
13 requirements; providing other requirements for
14 the use of such forms; creating s. 893.0655,
15 F.S.; requiring certain practitioners to
16 surrender such prescription forms; providing an
17 effective date.

18

19 Be It Enacted by the Legislature of the State of Florida:

20

21 Section 1. Physicians; rules establishing prescribing
22 guidelines.--To minimize the diversion and resultant abuse of
23 controlled substances, the Board of Medicine and the Board of
24 Osteopathic Medicine shall adopt rules to establish guidelines
25 for prescribing controlled substances to patients in emergency
26 department settings. Such guidelines must allow physicians to
27 provide legitimate medical treatment of acute and chronic pain
28 and require them to recognize and prevent abuse of pain
29 medications prescribed in emergency department settings. Each
30 board shall consult with the Florida College of Emergency
31 Physicians in developing these guidelines.

1 Section 2. Instruction required for certain licensees
2 in prescribing and pharmacology.--

3 (1) The appropriate professional licensing board shall
4 require each person licensed under chapter 458, chapter 459,
5 chapter 461, chapter 462, or chapter 466, Florida Statutes, to
6 complete a continuing educational course, approved by the
7 board, on appropriate prescribing and pharmacology of
8 controlled substances, as part of the licensee's initial
9 license renewal after January 1, 2003. The course shall
10 provide education in the state and federal laws and rules
11 governing the prescribing and dispensing of controlled
12 substances; in appropriate evaluation of patients for any risk
13 of drug diversion and the resulting abuse of controlled
14 substances; in the use of informed consent and other
15 protocols, such as discussing the risks and benefits of using
16 controlled substances, with patients to prevent drug
17 diversion; in the need to keep accurate and complete medical
18 records to justify treatment with controlled substances; in
19 addiction and substance-abuse issues with respect to patients;
20 in the appropriate use of recognized pain-management
21 guidelines; and in the need for consultation and referral of
22 patients who are at risk for misuse of medication or diversion
23 of controlled substances, when appropriate.

24 (2) Such licensees must submit confirmation of
25 completion of such a course, on a form provided by the board,
26 when submitting fees for the initial biennial license renewal
27 after January 1, 2003.

28 (3) The board may approve additional equivalent
29 courses that satisfy the requirements of subsection (1). Each
30 licensing board that requires a licensee to complete an
31 educational course pursuant to this section may include the

1 hours required to complete the course in the total required
2 continuing educational requirements.

3 (4) Any person who holds two or more licenses subject
4 to this section may satisfy the requirements of this section
5 by taking only one such board-approved course for relicensure
6 of all such licenses.

7 (5) A licensee who fails to comply with this section
8 is subject to disciplinary action under each respective
9 practice act and section 456.072(1)(k), Florida Statutes. In
10 addition to discipline by the board, the licensee must
11 complete the course.

12 (6) The board shall require, as a condition of
13 granting a license under the chapter specified in subsection
14 (1), that an applicant for initial licensure complete an
15 educational course in the appropriate prescribing and
16 pharmacology of controlled substances. An applicant who has
17 not taken a course at the time of licensure shall, upon
18 submitting an affidavit showing good cause, be allowed 6
19 months within which to complete this requirement.

20 (7) The board may adopt rules necessary to administer
21 this section.

22 (8) Each board shall report to the President of the
23 Senate, the Speaker of the House of Representatives, and the
24 chairpersons of the appropriate substantive committees of the
25 Legislature by March 1 of each year on the implementation of
26 and compliance with this section.

27 Section 3. Emergency suspension orders; controlled
28 substances.--Upon receipt of sufficient evidence from any
29 agency authorized to enforce chapter 893, Florida Statutes,
30 regarding a violation of sections 458.331(1)(g),
31 458.331(1)(r), 458.331(1)(aa), 459.015(1)(t), 459.015(1)(u),

1 459.015(1)(ee), 461.013(1)(o), 461.013(1)(p), 461.013(1)(dd),
2 462.14(1)(q), 462.14(1)(r), 462.14(1)(aa), 464.018(1)(i),
3 465.016(1)(e), 465.016(1)(i), 466.028(1)(p), 466.028(1)(q),
4 466.028(1)(r), or 466.028(1)(dd) or of chapter 893, Florida
5 Statutes, by a licensed health care practitioner who is
6 authorized to prescribe, dispense, or administer controlled
7 substances, the Department of Health shall recommend the
8 suspension or restriction of the practitioner's license to the
9 Secretary of Health within 10 working days after receiving
10 such evidence. The Secretary of Health may suspend or restrict
11 the license of the practitioner in accordance with section
12 120.60(6), Florida Statutes.

13 Section 4. Sharing of arrest and other information
14 regarding certain health care practitioners.--

15 (1) The Department of Health shall electronically
16 submit to the Department of Law Enforcement a list of health
17 care practitioners licensed in this state who are authorized
18 to prescribe, dispense, or administer controlled substances.
19 In order to facilitate the efficiency of the Department of
20 Health's investigation of applicable violations involving the
21 diversion of controlled substances by such practitioners, the
22 Department of Law Enforcement shall, when practicable, notify
23 and provide investigative information to the Department of
24 Health regarding the arrest of any such practitioner.

25 (2) The Medical Examiner's Commission within the
26 Department of Law Enforcement shall report quarterly to the
27 Department of Health any deaths attributed to the abuse of
28 controlled substances, based on autopsy reports completed
29 within this state, and any other public information that may
30 facilitate that department's expeditious investigation of the
31 information to determine whether any of the deaths have

1 involved conduct by a licensed health care practitioner which
2 is subject to disciplinary action under section 456.073,
3 Florida Statutes. The Department of Health or the board having
4 regulatory authority over the practitioner shall investigate
5 any information received by the department or the board when
6 it has reasonable grounds to believe that the practitioner has
7 violated any law relating to the practitioner's practice.

8 (3) To help the Department of Health and regulatory
9 boards control the diversion and resultant abuse of controlled
10 substances, the Department of Health and the Department of Law
11 Enforcement shall study the feasibility of expanding the
12 electronic exchange of information to facilitate the transfer
13 to the Department of Health of criminal history information
14 involving licensed health care practitioners who are
15 authorized to prescribe, administer, or dispense controlled
16 substances. The Department of Law Enforcement shall
17 investigate the feasibility of the electronic transmission of
18 information from medical examiners within this state to the
19 Department of Health regarding autopsies and other public
20 reports that attribute death to controlled-substance abuse.
21 The Department of Law Enforcement, in consultation with the
22 Department of Health, must submit a report of its findings to
23 the Legislature by November 1, 2002.

24 Section 5. Electronic monitoring system for
25 prescriptions.--

26 (1) By July 1, 2003, the Department of Legal Affairs
27 shall design and establish an electronic system to monitor the
28 prescribing of Schedule II and Schedule III controlled
29 substances by health care practitioners within the state or
30 the dispensing of such controlled substances to an address
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1 within the state by a pharmacy permitted or registered by the
2 Board of Pharmacy.

3 (2) The Attorney General may, by rule, designate any
4 opiate listed as a Schedule IV controlled substance for
5 inclusion in such system.

6 (3) Each pharmacist or other person authorized by law
7 to dispense controlled substances within this state must
8 timely report to the Department of Legal Affairs the data
9 required by this section each time that:

10 (a) A Schedule II controlled substance is dispensed;

11 (b) A Schedule III controlled substance is dispensed;

12 or

13 (c) An opiate is dispensed which is listed in Schedule
14 IV as a controlled substance and is designated by the Attorney
15 General.

16 (4) The data required under this section includes:

17 (a) The patient's name.

18 (b) The patient's address.

19 (c) The national drug code number of the substance
20 dispensed.

21 (d) The date that the substance is dispensed.

22 (e) The quantity of substance dispensed.

23 (f) The dispenser's United States Drug Enforcement
24 Administration Number.

25 (g) The prescribing practitioner's United States Drug
26 Enforcement Administration Number.

27 (5) The information must be reported within 15 days
28 after the date the controlled substance is dispensed.

29 (6) A dispenser must transmit the information required
30 by this section in an electronic format specified by the

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1 Department of Legal Affairs unless a specific waiver is
2 granted by the department to that dispenser.

3 (7) The Department of Legal Affairs shall establish a
4 7-member prescription monitoring program advisory council to
5 assist it in implementing the system.

6 (a) The Governor shall appoint members to serve on the
7 advisory council. The members of the council shall include the
8 Attorney General or his or her designee, the Secretary of
9 Health or his or her designee, the executive director of the
10 Department of Law Enforcement or his or her designee, the
11 director of the Office of Drug Control within the Executive
12 Office of Governor or his or her designee, a health care
13 practitioner who is licensed in this state and authorized to
14 prescribe controlled substances, a pharmacist who is licensed
15 in this state, and a prosecutor who has expertise in the
16 criminal prosecution of drug-diversion cases.

17 (b) The advisory council members shall serve without
18 compensation but may receive reimbursement, as provided in
19 section 112.061, Florida Statutes, for per diem and travel
20 expensed incurred in the performance of their official duties.

21 (c) The Department of Legal Affairs shall provide
22 staff and other administrative assistance that is reasonably
23 necessary to assist the advisory council in carrying out its
24 responsibilities. The advisory council is abolished July 1,
25 2003.

26 (8) The Department of Legal Affairs shall adopt rules
27 pursuant to section 120.536(1) and section 120.574, Florida
28 Statutes, necessary to administer this section.

29 Section 6. Subsections (1) and (9) of section 456.033,
30 Florida Statutes, are amended to read:

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1 456.033 Requirement for instruction for certain
2 licensees on HIV and AIDS.--

3 (1) The appropriate board shall require each person
4 licensed or certified under chapter 457; ~~chapter 458; chapter~~
5 ~~459;~~chapter 460; ~~chapter 461;~~chapter 463; part I of chapter
6 464; chapter 465; ~~chapter 466;~~part II, part III, part V, or
7 part X of chapter 468; or chapter 486 to complete a continuing
8 educational course, approved by the board, on human
9 immunodeficiency virus and acquired immune deficiency syndrome
10 as part of biennial relicensure or recertification. The course
11 shall consist of education on the modes of transmission,
12 infection control procedures, clinical management, and
13 prevention of human immunodeficiency virus and acquired immune
14 deficiency syndrome. Such course shall include information on
15 current Florida law on acquired immune deficiency syndrome and
16 its impact on testing, confidentiality of test results,
17 treatment of patients, and any protocols and procedures
18 applicable to human immunodeficiency virus counseling and
19 testing, reporting, the offering of HIV testing to pregnant
20 women, and partner notification issues pursuant to ss. 381.004
21 and 384.25.

22 (9)~~(a)~~ In lieu of completing a course as required in
23 subsection (1), the licensee may complete a course in
24 end-of-life care and palliative health care, so long as the
25 licensee completed an approved AIDS/HIV course in the
26 immediately preceding biennium.

27 ~~(b) In lieu of completing a course as required by~~
28 ~~subsection (1), a person licensed under chapter 466 who has~~
29 ~~completed an approved AIDS/HIV course in the immediately~~
30 ~~preceding 2 years may complete a course approved by the Board~~
31 ~~of Dentistry.~~

1 Section 7. Paragraph (d) of subsection (2) of section
2 456.072, Florida Statutes, is amended to read:

3 456.072 Grounds for discipline; penalties;
4 enforcement.--

5 (2) When the board, or the department when there is no
6 board, finds any person guilty of the grounds set forth in
7 subsection (1) or of any grounds set forth in the applicable
8 practice act, including conduct constituting a substantial
9 violation of subsection (1) or a violation of the applicable
10 practice act which occurred prior to obtaining a license, it
11 may enter an order imposing one or more of the following
12 penalties:

13 (d) Imposition of an administrative fine not to exceed
14 ~~\$25,000~~~~\$10,000~~ for each count or separate offense. If the
15 violation is for fraud or making a false or fraudulent
16 representation, the board, or the department if there is no
17 board, must impose a fine of \$10,000 per count or offense. If
18 the violation is for inappropriate or excessive prescribing of
19 any controlled substance, the board, or the department if
20 there is no board, must impose a fine of \$25,000 per count or
21 offense.

22 Section 8. Paragraph (d) is added to subsection (1) of
23 section 458.345, Florida Statutes, to read:

24 458.345 Registration of resident physicians, interns,
25 and fellows; list of hospital employees; prescribing of
26 medicinal drugs; penalty.--

27 (1) Any person desiring to practice as a resident
28 physician, assistant resident physician, house physician,
29 intern, or fellow in fellowship training which leads to
30 subspecialty board certification in this state, or any person
31 desiring to practice as a resident physician, assistant

1 resident physician, house physician, intern, or fellow in
2 fellowship training in a teaching hospital in this state as
3 defined in s. 408.07(44) or s. 395.805(2), who does not hold a
4 valid, active license issued under this chapter shall apply to
5 the department to be registered and shall remit a fee not to
6 exceed \$300 as set by the board. The department shall
7 register any applicant the board certifies has met the
8 following requirements:

9 (d) Has completed, upon initial registration, a 2-hour
10 educational course in the prescribing of controlled
11 substances. The course shall consist of education in state and
12 federal laws and rules governing the prescribing and
13 dispensing of controlled substances; in appropriate evaluation
14 of patients for any risk of drug diversion and the resulting
15 abuse of controlled substances; in the use of informed consent
16 and other protocols, such as a discussion of the risks and
17 benefits of the use of controlled substances with patients to
18 prevent drug diversion; in the need to keep accurate and
19 complete medical records to justify treatment with controlled
20 substances; in addiction and substance-abuse issues with
21 respect to patients; in the appropriate use of recognized
22 pain-management guidelines; and in the need for consultation
23 and referral of patients who are at risk for misuse of their
24 medication or diversion of controlled substances, when
25 appropriate. An applicant who has not taken a course at the
26 time of registration shall, upon submitting an affidavit
27 showing good cause, be allowed 6 months within which to
28 complete this requirement.

29 Section 9. Paragraph (dd) is added to subsection (1)
30 of section 461.013, Florida Statutes, to read:

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1 461.013 Grounds for disciplinary action; action by the
2 board; investigations by department.--

3 (1) The following acts constitute grounds for denial
4 of a license or disciplinary action, as specified in s.
5 456.072(2):

6 (dd) Presigning blank prescription forms.

7 Section 10. Paragraph (h) is added to subsection (1)
8 of section 893.04, Florida Statutes, and subsection (4) is
9 added to that section, to read:

10 893.04 Pharmacist and practitioner.--

11 (1) A pharmacist, in good faith and in the course of
12 professional practice only, may dispense controlled substances
13 upon a written or oral prescription of a practitioner, under
14 the following conditions:

15 (h) A pharmacist may not dispense a controlled
16 substance to any individual not known to the pharmacist,
17 without first obtaining proper identification and documenting,
18 by signature on a log book kept by the pharmacist, the
19 identity of the individual obtaining the controlled substance.
20 If the individual does not have proper identification, the
21 pharmacist must verify the validity of the prescription and
22 identity of the patient with the prescribing practitioner, or
23 the prescribing practitioner's authorized agent, before
24 dispensing the controlled substance. For purposes of this
25 section, identification is proper only if it contains the
26 photograph, the printed name, and the signature of the
27 individual obtaining the controlled substance.

28 (4) Any prescribing practitioner who surrenders, by
29 court order, or order of any state or governmental agency, or
30 voluntarily, his or her controlled substance privileges may
31 not possess, administer, dispense, or prescribe a controlled

1 substance unless those privileges have been restored and the
2 practitioner has obtained current registration from the
3 appropriate federal agency as provided by law.

4 Section 11. Section 893.065, Florida Statutes, is
5 created to read:

6 893.065 Triplicate prescriptions required for certain
7 controlled substances.--

8 (1) On or after July 1, 2002, a person may not issue a
9 prescription for a Schedule II or Schedule III controlled
10 substance, or an opiate listed in Schedule IV which has been
11 designed by the Attorney General by rule, unless the
12 prescription meets the requirements of this section.

13 (2) The Department of Legal Affairs shall develop a
14 counterfeit-proof prescription blank for use by practitioners
15 who prescribe controlled substances classified in:

16 (a) Schedule II;

17 (b) Schedule III; or

18 (c) Schedule IV, as an opiate that is designated by
19 the Attorney General by rule.

20 (3) Prescription blanks shall be issued by the
21 Department of Legal Affairs to such practitioners in serially
22 numbered groups of not more than 100 forms each in triplicate,
23 unless a practitioner orally, electronically, or in writing
24 requests a larger quantity. The prescription blanks must be
25 printed on distinctive paper; must contain the serial number
26 of the group; must be sequentially numbered; and must bear the
27 preprinted full name, address, and category of professional
28 licensure of the practitioner to whom they are issued and that
29 practitioner's federal registry number for controlled
30 substances. The prescription blanks may not be transferred.

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1 (4) The Department of Legal Affairs may charge a fee
2 for the prescription blanks in an amount sufficient to
3 reimburse the department for its actual costs of preparing,
4 issuing, and tracking such forms.

5 (5) Notwithstanding s. 893.04(1)(a)-(d), a person may
6 not prescribe a Schedule II or Schedule III controlled
7 substance, or an opiate listed in Schedule IV which has been
8 designated by the Attorney General by rule, nor may any person
9 fill, compound, or dispense such a prescription, unless it
10 complies with this section.

11 (a) The signature on each such prescription form must
12 be wholly written in ink or indelible pencil in the
13 handwriting of the prescribing practitioner. Each prescription
14 must be prepared in triplicate, dated, and signed by the
15 prescribing practitioner on the day when issued, and must
16 contain, typewritten or handwritten by the physician or an
17 employee of the physician, the full name and address of the
18 person for whom, or the owner of the animal for which, the
19 controlled substance is prescribed; the name, quantity, and
20 strength of the controlled substance; directions for use; and
21 the address, category of professional licensure, and federal
22 controlled substance registration number of the prescribing
23 practitioner. If the prescription is for an animal, the
24 prescription must state the species of animal for which it is
25 prescribed. If the prescribing practitioner does not specify
26 the address of the person for whom, or animal for which, the
27 prescription is prescribed, the pharmacist filling the
28 prescription or an employee acting under the direction of the
29 pharmacist must write or type the address on the prescription
30 or maintain the information in a readily retrievable form in
31 the pharmacy.

1 (b) The original and duplicate of the prescription
2 must be delivered to the pharmacist filling the prescription.
3 The duplicate must be retained on file by the proprietor of
4 the pharmacy in which it is filled for a period of 2 years,
5 and the original, properly endorsed by the pharmacist with the
6 name and address of the pharmacy, the pharmacy's state permit
7 number, the date that the prescription was filled, and the
8 signature of the pharmacist, must be transmitted to the
9 Department of Legal Affairs at the end of the month in which
10 the prescription was filled. Notwithstanding any provision of
11 this section, the prescribing practitioner's address, category
12 of professional licensure, or federal controlled substances
13 registration number need not appear on the prescription if
14 that information is readily retrievable in the pharmacy.

15 (c) All prescriptions issued for a Schedule II or
16 Schedule III controlled substance, or an opiate listed in
17 Schedule IV which has been designated by the Attorney General
18 by rule, must include both a written and numerical notation of
19 quantity on the face of the prescription.

20 (d) A pharmacist may not dispense more than a 30-day
21 supply of a controlled substance listed in Schedule III upon
22 an oral prescription.

23 (e) A pharmacist may not knowingly fill a prescription
24 that has been mutilated or forged for a Schedule II or
25 Schedule III controlled substance, or an opiate listed as a
26 Schedule IV controlled substance which has been designated by
27 the Attorney General by rule.

28 (f) Any controlled substance listed in Schedule III,
29 or any controlled substance that is an opiate listed as a
30 controlled substance in Schedule IV and which has been
31 designated by the Attorney General by rule, may be dispensed

1 by a pharmacist upon an oral prescription, if before filling
2 the prescription, the pharmacist reduces it to writing in ink
3 or indelible pencil in the handwriting of the pharmacist, upon
4 an official form issued by the Department of Legal Affairs for
5 that purpose. Such prescriptions must be prepared in
6 triplicate and must contain the date of the oral authorization
7 and the information required by paragraph (a).

8 Section 12. Section 893.0655, Florida Statutes, is
9 created to read:

10 893.0655 Surrender of prescription blanks.--

11 (1) When a practitioner who is named in a warrant of
12 arrest for, or is charged in an accusatory pleading with, a
13 felony violation of chapter 499 or chapter 893, the court in
14 which the pleading is filed or the magistrate who issued the
15 warrant shall, upon the motion of a law enforcement agency,
16 supported by probable cause, issue an order requiring the
17 practitioner to surrender to the clerk of the court all
18 triplicate prescription blanks in the practitioner's
19 possession at a specified time and shall direct the Department
20 of Health to withhold prescription blanks from the
21 practitioner. The law enforcement agency obtaining the order
22 shall notify the Department of Health of this order. Except as
23 provided in subsection (2), the order shall remain in effect
24 until further order of the court. Any practitioner possessing
25 prescription blanks in violation of the order commits a
26 misdemeanor of the first degree, punishable as provided in s.
27 775.082, s. 775.083, or s. 775.084.

28 (2) Such order shall be vacated if the court or
29 magistrate finds that the underlying violation is not
30 supported by reasonable cause, at a hearing held within two
31 court days after the practitioner files and personally serves

1 upon the prosecuting attorney and the law enforcement agency
2 that obtained the order a notice of motion to vacate the
3 order, with any affidavits on which the practitioner relies.
4 At the hearing, the burden of proof, by a preponderance of the
5 evidence, is on the prosecution. Evidence presented at the
6 hearing shall be limited to the warrant of arrest with
7 supporting affidavits, the motion to require the defendant to
8 surrender all triplicate prescription blanks with supporting
9 affidavits, the sworn complaint and any documents or reports
10 incorporated by reference thereto, which, if based on
11 information and belief, state the basis for the information,
12 or any other documents of similar reliability, as well as
13 affidavits submitted by the prosecution and defense. Granting
14 of the motion to vacate the order is no bar to prosecution of
15 the alleged violation.

16 Section 13. This act shall take effect July 1, 2002.

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19 SENATE SUMMARY

20 Provides for the regulation of the prescribing of
21 controlled substances. Requires education and continuing
22 education in the prescribing of controlled substances by
23 specified practitioners. Establishes penalties. Requires
24 certain state agencies to share information. Requires the
25 creation of an electronic monitoring system. Creates an
26 advisory council. Prohibits presigning prescriptions.
27 Requires state issuance and regulation of prescription
28 forms for controlled substances. Prohibits certain
29 practitioners from prescribing. Establishes
30 record-keeping requirements. Requires certain
31 practitioners to surrender their prescription forms. (See
bill for details.)