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S. 1560

To enhance access to controlled substances for residents of institutional long-term care facilities, and for other purposes.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 14, 2011

Mr. KOHL introduced the following bill; which was read twice and referred to the Committee on the Judiciary

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A BILL

To enhance access to controlled substances for residents of institutional long-term care facilities, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Nursing Home Resident Pain Relief Act of 2011''.

SEC. 2. DEFINITIONS.

Section 102 of the Controlled Substances Act (21 U.S.C. 802) is amended—

(1) in paragraph (3), by adding at the end the following: ''Solely for purposes of section 309(f), the term 'agent' includes a facility designee.''; and

(2) by adding at the end the following:

''(57) The term 'institutional long-term care facility' means—

''(A) a facility certified to participate in the Medicare or Medicaid programs as a nursing facility, as defined in section 1919(a) of the Social Security Act (42 U.S.C. 1396r(a));

''(B) a skilled nursing facility, as defined in section 1819(a) of the Social Security Act (42 U.S.C. 1395i–3(a)); or

''(C) any other entity of a type designated by the Attorney General by regulation.

''(58) The term 'administrator of an institutional long-term care facility' means—

''(A) a corporation, company, partnership, or other entity that—

''(i) owns, operates, or manages an institutional long-term care facility; and

''(ii) may be held liable, by law or by consent, for the acts or omissions of the facility designees who are delegated authority by the institutional long-term care

facility in connection with the dispensing of controlled substances, including liability for any civil penalties authorized under part D of this title; and

''(B) an individual who—

''(i) has been designated as a co-administrator by an entity described in subparagraph (A);

''(ii) is responsible for managing, supervising, or overseeing the care provided to residents of the institutional long-term care facility or the work of the employees of the institutional long-term care facility; and

''(iii) can be held personally liable, along with the entity described in subparagraph (A), at law or by consent, for the acts or omissions of the facility designees of the institutional long-term care facility in connection with the dispensing of controlled substances, including liability for any civil penalties authorized under section 402.''.

SEC. 3. ORAL COMMUNICATION OF PRESCRIPTION INFORMATION FOR RESIDENTS OF INSTITUTIONAL LONG-TERM CARE FACILITIES.

Section 309 of the Controlled Substances Act (21 U.S.C. 829) is amended—

(1) in subsection (a), in the first sentence, by inserting ''except as provided in subsection (f) and'' after ''without the written prescription of a practitioner''; and

(2) by adding at the end the following:

''(f) CONTROLLED SUBSTANCES DISPENSED TO RESIDENTS OF INSTITUTIONAL LONG-TERM CARE FACILITIES THROUGH THE USE OF FACILITY DESIGNEES.—

''(1) DEFINITIONS.—In this subsection—

''(A) the term 'authorizing agreement' means a written agreement—

''(i) between—

''(I) an individual practitioner providing medical care to, or supervising medical care being provided to, a resident of an institutional long-term care facility whose care is provided or supervised by the practitioner; and

''(II) an administrator of the institutional long-term care facility;

"(ii) that authorizes the administrator to designate 1 or more qualified individuals to act as facility designees for the purpose of dispensing a controlled substance to the resident; and

"(iii) that includes a written authorization from the practitioner, in a form and manner specified by the Attorney General, that specifies whether the scope of the authorization is for—

"(I) controlled substances in schedule II only; or

"(II) all controlled substances, regardless of schedule; and

"(B) the term 'facility designee' means an individual designated by the administrator to whom the authority to act as an agent of a practitioner is delegated under paragraph (3)(A).

"(2) AUTHORIZATION.—

"(A) IN GENERAL.—A practitioner may enter into an authorizing agreement with an administrator of an institutional long-term care facility if the administrator has—

"(i) adopted written policies and procedures that specify the duties and responsibilities of a facility designee and that require documentation of the acceptance of the duties and responsibilities by a facility designee, consistent with the authorizing agreement; and

"(ii) provided copies of the policies and procedures adopted under clause (i) to the practitioner and to each facility designee.

"(B) RESCISSION OF AUTHORITY.—A practitioner may in writing, at any time—

"(i) rescind the authorizing agreement;

"(ii) rescind the authority of a facility designee; or

"(iii) modify the scope of the authorization of a facility designee.

"(3) DELEGATION OF AUTHORITY.—

"(A) IN GENERAL.—Under an authorizing agreement, an administrator of an institutional long-term care facility may, in accordance with the policies and procedures described in paragraph (2)(A)(i) delegate, in writing, the author-

ity to act as a facility designee to 1 or more health care professionals who are qualified under subparagraph (B).

"(B) REQUIREMENTS FOR QUALIFICATION.—To qualify to be a facility designee under subparagraph (A), a health care professional shall be—

"(i) directly employed by, and subject to the supervision and control of, the institutional long-term care facility;

"(ii) lawfully acting within the scope of the employment of the individual; and

"(iii) be a registered nurse, advanced practice nurse, physician's assistant, or equivalent professional who is licensed, certified, registered, or otherwise permitted to provide professional nursing or health care by the jurisdiction in which the individual is employed.

"(C) REQUIREMENT.—A written delegation of authority under subparagraph (A) shall specify, at the option of the practitioner, and in accordance with the authorizing agreement, whether the scope of the authorization is for—

"(i) schedule II controlled substances only; or

"(ii) all controlled substances, regardless of schedule.

"(D) SERVICE AS A FACILITY DESIGNEE.—A facility designee shall act in accordance with the policies and procedures described in paragraph (2)(A)(i).

"(E) LIST OF AUTHORIZING AGREEMENTS AND FACILITY DESIGNEES.—

"(i) IN GENERAL.—An administrator of an institutional long-term care facility shall establish and maintain a current list of—

"(I) all practitioners who have entered into an authorizing agreement with the administrator; and

"(II) all facility designees of each practitioner described in subclause (I) that are employees of the institutional long-term care facility.

"(ii) REQUIREMENTS.—The list required under clause (i) shall—

"(I) be—

"(aa) dated upon establishment and each time the list is updated; and

"(bb) made readily available in appropriate places on the premises of the institutional long-term care facility to ensure proper notice of which employees of the institutional long-term care facility are facility designees for which practitioners; and

"(II) include—

"(aa) the name and address of the institutional long-term care facility and the administrator of the institutional long-term care facility;

"(bb) the name of each practitioner who has entered into an authorizing agreement with the administrator of the institutional long-term care facility; and

"(cc) for each practitioner listed under item (bb)—

"(AA) the name of each facility designee; and

"(BB) whether practitioner is providing authorization for schedule II controlled substances only or all controlled substances, regardless of schedule.

"(iii) DISTRIBUTION OF LIST.—An administrator of an institutional long-term care facility shall provide the list established under clause (i) to—

"(I) all pharmacies to which the institutional long-term care facility submits prescriptions for dispensing; and

"(II) each practitioner who has entered into an authorizing agreement with the administrator of the institutional long-term care facility.

"(iv) UPDATES.—The administrator of an institutional long-term care facility shall promptly update and redistribute a list established under clause (i) if—

"(I) there are any changes to the information required to be included in the list under clause (ii); or

"(II) the authority of any facility designee on the list is rescinded or modified under paragraph (2)(B).

"(F) PROHIBITION OF REDELEGATION OF AUTHORITY.—A facility designee may not redelegate any aspect of the authorization of the practitioner to another individual.

"(4) TRANSMISSION BY A FACILITY DESIGNEE OF A VALID ORAL PRESCRIPTION ISSUED BY PRACTITIONER.—

"(A) IN GENERAL.—Except as provided in subparagraph (D), a practitioner who is providing medical care to, or supervising medical care being provided to, a resident of an institutional long-term care facility may issue an oral prescription for the resident for a controlled substance which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), and the oral prescription may be communicated through a facility designee acting under the authorizing agreement of the practitioner.

"(B) POLICIES.—A practitioner or a facility designee acting under this subsection shall follow the requirements of this subsection regardless of the schedule of the controlled substance for which an oral prescription is being communicated.

"(C) REQUIREMENTS.—

"(i) RESPONSIBILITIES OF PRACTITIONER.—In issuing an oral prescription under subparagraph (A), a practitioner shall provide to the facility designee—

"(I) the full name of the resident;

"(II) the drug name, strength, and dosage form;

"(III) the quantity prescribed;

"(IV) the directions for use; and

"(V) the name, address, and Drug Enforcement Administration registration number of the prescribing practitioner.

"(ii) RESPONSIBILITIES OF A FACILITY DESIGNEE.—A facility designee that receives an oral prescription issued under subparagraph (A) shall promptly—

"(I) create a document that reduces such oral prescription to writing, which shall include—

"(aa) all of the information provided by the practitioner under clause (i);

"(bb) the legible full name and signature of the facility designee;

"(cc) the name and address of the institutional long-term care facility;

"(dd) the date and time the facility designee received the oral prescription; and

"(ee) an attestation by the covered individual, under penalty of perjury as provided in section 1746 of title 28, United States Code, that—

"(AA) the facility designee has personally spoken with the prescribing practitioner; and

"(BB) all the information required under clause (i) was provided by the practitioner and is accurately and completely recorded by the facility designee on the document; and

"(II) transmit the written document, or a facsimile thereof, to a pharmacy for dispensing.

"(iii) PROHIBITION.—A document described in clause (ii)(I) may not be prepared, in whole or in part, by a pharmacy.

"(iv) FACSIMILES.—If a facility designee transmits a written document described in clause (ii)(I) by facsimile, the facsimile shall serve as the original written prescription and shall be maintained in accordance with regulations promulgated by the Attorney General.

"(D) SCHEDULE II CONTROLLED SUBSTANCES.—

"(i) IN GENERAL.—An oral prescription for a schedule II controlled substance shall only be issued through or transmitted

by a facility designee under subparagraph (A) during an emergency situation, as described in subsection (a), and the quantity prescribed shall be limited to an amount adequate to treat the patient during the emergency situation.

"(ii) NON-EMERGENCY SITUATIONS.—A schedule II controlled substance may only be dispensed for treatment of a resident of an institutional long-term care facility in a non-emergency situation if the prescription is in writing and signed by the prescribing individual practitioner, as described in subsection (a).

"(E) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to—

"(i) preclude a practitioner from issuing—

"(I) a prescription for a controlled substance and transmitting the prescription directly to the pharmacy, as otherwise authorized in subsections (a), (b), or (c) or by regulations issued by the Attorney General; or

"(II) a written prescription for a controlled substance, signed by the practitioner, and having the written prescription transmitted to the pharmacy through a duly authorized agent of the practitioner (including a facility designee), as otherwise authorized by subsections (a), (b), or (c) of this section or by regulations issued by the Attorney General; or

"(ii) authorize a facility designee to make any determination that underlies any element of a prescription.

"(F) RULEMAKING AUTHORITY.—The Attorney General may, by regulation, promulgate rules specifying additional requirements with respect to the formatting, content, and creation of the written document described in subparagraph (C)(ii).

"(G) RECORD OF ORAL PRESCRIPTIONS.—

"(i) IN GENERAL.—Each practitioner who issues an oral prescription to a facility designee shall—

"(I) create a contemporaneous record of the oral prescription; and

"(II) maintain the record in a written or electronic log at the registered location of the practitioner, in accordance with section 307.

"(ii) CONTENTS AND RETENTION REQUIREMENTS.—The Attorney General shall specify by regulation the contents and retention requirements for record required to be kept under clause (i).

"(iii) RESPONSIBILITY OF THE PRACTITIONER.—A practitioner shall be responsible for the creation of the contemporaneous record of the oral prescription required under clause (i)(I), and may not delegate or assign any responsibilities under clause (i), in whole or in part, to—

"(I) a pharmacy;

"(II) a facility designee; or

"(III) an institutional long-term care facility (including an employee of the institutional long-term care facility).

"(H) DEFINITION OF ORAL PRESCRIPTION.—The Attorney General may, if determined by the Attorney General to be necessary,

define by regulation the term 'oral prescription' for purposes of this subsection.

"(5) PHARMACY VERIFICATION OF ORAL PRESCRIPTIONS TRANSMITTED BY FACILITY DESIGNEES.—

"(A) IN GENERAL.—Upon receiving an oral prescription from a practitioner that was reduced to writing and transmitted under paragraph (4), a pharmacy shall—

"(i) determine whether the institutional long-term care facility employee who transmitted the prescription is a facility designee for the prescribing practitioner for the prescribed controlled substance based on the most recent list of the facility designees that the institutional long-term care facility provided to the pharmacy under paragraph (3)(E)(iii); and

"(ii) document the determination under clause (i), which shall include a notation on the prescription document to memorialize that the cross-check was completed that includes—

"(I) the initials of the verifying pharmacist; and

"(II) the date and time of the verification.

"(B) TRANSMISSION TO PRESCRIBING PRACTITIONER.—Not later than 72 hours after a pharmacy dispenses a controlled substance pursuant to an oral prescription issued under paragraph (4), the pharmacy shall transmit a copy of the prescription document that the pharmacy received from the facility designee under paragraph (4)(C)(ii), clearly marked as having been dispensed, to the prescribing practitioner.

"(C) PRACTITIONER REQUIREMENT.—A practitioner shall—

"(i) endorse, by physically affixing his written signature to the copy of the prescription the pharmacy transmitted to the practitioner under subparagraph (B), if the prescription was issued by the practitioner; and

"(ii) not later than 5 business days after receiving the copy of the prescription from the pharmacy, return the prescription to the pharmacy in accordance with subparagraph (E).

"(D) ENDORSEMENT OF PRESCRIPTION.—By endorsing a prescription under subparagraph (C), the practitioner—

"(i) attests that the oral prescription memorialized and transmitted by a facility designee was authorized by the practitioner named on the prescription; and

"(ii) certifies that the prescription information conveyed by the facility designee—

"(I) was accurate;

"(II) matches the information in the record kept by the practitioner under paragraph (4)(G); and

"(III) was based on determinations and instructions made by the practitioner.

"(E) RETURN OF ENDORSED PRESCRIPTION TO PHARMACY.—The practitioner may deliver a prescription endorsed under subparagraph (C)(i) to the pharmacy in person, by mail, by facsimile, or by other appropriate means of delivery, except that if the practitioner uses the mail for delivery, the prescription shall

be postmarked during the 5-business-day period described in subparagraph (C)(ii).

"(F) ATTACHMENT OF ENDORSEMENT TO PRESCRIPTION.—A dispensing pharmacy shall attach a prescription endorsed under subparagraph (C)(i) to the prescription document that the pharmacy received from the facility designee under paragraph (4)(C).

"(G) NONCOMPLIANCE.—

"(i) IN GENERAL.—If a pharmacy does not receive an endorsed prescription required under this paragraph from a practitioner within the 5-business-day period described in subparagraph (C)(ii), the pharmacy—

"(I) may not dispense any subsequent prescriptions for controlled substances issued by or on behalf of the practitioner for residents at the institutional long-term care facility, unless the prescription is a written prescription issued directly by the practitioner, until the required endorsement of the oral prescription is received; and

"(II) shall note the limitation described in subclause (I) on the most recent copy of the list that the institutional long-term care facility provided to the pharmacy under paragraph (3)(E)(iii).

"(ii) NOTICE TO DEA.—A pharmacy shall notify the nearest office of the Drug Enforcement Administration if the pharmacy does not receive an endorsed prescription from a practitioner by the end of the 10-business-day period beginning on the date on which the pharmacy transmitted notice to the practitioner under subparagraph (B).

"(6) RECORDKEEPING.—

"(A) IN GENERAL.—Each institutional long-term care facility shall—

"(i) maintain a readily retrievable written or electronic logbook, in which it records each instance in which a facility designee memorializes and transmits an oral prescription for a controlled substance to a pharmacy on behalf of a practitioner under paragraph (4); and

"(ii) keep, on the premises of the institutional long-term care facility—

"(I) the logbook described in clause (i); and

"(II) copies of—

"(aa) any authorizing agreements;

"(bb) any policies and procedures issued by the institutional long-term care facility under paragraph (2)(A)(i);

"(cc) any notice of rescission or modification of the authority of a facility designee;

"(dd) each list prepared by the administrator of the institutional long-term care facility under paragraph (3)(E); and

"(ee) all documents created by facility designees to reduce oral prescriptions to writing, under paragraph (4)(C)(ii)(I).

"(B) RETENTION OF COPIES.—An institutional long-term care facility shall—

"(i) retain a copy of any document described in subparagraph (A)(ii)(II) until the end of the 5-year period beginning on the date on which the document was created; and

"(ii) whether retained in written or electronic form, make available for inspection and copying by the Attorney General under section 510—

"(I) the logbook described in subparagraph (A)(i); and

"(II) copies of the documents described in subparagraph (A)(ii)(II).

"(C) PROHIBITION.—The logbook required under subparagraph (A)(i) may not be prepared, maintained, or updated, in whole or in part, by a pharmacy.

"(D) CONTENTS OF LOGBOOK.—The logbook shall contain, at a minimum—

"(i) all of the information required under paragraph (4)(C); and

"(ii) the name, address, and telephone number of the pharmacy to which each prescription was transmitted.

"(E) RULEMAKING AUTHORITY.—The Attorney General may promulgate rules relating to the formatting, content, and updating of the logbook required to be kept under clause (A)(i).

"(7) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to allow an institutional long-term care facility, or an administrator, employee, or agent of an institutional long-term care facility, who is not a practitioner, to prescribe, administer, dispense, distribute, deliver, possess, maintain, stock, or otherwise use a controlled substance except as expressly provided by this title.".

SEC. 4. PRACTITIONER RECORDKEEPING.

Section 307 of the Controlled Substances Act (21 U.S.C. 827) is amended—

(1) in subsection (a)—

(A) in paragraph (2), by striking "and" at the end;

(B) in paragraph (3), by striking "inventory." and inserting "inventory; and"; and

(C) by adding at the end the following:

"(4) every registrant who prescribes a controlled substance for a patient residing at an institutional long-term care facility under section 309(f)

shall maintain the prescribing log described in subsection (f)(2)(G) of that section.''; and

(2) in subsection (c)(1)(A), by adding after ''treatment of an individual'' the following: '', or under section 309(f)''.

SEC. 5. PENALTIES.

(a) IN GENERAL.—Section 402 of the Controlled Substances Act (21 U.S.C. 842) is amended—

(1) by amending subsection (a)(1) to read as follows:

''(1) who is subject to the requirements of part C, including an institutional long-term care facility and an administrator or employee of an institutional long-term care facility who are subject to any of the requirements under section 309(f), to distribute or dispense a controlled substance, or to aid in the prescribing or dispensing of a controlled substance, in violation of section 309;''; and

(2) in subsection (c)—

(A) in paragraph (1)—

(i) by amending subparagraph (B) to read as follows:

''(B) In the case of a violation of paragraph (5) or (10) of subsection (a) of this section, the civil penalty for each violation shall

not exceed $10,000, except that if a person refuses or negligently fails to make any record, report, notification, declaration, or statement required by section 309(f), the civil penalty for each violation shall be not less than $3,000 and not more than $10,000.''; and

(ii) by adding at the end the following:

''(C) In the case of a violation of subsection (a)(1), the civil penalty shall be not less than $5,000 for each violation.''; and

(B) in paragraph (2)—

(i) in subparagraph (A), by striking ''sentenced to imprisonment of not more than one year'' and inserting ''sentenced to a term of imprisonment of not more than 3 years''; and

(ii) in subparagraph (B), by striking ''2 years'' and inserting ''5 years''.

(b) DIRECTIVE TO THE UNITED STATES SENTENCING COMMISSION.—

(1) IN GENERAL.—Pursuant to its authority under section 994 of title 28, United States Code, and in accordance with this subsection, the United States Sentencing Commission shall review and, if

appropriate, amend the Federal Sentencing Guidelines and policy statements to conform to the amendments made by this Act.

(2) REQUIREMENTS.—In carrying out this subsection, the Commission shall—

(A) establish new guidelines and policy statements, as warranted, in order to implement new or revised criminal offenses created under this title;

(B) assure reasonable consistency with other relevant directives and with other sentencing guidelines;

(C) account for any additional aggravating or mitigating circumstances that might justify exceptions to the generally applicable sentencing ranges;

(D) make any necessary conforming changes to the sentencing guidelines; and

(E) assure that the guidelines adequately meet the purposes of sentencing under section 3553(a)(2) of title 18, United States Code.

SEC. 6. RULE OF CONSTRUCTION.

Nothing in this Act or in the amendments made by this Act shall be construed to alter or eliminate the requirements relating to electronic prescriptions for con-

1 trolled substances in effect on the date of enactment of
2 this Act, as established by the Attorney General.

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