

Calendar No. 566

106TH CONGRESS
2^D SESSION**H. R. 2260****[Report No. 106–299]**

IN THE SENATE OF THE UNITED STATES

OCTOBER 28, 1999

Received

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Read twice and referred to the Committee on the Judiciary

MAY 23, 2000

Reported by Mr. HATCH, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italie*]**AN ACT**

To amend the Controlled Substances Act to promote pain management and palliative care without permitting assisted suicide and euthanasia, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Pain Relief Promotion
5 Act of 1999”.

1 **TITLE I—USE OF CONTROLLED**
2 **SUBSTANCES CONSISTENT**
3 **WITH THE CONTROLLED SUB-**
4 **STANCES ACT**

5 **SEC. 101. REINFORCING EXISTING STANDARD FOR LEGITI-**
6 **MATE USE OF CONTROLLED SUBSTANCES.**

7 Section 303 of the Controlled Substances Act (21
8 U.S.C. 823) is amended by adding at the end the fol-
9 lowing:

10 “(i)(1) For purposes of this Act and any regulations
11 to implement this Act, alleviating pain or discomfort in
12 the usual course of professional practice is a legitimate
13 medical purpose for the dispensing, distributing, or admin-
14 istering of a controlled substance that is consistent with
15 public health and safety, even if the use of such a sub-
16 stance may increase the risk of death. Nothing in this sec-
17 tion authorizes intentionally dispensing, distributing, or
18 administering a controlled substance for the purpose of
19 causing death or assisting another person in causing
20 death.

21 “(2) Notwithstanding any other provision of this Act,
22 in determining whether a registration is consistent with
23 the public interest under this Act, the Attorney General
24 shall give no force and effect to State law authorizing or
25 permitting assisted suicide or euthanasia.

1 “(3) Paragraph (2) applies only to conduct occurring
 2 after the date of the enactment of this subsection.”.

3 **SEC. 102. EDUCATION AND TRAINING PROGRAMS.**

4 Section 502(a) of the Controlled Substances Act (21
 5 U.S.C. 872(a)) is amended—

6 (1) by striking “and” at the end of paragraph
 7 (5);

8 (2) by striking the period at the end of para-
 9 graph (6) and inserting “; and”; and

10 (3) by adding at the end the following:

11 “(7) educational and training programs for
 12 local, State, and Federal personnel, incorporating
 13 recommendations by the Secretary of Health and
 14 Human Services, on the necessary and legitimate
 15 use of controlled substances in pain management
 16 and palliative care, and means by which investiga-
 17 tion and enforcement actions by law enforcement
 18 personnel may accommodate such use.”.

19 **TITLE II—PROMOTING**
 20 **PALLIATIVE CARE**

21 **SEC. 201. ACTIVITIES OF AGENCY FOR HEALTH CARE POL-**
 22 **ICY AND RESEARCH.**

23 Part A of title IX of the Public Health Service Act
 24 (42 U.S.C. 299 et seq.) is amended by adding at the end
 25 the following section:

1 **“SEC. 906. PROGRAM FOR PALLIATIVE CARE RESEARCH**
 2 **AND QUALITY.**

3 “(a) IN GENERAL.—The Administrator shall carry
 4 out a program to accomplish the following:

5 “(1) Develop and advance scientific under-
 6 standing of palliative care.

7 “(2) Collect and disseminate protocols and evi-
 8 dence-based practices regarding palliative care, with
 9 priority given to pain management for terminally ill
 10 patients, and make such information available to
 11 public and private health care programs and pro-
 12 viders, health professions schools, and hospices, and
 13 to the general public.

14 “(b) DEFINITION.—For purposes of this section, the
 15 term ‘palliative care’ means the active, total care of pa-
 16 tients whose disease or medical condition is not responsive
 17 to curative treatment or whose prognosis is limited due
 18 to progressive, far-advanced disease. The purpose of such
 19 care is to alleviate pain and other distressing symptoms
 20 and to enhance the quality of life, not to hasten or post-
 21 pone death.”.

22 **SEC. 202. ACTIVITIES OF HEALTH RESOURCES AND SERV-**
 23 **ICES ADMINISTRATION.**

24 (a) IN GENERAL.—Part D of title VII of the Public
 25 Health Service Act (42 U.S.C. 294 et seq.), as amended

1 by section ~~103~~ of Public Law ~~105-392~~ (~~112 Stat. 3541~~),
 2 is amended—

3 (1) by redesignating sections ~~754~~ through ~~757~~
 4 as sections ~~755~~ through ~~758~~, respectively; and

5 (2) by inserting after section ~~753~~ the following
 6 section:

7 **“SEC. 754. PROGRAM FOR EDUCATION AND TRAINING IN**
 8 **PALLIATIVE CARE.**

9 “(a) IN GENERAL.—The Secretary, in consultation
 10 with the Administrator for Health Care Policy and Re-
 11 search, may make awards of grants, cooperative agree-
 12 ments, and contracts to health professions schools, hos-
 13 pices, and other public and private entities for the develop-
 14 ment and implementation of programs to provide edu-
 15 cation and training to health care professionals in pallia-
 16 tive care.

17 “(b) PRIORITIES.—In making awards under sub-
 18 section (a), the Secretary shall give priority to awards for
 19 the implementation of programs under such subsection.

20 “(c) CERTAIN TOPICS.—An award may be made
 21 under subsection (a) only if the applicant for the award
 22 agrees that the program carried out with the award will
 23 include information and education on—

24 “(1) means for alleviating pain and discomfort
 25 of patients, especially terminally ill patients, includ-

1 ing the medically appropriate use of controlled sub-
2 stances;

3 ~~“(2)~~ applicable laws on controlled substances;
4 including laws permitting health care professionals
5 to dispense or administer controlled substances as
6 needed to relieve pain even in cases where such ef-
7 forts may unintentionally increase the risk of death;
8 and

9 ~~“(3)~~ recent findings, developments, and im-
10 provements in the provision of palliative care.

11 ~~“(d) PROGRAM SITES.—~~Education and training
12 under subsection (a) may be provided at or through health
13 professions schools, residency training programs and other
14 graduate programs in the health professions, entities that
15 provide continuing medical education, hospices, and such
16 other programs or sites as the Secretary determines to be
17 appropriate.

18 ~~“(e) EVALUATION OF PROGRAMS.—~~The Secretary
19 shall (directly or through grants or contracts) provide for
20 the evaluation of programs implemented under subsection
21 (a) in order to determine the effect of such programs on
22 knowledge and practice regarding palliative care.

23 ~~“(f) PEER REVIEW GROUPS.—~~In carrying out section
24 799(f) with respect to this section, the Secretary shall en-
25 sure that the membership of each peer review group in-

1 volved includes one or more individuals with expertise and
 2 experience in palliative care.

3 “(g) DEFINITION.—For purposes of this section, the
 4 term ‘palliative care’ means the active, total care of pa-
 5 tients whose disease or medical condition is not responsive
 6 to curative treatment or whose prognosis is limited due
 7 to progressive, far-advanced disease. The purpose of such
 8 care is to alleviate pain and other distressing symptoms
 9 and to enhance the quality of life, not to hasten or post-
 10 pone death.”.

11 (b) AUTHORIZATION OF APPROPRIATIONS; ALLOCA-
 12 TION.—

13 (1) IN GENERAL.—Section 758 of the Public
 14 Health Service Act (as redesignated by subsection
 15 (a)(1) of this section) is amended in subsection
 16 (b)(1)(C) by striking “sections 753, 754, and 755”
 17 and inserting “sections 753, 754, 755, and 756”.

18 (2) AMOUNT.—With respect to section 758 of
 19 the Public Health Service Act (as redesignated by
 20 subsection (a)(1) of this section), the dollar amount
 21 specified in subsection (b)(1)(C) of such section is
 22 deemed to be increased by \$5,000,000.

1 **SEC. 203. EFFECTIVE DATE.**

2 The amendments made by this title take effect Octo-
3 ber 1, 1999, or upon the date of the enactment of this
4 Act, whichever occurs later.

5 **SECTION 1. SHORT TITLE.**

6 *This Act may be cited as the “Pain Relief Promotion*
7 *Act of 2000”.*

8 **SEC. 2. FINDINGS.**

9 *Congress finds that—*

10 *(1) in the first decade of the new millennium*
11 *there should be a new emphasis on pain management*
12 *and palliative care;*

13 *(2) the use of certain narcotics and other drugs*
14 *or substances with a potential for abuse is strictly*
15 *regulated under the Controlled Substances Act;*

16 *(3) the dispensing and distribution of certain*
17 *controlled substances by properly registered practi-*
18 *tioners for legitimate medical purposes are permitted*
19 *under the Controlled Substances Act and imple-*
20 *menting regulations;*

21 *(4) the dispensing or distribution of certain con-*
22 *trolled substances for the purpose of relieving pain*
23 *and discomfort even if it increases the risk of death*
24 *is a legitimate medical purpose and is permissible*
25 *under the Controlled Substances Act;*

1 (5) *inadequate treatment of pain, especially for*
 2 *chronic diseases and conditions, irreversible diseases*
 3 *such as cancer, and end-of-life care, is a serious pub-*
 4 *lic health problem affecting hundreds of thousands of*
 5 *patients every year; physicians should not hesitate to*
 6 *dispense or distribute controlled substances when*
 7 *medically indicated for these conditions; and*

8 (6) *for the reasons set forth in section 101 of the*
 9 *Controlled Substances Act (21 U.S.C. 801), the dis-*
 10 *persing and distribution of controlled substances for*
 11 *any purpose affect interstate commerce.*

12 ***TITLE I—PROMOTING PAIN MAN-***
 13 ***AGEMENT AND PALLIATIVE***
 14 ***CARE***

15 ***SEC. 101. ACTIVITIES OF AGENCY FOR HEALTHCARE RE-***
 16 ***SEARCH AND QUALITY.***

17 *Part A of title IX of the Public Health Service Act*
 18 *(42 U.S.C. 299 et seq.) is amended by adding at the end*
 19 *the following:*

20 ***“SEC. 903. PROGRAM FOR PAIN MANAGEMENT AND PALLIA-***
 21 ***TIVE CARE RESEARCH AND QUALITY.***

22 ***“(a) IN GENERAL.—****Subject to subsections (e) and (f)*
 23 *of section 902, the Director shall carry out a program to*
 24 *accomplish the following:*

1 “(1) *Promote and advance scientific under-*
2 *standing of pain management and palliative care.*

3 “(2) *Collect and disseminate protocols and evi-*
4 *dence-based practices regarding pain management*
5 *and palliative care, with priority given to pain man-*
6 *agement for terminally ill patients, and make such*
7 *information available to public and private health*
8 *care programs and providers, health professions*
9 *schools, and hospices, and to the general public.*

10 “(b) *DEFINITION.—In this section, the term ‘pain*
11 *management and palliative care’ means—*

12 “(1) *the active, total care of patients whose dis-*
13 *ease or medical condition is not responsive to curative*
14 *treatment or whose prognosis is limited due to pro-*
15 *gressive, far-advanced disease; and*

16 “(2) *the evaluation, diagnosis, treatment, and*
17 *management of primary and secondary pain, whether*
18 *acute, chronic, persistent, intractable, or associated*
19 *with the end of life;*

20 *the purpose of which is to diagnose and alleviate pain and*
21 *other distressing signs and symptoms and to enhance the*
22 *quality of life, not to hasten or postpone death.”.*

1 **SEC. 102. ACTIVITIES OF HEALTH RESOURCES AND SERV-**
2 **ICES ADMINISTRATION.**

3 (a) *IN GENERAL.*—Part D of title VII of the Public
4 Health Service Act (42 U.S.C. 294 et seq.) is amended—

5 (1) by redesignating sections 754 through 757 as
6 sections 755 through 758, respectively; and

7 (2) by inserting after section 753 the following:

8 **“SEC. 754. PROGRAM FOR EDUCATION AND TRAINING IN**
9 **PAIN MANAGEMENT AND PALLIATIVE CARE.**

10 “(a) *IN GENERAL.*—The Secretary, in consultation
11 with the Director of the Agency for Healthcare Research and
12 Quality, may award grants, cooperative agreements, and
13 contracts to health professions schools, hospices, and other
14 public and private entities for the development and imple-
15 mentation of programs to provide education and training
16 to health care professionals in pain management and pal-
17 liative care.

18 “(b) *PRIORITY.*—In making awards under subsection
19 (a), the Secretary shall give priority to awards for the im-
20 plementation of programs under such subsection.

21 “(c) *CERTAIN TOPICS.*—An award may be made under
22 subsection (a) only if the applicant for the award agrees
23 that the program to be carried out with the award will in-
24 clude information and education on—

25 “(1) means for diagnosing and alleviating pain
26 and other distressing signs and symptoms of patients,

1 *especially terminally ill patients, including the medi-*
2 *cally appropriate use of controlled substances;*

3 *“(2) applicable laws on controlled substances, in-*
4 *cluding laws permitting health care professionals to*
5 *dispense or administer controlled substances as needed*
6 *to relieve pain even in cases where such efforts may*
7 *unintentionally increase the risk of death; and*

8 *“(3) recent findings, developments, and improve-*
9 *ments in the provision of pain management and pal-*
10 *liative care.*

11 *“(d) PROGRAM SITES.—Education and training*
12 *under subsection (a) may be provided at or through health*
13 *professions schools, residency training programs and other*
14 *graduate programs in the health professions, entities that*
15 *provide continuing medical education, hospices, and such*
16 *other programs or sites as the Secretary determines to be*
17 *appropriate.*

18 *“(e) EVALUATION OF PROGRAMS.—The Secretary shall*
19 *(directly or through grants or contracts) provide for the*
20 *evaluation of programs implemented under subsection (a)*
21 *in order to determine the effect of such programs on knowl-*
22 *edge and practice regarding pain management and pallia-*
23 *tive care.*

24 *“(f) PEER REVIEW GROUPS.—In carrying out section*
25 *799(f) with respect to this section, the Secretary shall ensure*

1 *that the membership of each peer review group involved in-*
 2 *cludes individuals with expertise and experience in pain*
 3 *management and palliative care for the population of pa-*
 4 *tients whose needs are to be served by the program.*

5 “(g) *DEFINITION.—In this section, the term ‘pain*
 6 *management and palliative care’ means—*

7 “(1) *the active, total care of patients whose dis-*
 8 *ease or medical condition is not responsive to curative*
 9 *treatment or whose prognosis is limited due to pro-*
 10 *gressive, far-advanced disease; and*

11 “(2) *the evaluation, diagnosis, treatment, and*
 12 *management of primary and secondary pain, whether*
 13 *acute, chronic, persistent, intractable, or associated*
 14 *with the end of life;*

15 *the purpose of which is to diagnose and alleviate pain and*
 16 *other distressing signs and symptoms and to enhance the*
 17 *quality of life, not to hasten or postpone death.”.*

18 (b) *AUTHORIZATION OF APPROPRIATIONS; ALLOCA-*
 19 *TION.—*

20 (1) *IN GENERAL.—Section 758 of the Public*
 21 *Health Service Act (as redesignated by subsection*
 22 *(a)(1) of this section) is amended, in subsection*
 23 *(b)(1)(C), by striking “sections 753, 754, and 755”*
 24 *and inserting “sections 753, 754, 755, and 756”.*

1 (2) *AMOUNT.*—*With respect to section 758 of the*
 2 *Public Health Service Act (as redesignated by sub-*
 3 *section (a)(1) of this section), the dollar amount spec-*
 4 *ified in subsection (b)(1)(C) of such section is deemed*
 5 *to be increased by \$5,000,000.*

6 **SEC. 103. DECADE OF PAIN CONTROL AND RESEARCH.**

7 *The calendar decade beginning January 1, 2001, is*
 8 *designated as the “Decade of Pain Control and Research”.*

9 **SEC. 104. EFFECTIVE DATE.**

10 *The amendments made by this title shall take effect*
 11 *on the date of enactment of this Act.*

12 **TITLE II—USE OF CONTROLLED**
 13 **SUBSTANCES CONSISTENT**
 14 **WITH THE CONTROLLED SUB-**
 15 **STANCES ACT**

16 **SEC. 201. REINFORCING EXISTING STANDARD FOR LEGITI-**
 17 **MATE USE OF CONTROLLED SUBSTANCES.**

18 (a) *IN GENERAL.*—*Section 303 of the Controlled Sub-*
 19 *stances Act (21 U.S.C. 823) is amended by adding at the*
 20 *end the following:*

21 “(i)(1) *For purposes of this Act and any regulations*
 22 *to implement this Act, alleviating pain or discomfort in the*
 23 *usual course of professional practice is a legitimate medical*
 24 *purpose for the dispensing, distributing, or administering*
 25 *of a controlled substance that is consistent with public*

1 *health and safety, even if the use of such a substance may*
2 *increase the risk of death. Nothing in this section authorizes*
3 *intentionally dispensing, distributing, or administering a*
4 *controlled substance for the purpose of causing death or as-*
5 *sisting another person in causing death.*

6 “(2)(A) *Notwithstanding any other provision of this*
7 *Act, in determining whether a registration is consistent*
8 *with the public interest under this Act, the Attorney Gen-*
9 *eral shall give no force and effect to State law authorizing*
10 *or permitting assisted suicide or euthanasia.*

11 “(B) *Paragraph (2) applies only to conduct occurring*
12 *after the date of enactment of this subsection.*

13 “(3) *Nothing in this subsection shall be construed to*
14 *alter the roles of the Federal and State governments in regu-*
15 *lating the practice of medicine. Regardless of whether the*
16 *Attorney General determines pursuant to this section that*
17 *the registration of a practitioner is inconsistent with the*
18 *public interest, it remains solely within the discretion of*
19 *State authorities to determine whether action should be*
20 *taken with respect to the State professional license of the*
21 *practitioner or State prescribing privileges.*

22 “(4) *Nothing in the Pain Relief Promotion Act of 2000*
23 *(including the amendments made by such Act) shall be*
24 *construed—*

1 “(A) to modify the Federal requirements that a
2 controlled substance be dispensed only for a legitimate
3 medical purpose pursuant to paragraph (1); or

4 “(B) to provide the Attorney General with the
5 authority to issue national standards for pain man-
6 agement and palliative care clinical practice, re-
7 search, or quality;

8 except that the Attorney General may take such other ac-
9 tions as may be necessary to enforce this Act.”.

10 (b) *PAIN RELIEF*.—Section 304(c) of the Controlled
11 Substances Act (21 U.S.C. 824(c)) is amended—

12 (1) by striking “(c) Before” and inserting the fol-
13 lowing:

14 “(c) *PROCEDURES*.—

15 “(1) *ORDER TO SHOW CAUSE*.—Before”; and

16 (2) by adding at the end the following:

17 “(2) *BURDEN OF PROOF*.—At any proceeding
18 under paragraph (1), where the order to show cause
19 is based on the alleged intentions of the applicant or
20 registrant to cause or assist in causing death, and the
21 practitioner claims a defense under paragraph (1) of
22 section 303(i), the Attorney General shall have the
23 burden of proving, by clear and convincing evidence,
24 that the practitioner’s intent was to dispense, dis-
25 tribute, or administer a controlled substance for the

1 *purpose of causing death or assisting another person*
2 *in causing death. In meeting such burden, it shall not*
3 *be sufficient to prove that the applicant or registrant*
4 *knew that the use of controlled substance may in-*
5 *crease the risk of death.”.*

6 **SEC. 202. EDUCATION AND TRAINING PROGRAMS.**

7 *Section 502(a) of the Controlled Substances Act (21*
8 *U.S.C. 872(a)) is amended—*

9 *(1) by striking “and” at the end of paragraph*
10 *(5);*

11 *(2) by striking the period at the end of para-*
12 *graph (6) and inserting “; and”; and*

13 *(3) by adding at the end the following:*

14 *“(7) educational and training programs for Fed-*
15 *eral, State, and local personnel, incorporating rec-*
16 *ommendations, subject to the provisions of subsections*
17 *(e) and (f) of section 902 of the Public Health Service*
18 *Act, by the Secretary of Health and Human Services,*
19 *on the means by which investigation and enforcement*
20 *actions by law enforcement personnel may better ac-*
21 *commodate the necessary and legitimate use of con-*
22 *trolled substances in pain management and palliative*
23 *care.*

1 *Nothing in this subsection shall be construed to alter the*
2 *roles of the Federal and State governments in regulating*
3 *the practice of medicine.”.*

4 **SEC. 203. FUNDING AUTHORITY.**

5 *Notwithstanding any other provision of law, the oper-*
6 *ation of the diversion control fee account program of the*
7 *Drug Enforcement Administration shall be construed to in-*
8 *clude carrying out section 303(i) of the Controlled Sub-*
9 *stances Act (21 U.S.C. 823(i)), as added by this Act, and*
10 *subsections (a)(4) and (c)(2) of section 304 of the Controlled*
11 *Substances Act (21 U.S.C. 824), as amended by this Act.*

12 **SEC. 204. EFFECTIVE DATE.**

13 *The amendments made by this title shall take effect*
14 *on the date of enactment of this Act.*

Calendar No. 566

106TH CONGRESS
2D SESSION

H. R. 2260

[Report No. 106-299]

AN ACT

To amend the Controlled Substances Act to promote pain management and palliative care without permitting assisted suicide and euthanasia, and for other purposes.

MAY 23, 2000

Reported with an amendment