108TH CONGRESS
1ST SESSION

S. 1278

To amend the Public Health Service Act to provide for a public response to the public health crisis of pain, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 18, 2003

Mr. WYDEN, (for himself, Mr. SMITH, Mr. ROCKEFELLER, and Mr. BREAUX) introduced the following bill; which was read twice and referred to the Committee on Health, Education, and Labor, and Pensions

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A BILL

To amend the Public Health Service Act to provide for a public response to the public health crisis of pain, 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; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Conquering Pain Act of 2003''.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

SEC. 2. FINDINGS.

Congress finds that—

(1) pain is often left untreated or under-treated especially among older patients, African Americans, Hispanics and other minorities, and children;

(2) chronic pain is a public health problem affecting at least 50,000,000 Americans through some form of persisting or recurring symptom;

(3) 40 to 50 percent of patients experience moderate to severe pain at least half the time in their last days of life;

(4) 70 to 80 percent of cancer patients experience significant pain during their illness;

(5) one in 7 nursing home residents experience persistent pain that may diminish their quality of life;

(6) despite the best intentions of physicians, nurses, pharmacists, and other health care professionals, pain is often under-treated because of the inadequate training of clinicians in pain management;

(7) despite the best intentions of physicians, nurses, pharmacists, mental health professionals, and other health care professionals, pain and symptom management is often suboptimal because the health care system has focused on cure of disease rather than the management of a patient's pain and other symptoms;

(8) the technology and scientific basis to adequately manage most pain is known;

(9) pain should be considered the fifth vital sign; and

(10) coordination of Federal efforts is needed to improve access to high quality effective pain and symptom management in order to assure the needs

of chronic pain patients and those who are terminally ill are met.

SEC. 3. DEFINITIONS.

In this Act:

(1) CHRONIC PAIN.—The term ''chronic pain'' means a pain state that is persistent and in which the cause of the pain cannot be removed or otherwise alleviated. Such term includes pain that may be associated with long-term incurable or intractable medical conditions or disease.

(2) END OF LIFE CARE.—The term ''end of life care'' means a range of services, including hospice care, provided to a patient, in the final stages of his or her life, who is suffering from 1 or more conditions for which treatment toward a cure or reasonable improvement is not possible, and whose focus of care is palliative rather than curative.

(3) FAMILY SUPPORT NETWORK.—The term ''family support network'' means an association of 2 or more individuals or entities in a collaborative effort to develop multi-disciplinary integrated patient care approaches that involve medical staff and ancillary services to provide support to chronic pain patients and patients at the end of life and their care-

givers across a broad range of settings in which pain management might be delivered.

(4) HOSPICE.—The term ''hospice care'' has the meaning given such term in section 1861(dd)(1) of the Social Security Act (42 U.S.C. 1395x(dd)(1)).

(5) MEDICATION THERAPY MANAGEMENT SERVICES.—The term ''medication therapy management services'' means consultations with a physician or other health care professional (including a pharmacist) who is practicing within the scope of the professional's license, concerning a patient which results in—

(A) a change in the drug regimen of the patient to avoid an adverse drug interaction with another drug or disease state;

(B) a change in inappropriate drug dosage or dosage form with respect to the patient;

(C) discontinuing an unnecessary or harmful medication with respect to the patient;

(D) an initiation of medication therapy for a medical condition of the patient;

(E) consultation with the patient or a caregiver in a manner that results in a significant improvement in drug regimen compliance; or

(F) patient and caregiver understanding of the appropriate use and adherence to medication therapy.

(6) PAIN AND SYMPTOM MANAGEMENT.—The term ''pain and symptom management'' means services provided to relieve physical or psychological pain or suffering, including any 1 or more of the following physical complaints—

(A) weakness and fatigue;

(B) shortness of breath;

(C) nausea and vomiting;

(D) diminished appetite;

(E) wasting of muscle mass;

(F) difficulty in swallowing;

(G) bowel problems;

(H) dry mouth;

(I) failure of lymph drainage resulting in tissue swelling;

(J) confusion;

(K) dementia;

(L) delirium;

(M) anxiety;

(N) depression; and

(O) other related symptoms.

(7) PALLIATIVE CARE.—The term ''palliative care'' means the total care of patients whose disease is not responsive to curative treatment, the goal of which is to provide the best quality of life for such patients and their families. Such care—

(A) may include the control of pain and of other symptoms, including psychological, social and spiritual problems;

(B) affirms life and regards dying as a normal process;

(C) provides relief from pain and other distressing symptoms;

(D) integrates the psychological and spiritual aspects of patient care;

(E) offers a support system to help patients live as actively as possible until death; and

(F) offers a support system to help the family cope during the patient's illness and in their own bereavement.

(8) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

TITLE I—EMERGENCY RESPONSE TO THE PUBLIC HEALTH CRISIS OF PAIN

SEC. 101. GUIDELINES FOR THE TREATMENT OF PAIN.

(a) DEVELOPMENT OF WEBSITE.—Not later than 2 months after the date of enactment of this Act, the Secretary, acting through the Agency for Healthcare Research and Quality, shall develop and maintain an Internet website to provide information to individuals, health care practitioners, and health facilities concerning evidence-based practice guidelines developed for the treatment of physical and psychological pain. Websites in existence on such date may be used if such websites meet the requirements of this section.

(b) REQUIREMENTS.—The website established under subsection (a) shall—

(1) be designed to be quickly referenced by health care practitioners; and

(2) provide for the updating of guidelines as scientific data warrants.

(c) PROVIDER ACCESS TO GUIDELINES.—

(1) IN GENERAL.—In establishing the website under subsection (a), the Secretary shall ensure that health care facilities have made the website known to health care practitioners and that the website is

easily available to all health care personnel providing care or services at a health care facility.

(2) USE OF CERTAIN EQUIPMENT.—In making the information described in paragraph (1) available to health care personnel, the facility involved shall—

(A) ensure that such personnel have access to the website through the computer equipment of the facility;

(B) carry out efforts to inform personnel at the facility of the location of such equipment; and

(C) ensure that patients, caregivers, and support groups are provided with access to the website.

(3) RURAL AREAS.—

(A) IN GENERAL.—A health care facility, particularly a facility located in a rural or underserved area, without access to the Internet shall provide an alternative means of providing practice guideline information to all health care personnel.

(B) ALTERNATIVE MEANS.—The Secretary shall determine appropriate alternative means by which a health care facility may make available practice guideline information on a 24-hour

basis, 7 days a week if the facility does not have Internet access. The criteria for adopting such alternative means should be clear in permitting facilities to develop alternative means without placing a significant financial burden on the facility and in permitting flexibility for facilities to develop alternative means of making guidelines available. Such criteria shall be published in the Federal Register.

SEC. 102. PATIENT EXPECTATIONS TO HAVE PAIN AND SYMPTOM MANAGEMENT.

(a) IN GENERAL.—The administrator of each of the programs described in subsection (b) shall ensure that, as part of any informational materials provided to individuals under such programs, such materials shall include information, where relevant, to inform such individuals that they should expect to have their pain assessed and should expect to be provided with effective pain and symptom relief, when receiving benefits under such program.

(b) PROGRAMS.—The programs described in this subsection shall include—

(1) the medicare and medicaid programs under titles XIX and XXI of the Social Security Act (42 U.S.C. 1935 et seq., 1936 et seq.);

(2) programs carried out through the Public Health Service;

(3) programs carried out through the Indian Health Service;

(4) programs carried out through health centers under section 330 of the Public Health Service Act (42 U.S.C. 254b);

(5) the Federal Employee Health Benefits Program under title 5, United States Code;

(6) the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) as defined in section 1073(4) of title 10, United States Code; and

(7) other programs administered by the Secretary.

SEC. 103. QUALITY IMPROVEMENT EDUCATION PROJECTS.

The Secretary shall provide funds for the implementation of special education projects, in as many States as is practicable, to be carried out by peer review organizations of the type described in section 1152 of the Social Security Act (42 U.S.C. 1320c–1) to improve the quality of pain and symptom management. Such projects shall place an emphasis on improving pain and symptom management at the end of life, and may also include efforts to increase the quality of services delivered to chronic pain

patients and the chronically ill for whom pain may be a significant symptom.

SEC. 104. PAIN COVERAGE QUALITY EVALUATION AND INFORMATION.

(a) IN GENERAL.—Section 1851(d)(4) of the Social Security Act (42 U.S.C. 42 U.S.C. 1395w–21(d)(4)) is amended—

(1) in subparagraph (A), by adding at the end the following:

''(ix) The organization's coverage of pain and symptom management.''; and

(2) in subparagraph (D)—

(A) in clause (iii), by striking ''and'' at the end;

(B) in clause (iv), by striking the period and inserting '', and''; and

(C) by adding at the end the following:

''(v) not later than 2 years after the date of enactment of this clause, an evaluation (which may be made part of any other relevant report of quality evaluation that the plan is required to prepare) for the plan (updated annually) that indicates the performance of the plan with respect to access to, and quality of, pain and symp-

tom management, including such management as part of end of life care. Data shall be posted in a comparable manner for consumer use on www.medicare.gov.''.

(b) EFFECTIVE DATE.—The amendments made by paragraph (1) apply to information provided with respect to annual, coordinated election periods (as defined in section 1851(e)(3)(B) of the Social Security Act (42 U.S.C. 1395–21(e)(3)(B)) beginning after the date of enactment of this Act.

SEC. 105. SURGEON GENERAL'S REPORT.

Not later than October 1, 2004, the Surgeon General shall prepare and submit to the appropriate committees of Congress and the public, a report concerning the state of pain and symptom management in the United States. The report shall include—

(1) a description of the legal and regulatory barriers that may exist at the Federal and State levels to providing adequate pain and symptom management;

(2) an evaluation of provider competency in providing pain and symptom management;

(3) an identification of vulnerable populations, including children, advanced elderly, non-English speakers, and minorities, who may be likely to be

underserved or may face barriers to access to pain management and recommendations to improve access to pain management for these populations;

(4) an identification of barriers that may exist in providing pain and symptom management in health care settings, including assisted living facilities;

(5) an identification of patient and family attitudes that may exist which pose barriers in accessing pain and symptom management or in the proper use of pain medications;

(6) an evaluation of medical, nursing, and pharmacy school training and residency training for pain and symptom management;

(7) a review of continuing medical education programs in pain and symptom management; and

(8) a description of the use of and access to mental health services for patients in pain and patients at the end of life.

TITLE II—DEVELOPING COMMUNITY RESOURCES

SEC. 201. FAMILY SUPPORT NETWORKS IN PAIN AND SYMPTOM MANAGEMENT.

(a) ESTABLISHMENT.—The Secretary, acting through the Public Health Service, shall award grants for

the establishment of 6 National Family Support Networks in Pain and Symptom Management (in this section referred to as the ''Networks'') to serve as national models for improving the access and quality of pain and symptom management to chronic pain patients (including chronically ill patients for whom pain is a significant symptom) and those individuals in need of pain and symptom management at the end of life and to provide assistance to family members and caregivers.

(b) ELIGIBILITY AND DISTRIBUTION.—

(1) ELIGIBILITY.—To be eligible to receive a grant under subsection (a), an entity shall—

(A) be an academic facility or other entity that has demonstrated an effective approach to training health care providers including mental health professionals concerning pain and symptom management and palliative care services; and

(B) prepare and submit to the Secretary an application (to be peer reviewed by a committee established by the Secretary), at such time, in such manner, and containing such information as the Secretary may require.

(2) DISTRIBUTION.—In providing for the establishment of Networks under subsection (a), the Secretary shall ensure that—

(A) the geographic distribution of such Networks reflects a balance between rural and urban needs; and

(B) at least 3 Networks are established at academic facilities.

(c) ACTIVITIES OF NETWORKS.—A Network that is established under this section—

(1) shall provide for an integrated interdisciplinary approach, that includes psychological and counseling services, to the delivery of pain and symptom management;

(2) shall provide community leadership in establishing and expanding public access to appropriate pain care, including pain care at the end of life;

(3) shall provide assistance, through caregiver supportive services, that include counseling and education services;

(4) shall develop a research agenda to promote effective pain and symptom management for the broad spectrum of patients in need of access to such care that can be implemented by the Network;

(5) shall provide for coordination and linkages between clinical services in academic centers and surrounding communities to assist in the widespread dissemination of provider and patient information concerning how to access options for pain management;

(6) shall establish telemedicine links to provide education and for the delivery of services in pain and symptom management;

(7) shall develop effective means of providing assistance to providers and families for the management of a patient's pain 24 hours a day, 7 days a week; and

(8) may include complimentary medicine provided in conjunction with traditional medical services.

(d) PROVIDER PAIN AND SYMPTOM MANAGEMENT COMMUNICATIONS PROJECTS.—

(1) IN GENERAL.—Each Network shall establish a process to provide health care personnel with information 24 hours a day, 7 days a week, concerning pain and symptom management. Such process shall be designed to test the effectiveness of specific forms of communications with health care personnel so that such personnel may obtain informa-

tion to ensure that all appropriate patients are provided with pain and symptom management.

(2) TERMINATION.—The requirement of paragraph (1) shall terminate with respect to a Network on the day that is 2 years after the date on which the Network has established the communications method.

(3) EVALUATION.—Not later than 60 days after the expiration of the 2-year period referred to in paragraph (2), a Network shall conduct an evaluation and prepare and submit to the Secretary a report concerning the costs of operation and whether the form of communication can be shown to have had a positive impact on the care of patients in chronic pain or on patients with pain at the end of life.

(4) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed as limiting a Network from developing other ways in which to provide support to families and providers, 24 hours a day, 7 days a week.

(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $18,000,000 for fiscal years 2004 through 2006.

TITLE III—REIMBURSEMENT BARRIERS

SEC. 301. REIMBURSEMENT BARRIERS REPORT.

The Medicare Payment Advisory Commission (MedPac) established under section 1805 of the Social Security Act (42 U.S.C. 1396b–6) shall conduct a study, and prepare and submit to the appropriate committees of Congress a report, concerning—

(1) the manner in which medicare policies may pose barriers in providing pain and symptom management and palliative care services in different settings, including a focus on payment for nursing home and home health services;

(2) the identification of any financial barriers that may exist within the medicare and medicaid programs under titles XVIII and XIX of the Social Security Act (42 U.S.C. 1395 et seq., 1396 et seq.) that interfere with continuity of care and interdisciplinary care or supportive care for the broad range of chronic pain patients (including patients who are chronically ill for whom pain is a significant symptom), and for those who are terminally ill, and include the recommendations of the Commission on ways to eliminate those barriers that the Commission may identify;

(3) the reimbursement barriers that exist, if any, in providing pain and symptom management through hospice care, particularly in rural areas, and if barriers exist, recommendations concerning adjustments that would assist in assuring patient access to pain and symptom management through hospice care in rural areas;

(4) whether the medicare reimbursement system provides incentives to providers to delay informing terminally ill patients of the availability of hospice and palliative care; and

(5) the impact of providing payments for medication therapy management services in pain and symptom management and palliative care services.

SEC. 302. INSURANCE COVERAGE OF PAIN AND SYMPTOM MANAGEMENT.

(a) IN GENERAL.—The General Accounting Office shall conduct a survey of public and private health insurance providers, including managed care entities, to determine whether the reimbursement policies of such insurers inhibit the access of chronic pain patients to pain and symptom management and pain and symptom management for those in need of end-of-life care (including patients who are chronically ill for whom pain is a significant symptom). The survey shall include a review of

formularies for pain medication and the effect of such formularies on pain and symptom management.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the General Accounting Office shall prepare and submit to the appropriate committees of Congress a report concerning the survey conducted under subsection (a).

TITLE IV—IMPROVING FEDERAL COORDINATION OF POLICY, RESEARCH, AND INFORMATION

SEC. 401. ADVISORY COMMITTEE ON PAIN AND SYMPTOM MANAGEMENT.

(a) ESTABLISHMENT.—The Secretary shall establish an advisory committee, to be known as the Advisory Committee on Pain and Symptom Management, to make recommendations to the Secretary concerning a coordinated Federal agenda on pain and symptom management.

(b) MEMBERSHIP.—The Advisory Committee established under subsection (a) shall be comprised of 11 individuals to be appointed by the Secretary, of which at least 1 member shall be a representative of—

(1) physicians (medical doctors or doctors of osteopathy) who treat chronic pain patients or the terminally ill;

(2) nurses who treat chronic pain patients or the terminally ill;

(3) pharmacists;

(4) hospice;

(5) pain researchers;

(6) patient advocates;

(7) caregivers; and

(8) mental health providers.

The members of the Committee shall designate 1 member to serve as the chairperson of the Committee.

(c) MEETINGS.—The Advisory Committee shall meet at the call of the chairperson of the Committee.

(d) AGENDA.—The agenda of the Advisory Committee established under subsection (a) shall include—

(1) the development of recommendations to create a coordinated Federal agenda on pain and symptom management;

(2) the development of proposals to ensure that pain is considered as the fifth vital sign for all patients;

(3) the identification of research needs in pain and symptom management, including gaps in pain and symptom management guidelines;

(4) the identification and dissemination of pain and symptom management practice guidelines, research information, and best practices;

(5) proposals for patient education concerning how to access pain and symptom management across health care settings;

(6) the manner in which to measure improvement in access to pain and symptom management and improvement in the delivery of care;

(7) the development of ongoing strategies to assure the aggressive use of pain medications, including opiods, regardless of health care setting; and

(8) the development of an ongoing mechanism to identify barriers or potential barriers to pain and symptom management created by Federal policies.

(e) RECOMMENDATION.—Not later than 2 years after the date of enactment of this Act, the Advisory Committee established under subsection (a) shall prepare and submit to the Secretary recommendations concerning a prioritization of the need for a Federal agenda on pain and symptom management, and ways in which to better coordinate the activities of entities within the Department of Health and Human Services, and other Federal entities charged with the responsibility for the delivery of health

care services or research on pain and symptom management with respect to pain management.

(f) CONSULTATION.—In carrying out this section, the Advisory Committee shall consult with all Federal agencies that are responsible for providing health care services or access to health services to determine the best means to ensure that all Federal activities are coordinated with respect to research and access to pain and symptom management.

(g) ADMINISTRATIVE SUPPORT; TERMS OF SERVICE; OTHER PROVISIONS.—The following shall apply with respect to the Advisory Committee:

(1) The Committee shall receive necessary and appropriate administrative support, including appropriate funding, from the Department of Health and Human Services.

(2) The Committee shall hold open meetings and meet not less than 4 times per year.

(3) Members of the Committee shall not receive additional compensation for their service. Such members may receive reimbursement for appropriate and additional expenses that are incurred through service on the Committee which would not have incurred had they not been a member of the Committee.

(4) The requirements of Appendix 2 of title 5, United States Code.

SEC. 402. INSTITUTES OF MEDICINE REPORT ON CONTROLLED SUBSTANCE REGULATION AND THE USE OF PAIN MEDICATIONS.

(a) IN GENERAL.—The Secretary, acting through a contract entered into with the Institute of Medicine, shall review findings that have been developed through research conducted concerning—

(1) the effects of controlled substance regulation on patient access to effective care;

(2) factors, if any, that may contribute to the underuse of pain medications, including opiods;

(3) the identification of State legal and regulatory barriers, if any, that may impact patient access to medications used for pain and symptom management; and

(4) strategies to assure the aggressive use of pain medications, including opiods, regardless of health care setting.

(b) REPORT.—Not later than 18 months after the date of enactment of this Act, the Secretary shall prepare and submit to the appropriate committees of Congress a report concerning the findings described in subsection (a).

SEC. 403. CONFERENCE ON PAIN RESEARCH AND CARE.

Not later than December 31, 2007, the Secretary, acting through the National Institutes of Health, shall convene a national conference to discuss the translation of pain research into the delivery of health services including mental health services to chronic pain patients and those needing end-of-life care. The Secretary shall use unobligated amounts appropriated for the Department of Health and Human Services to carry out this section.

TITLE V—DEMONSTRATION PROJECTS

SEC. 501. PROVIDER PERFORMANCE STANDARDS FOR IMPROVEMENT IN PAIN AND SYMPTOM MANAGEMENT.

(a) IN GENERAL.—The Secretary, acting through the Health Resources Services Administration, shall award grants for the establishment of not less than 5 demonstration projects to determine effective methods to measure improvement in the skills, knowledge, and attitudes and beliefs of health care personnel in pain and symptom management as such skill, knowledge, and attitudes and beliefs apply to providing services to chronic pain patients and those patients requiring pain and symptom management at the end of life.

(b) EVALUATION.—Projects established under subsection (a) shall be evaluated to determine patient and

caregiver knowledge and attitudes toward pain and symptom management.

(c) APPLICATION.—To be eligible to receive a grant under subsection (a), an entity shall prepare and submit to the Secretary an application at such time, in such manner and containing such information as the Secretary may require.

(d) TERMINATION.—A project established under subsection (a) shall terminate after the expiration of the 2-year period beginning on the date on which such project was established.

(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as may be necessary to carry out this section.

SEC. 502. END OF LIFE CARE DEMONSTRATION PROJECTS.

The Secretary, acting through the Health Resources and Services Administration, shall—

(1) not later than January 1, 2006, carry out not less than 5 demonstration and evaluation projects that implement care models for individuals at the end of life, at least one of which shall be developed to assist those individuals who are terminally ill and have no family or extended support, and each of which may be carried out in collaboration with do-

mestic and international entities to gain and share knowledge and experience on end of life care;

(2) conduct 3 demonstration and evaluation activities concerning the education and training of clinicians in end of life care, and assist in the development and distribution of accurate educational materials on both pain and symptom management and end of life care;

(3) in awarding grants for the training of health professionals, give priority to awarding grants to entities that will provide training for health professionals in pain and symptom management and in end-of-life care at the undergraduate level;

(4) shall evaluate demonstration projects carried out under this section within the 5-year period beginning on the commencement of each such project; and

(5) develop a strategy and make recommendations to Congress to ensure that the United States health care system—

(A) has a meaningful, comprehensive, and effective approach to meet the needs of individuals and their caregivers as the patient approaches death; and

(B) integrates broader supportive services.

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