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ESTABLISHING EPILEPSY CENTERS OF EXCELLENCE IN THE VETERANS HEALTH ADMINISTRATION

DECEMBER 12, 2007.—Ordered to be printed

Mr. AKAKA, from the Committee on Veterans' Affairs, submitted the following

R E P O R T

[To accompany S. 2004]

The Committee on Veterans' Affairs (hereinafter, "the Committee"), to which was referred the bill (S. 2004) to amend title 38, United States Code, to establish epilepsy centers of excellence in the Veterans Health Administration of the Department of Veterans Affairs, and for other purposes, having considered the same, reports favorably thereon and recommends that the bill do pass.

INTRODUCTION

On August 3, 2007, Senator Murray, for herself and Senator Craig, introduced S. 2004. S. 2004 would designate six health care facilities of the Department of Veterans Affairs as centers of excellence for research, education, and clinical care of epilepsy. S. 2004 is also cosponsored by Senators Lincoln and Obama.

On October 24, 2007, the Committee held a hearing on pending veterans' health legislation at which testimony was offered by: the Honorable Michael J. Kussman, M.D., M.S., M.A.C.P., Under Secretary for Health, Department of Veterans Affairs, accompanied by Walter Hall, Assistant General Counsel, Department of Veterans Affairs; Carl Blake, National Legislative Director, Paralyzed Veterans of America; Joy J. Ilem, Assistant National Legislative Director, Disabled Veterans of America; Brenda Murdough, M.S.N., RN–C, Military/Veterans Initiative Coordinator, American Pain Foundation; Brien J. Smith, M.D., Director, Epilepsy Monitoring Unit, Henry Ford Hospital; and Capt. Constance Walker, USN (Ret.), President, Southern Maryland Chapter of the National Alliance on Mental Illness.

69–010

Earlier, on May 23, 2007, the Committee held a hearing on pending veterans' health legislation. The testimony of John Booss, M.D., American Academy of Neurology included a discussion about epilepsy care and research within VA and the veteran population.

COMMITTEE MEETING

After carefully reviewing the testimony from the foregoing hearings, the Committee met in open session on November 14, 2007, to consider, among other legislation, S. 2004. The Committee voted unanimously to report favorably S. 2004.

SUMMARY OF S. 2004 AS REPORTED

S. 2004, as reported, (hereinafter, "the Committee bill") would establish within the Veterans Health Administration epilepsy centers of excellence.

Section (a) of the Committee bill would amend chapter 73 of title 38, United States Code, by adding a new section 7330A, consisting of six subsections (a) through (f) as follows:

New subsection (a) would require the Secretary to designate not less than six Department health care facilities as locations for epilepsy centers of excellence, and, subject to the availability of appropriations, establish and operate such centers.

New subsection (b) would stipulate that the Secretary may not designate a Department health care facility as a location for an epilepsy center of excellence without the approval of the peer review panel established under new subsection (c).

New subsection (c) would establish a peer review panel to assess the scientific and clinical merit of proposals submitted to the Secretary for the designation of epilepsy centers of excellence. This subsection would also set forth requirements concerning the composition and operation of the peer review panel.

New subsection (d) would define "epilepsy center of excellence" as a facility that has, or can develop, the necessary capacity to function as a center of excellence in research, education, and clinical care activities in the diagnosis and treatment of epilepsy.

New subsection (e) would require the Secretary to designate an individual in the VHA to act as a national coordinator for epilepsy programs of the VHA, and would specify the duties of that coordinator.

New subsection (f) would authorize $6,000,000 to be appropriated for the operation of the centers under this section for each fiscal year 2008 through 2012. In addition, such sums as may be necessary would be authorized to be appropriated to fund the national coordinator designated under subsection (e).

Section (b) of the Committee bill would make a clerical amendment to the table of contents of chapter 73 of title 38.

BACKGROUND AND DISCUSSION

The Committee bill would add a new section 7330A to title 38, United States Code, which would require the Secretary to designate not less than six Department facilities as locations for epilepsy centers of excellence. For a wide range of diseases and disabilities, VA Centers of Excellence are the model of innovation in the delivery of specialized health care and research. As discussed

below, the centers would fill gaps in research, care, and education for epilepsy.

The need for these centers has been demonstrated by both past experience and current research. Following the return of veterans from Vietnam, VA became a leader in research and treatment of epilepsy. VA's efforts were, however, reactive, and the opportunity to intervene early to prevent epilepsy was missed.

Dr. John Booss, of the American Academy of Neurology, and formerly the national director of neurology for the VA, said in testimony before the Committee on May 23, 2007, that

> At one point, the VA was a national leader in care and research for patients with epilepsy. As early as 1972 the VA recognized the need for VA health centers that specialized in epilepsy. But starting in the 1990's these epilepsy centers have languished due to lack of funds.

This sentiment was echoed by Dr. Brien J. Smith, Medical Director of the Comprehensive Epilepsy Program at the Henry Ford Hospital in Detroit, in testimony before the Committee on October 24, 2007.

> The VA established Epilepsy Centers as early as 1972, but these Centers have languished over the years with few staff and no national budget. The net result of allowing these Centers to fall by the wayside is that veterans with post traumatic brain injury epilepsy are at the variable mercy of a system with markedly uneven distribution of epilepsy services. This often results in denial of services in locations without the necessary epilepsy facilities and in which administrators are hard pressed to meet their budget. Sadly, the potential of these Centers to be the backbone of a national epilepsy program never materialized.

The centers of excellence that would be created by this bill would provide VA with the wherewithal to research the connection between epilepsy and Traumatic Brain Injury (TBI), and to provide timely care to veterans who develop epilepsy.

Although we do not yet have data on post-traumatic epilepsy for current conflicts, past experience suggests the rate may be high. Statistics from the Vietnam era indicate that soldiers with an open TBI faced at least a fifty percent chance of experiencing epilepsy. VA-funded research conducted in collaboration with the Department of Defense found that 53 percent of veterans who suffered a penetrating TBI in Vietnam developed epilepsy within 15 years. The risk of epilepsy associated with closed TBI, a wound common among veterans of Operations Enduring Freedom and Iraqi Freedom, has not been clearly established. Dr. Booss testified that "As neurologists, we believe that the rate of epilepsy from blast TBI will also be high."

The creation of national epilepsy centers of excellence is supported by the American Academy of Neurology, the Epilepsy Foundation, the Brain Injury Association of America, Disabled American Veterans, Paralyzed Veterans of America, Blinded Veterans Association, the Marine Corp League, Vietnam Veterans of America, Military Order of the Purple Heart and Iraq and Afghanistan Veterans of America.

Subsections (b) and (c) of new section 7330A would establish and define a peer review panel to assess the scientific and clinical merit of proposals submitted to the Secretary for the designation of epilepsy centers of excellence. A similar process is used by VA to create and award other centers of excellence to ensure the awards are based on objective criteria. Similar panels have been used in the creation of centers of excellence for Parkinson's disease and multiple sclerosis. Other government agencies, such as the National Institutes of Health (NIH), use this mechanism to award clinical center contracts.

Subsection (d) of new section 7330A would define "epilepsy center of excellence", and describes the purpose of the centers. In designating the centers, facilities would have to demonstrate a number of qualifications, or the ability to meet such requirements, including those described below.

Facilities would be required to have or develop an affiliation with an accredited medical school that provides education and training in neurology. In testimony before the Committee on May 23, 2007, Dr. John Booss said that

> A VA health care facility affiliated with a medical school that trains residents in the diagnosis and treatment of epilepsy, including epilepsy surgery, would be able to attract the participation of clinicians and scientists capable of driving innovation in the prevention and treatment of post-traumatic epilepsy.

Affiliations with research universities greatly expand the strength, range, and diversity of research capacities of affiliated VA research units.

Facilities would also be required to have an advisory committee to advise the facility on policy matters pertaining to the activities of the center. Further, the facility would have to have the capability to conduct appropriate evaluations of the activities of the center.

In the Committee's view, the proposed new epilepsy centers of excellence would serve a number of essential purposes. Most importantly, the centers would improve quality of care for veterans around the country. In addition, the centers would prepare VA to meet the growing demand for specialized treatment of epilepsy and seizure disorders, a demand that is likely to grow, given the high incidence of TBI among veterans of Operations Enduring Freedom and Iraqi Freedom.

The Committee is concerned that VA lacks clear evidence-based guidelines for the referral of veterans for epilepsy screening and treatment. To address this issue, facilities would be required to participate in research, education, and dissemination of clinical best-practices coordinated at a national level. These measures are essential to the effective promotion of quality care and treatment of epilepsy beyond the six centers to meet the needs of the entire veteran population. Coordination and collaboration with other Department facilities and centers, especially those focused on TBI, would also be required.

The incidence of epilepsy among the veteran population is not precisely known, and the creation of these centers would improve VA's ability to study this population. In the general population, the

incidence of epilepsy is approximately one percent. To study the veteran population more closely, VA officials appointed the Epilepsy Advisory Committee in 1999. This committee estimated that 50,000 veterans were seeking care at VA facilities for epilepsy or seizure disorders at the time of the study. That number may have grown to 79,000, based on the national rate, and on the number of veterans enrolled in VA health care today.

Subsection (e) of new section 7330A would require the Secretary to designate an individual in the VHA to act as a national coordinator for epilepsy programs of the VHA. The national coordinator would supervise the operation of the centers established by this Act, and would coordinate and support the promotion of research, education and care for epilepsy throughout the Department. The national coordinator would also be responsible for regularly evaluating the centers.

Subsection (f) of new section 7330A would authorize the appropriation of $6,000,000 for the operation of the centers under this section for each fiscal year 2008 through 2012, and would authorize for each fiscal year after 2012 such sums as may be necessary for the operation of the centers. Centers established with sufficient funding would lay the foundation for enduring programs in epilepsy care, research, and education. Once established, the Centers would be equipped to compete for funding from NIH, and funds from other sources, to further advance care for veterans with epilepsy.

In addition, the Committee bill would authorize the appropriation of such sums as may be necessary to fund the national coordinator position that would be established by subsection (e).

COMMITTEE BILL COST ESTIMATE

In compliance with paragraph 11(a) of rule XXVI of the Standing Rules of the Senate, the Committee, based on information supplied by the CBO, estimates that enactment of the Committee bill would, relative to current law, increase discretionary spending by $3,000,000 in 2008 and by $31,000,000 over the 2008–2012 period, assuming appropriation of the necessary amounts. The Committee bill would not increase direct spending, based on information supplied by the CBO. Enactment of the Committee bill would not affect receipts, and would not affect the budget of state, local or tribal governments.

The cost estimate provided by CBO, setting forth a detailed breakdown of costs, follows:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, November 30, 2007.

Hon. DANIEL K. AKAKA,
Chairman,
Committee on Veterans' Affairs,
U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 2004, a bill to amend title 38, United States Code, to establish epilepsy centers of excellence in the Veterans Health Administration of the Department of Veterans Affairs, and for other purposes.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Sunita D'Monte, who can be reached at 226-2840.

Sincerely,

PETER R. ORSZAG,
Director.

Enclosure.
cc: Honorable Richard Burr, Ranking Member.

S. 2004—A bill to amend title 38, United States Code, to establish epilepsy centers of excellence in the Veterans Health Administration of the Department of Veterans Affairs, and for other purposes

S. 2004 would require the Secretary of the Department of Veterans Affairs (VA) to establish at least six centers of excellence for epilepsy research, education, and clinical care at VA health care facilities, and to appoint a national coordinator for those centers and for other epilepsy programs at the Veterans Health Administration. The bill would authorize the appropriation of $6 million each year over the 2008–2012 period and such sums as may be necessary for the national coordinator. CBO estimates that in addition to the specified authorizations, VA would require less than $500,000 annually for the national coordinator.

In total, CBO estimates that implementing S. 2004 would cost $3 million in 2008 and $31 million over the 2008–2012 period, assuming that the specified and estimated amounts are appropriated and that outlays follow historical spending patterns for similar programs. Enacting the bill would have no effect on direct spending or revenues.

S. 2004 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would impose no costs on state, local, or tribal governments.

The CBO staff contact for this estimate is Sunita D'Monte, who can be reached at 226–2840. This estimate was approved by Peter H. Fontaine, Assistant Director for Budget Analysis.

REGULATORY IMPACT STATEMENT

In compliance with paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the Committee on Veterans' Affairs has made an evaluation of the regulatory impact that would be incurred in carrying out the Committee bill. The Committee finds that the Committee bill would not entail any regulation of individuals or businesses or result in any impact on the personal privacy of any individuals and that the paperwork resulting from enactment would be minimal.

TABULATION OF VOTES CAST IN COMMITTEE

In compliance with paragraph 7 of rule XXVI of the Standing Rules of the Senate, the following is a tabulation of votes cast in person or by proxy by members of the Committee on Veterans' Affairs at its November 14, 2007 meeting. On that date, the Committee ordered S. 2004 reported favorably to the Senate, by voice vote.

AGENCY REPORT

On October 24, 2007, the Honorable Michael J. Kussman, Under Secretary for Health, Department of Veterans Affairs, appeared before the Committee and submitted testimony on, among other things, S. 2004. Excerpts from this statement are reprinted below:

STATEMENT OF HON. MICHAEL J. KUSSMAN, UNDER SECRETARY FOR HEALTH, DEPARTMENT OF VETERANS AFFAIRS

Good morning Mr. Chairman and Members of the Committee:

Thank you for inviting me here today to present the Administration's views on several bills that would affect Department of Veterans Affairs (VA) programs that provide veterans benefits and services. With me today is Walter A. Hall, Assistant General Counsel. I will address the five bills on today's agenda and then I would be happy to answer any questions you and the Committee members may have.

S. 2004 would require the Secretary, not later than 120 days after enactment of this provision, to designate at least six Department health-care facilities as epilepsy centers of excellence based on the recommendation of the Under Secretary for Health (USH). The mandate to establish and operate these centers, however, would be subject to the availability of appropriations for this purpose.

The bill defines an "epilepsy center of excellence" as a Department health-care facility that has (or in the foreseeable future can develop) the necessary capacity to function as a center of excellence in research, education, and clinical care activities in the diagnosis and treatment of epilepsy. To qualify as a center, the facility would need:

- An affiliation with an accredited medical school that provides education and training in neurology (or may reasonably be anticipated to develop such an affiliation).
- The ability to attract scientists of ingenuity and creativity.
- An advisory committee composed of veterans and appropriate health-care and research representatives of the facility and of the affiliate.
- The capability to effectively evaluate the activities of the centers.
- The capability to coordinate the centers' education, clinical care, and research activities.
- The capability to develop a national consortium of providers with interest in treating epilepsy at VA medical centers; the consortium would have to include a designated epilepsy referral clinical in each Veterans Integrated Service Network.
- The capability to assist in the expansion of VA's use of information systems and databases to improve the quality and delivery of care.
- The capability to assist in the expansion of VA's tele-health program to develop, transmit, monitor, and review neurological diagnostic tests.
- The ability to perform epilepsy research, education, and clinical care activities in collaboration with VA's Poly-Trauma Centers.

A number of specific requirements governing the competitive selection of the six facilities are set forth in the bill, including a requirement that the Secretary consider appropriate geographic distribution when making the selections.

S. 2004 would further mandate the designation of an individual in VHA to act as a national coordinator for VHA's epilepsy programs. The bill includes a list of duties for that position, including that such individual report to the VHA official responsible for neurology.

The bill would authorize $6 million for each of fiscal years 2008 through 2012 to establish and operate the centers; such sums as may be necessary for operating the centers for each fiscal year after fiscal year 2012 would also be authorized. For the first three years of the centers operation, the bill would require that the centers be designated as a special purpose program in order to avoid funds for the centers being allocated through the Veterans Equitable Resource Allocation system. In addition to those amounts, the USH would be required to allocate such amounts as he deems appropriate from other funds made available to VHA. The bill includes a separate authorization of appropriations to fund the national coordinator position.

VA does not support S. 2004. As I have discussed in the past, I am concerned that statutory mandates for "disease specific" centers have the potential to fragment care in what is otherwise a well-designed, world-class integrated health care system. I am increasingly concerned about the proliferation of this disease-specific model and its impact on patient care and VA's integrated health care model. As it relates to a particular disease, I believe that it is much more important for VA to disseminate the best in evidence-based practices across its health care system than to establish centers that provide care for a particular disease.

Treating epilepsy, like every other serious condition, requires an interdisciplinary approach. By mandating new "education, research, and clinical centers" that are disease-specific, flexibility to respond to changing combinations of related conditions is reduced. The centers' mandated collaboration with VA's Poly-trauma Centers would not cure this short-coming.

It is also important to note that the "models" on which these Epilepsy Centers are based, the successful Geriatric Research, Education and Clinical Center (GRECC) and Mental Illness Research, Education and Clinical Center (MIRECC) programs, are not narrowly-focused on a disease process but address a wide gamut of issues facing a significant portion of the veteran population.

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CHANGES IN EXISTING LAW

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman).

TITLE 38—VETERANS BENEFITS

PART V—BOARDS, ADMINISTRATIONS, AND SERVICES

CHAPTER 73—VETERANS HEALTH ADMINISTRATION—ORGANIZATION AND FUNCTIONS

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SEC. 7330A. EPILEPSY CENTERS OF EXCELLENCE.

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Subchapter II—General Authority and Administration

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SEC. 7330A. EPILEPSY CENTERS OF EXCELLENCE

(a) ESTABLISHMENT OF CENTERS.—(1) Not later than 120 days after the date of the enactment of this section, the Secretary shall, upon the recommendation of the Under Secretary for Health, designate not less than six Department health-care facilities as the locations for epilepsy centers of excellence.

(2) Subject to the availability of appropriations for such purpose, the Secretary shall establish and operate epilepsy centers of excellence at the locations designated pursuant to paragraph (1).

(b) DESIGNATION OF FACILITIES.—(1) The Secretary may not designate a Department health-care facility as a location for an epilepsy center of excellence under subsection (a)(1) unless the peer review panel established under subsection (c) has determined under that subsection that the proposal submitted by such facility seeking designation as a location for an epilepsy center of excellence is among those proposals that meet the highest competitive standards of scientific and clinical merit.

(2) In choosing from among the facilities meeting the requirements of paragraph (1), the Secretary shall also consider appropriate geographic distribution when designating the epilepsy centers of excellence under subsection (a)(1).

(c) PEER REVIEW PANEL.—(1) The Under Secretary for Health shall establish a peer review panel to assess the scientific and clin-

ical merit of proposals that are submitted to the Secretary for the designation of epilepsy centers of excellence under this section.

(2)(A) The membership of the peer review panel shall consist of experts on epilepsy, including post-traumatic epilepsy.

(B) Members of the peer review panel shall serve for a period of no longer than two years, except as specified in subparagraph (C).

(C) Of the members first appointed to the panel, one half shall be appointed for a period of three years and one half shall be appointed for a period of two years, as designated by the Under Secretary at the time of appointment.

(3) The peer review panel shall review each proposal submitted to the panel by the Under Secretary for Health and shall submit its views on the relative scientific and clinical merit of each such proposal to the Under Secretary.

(4) The peer review panel shall not be subject to the Federal Advisory Committee Act.

(d) EPILEPSY CENTER OF EXCELLENCE DEFINED.—In this section, the term "epilepsy center of excellence" means a Department health-care facility that has (or in the foreseeable future can develop) the necessary capacity to function as a center of excellence in research, education, and clinical care activities in the diagnosis and treatment of epilepsy and has (or may reasonably be anticipated to develop) each of the following:

(1) An affiliation with an accredited medical school that provides education and training in neurology, including an arrangement with such school under which medical residents receive education and training in the diagnosis and treatment of epilepsy (including neurosurgery).

(2) The ability to attract the participation of scientists who are capable of ingenuity and creativity in health-care research efforts.

(3) An advisory committee composed of veterans and appropriate health-care and research representatives of the facility and of the affiliated school or schools to advise the directors of such facility and such center on policy matters pertaining to the activities of the center during the period of the operation of such center.

(4) The capability to conduct effectively evaluations of the activities of such center.

(5) The capability to coordinate (as part of an integrated national system) education, clinical care, and research activities within all facilities with such centers.

(6) The capability to develop jointly a national consortium of providers with interest in treating epilepsy at Department health-care facilities lacking such centers in order to ensure better access to state-of-the-art diagnosis, research, clinical care, and education for traumatic brain injury and epilepsy throughout the health-care system of the Department. Such consortium should include a designated epilepsy referral clinic in each Veterans Integrated Service Network.

(7) The capability to assist in the expansion of the Department's use of information systems and databases to improve the quality and delivery of care for veterans enrolled within the Department's health care system.

(8) The capability to assist in the expansion of the Department telehealth program to develop, transmit, monitor, and review neurological diagnostic tests.

(9) The ability to perform epilepsy research, education, and clinical care activities in collaboration with Department medical facilities that have centers for research, education, and clinical care activities on complex multi-trauma associated with combat injuries established under section 7327 of this title.

(e) NATIONAL COORDINATOR FOR EPILEPSY PROGRAMS.—(1) To assist the Secretary and the Under Secretary for Health in carrying out this section, the Secretary shall designate an individual in the Veterans Health Administration to act as a national coordinator for epilepsy programs of the Veterans Health Administration.

(2) The duties of the national coordinator for epilepsy programs shall include the following:

(A) To supervise the operation of the centers established pursuant to this section.

(B) To coordinate and support the national consortium of providers with interest in treating epilepsy at Department health-care facilities lacking such centers in order to ensure better access to state-of-the-art diagnosis, research, clinical care, and education for traumatic brain injury and epilepsy throughout the health-care system of the Department.

(C) To conduct regular evaluations of the epilepsy centers of excellence to ensure compliance with the requirements of this section.

(3) In carrying out duties under this subsection, the national coordinator for epilepsy programs shall report to the official of the Veterans Health Administration responsible for neurology.

(f) AUTHORIZATION OF APPROPRIATIONS.—(1) There are authorized to be appropriated $6,000,000 for each of fiscal years 2008 through 2012 for the support of the clinical care, research, and education activities of the epilepsy centers of excellence established and operated pursuant to subsection (a)(2).

(2) There are authorized to be appropriated for each fiscal year after fiscal year 2012 such sums as may be necessary for the support of the clinical care, research, and education activities of the epilepsy centers of excellence established and operated pursuant to subsection (a)(2).

(3) The Secretary shall ensure that funds for such centers are designated for the first three years of operation as a special purpose program for which funds are not allocated through the Veterans Equitable Resource Allocation system.

(4) In addition to amounts authorized to be appropriated under paragraphs (1) and (2) for a fiscal year, the Under Secretary for Health shall allocate to such centers from other funds appropriated generally for the Department medical services account and medical and prosthetics research account, as appropriate, such amounts as the Under Secretary for Health determines appropriate.

(5) In addition to amounts authorized to be appropriated under paragraphs (1) and (2) for a fiscal year, there are authorized to be

appropriated such sums as may be necessary to fund the national coordinator established by subsection (e).

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