H-5040.2

SECOND SUBSTITUTE HOUSE BILL 2575

State of Washington 59th Legislature 2006 Regular Session

By House Committee on Appropriations (originally sponsored by Representatives Cody, Morrell and Moeller; by request of Governor Gregoire)

READ FIRST TIME 02/07/06.

AN ACT Relating to establishing a state health technology assessment program; amending RCW 41.05.013; adding new sections to chapter 70.14 RCW; and creating a new section.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

NEW SECTION. **Sec. 1.** The legislature finds that a systematic assessment of the best available scientific and medical evidence and timely application of this evidence to informed coverage and medical necessity decisions by state purchased health care programs should result in improved access, prevention, and health outcomes for Washington citizens. The legislature further finds that transparency and public participation in this program is important and should be incorporated. Therefore, it is the intent of the legislature to support the establishment by the state of an evidence-based health technology assessment program that:

(1) Conducts systematic reviews of scientific and medical literature to identify safe, efficacious, and cost-effective health technologies;

(2) Provides for the establishment of a statewide health technology clinical committee;

(3) Develops methods and processes to track the application of evidence-based practice and health outcomes across state agencies;

(4) Provides clear and transparent access to the scientific basis of coverage decisions and coverage criteria developed under this program; and

(5) To the extent possible, collaborates with other states in the development and implementation of the program.

NEW SECTION. **Sec. 2.** A new section is added to chapter 70.14 RCW to read as follows:

The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "Administrator" means the administrator of the Washington state health care authority under chapter 41.05 RCW.

(2) "Agency" means a state agency administering a state purchased health care program as defined in RCW 41.05.011(2).

(3) "Best available scientific and medical evidence" means the best available clinical evidence derived from systematic research and is based upon a hierarchy of evidence to determine the weight given to available data. The weight of medical evidence depends on objective indicators of its validity and reliability including the nature and source of the evidence, the empirical characteristics of the studies or trials upon which the evidence is based, and the consistency of the outcome with comparable studies. The hierarchy, in descending order with meta-analyses given the greatest weight, is:

(a) Meta-analysis done with multiple, well-designed controlled studies;

(b) One or more well-designed experimental studies;

(c) Well-designed, quasi-experimental studies such as nonrandomized controlled, single group prepost, cohort, time series, or matched case-controlled studies;

(d) Well-designed, nonexperimental studies, such as comparative and correlation descriptive, and case studies; and

(e) Other credible evidence, such as clinical guidelines, information produced by governmental sources, independent technology assessment organizations, medical and hospital associations, and health carriers as defined in RCW 48.43.005.

The agencies may modify the hierarchy of evidence, by rule, to the extent that emerging research or practice related to health technology assessment indicates that modification of the hierarchy is appropriate.

(4) "Coverage criteria" means an evidence-based set of explicit clinical criteria that define the circumstances under which use of a covered health technology will be approved for individual patients.

(5) "Coverage decision" means a determination regarding including or excluding a health technology as a covered benefit, and if covered, under what circumstances.

(6) "Evidence-based health technology assessment center" means an assessment center responsible for conducting systematic reviews and assessments of best available scientific and medical evidence related to health technologies identified under section 3(3) of this act. "Evidence-based health technology assessment center" includes, but is not limited to, evidence-based practice centers designated as such by the federal agency for health care research and quality.

(7) "Health technology" means medical and surgical devices and procedures, medical equipment, and diagnostic tests. Health technologies does not include prescription drugs governed by RCW 70.14.050.

(8) "Health technology clinical committee" means the committee established under section 4 of this act.

(9) "Medical necessity decision" or "proper and necessary decision" means a determination whether or not to provide reimbursement for a covered health technology in a specific circumstance for an individual patient who is eligible to receive health care services from the state purchased health care program making the decision.

NEW SECTION. **Sec. 3.** A new section is added to chapter 70.14 RCW to read as follows:

(1) Each state agency administering a state purchased health care program shall, in cooperation with other such agencies, take action to prevent the application of health technologies where scientific and medical evidence suggests little or no benefit or possible harm, and to enhance the use of health technologies in circumstances where evidence suggests substantial benefits. To accomplish this purpose, the agencies shall establish an evidence-based health technology assessment program.

(2) In developing the evidence-based health technology assessment program, the agencies, to the extent permitted under federal and state law governing each agency:

(a) Shall use the best available scientific and medical evidence to make coverage and medical necessity decisions consistent with sections 2 through 5 of this act and RCW 41.05.013; and

(b) Shall develop and implement uniform policies for health technology assessments as provided in sections 2 through 5 of this act and RCW 41.05.013, including development of common coverage decisions and coverage criteria.

(3) In designing and implementing the health technology assessment program and developing uniform, consistent policies and decisions, the agencies:

(a) Shall determine, after consultation with the health technology clinical committee, which health technologies will be reviewed using explicit prioritization criteria developed for this purpose. These criteria may include, but are not limited to:

(i) The expected or demonstrated prevalence of use of the technology in the population;

(ii) Significant variation in use of the health technology;

(iii) Substantial evidence of harm from use of the health technology;

(iv) The health technology is costly, there is evidence of little health benefit derived from use of the health technology, and there are effective alternatives available for treatment of the underlying condition;

(v) Whether there is no demonstrated medical or scientific value for use of the health technology; and

(vi) Whether there is adequate available evidence of sufficient quality to evaluate the medical or scientific value for use of the health technology;

(b) Shall contract with one or more evidence-based health technology assessment centers to conduct systematic reviews and assessments of the best available scientific and medical evidence related to health technologies identified for review under this section. Systematic reviews and assessments should include an assessment of the scientific literature regarding safety, efficacy, and cost-effectiveness of the health technology, and the adequacy and

quality of systematic reviews undertaken by other national or internationally recognized health technology assessment programs. The systematic reviews must be conducted in a manner that provides an opportunity for interested individuals and entities to submit scientific or medical evidence to the center for their consideration. Upon their completion, the systematic reviews must be transmitted to the agencies and to the health technology clinical committee. Each health technology that has been initially reviewed under this section shall be reviewed at intervals of no less than eighteen months to determine if new scientific or medical evidence has emerged that could potentially change a health care coverage recommendation, or recommendation related to medical necessity or proper or necessary determinations;

(c) Shall establish a health technology clinical committee as provided in section 4 of this act to make recommendations to the agencies regarding coverage of health technologies and any coverage criteria they would recommend related to medical necessity or proper and necessary decisions regarding covered health technologies;

(d) May adopt coverage criteria to assist in the appropriate application of medical necessity or proper and necessary decisions, consistent with section 4 of this act;

(e) May develop criteria for payment of health technologies under reasonable exceptions, such as experimental or investigational treatment, services under a clinical investigation approved by an institutional review board, or health technologies that have a humanitarian device exemption from the federal food and drug administration. Exceptions for deviations from clinical guidelines may be considered when the exception is based on the best available scientific and medical evidence and the specific clinical circumstances for which an exception has been requested are not substantially addressed in the applicable clinical guidelines; and

(f) Shall track and share safety, health outcome, exceptions to coverage criteria, and cost data related to use of health technologies to help inform health technology decisions. The agencies shall provide such data to an evidence-based health technology assessment center or the health technology clinical committee when the information will inform their deliberations.

(4) The agencies shall develop methods to report on the performance of the health technology assessment program, with respect to health care outcomes, frequency of exceptions, cost outcomes, and other matters deemed appropriate by the administrator.

(5) The agencies shall develop a centralized, web-based communication tool that provides, at a minimum:

(a) Notification of health technologies that have been chosen for review. Notification shall be provided at least thirty days before initiation of review by an evidence-based health technology assessment center and shall note the opportunity of interested parties to submit scientific or medical evidence to the center for consideration as part of their systematic review;

(b) Notification of all coverage decisions and coverage criteria developed under this program, their effective date, and the scientific basis for the decisions and guidelines; and

(c) Access to all reports produced under subsection (4) of this section.

(6) The standard of medical necessity or proper and necessary shall not apply to health technologies that are determined not to be covered under sections 2 through 5 of this act and RCW 41.05.013. The agencies' authority to develop criteria for payment of health technologies under reasonable exceptions, as provided in subsection (3)(e) of this section, is not limited by this subsection.

(7) Appeals of decisions made under sections 2 through 5 of this act shall be governed by state and federal law applicable to participating agency decisions. Nothing in this act diminishes an individual's right to appeal an action or decision under the evidence-based health technology assessment program.

(8) The provisions of the health technology assessment program apply to health technologies that have been reviewed by an evidence-based health technology assessment center and the health technology clinical committee, and adopted by the agencies under this section. For those health technologies that have not been identified for review under subsection (3) of this section, the agencies may use their existing statutory and rule-making authority to make coverage and medical necessity or proper and necessary decisions. These decisions shall be shared among the agencies, with a goal of maximizing each agency's understanding of the basis for the other's decisions and

providing opportunities for agencies to collaborate in the decision-making process. The agencies also shall provide explanations of and access to the scientific basis for coverage decisions related to health technologies that have not been identified for systematic assessment under the health technology assessment program.

(9) The agencies shall adopt rules as necessary to implement this act.

(10) The health technology legislative oversight committee is established. The committee shall consist of two members from each caucus of the senate, and two members from each caucus of the house of representatives. The health technology legislative oversight committee shall:

(a) Review and report at least annually on the impact of health technology coverage decisions made by the health technology clinical committee and state agencies on patient access, treatment quality, and overall health care costs;

(b) Provide manufacturers of a health technology and organizations with an interest in a health technology an opportunity to present information related to the operation of the health technology assessment program, including coverage decisions and other matters at the discretion of the health technology legislative oversight committee; and

(c) Request the health technology clinical committee to reconsider a recommendation when, in the judgment of the health technology legislative oversight committee, the health technology clinical committee reached an erroneous conclusion.

NEW SECTION. **Sec. 4.** A new section is added to chapter 70.14 RCW to read as follows:

(1) The administrator of the health care authority, in consultation with the participating agencies and their medical directors, shall establish a health technology clinical committee. The health technology clinical committee shall be comprised of eleven members, including six practicing licensed physicians and five other practicing licensed health professionals who utilize health technology in the professional scope of their practice. At least two members of the committee must have demonstrated experience in serving women, children, elderly persons, and people of color.

(2) The health technology clinical committee shall review the results of the systematic assessments of health technologies conducted by an evidence-based health technology assessment center. The committee must use medical and scientific evidence in an open and transparent process that evaluates the efficacy of health technologies, considering safety, efficacy, likelihood of compliance, outcomes, and any unique impacts on specific populations based upon factors such as sex, age, ethnicity, race, or disability. The review process shall include an opportunity for public comment. For each health technology reviewed, the committee shall develop recommendations related to whether the health technology should be covered by state purchased health care programs, and if covered, any coverage criteria that should be used to assist in determining the appropriate application of medical necessity or proper and necessary decisions. Committee recommendations are binding on the agencies, unless the recommendations are contrary to applicable federal statute, regulation, or case law, or state statute or case law, or the agencies provide written findings that include a detailed explanation of the reason for rejecting the recommendation.

(3) The administrator may establish time limited subcommittees of the health technology clinical committee where specific expertise is needed to review a particular health technology or group of technologies.

(4) Members of the health technology clinical committee, or any subcommittee established under subsection (3) of this section are prohibited from being employed by a health technology manufacturer or by any agency administering state purchased health care programs. As a condition of appointment to the committee or any subcommittee, each member must disclose any potential conflict of interest, including receipt of any remuneration, grants, or other compensation from a health technology manufacturer.

(5) Members of the health technology clinical committee and any subcommittees formed under subsection (3) of this section are immune from civil liability for any official acts performed in good faith as members of the committee or subcommittee.

(6) Meetings of the health technology clinical committee are subject to the open public meetings act, as provided in chapter 42.30 RCW, including RCW 42.30.110(1)(l), which authorizes an executive

session during a regular or special meeting to consider proprietary or confidential nonpublished information.

NEW SECTION. **Sec. 5.** A new section is added to chapter 70.14 RCW to read as follows:

In the conduct of systematic reviews by the evidence-based health technology assessment center, and in the conduct of business by the health technology clinical advisory committee, the health technology assessment program must ensure that conflicts of interest regarding a specific health technology be minimized and fully disclosed to the extent possible.

Sec. 6. RCW 41.05.013 and 2005 c 462 s 3 are each amended to read as follows:

(1) The authority shall coordinate state agency efforts to develop and implement uniform policies across state purchased health care programs that will ensure prudent, cost-effective health services purchasing, maximize efficiencies in administration of state purchased health care programs, improve the quality of care provided through state purchased health care programs, and reduce administrative burdens on health care providers participating in state purchased health care programs. The policies adopted should be based, to the extent possible, upon the best available scientific and medical evidence and shall endeavor to address:

(a) Methods of formal assessment, such as a health technology assessment under sections 2 through 5 of this act. Consideration of the best available scientific evidence does not preclude consideration of experimental or investigational treatment or services under a clinical investigation approved by an institutional review board;

(b) Monitoring of health outcomes, adverse events, quality, and cost-effectiveness of health services;

(c) Development of a common definition of medical necessity; and

(d) Exploration of common strategies for disease management and demand management programs, including asthma, diabetes, heart disease, and similar common chronic diseases. Strategies to be explored include individual asthma management plans. On January 1, 2007, and January 1, 2009, the authority shall issue a status report to the legislature

summarizing any results it attains in exploring and coordinating strategies for asthma, diabetes, heart disease, and other chronic diseases.

(2) The administrator may invite health care provider organizations, carriers, other health care purchasers, and consumers to participate in efforts undertaken under this section.

(3) For the purposes of this section "best available scientific and medical evidence" means the best available clinical evidence derived from systematic research.

NEW SECTION. **Sec. 7.** A new section is added to chapter 70.14 RCW to read as follows:

Sections 2 through 5 of this act and RCW 41.05.013 do not apply to state purchased health care services that are purchased from or through health carriers as defined in RCW 48.43.005.

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