CERTIFICATION OF ENROLLMENT

# ENGROSSED SECOND SUBSTITUTE HOUSE BILL 2575

Chapter 307, Laws of 2006

(partial veto)

59th Legislature
2006 Regular Session

HEALTH TECHNOLOGY CLINICAL COMMITTEE

EFFECTIVE DATE: 6/7/06

Passed by the House March 6, 2006
Yeas 97 Nays 1

FRANK CHOPP

**Speaker of the House of Representatives**

Passed by the Senate March 3, 2006
Yeas 48 Nays 0

BRAD OWEN

**President of the Senate**

Approved March 29, 2006, with the exception of section 6, which is vetoed.

CHRISTINE GREGOIRE

**Governor of the State of Washington**

CERTIFICATE

I, Richard Nafziger, Chief Clerk of the House of Representatives of the State of Washington, do hereby certify that the attached is **ENGROSSED SECOND SUBSTITUTE HOUSE BILL 2575** as passed by the House of Representatives and the Senate on the dates hereon set forth.

RICHARD NAFZIGER

**Chief Clerk**

FILED

March 29, 2006 - 3:59 p.m.

**Secretary of State**
**State of Washington**

# ENGROSSED SECOND SUBSTITUTE HOUSE BILL 2575

AS AMENDED BY THE SENATE

Passed Legislature - 2006 Regular Session

**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 new sections.

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

NEW SECTION. **Sec. 1.** A new section is added to chapter 70.14 RCW to read as follows:

DEFINITIONS. The definitions in this section apply throughout sections 2 through 7 of this act unless the context clearly requires otherwise.

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

(2) "Advisory group" means a group established under section 4(2)(c) of this act.

(3) "Committee" means the health technology clinical committee established under section 2 of this act.

(4) "Coverage determination" means a determination of the circumstances, if any, under which a health technology will be included as a covered benefit in a state purchased health care program.

(5) "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.

(6) "Participating agency" means the department of social and health services, the state health care authority, and the department of labor and industries.

(7) "Reimbursement determination" means a determination to provide or deny reimbursement for a health technology included as a covered benefit 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 determination.

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

HEALTH TECHNOLOGY COMMITTEE ESTABLISHED. (1) A health technology clinical committee is established, to include the following eleven members appointed by the administrator in consultation with participating state agencies:

(a) Six practicing physicians licensed under chapter 18.57 or 18.71 RCW; and

(b) Five other practicing licensed health professionals who use health technology in their scope of practice.

At least two members of the committee must have professional experience treating women, children, elderly persons, and people with diverse ethnic and racial backgrounds.

(2) Members of the committee:

(a) Shall not contract with or be employed by a health technology manufacturer or a participating agency during their term or for eighteen months before their appointment. As a condition of appointment, each person shall agree to the terms and conditions imposed by the administrator regarding conflicts of interest;

(b) Are immune from civil liability for any official acts performed in good faith as members of the committee; and

(c) Shall be compensated for participation in the work of the committee in accordance with a personal services contract to be executed after appointment and before commencement of activities related to the work of the committee.

(3) Meetings of the committee and any advisory group are subject to chapter 42.30 RCW, the open public meetings act, 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.

(4) Neither the committee nor any advisory group is an agency for purposes of chapter 34.05 RCW.

(5) The health care authority shall provide administrative support to the committee and any advisory group, and may adopt rules governing their operation.

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

TECHNOLOGY SELECTION AND ASSESSMENT. (1) The administrator, in consultation with participating agencies and the committee, shall select the health technologies to be reviewed by the committee under section 4 of this act. Up to six may be selected for review in the first year after the effective date of this act, and up to eight may be selected in the second year after the effective date of this act. In making the selection, priority shall be given to any technology for which:

(a) There are concerns about its safety, efficacy, or cost-effectiveness, especially relative to existing alternatives, or significant variations in its use;

(b) Actual or expected state expenditures are high, due to demand for the technology, its cost, or both; and

(c) There is adequate evidence available to conduct the complete review.

(2) A health technology for which the committee has made a determination under section 4 of this act shall be considered for rereview at least once every eighteen months, beginning the date the determination is made. The administrator, in consultation with participating agencies and the committee, shall select the technology for rereview if he or she decides that evidence has since become available that could change a previous determination. Upon rereview, consideration shall be given only to evidence made available since the previous determination.

(3) Pursuant to a petition submitted by an interested party, the health technology clinical committee may select health technologies for review that have not otherwise been selected by the administrator under subsection (1) or (2) of this section.

(4) Upon the selection of a health technology for review, the administrator shall contract for a systematic evidence-based assessment of the technology's safety, efficacy, and cost-effectiveness. The contract shall:

(a) Be with an evidence-based practice center designated as such by the federal agency for health care research and quality, or other appropriate entity;

(b) Require the assessment be initiated no sooner than thirty days after notice of the selection of the health technology for review is posted on the internet under section 7 of this act;

(c) Require, in addition to other information considered as part of the assessment, consideration of: (i) Safety, health outcome, and cost data submitted by a participating agency; and (ii) evidence submitted by any interested party; and

(d) Require the assessment to: (i) Give the greatest weight to the evidence determined, based on objective indicators, to be the most valid and reliable, considering the nature and source of the evidence, the empirical characteristic of the studies or trials upon which the evidence is based, and the consistency of the outcome with comparable studies; and (ii) take into account any unique impacts of the technology on specific populations based upon factors such as sex, age, ethnicity, race, or disability.

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

HEALTH TECHNOLOGY COMMITTEE DETERMINATIONS. (1) The committee shall determine, for each health technology selected for review under section 3 of this act: (a) The conditions, if any, under which the health technology will be included as a covered benefit in health care programs of participating agencies; and (b) if covered, the criteria which the participating agency administering the program must use to decide whether the technology is medically necessary, or proper and necessary treatment.

(2) In making a determination under subsection (1) of this section, the committee:

(a) Shall consider, in an open and transparent process, evidence regarding the safety, efficacy, and cost-effectiveness of the technology as set forth in the systematic assessment conducted under section 3(4) of this act;

(b) Shall provide an opportunity for public comment; and

(c) May establish ad hoc temporary advisory groups if specialized expertise is needed to review a particular health technology or group of health technologies, or to seek input from enrollees or clients of state purchased health care programs. Advisory group members are immune from civil liability for any official act performed in good faith as a member of the group. As a condition of appointment, each person shall agree to the terms and conditions imposed by the administrator regarding conflicts of interest.

(3) Determinations of the committee under subsection (1) of this section shall be consistent with decisions made under the federal medicare program and in expert treatment guidelines, including those from specialty physician organizations and patient advocacy organizations, unless the committee concludes, based on its review of the systematic assessment, that substantial evidence regarding the safety, efficacy, and cost-effectiveness of the technology supports a contrary determination.

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

COMPLIANCE BY STATE AGENCIES. (1) A participating agency shall comply with a determination of the committee under section 4 of this act unless:

(a) The determination conflicts with an applicable federal statute or regulation, or applicable state statute; or

(b) Reimbursement is provided under an agency policy regarding 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.

(2) For a health technology not selected for review under section 3 of this act, a participating agency may use its existing statutory

and administrative authority to make coverage and reimbursement determinations. Such determinations shall be shared among agencies, with a goal of maximizing each agency's understanding of the basis for the other's decisions and providing opportunities for agency collaboration.

(3) A health technology not included as a covered benefit under a state purchased health care program pursuant to a determination of the health technology clinical committee under section 4 of this act, or for which a condition of coverage established by the committee is not met, shall not be subject to a determination in the case of an individual patient as to whether it is medically necessary, or proper and necessary treatment.

(4) Nothing in this act diminishes an individual's right under existing law to appeal an action or decision of a participating agency regarding a state purchased health care program. Appeals shall be governed by state and federal law applicable to participating agency decisions.

***NEW SECTION.** Sec. 6. A new section is added to chapter 70.14 RCW to read as follows:*

***APPEAL PROCESS.** The administrator shall establish an open, independent, transparent, and timely process to enable patients, providers, and other stakeholders to appeal the determinations of the health technology clinical committee made under section 4 of this act.*

***Sec. 6 was vetoed. See message at end of chapter.***

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

PUBLIC NOTICE. (1) The administrator shall develop a centralized, internet-based communication tool that provides, at a minimum:

(a) Notification when a health technology is selected for review under section 3 of this act, indicating when the review will be initiated and how an interested party may submit evidence, or provide public comment, for consideration during the review;

(b) Notification of any determination made by the committee under section 4(1) of this act, its effective date, and an explanation of the basis for the determination; and

(c) Access to the systematic assessment completed under section

3(4) of this act, and reports completed under subsection (2) of this section.

(2) Participating agencies shall develop methods to report on the implementation of this section and sections 1 through 6 of this act with respect to health care outcomes, frequency of exceptions, cost outcomes, and other matters deemed appropriate by the administrator.

**Sec. 8.** 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 1 through 7 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. 9.** A new section is added to chapter 70.14 RCW to read as follows:

Sections 1 through 7 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.

NEW SECTION. **Sec. 10.** Captions used in this act are not any part of the law.

NEW SECTION. **Sec. 11.** If any part of this act is found to be in conflict with federal requirements that are a prescribed condition to the allocation of federal funds to the state, the conflicting part of this act is inoperative solely to the extent of the conflict and with respect to the agencies directly affected, and this finding does not affect the operation of the remainder of this act in its application to the agencies concerned. Rules adopted under this act must meet federal requirements that are a necessary condition to the receipt of federal funds by the state.

Passed by the House March 6, 2006.
Passed by the Senate March 3, 2006.
Approved by the Governor March 29, 2006, with the exception of certain items that were vetoed.
Filed in Office of Secretary of State March 29, 2006.

Note: Governor's explanation of partial veto is as follows:

"I am returning, without my approval as to Section 6, Engrossed Second Substitute House Bill No. 2575 entitled:

"AN ACT Relating to establishing a state health technology assessment program."

I strongly support ESSHB No. 2575 and particularly its inclusion of language that protects an individual's right to appeal. Section 5 (4) of the bill states that "nothing in this act diminishes an individual's right under existing law to appeal an action or decision of a participating agency regarding a state purchased health care program. Appeals shall be governed by state and federal law applicable to participating agency decisions." This is an important provision and one that I support whole-heartedly.

I am, however, vetoing Section 6 of this bill, which establishes an additional appeals process for patients, providers, and other stakeholders who disagree with the coverage determinations of the Health Technology Clinical Committee. The health care provider expertise on the clinical committee and the use of an evidence-based practice center should lend sufficient confidence in the quality of

decisions made. Where issues may arise, I believe the individual appeal process highlighted above is sufficient to address them, without creating a duplicative and more costly process.

In the implementation of this bill, I expect the Health Care Authority, with the cooperation of participating agencies, to facilitate a timely and transparent process, to prioritize and manage the review of technologies within appropriated funds, and to meaningfully consider stakeholder feedback regarding the program and appeals processes. I further expect that the implementation of the Health Technology Assessment Program will be consistent with sound methods of assessment and the principles of evidence-based medicine.

I appreciate the Legislature's passage of this bill and have full confidence that it will help ensure that Washingtonians receive health care services that are safe and effective.

For these reasons, I have vetoed Section 6 of ESSHB No. 2575.

With the exception of Section 6, ESSHB No. 2575 is approved."