

FILED
SUPREME COURT
STATE OF WASHINGTON
6/28/2018 2:30 PM
BY SUSAN L. CARLSON
CLERK

No. 95251-5

IN THE SUPREME COURT
FOR THE STATE OF WASHINGTON

MICHAEL MURRAY, Petitioner,

v.

DEPARTMENT OF LABOR AND INDUSTRIES, Respondent.

ON REVIEW FROM THE SUPERIOR COURT OF THE
STATE OF WASHINGTON FOR KITSAP COUNTY

#15-2-00566-1

**PETITIONER MICHAEL MURRAY'S
SUPPLEMENTAL BRIEF ON THE
GOVERNOR'S VETO**

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INTRODUCTION

When it passed ESSHB 2575, the Health Technology Clinical Committee bill, the Legislature expressly preserved all appellate rights an injured worker has under the Industrial Insurance Act. RCW 70.14.120(4) (“nothing...*diminishes* an individual’s right under existing law to appeal an action or decision of a participating agency”). Governor Christine Gregoire relied on this guarantee when she vetoed section 6 of the bill that provided immediate appellate review of an HTCC decision. “I strongly support ESSHB No. 2575 and particularly its inclusion of language that *protects an individual's right to appeal.*” (Governor’s Veto Message ESSHB 2575) (emphasis added) (Attached as Appendix A). This Court now asks for supplemental briefing on the legal significance of the Governor’s veto.

The Governor’s veto has three consequences for Appellant Michael Murray’s request for necessary and proper medical care. First, the Governor’s veto statement reinforces the legislative history behind the HTCC statute: The Legislature intended to protect rather than preempt an injured worker’s right to appeal a denial of coverage. Second, under the Department of Labor and Industries’ medical aid rules, WAC Ch. 296-20, Mr. Murray has a

right to prove FAI surgery rehabilitated his damaged right hip. And third, under the statutory appeals process, RCW Ch. 51.52, the Legislature entitled Mr. Murray to individual consideration of what is necessary and proper medical care for him.

I. BOTH THE LEGISLATURE AND THE GOVERNOR INTENDED TO PROTECT MR. MURRAY'S RIGHT TO INDIVIDUAL CONSIDERATION.

The HTCC statute's legislative history underscores the Legislature's and Governor's intent to assess health technologies *without* rationing necessary care or reducing a claimant's right to establish coverage. In the 2006 legislative session, the Governor's office requested introduction of identical bills in the House and Senate to create health technology assessment programs. (HB 2575; Attached as Appendix B) (SB 6306; Attached as Appendix C). Both bills provided individual appeals from program decisions that recommended no coverage for controversial treatments.

Appeals by persons or groups of an agency coverage decision or a medical necessity or proper and necessary decision must demonstrate that the decision is inconsistent with sound, evidence-based medical practice.

(HB 2575 § 3(7); SB 6306 § 3(7)). Each agency would make a coverage decision, and affected claimants would have the ability to rebut the decision with competent medical evidence.

The House took up the bill and eventually passed three subsequent versions, SHB 2575 (Attached as Appendix D), SSHB 2575 (Attached as Appendix E), and ESSHB 2575 (Attached as Appendix F). The first substitute bill had a generic appellate section that did not expressly protect an individual's right to appeal a coverage decision.

(6) The standard of medical necessity or proper and necessary shall not apply to health technologies that are determined not to be covered based on the availability of adequate and quality scientific evidence.

(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.

(SHB 2575 §§ 6-7).

The second substitute bill and the engrossed second substitute bill clarified this. Both versions expressly protected a claimant's right to appeal the denial of coverage.

(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.

(SSHB 2575 §§ 6-7; ESSHB 2575 §§ 6-7). This is the version that the House sent to the Senate for approval.

The Senate rewrote the entire HTCC bill into its current form. (3/3/06 Senate Committee Amendment; Attached as Appendix G). The Senate Amendment made four fundamental changes to the proposed program. First, rather than have each participating agency create a health technology assessment committee, the Senate combined the functions into a single Health Technology Clinical Committee under the State Health Care Authority. (Senate Amendment § 2). Second, it made HTCC coverage decisions binding on agencies rather than advisory. Compare Senate Amendment § 5 ("a participating agency shall comply") with ESSHB 2575 § 3(3)(c) ("establish a health technology clinical committee...to make recommendations").

Third, the Senate Amendment first incorporated the conflicting provisions that became RCW 70.14.120(3) and (4), but changed the order of subsection 4 to emphasize the protected appellate rights.

(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.

(Senate Amendment § 5(3)-(4)).

And fourth, the Amendment created a new section for direct appeals from HTCC determinations.

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.

(Senate Amendment § 6). The Senate adopted the amended bill on March 3, 2006, and on March 6, 2006, the House approved the amended bill. On March 8, 2006, the Legislature sent the bill to the Governor for signature.

When she vetoed section 6 of the bill on March 29, 2006, Governor Gregoire did so on legislation that always preserved an

individual claimant's right to appeal. In earlier versions of the bill, that appeal was from each agency's coverage decision. In the final version, the appeal process in Section 5(4) incorporated the respective agency procedures and applied them to an HTCC coverage determination. Governor Gregoire's veto message expressly relied on a participating agency's appeal rights to protect a claimant's ability to establish coverage in a specific case. "Where issues may arise, I believe the individual appeal process highlighted above is sufficient to address them." (Governor's Veto Message at 1) (Appendix A).

This veto statement is compelling evidence of legislative intent. "In determining legislative intent of a statute, the reviewing court considers the intent of the Governor when he vetoes a section." State, Dep't of Ecology v. Theodoratus, 135 Wn.2d 582, 594, 957 P.2d 1241 (1998). "In approving or disapproving legislation, the Governor acts in a legislative capacity and as part of the legislative branch of government." State v. Reis, 183 Wn.2d 197, 213, 351 P.3d 127 (2015). The Governor concluded a direct appeal from an HTCC decision was duplicative because claimants could rebut a denial of coverage in an individual appeal.

II. A WORKER'S RIGHT TO CONTROVERSIAL TREATMENT.

Mr. Murray has a right under the Department's medical aid rules to prove that FAI surgery, a controversial treatment, rehabilitated his hip. Under WAC 296-20-03002, the Department will normally not pay for treatment deemed controversial. However, under WAC 296-20-02805, an injured worker can provide competent medical evidence that rebuts this presumption against coverage. WAC 296-20-02850 ("under certain conditions, the director or the director's designee may determine that such treatment is appropriate").

The Board of Industrial Appeals in In re Susan Pleas outlined how a claimant proves a controversial treatment is medically necessary and proper, and therefore covered. In Re: Susan M. Pleas, 96 7931, 1998 WL 718232 (Aug. 31, 1998) (Appendix A to Petitioner's Consolidated Answer to Amici). First, "services which are controversial, obsolete, experimental, or investigational are *presumed* not to be medically necessary, and shall be authorized only as provided in WAC 296-20-03002(6)." Pleas, 1998 WL 718232 at 3 (emphasis added).

Second, a claimant can rebut this presumption by proving the treatment is either curative or rehabilitative under WAC 296-20-

01002. Pleas, 1998 WL 718232 at 5 (“case-by-case analysis based on the definition of medically necessary found in WAC 296-20-01002”). And third, successful results from surgery can prove treatment was necessary and proper. “The claimant's dramatic post-implant improvement and the testimony of Dr. Oakley provide sufficient proof that SCS was medically necessary treatment for a condition proximately related to the industrial injury.” Pleas, 1998 WL 718232 at 8.

Until the Court of Appeal’s decision in Joy v. Dep't of Labor & Indus., 170 Wn. App. 614, 285 P.3d 187 (2012), the Department examined controversial treatments case-by-case, providing claimants the right to rebut the presumption against coverage. “WAC 296-20-01002(4), -02850, and -03002 together state that the Department shall authorize controversial treatments under very limited circumstances.” In Re: Duane A. Bolton, 04 14031, 2005 WL 2386294 at 3 (June 23, 2005). After Joy, the Department prohibited claimants from rebutting the presumption for treatments the HTCC deemed not covered. In Re: Ladonia M. Skinner, 14 10594, 2015 WL 4153105 at 4 (June 12, 2015) (Appendix B to Petitioner’s Consolidated Answer to Amici).

By any measure, the Department has allowed HTCC decisions to diminish claimant's rights to appeal a denial of coverage. Mr. Murray has never had an opportunity to prove that FAI surgery rehabilitated his right hip.

III. A WORKER'S RIGHT TO INDIVIDUAL CONSIDERATION ON APPEAL.

The Legislature in RCW Ch. 51.52 provides injured workers five levels of review to qualify for necessary and proper medical care. The Department makes the initial coverage determination based on its medical aid rules and RCW 51.36.010. WAC 296-20-02700. The first level of review is to an Industrial Appeals Judge (IAJ) at the Board of Industrial Appeals. WAC 296-12-045; RCW 51.52.104. A party may then petition for review of the IAJ's decision by the full Board of Industrial Appeals. WAC 296-12-145. If it accepts review, the Board may affirm, reverse or remand. WAC 296-12-145; RCW 51.52.106.

Once the Board makes a final decisions, parties may appeal to Superior Court. RCW 51.52.110. The Superior Court reviews the Board's decision de novo, based only on the evidence presented to the Board. RCW 51.52.110. From the Superior Court's decision, parties may appeal to the Court of Appeals and

this Court under the Rules of Appellate Procedure. RCW 51.52.140.

None of this appellate process matters if, as in Mr. Murray's case, the Department refuses to admit or consider any evidence that a medical procedure was rehabilitative. By treating RCW 70.14.120(3) as preclusive, the Department has preempted its authority to make coverage decisions, its medical aid rules, the statutory guarantee of necessary and proper medical care, and the statutory appellate process under RCW Ch. 51.52.

The Governor and the Legislature never intended this drastic result. Instead, both relied on the existing appellate rights in agency statutes and regulations to protect against an unfair result in an individual case. Mr. Murray deserves his right to prove that FAI surgery rehabilitated his right hip and therefore is necessary and proper medical care under the Industrial Insurance Act.

CONCLUSION

The language of RCW 70.14.120(3) and .120(4) conflict. To harmonize this conflict, the Court appropriately looks to the Legislature's and Governor's intent in the adopting the HTCC statute. Both sought to protect the rights of injured workers, not diminish them.

DATED this 28th day of June, 2018.

BURI FUNSTON MUMFORD & FURLONG, PLLC



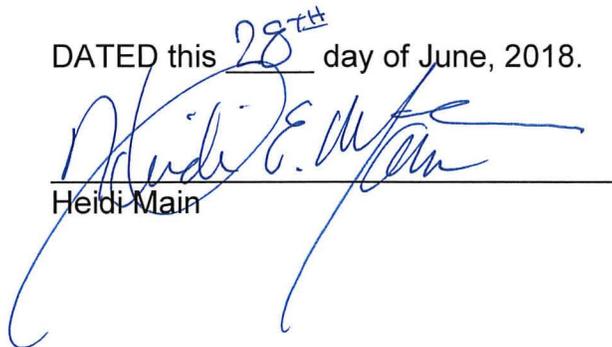
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DECLARATION OF SERVICE

The undersigned declares under penalty of perjury under the laws of the State of Washington that on the date stated below, I mailed or caused delivery of Appellant Michael Murray's Supplemental Brief to :

Anastasia R. Sandstrom
Attorney General's Office
800 5th Ave Ste 2000
Seattle WA 98104-3188

DATED this 28th day of June, 2018.



Heidi Main

Appendix A

VETO MESSAGE ON E2SHB 2575

March 29, 2006

To the Honorable Speaker and Members,
The House of Representatives of the State of Washington

Ladies and Gentlemen:

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.

Respectfully submitted,
Christine O. Gregoire
Governor

Appendix B

Z-1098.1

HOUSE BILL 2575

State of Washington

59th Legislature

2006 Regular Session

By Representatives Cody, Morrell and Moeller; by request of Governor Gregoire

Read first time 01/10/2006. Referred to Committee on Health Care.

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

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

5 NEW SECTION. **Sec. 1.** The legislature finds that a systematic
6 assessment of the best available scientific and medical evidence and
7 timely application of this evidence to informed coverage and medical
8 necessity decisions by state purchased health care programs should
9 result in improved access, prevention, and health outcomes for
10 Washington citizens. Therefore, it is the intent of the legislature to
11 support the establishment by the state of an evidence-based health
12 technology assessment program that:

13 (1) Conducts systematic reviews of scientific and medical
14 literature to identify safe, efficacious, and cost-effective
15 treatments;

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

18 (3) Provides for the establishment of an evidence-based health
19 technology assessment center;

1 (4) Develops methods and processes to track health outcomes across
2 state agencies; and

3 (5) Provides clear and transparent access to the scientific basis
4 of coverage decisions and treatment guidelines developed under this
5 program.

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

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

10 (1) "Best available scientific and medical evidence" means the best
11 available external clinical evidence derived from systematic research.

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

15 (3) "Health technology" means a medical device, surgical and other
16 procedures, medical equipment, diagnostic tests, and other health care
17 services.

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

23 (5) "Treatment guideline" means an evidence-based set of explicit
24 clinical recommendations for the appropriate application and use of a
25 covered health technology for an individual circumstance, and developed
26 or adopted by the health technology assessment program.

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

29 (1) Each agency administering a state purchased health care program
30 as defined in RCW 41.05.011(2) shall, in cooperation with other
31 agencies, take action to prevent the application of health technologies
32 where scientific and medical evidence suggests little or no benefit or
33 possible harm, and to enhance the use of health technologies where
34 evidence suggests substantial benefits. To accomplish this purpose,
35 participating agencies may establish an evidence-based health
36 technology assessment program. The provisions of the health technology

1 assessment program do not apply to agency health technology decisions
2 that have not been reviewed by the health technology clinical advisory
3 committee and adopted by the agencies.

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

7 (a) Shall use the best available scientific and medical evidence to
8 make coverage and medical necessity decisions and shall develop the
9 resources necessary to collect and analyze the available scientific and
10 medical evidence regarding a medical technology under review, including
11 coordinating efforts with the evidence-based health technology
12 assessment center in section 4 of this act;

13 (b) Shall develop and implement uniform policies for a health
14 technology assessment as provided in RCW 41.05.013, including
15 development of common coverage decisions and treatment guidelines;

16 (c) May develop treatment guidelines to assist in the appropriate
17 application of medical necessity or proper and necessary decisions;

18 (d) May develop criteria for payment of health technologies under
19 reasonable exceptions, such as experimental or investigational
20 treatment or services under a clinical investigation approved by an
21 institutional review board;

22 (e) May track and share safety, health outcome, and cost data
23 related to use of health technologies to help inform health technology
24 decisions;

25 (f) For decisions related to the use of prescription drugs, shall
26 develop policies and decisions consistent with RCW 70.14.050; and

27 (g) Shall adopt rules as necessary to implement this section.

28 (3) The agencies shall establish a health technology clinical
29 advisory committee to make recommendations to the agencies regarding
30 this act, including the development of treatment guidelines as
31 appropriate.

32 (4) The agencies may develop methods to report cost and outcome
33 performance of the health technology assessment program.

34 (5) The agencies shall develop a centralized, web-based
35 communication tool that allows clear and transparent access to the
36 scientific basis of coverage decisions and treatment guidelines
37 developed under this program.

1 (6) The standard of medical necessity or proper and necessary shall
2 not apply to health technologies that are determined not to be covered
3 based on the best available scientific evidence.

4 (7) Appeals by persons or groups of an agency coverage decision or
5 a medical necessity or proper and necessary decision must demonstrate
6 that the decision is inconsistent with sound, evidence-based medical
7 practice.

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

10 (1) An evidence-based health technology assessment center is
11 established to:

12 (a) Conduct systematic reviews of the scientific literature
13 regarding safety, efficacy, and cost-effectiveness; and

14 (b) Assess the adequacy and quality of systematic reviews
15 undertaken by other national or internationally recognized health
16 technology assessment programs using systematic review methods
17 substantially similar to those developed by the health technology
18 assessment program.

19 (2) Completed or received health technology assessments must be
20 conducted in a timely manner and at the request of the health
21 technology assessment program.

22 (3) Requests for the conduct of a new health technology assessment
23 must be proposed according to explicit prioritization criteria
24 developed by the health technology assessment program.

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

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

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

35 (1) The authority shall coordinate state agency efforts to develop

1 and implement uniform policies across state purchased health care
2 programs that will ensure prudent, cost-effective health services
3 purchasing, maximize efficiencies in administration of state purchased
4 health care programs, improve the quality of care provided through
5 state purchased health care programs, and reduce administrative burdens
6 on health care providers participating in state purchased health care
7 programs. The policies adopted should be based, to the extent
8 possible, upon the best available scientific and medical evidence and
9 shall endeavor to address:

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

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

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

18 (d) Exploration of common strategies for disease management and
19 demand management programs, including asthma, diabetes, heart disease,
20 and similar common chronic diseases. Strategies to be explored include
21 individual asthma management plans. On January 1, 2007, and January 1,
22 2009, the authority shall issue a status report to the legislature
23 summarizing any results it attains in exploring and coordinating
24 strategies for asthma, diabetes, heart disease, and other chronic
25 diseases.

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

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

--- END ---

Appendix C

Z-1045.2

SENATE BILL 6306

State of Washington

59th Legislature

2006 Regular Session

By Senators Keiser, Deccio, Kastama, Poulsen, Parlette, Franklin, Thibaudeau, Kline and McAuliffe; by request of Governor Gregoire

Read first time 01/10/2006. Referred to Committee on Health & Long-Term Care.

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

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

5 NEW SECTION. **Sec. 1.** The legislature finds that a systematic
6 assessment of the best available scientific and medical evidence and
7 timely application of this evidence to informed coverage and medical
8 necessity decisions by state purchased health care programs should
9 result in improved access, prevention, and health outcomes for
10 Washington citizens. Therefore, it is the intent of the legislature to
11 support the establishment by the state of an evidence-based health
12 technology assessment program that:

13 (1) Conducts systematic reviews of scientific and medical
14 literature to identify safe, efficacious, and cost-effective
15 treatments;

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

18 (3) Provides for the establishment of an evidence-based health
19 technology assessment center;

1 (4) Develops methods and processes to track health outcomes across
2 state agencies; and

3 (5) Provides clear and transparent access to the scientific basis
4 of coverage decisions and treatment guidelines developed under this
5 program.

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

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

10 (1) "Best available scientific and medical evidence" means the best
11 available external clinical evidence derived from systematic research.

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

15 (3) "Health technology" means a medical device, surgical and other
16 procedures, medical equipment, diagnostic tests, and other health care
17 services.

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

23 (5) "Treatment guideline" means an evidence-based set of explicit
24 clinical recommendations for the appropriate application and use of a
25 covered health technology for an individual circumstance, and developed
26 or adopted by the health technology assessment program.

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

29 (1) Each agency administering a state purchased health care program
30 as defined in RCW 41.05.011(2) shall, in cooperation with other
31 agencies, take action to prevent the application of health technologies
32 where scientific and medical evidence suggests little or no benefit or
33 possible harm, and to enhance the use of health technologies where
34 evidence suggests substantial benefits. To accomplish this purpose,
35 participating agencies may establish an evidence-based health
36 technology assessment program. The provisions of the health technology

1 assessment program do not apply to agency health technology decisions
2 that have not been reviewed by the health technology clinical advisory
3 committee and adopted by the agencies.

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

7 (a) Shall use the best available scientific and medical evidence to
8 make coverage and medical necessity decisions and shall develop the
9 resources necessary to collect and analyze the available scientific and
10 medical evidence regarding a medical technology under review, including
11 coordinating efforts with the evidence-based health technology
12 assessment center in section 4 of this act;

13 (b) Shall develop and implement uniform policies for a health
14 technology assessment as provided in RCW 41.05.013, including
15 development of common coverage decisions and treatment guidelines;

16 (c) May develop treatment guidelines to assist in the appropriate
17 application of medical necessity or proper and necessary decisions;

18 (d) May develop criteria for payment of health technologies under
19 reasonable exceptions, such as experimental or investigational
20 treatment or services under a clinical investigation approved by an
21 institutional review board;

22 (e) May track and share safety, health outcome, and cost data
23 related to use of health technologies to help inform health technology
24 decisions;

25 (f) For decisions related to the use of prescription drugs, shall
26 develop policies and decisions consistent with RCW 70.14.050; and

27 (g) Shall adopt rules as necessary to implement this section.

28 (3) The agencies shall establish a health technology clinical
29 advisory committee to make recommendations to the agencies regarding
30 this act, including the development of treatment guidelines as
31 appropriate.

32 (4) The agencies may develop methods to report cost and outcome
33 performance of the health technology assessment program.

34 (5) The agencies shall develop a centralized, web-based
35 communication tool that allows clear and transparent access to the
36 scientific basis of coverage decisions and treatment guidelines
37 developed under this program.

1 (6) The standard of medical necessity or proper and necessary shall
2 not apply to health technologies that are determined not to be covered
3 based on the best available scientific evidence.

4 (7) Appeals by persons or groups of an agency coverage decision or
5 a medical necessity or proper and necessary decision must demonstrate
6 that the decision is inconsistent with sound, evidence-based medical
7 practice.

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

10 (1) An evidence-based health technology assessment center is
11 established to:

12 (a) Conduct systematic reviews of the scientific literature
13 regarding safety, efficacy, and cost-effectiveness; and

14 (b) Assess the adequacy and quality of systematic reviews
15 undertaken by other national or internationally recognized health
16 technology assessment programs using systematic review methods
17 substantially similar to those developed by the health technology
18 assessment program.

19 (2) Completed or received health technology assessments must be
20 conducted in a timely manner and at the request of the health
21 technology assessment program.

22 (3) Requests for the conduct of a new health technology assessment
23 must be proposed according to explicit prioritization criteria
24 developed by the health technology assessment program.

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

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

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

35 (1) The authority shall coordinate state agency efforts to develop

1 and implement uniform policies across state purchased health care
2 programs that will ensure prudent, cost-effective health services
3 purchasing, maximize efficiencies in administration of state purchased
4 health care programs, improve the quality of care provided through
5 state purchased health care programs, and reduce administrative burdens
6 on health care providers participating in state purchased health care
7 programs. The policies adopted should be based, to the extent
8 possible, upon the best available scientific and medical evidence and
9 shall endeavor to address:

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

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

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

18 (d) Exploration of common strategies for disease management and
19 demand management programs, including asthma, diabetes, heart disease,
20 and similar common chronic diseases. Strategies to be explored include
21 individual asthma management plans. On January 1, 2007, and January 1,
22 2009, the authority shall issue a status report to the legislature
23 summarizing any results it attains in exploring and coordinating
24 strategies for asthma, diabetes, heart disease, and other chronic
25 diseases.

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

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

--- END ---

Appendix D

H-4887.1

SUBSTITUTE HOUSE BILL 2575

State of Washington 59th Legislature 2006 Regular Session

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

READ FIRST TIME 02/03/06.

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

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

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

15 (1) Conducts systematic reviews of scientific and medical
16 literature to identify safe, efficacious, and cost-effective
17 treatments;

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

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

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

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

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

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

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

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

16 (3) "Best available scientific and medical evidence" means the best
17 available external clinical evidence derived from systematic research.

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

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

28 (6) "Health technology" means a medical device, surgical and other
29 procedures, medical equipment, and diagnostic tests. Health
30 technologies does not include prescription drugs governed by RCW
31 70.14.050.

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

34 (8) "Medical necessity decision" or "proper and necessary decision"
35 means a determination whether or not to provide reimbursement for a
36 covered health technology in a specific circumstance for an individual

1 patient who is eligible to receive health care services from the state
2 purchased health care program making the decision.

3 (9) "Treatment guideline" means an evidence-based set of explicit
4 clinical recommendations for the appropriate application and use of a
5 covered health technology for an individual circumstance, as adopted by
6 the agencies under this act.

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

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

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

19 (a) Shall use the best available scientific and medical evidence to
20 make coverage and medical necessity decisions consistent with sections
21 2 through 5 of this act and RCW 41.05.013; and

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

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

29 (a) Shall determine which health technologies will be reviewed
30 using explicit prioritization criteria developed for this purpose.
31 These criteria may include, but are not limited to:

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

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

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

1 (iv) Whether the health technology is costly and if there is little
2 evidence of health benefits derived from use of the health technology;
3 and

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

6 (b) Shall contract with one or more evidence-based health
7 technology assessment centers to conduct systematic reviews and
8 assessments of the best available scientific and medical evidence
9 related to health technologies identified for review under this
10 section. Systematic reviews and assessments should include an
11 assessment of the scientific literature regarding safety, efficacy, and
12 cost-effectiveness of the health technology, and the adequacy and
13 quality of systematic reviews undertaken by other national or
14 internationally recognized health technology assessment programs. The
15 systematic reviews must be conducted in a manner that provides an
16 opportunity for interested individuals and entities to submit
17 scientific or medical evidence to the center for their consideration.
18 Upon their completion, the systematic reviews must be transmitted to
19 the agencies and to the health technology clinical committee. Each
20 health technology that has been initially reviewed under this section
21 shall be reviewed at intervals of no less than eighteen months to
22 determine if new scientific or medical evidence has emerged that could
23 potentially change a health care coverage recommendation, or
24 recommendation related to medical necessity or proper or necessary
25 determinations;

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

31 (d) May adopt treatment guidelines to assist in the appropriate
32 application of medical necessity or proper and necessary decisions,
33 consistent with section 4 of this act;

34 (e) May develop criteria for payment of health technologies under
35 reasonable exceptions, such as experimental or investigational
36 treatment, services under a clinical investigation approved by an
37 institutional review board, or health technologies that have a
38 humanitarian device exemption from the federal food and drug

1 administration. Exceptions for deviations from clinical guidelines may
2 be considered when the exception is based on the best available
3 scientific and medical evidence and the specific clinical circumstances
4 for which an exception has been requested are not substantially
5 addressed in the applicable clinical guidelines; and

6 (f) Shall track and share safety, health outcome, exceptions to
7 treatment guidelines, and cost data related to use of health
8 technologies to help inform health technology decisions. The agencies
9 may provide such data to an evidence-based health technology assessment
10 center or the health technology clinical committee when the information
11 will inform their deliberations.

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

16 (5) The agencies shall develop a centralized, web-based
17 communication tool that allows clear and transparent access to the
18 scientific basis of coverage decisions and treatment guidelines
19 developed under this program.

20 (6) The standard of medical necessity or proper and necessary shall
21 not apply to health technologies that are determined not to be covered
22 based on the availability of adequate and quality scientific evidence.

23 (7) Appeals of decisions made under sections 2 through 5 of this
24 act shall be governed by state and federal law applicable to
25 participating agency decisions.

26 (8) The provisions of the health technology assessment program
27 apply to health technologies that have been reviewed by an evidence-
28 based health technology assessment center and the health technology
29 clinical committee, and adopted by the agencies under this section.
30 For those health technologies that have not been identified for review
31 under subsection (3) of this section, the agencies may use their
32 existing statutory and rule-making authority to make coverage and
33 medical necessity or proper and necessary decisions. These decisions
34 shall be shared among the agencies, with a goal of maximizing each
35 agency's understanding of the basis for the other's decisions and
36 providing opportunities for agencies to collaborate in the decision-
37 making process. The agencies also shall attempt to provide
38 explanations of and access to the scientific basis for coverage

1 decisions related to health technologies that have not been identified
2 for systematic assessment under the health technology assessment
3 program.

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

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

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

17 (2) The health technology clinical committee shall review the
18 results of the systematic assessments of health technologies conducted
19 by an evidence-based health technology assessment center. The
20 committee must use an evidence-based process that evaluates the
21 efficacy of health technologies, considering safety, efficacy,
22 likelihood of compliance, outcomes, and any unique impacts on specific
23 populations based upon factors such as sex, age, ethnicity, race, or
24 disability. The review process shall include an opportunity for public
25 comment. For each health technology reviewed, the committee shall
26 develop recommendations related to whether the health technology should
27 be covered by state purchased health care programs, and if covered, any
28 treatment guidelines that should be used to assist in determining the
29 appropriate application of medical necessity or proper and necessary
30 decisions. Committee recommendations are binding on the agencies,
31 unless the recommendations are contrary to applicable federal or state
32 law, or the agencies provide written findings that include a detailed
33 explanation of the reason for rejecting the recommendation.

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

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

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

13 (6) Meetings of the health technology clinical committee are
14 subject to the open public meetings act, as provided in chapter 42.30
15 RCW, including RCW 42.30.110(1)(1), which authorizes an executive
16 session during a regular or special meeting to consider proprietary or
17 confidential nonpublished information.

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

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

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

28 (1) The authority shall coordinate state agency efforts to develop
29 and implement uniform policies across state purchased health care
30 programs that will ensure prudent, cost-effective health services
31 purchasing, maximize efficiencies in administration of state purchased
32 health care programs, improve the quality of care provided through
33 state purchased health care programs, and reduce administrative burdens
34 on health care providers participating in state purchased health care
35 programs. The policies adopted should be based, to the extent

1 possible, upon the best available scientific and medical evidence and
2 shall endeavor to address:

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

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

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

11 (d) Exploration of common strategies for disease management and
12 demand management programs, including asthma, diabetes, heart disease,
13 and similar common chronic diseases. Strategies to be explored include
14 individual asthma management plans. On January 1, 2007, and January 1,
15 2009, the authority shall issue a status report to the legislature
16 summarizing any results it attains in exploring and coordinating
17 strategies for asthma, diabetes, heart disease, and other chronic
18 diseases.

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

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

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

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

30 NEW SECTION. Sec. 8. A new section is added to chapter 70.14 RCW
31 to read as follows:

32 A health technology legislative oversight committee is established.
33 The committee shall consist of two members from each caucus of the
34 senate, and two members from each caucus of the house of
35 representatives. The health technology legislative oversight committee
36 shall:

1 (1) Review and report at least annually on the impact of health
2 technology coverage decisions made by the health technology clinical
3 committee and state agencies on patient access, treatment quality, and
4 overall health care costs; and
5 (2) Provide manufacturers of a health technology and organizations
6 with an interest in a health technology an opportunity to present
7 information related to the operation of the health technology
8 assessment program, including coverage decisions and other matters at
9 the discretion of the health technology legislative oversight
10 committee.

--- END ---

Appendix E

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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

17 (7) "Health technology" means medical and surgical devices and
18 procedures, medical equipment, and diagnostic tests. Health
19 technologies does not include prescription drugs governed by RCW
20 70.14.050.

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

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

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

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

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

4 (a) Shall use the best available scientific and medical evidence to
5 make coverage and medical necessity decisions consistent with sections
6 2 through 5 of this act and RCW 41.05.013; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

31 (d) Exploration of common strategies for disease management and
32 demand management programs, including asthma, diabetes, heart disease,
33 and similar common chronic diseases. Strategies to be explored include
34 individual asthma management plans. On January 1, 2007, and January 1,
35 2009, the authority shall issue a status report to the legislature

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

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

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

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

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

--- END ---

Appendix F

ENGROSSED 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.

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

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

5 NEW SECTION. **Sec. 1.** The legislature finds that a systematic
6 assessment of the best available scientific and medical evidence and
7 timely application of this evidence to informed coverage and medical
8 necessity decisions by state purchased health care programs should
9 result in improved access, prevention, and health outcomes for
10 Washington citizens. The legislature further finds that transparency
11 and public participation in this program is important and should be
12 incorporated. Nothing in this act is intended to ration health care
13 that is provided to individuals in a state purchased health care
14 program. Therefore, it is the intent of the legislature to support the
15 establishment by the state of an evidence-based health technology
16 assessment program that:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

35 (e) Other credible evidence, such as clinical guidelines,
36 information produced by governmental sources, independent technology

1 assessment organizations, medical and hospital associations, and health
2 carriers as defined in RCW 48.43.005.

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

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

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

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

19 (7) "Health technology" means medical and surgical devices and
20 procedures, medical equipment, and diagnostic tests. Health
21 technologies does not include prescription drugs governed by RCW
22 70.14.050.

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

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

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

32 (1) Each state agency administering a state purchased health care
33 program shall, in cooperation with other such agencies, take action to
34 prevent the application of health technologies where scientific and
35 medical evidence suggests little or no benefit or possible harm, and to
36 enhance the use of health technologies in circumstances where evidence

1 suggests substantial benefits. To accomplish this purpose, the
2 agencies shall establish an evidence-based health technology assessment
3 program.

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

7 (a) Shall use the best available scientific and medical evidence to
8 make coverage and medical necessity decisions consistent with sections
9 2 through 5 of this act and RCW 41.05.013; and

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

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

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

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

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

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

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

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

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

35 (b) Shall contract with one or more evidence-based health
36 technology assessment centers to conduct systematic reviews and
37 assessments of the best available scientific and medical evidence
38 related to health technologies identified for review under this

1 section. Systematic reviews and assessments should include an
2 assessment of the scientific literature regarding safety, efficacy, and
3 cost-effectiveness of the health technology, and the adequacy and
4 quality of systematic reviews undertaken by other national or
5 internationally recognized health technology assessment programs. The
6 systematic reviews must be conducted in a manner that provides an
7 opportunity for interested individuals and entities to submit
8 scientific or medical evidence to the center for their consideration.
9 Upon their completion, the systematic reviews must be transmitted to
10 the agencies and to the health technology clinical committee. Each
11 health technology that has been initially reviewed under this section
12 shall be reviewed at intervals of no less than eighteen months to
13 determine if new scientific or medical evidence has emerged that could
14 potentially change a health care coverage recommendation, or
15 recommendation related to medical necessity or proper or necessary
16 determinations;

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

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

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

35 (f) Shall track and share safety, health outcome, exceptions to
36 coverage criteria, and cost data related to use of health technologies
37 to help inform health technology decisions. The agencies shall provide

1 such data to an evidence-based health technology assessment center or
2 the health technology clinical committee when the information will
3 inform their deliberations.

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

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

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

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

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

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

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

32 (8) The provisions of the health technology assessment program
33 apply to health technologies that have been reviewed by an evidence-
34 based health technology assessment center and the health technology
35 clinical committee, and adopted by the agencies under this section.
36 For those health technologies that have not been identified for review
37 under subsection (3) of this section, the agencies may use their
38 existing statutory and rule-making authority to make coverage and

1 medical necessity or proper and necessary decisions. These decisions
2 shall be shared among the agencies, with a goal of maximizing each
3 agency's understanding of the basis for the other's decisions and
4 providing opportunities for agencies to collaborate in the decision-
5 making process. The agencies also shall provide explanations of and
6 access to the scientific basis for coverage decisions related to health
7 technologies that have not been identified for systematic assessment
8 under the health technology assessment program.

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

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

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

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

26 (c) Request the health technology clinical committee to reconsider
27 a recommendation, at the discretion of the oversight committee.

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

30 (1) The administrator of the health care authority, in consultation
31 with the participating agencies and their medical directors, shall
32 establish a health technology clinical committee. The health
33 technology clinical committee shall be comprised of eleven members,
34 including six practicing licensed physicians and five other practicing
35 licensed health professionals who utilize health technology in the
36 professional scope of their practice. At least two members of the

1 committee must have demonstrated experience in serving women, children,
2 elderly persons, and people of color.

3 (2) The health technology clinical committee shall review the
4 results of the systematic assessments of health technologies conducted
5 by an evidence-based health technology assessment center. The
6 committee must use medical and scientific evidence in an open and
7 transparent process that evaluates the efficacy of health technologies,
8 considering safety, efficacy, likelihood of compliance, outcomes, and
9 any unique impacts on specific populations based upon factors such as
10 sex, age, ethnicity, race, or disability. The review process shall
11 include an opportunity for public comment. For each health technology
12 reviewed, the committee shall develop recommendations related to
13 whether the health technology should be covered by state purchased
14 health care programs, and if covered, any coverage criteria that should
15 be used to assist in determining the appropriate application of medical
16 necessity or proper and necessary decisions. Committee recommendations
17 are binding on the agencies, unless the recommendations are contrary to
18 an applicable federal statute or regulation, or state statute.

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

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

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

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

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

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

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

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

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

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

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

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

31 (d) Exploration of common strategies for disease management and
32 demand management programs, including asthma, diabetes, heart disease,
33 and similar common chronic diseases. Strategies to be explored include
34 individual asthma management plans. On January 1, 2007, and January 1,
35 2009, the authority shall issue a status report to the legislature

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

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

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

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

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

15 NEW SECTION. **Sec. 8.** If any part of this act is found to be in
16 conflict with federal requirements that are a prescribed condition to
17 the allocation of federal funds to the state, the conflicting part of
18 this act is inoperative solely to the extent of the conflict and with
19 respect to the agencies directly affected, and this finding does not
20 affect the operation of the remainder of this act in its application to
21 the agencies concerned. Rules adopted under this act must meet federal
22 requirements that are a necessary condition to the receipt of federal
23 funds by the state.

--- END ---

Appendix G

2575-S2.E AMS WM S5827.1

E2SHB 2575 - S COMM AMD
By Committee on Ways & Means

ADOPTED 03/03/2006

1 Strike everything after the enacting clause and insert the
2 following:

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

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

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

10 (2) "Advisory group" means a group established under section
11 4(2)(c) of this act.

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

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

17 (5) "Health technology" means medical and surgical devices and
18 procedures, medical equipment, and diagnostic tests. Health
19 technologies does not include prescription drugs governed by RCW
20 70.14.050.

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

24 (7) "Reimbursement determination" means a determination to provide
25 or deny reimbursement for a health technology included as a covered
26 benefit in a specific circumstance for an individual patient who is
27 eligible to receive health care services from the state purchased
28 health care program making the determination.

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

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

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

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

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

14 (2) Members of the committee:

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

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

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

26 (3) Meetings of the committee and any advisory group are subject to
27 chapter 42.30 RCW, the open public meetings act, including RCW
28 42.30.110(1)(1), which authorizes an executive session during a regular
29 or special meeting to consider proprietary or confidential nonpublished
30 information.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16 (b) Reimbursement is provided under an agency policy regarding
17 experimental or investigational treatment, services under a clinical
18 investigation approved by an institutional review board, or health
19 technologies that have a humanitarian device exemption from the federal
20 food and drug administration.

21 (2) For a health technology not selected for review under section
22 3 of this act, a participating agency may use its existing statutory
23 and administrative authority to make coverage and reimbursement
24 determinations. Such determinations shall be shared among agencies,
25 with a goal of maximizing each agency's understanding of the basis for
26 the other's decisions and providing opportunities for agency
27 collaboration.

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

35 (4) Nothing in this act diminishes an individual's right under
36 existing law to appeal an action or decision of a participating agency

1 regarding a state purchased health care program. Appeals shall be
2 governed by state and federal law applicable to participating agency
3 decisions.

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

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

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

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

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

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

21 (c) Access to the systematic assessment completed under section
22 3(4) of this act, and reports completed under subsection (2) of this
23 section.

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

28 **Sec. 8.** RCW 41.05.013 and 2005 c 462 s 3 are each amended to read
29 as follows:

30 (1) The authority shall coordinate state agency efforts to develop
31 and implement uniform policies across state purchased health care
32 programs that will ensure prudent, cost-effective health services
33 purchasing, maximize efficiencies in administration of state purchased
34 health care programs, improve the quality of care provided through
35 state purchased health care programs, and reduce administrative burdens

1 on health care providers participating in state purchased health care
2 programs. The policies adopted should be based, to the extent
3 possible, upon the best available scientific and medical evidence and
4 shall endeavor to address:

5 (a) Methods of formal assessment, such as a health technology
6 assessment under sections 1 through 7 of this act. Consideration of
7 the best available scientific evidence does not preclude consideration
8 of experimental or investigational treatment or services under a
9 clinical investigation approved by an institutional review board;

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

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

13 (d) Exploration of common strategies for disease management and
14 demand management programs, including asthma, diabetes, heart disease,
15 and similar common chronic diseases. Strategies to be explored include
16 individual asthma management plans. On January 1, 2007, and January 1,
17 2009, the authority shall issue a status report to the legislature
18 summarizing any results it attains in exploring and coordinating
19 strategies for asthma, diabetes, heart disease, and other chronic
20 diseases.

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

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

27 NEW SECTION. **Sec. 9.** A new section is added to chapter 70.14 RCW
28 to read as follows:

29 Sections 1 through 7 of this act and RCW 41.05.013 do not apply to
30 state purchased health care services that are purchased from or through
31 health carriers as defined in RCW 48.43.005.

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

34 NEW SECTION. **Sec. 11.** If any part of this act is found to be in
35 conflict with federal requirements that are a prescribed condition to

1 the allocation of federal funds to the state, the conflicting part of
2 this act is inoperative solely to the extent of the conflict and with
3 respect to the agencies directly affected, and this finding does not
4 affect the operation of the remainder of this act in its application to
5 the agencies concerned. Rules adopted under this act must meet federal
6 requirements that are a necessary condition to the receipt of federal
7 funds by the state."

E2SHB 2575 - S COMM AMD
By Committee on Ways & Means

ADOPTED 03/03/2006

8 On page 1, line 2 of the title, after "program;" strike the
9 remainder of the title and insert "amending RCW 41.05.013; adding new
10 sections to chapter 70.14 RCW; and creating new sections."

EFFECT: Clarifies the language and substantially reorganizes the bill. Substantive changes include: (1) Limiting the number of assessments done in the program's first two years of operation; (2) allowing interested parties to petition to have a technology reviewed; (3) explicitly allowing any advisory groups to include enrollees in state health care programs; (4) requiring the clinical committee to follow decisions made under Medicare unless evidence supports a contrary determination; (5) directing the HCA administrator to establish an appeals process; (6) removing a legislative oversight committee.

--- END ---

BURI FUNSTON MUMFORD, PLLC

June 28, 2018 - 2:30 PM

Transmittal Information

Filed with Court: Supreme Court
Appellate Court Case Number: 95251-5
Appellate Court Case Title: Michael E. Murray v. State of Washington, Department of Labor & Industries
Superior Court Case Number: 15-2-00566-1

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