

FILED
COURT OF APPEALS
DIVISION II

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NO. 42118-6-II
COURT OF APPEALS OF THE STATE OF WASHINGTON
DIVISION II

STATE OF WASHINGTON
BY 
DEPUTY

CHERYL JOY, *APPELLANT/PLAINTIFF*

v.

DEPARTMENT OF LABOR AND INDUSTRIES, *RESPONDANT/DEFENDANT*.

APPEAL FROM THE SUPERIOR COURT OF CLARK COUNTY
HONORABLE ROGER A. BENNETT

BRIEF OF THE APPELLANT/PLAINTIFF

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I. INTRODUCTION

Cheryl Joy, an injured worker under the Industrial Insurance Act, is entitled to receive proper and necessary medical treatment at the hands of physician of her choice. RCW 51.36.010. Her physicians have recommended that she undergo a 7-day trial implantation of a spinal cord stimulator to determine if it would be effective and reducing her chronic nerve pain and improve her ability to perform activities of daily living.

The Department of Labor and Industries has denied authorization of this medical treatment on September 24, 2009. On appeal to the Board of Industrial Insurance Appeals, the Department's decision was upheld on September 10, 2010. Ms. Joy then appealed the Board's decision to Clark County Superior Court.

Subsequent to Ms. Joy's appeal to Clark County Superior Court, the Health Technology Assessment Clinical Committee (hereinafter "HTACC") on October 22, 2010 determined Spinal Cord Stimulators for chronic neuropathic pain is not a covered benefit. This decision was made pursuant to its authority under RCW 70.14.110. This decision is binding on "participating" state agencies, which includes the Department of Labor and Industries. RCW 70.14.080(6); RCW 70.14.120(1).

Following the presentation of Plaintiff's case-in-chief, the Defendant then moved for a directed verdict. The Honorable Roger A. Bennett granted the Defendant's motion finding that RCW 70.14.120 removes all discretion from the Department of Labor and Industries in authorizing a spinal cord stimulator, even if the jury finds the spinal cord stimulator medically necessary and proper treatment pursuant to RCW

1 51.36.010. Plaintiff assigns error to the Judgment of the Superior Court
2 and seeks review.

3 II. ASSIGNMENT OF ERROR

4 Did the trial court err when it granted Defendant's Motion for
5 Directed Verdict finding there was no issue of fact for the jury to decide?

6 When reviewing a motion for directed verdict, the Court of
7 Appeals engages in the same inquiry as the trial court. *Stiley v. Block*, 130
8 Wn.2d 486 (1996).

9 III. STATEMENT OF THE CASE

10 Cheryl Joy was injured on October 16, 2006. Subsequent to her
11 injury, she underwent two cervical spine surgeries, leaving her with
12 chronic neuropathic pain in her neck, shoulders, and arms. (4/5/10 Tr. pp.
13 21, 24, 37-8). On September 24, 2009, the Department of Labor and
14 Industries issued an order denying authorization for a spinal cord
15 stimulator. Ms. Joy appealed to the Board of Industrial Insurance
16 Appeals. Before the Board, Plaintiff's attending surgeon, Dr. Hong,
17 testified the injury and subsequent surgeries were the cause of her chronic
18 pain. (Dep Dr. Hong p. 26). Dr. Hong testified that a spinal cord
19 stimulator was medically necessary and proper treatment for Plaintiff's
20 chronic cervical neuropathic pain. (Dep. Dr. Hong pp. 29-31). The
21 Department's only medical expert was Dr. Gary Franklin, the Director of
22 the Department's Office of Medical Director. Dr. Franklin testified about
23 the Department's policy, but nowhere did he testify that a spinal cord
24 stimulator was not medically necessary and proper treatment for Ms. Joy.
25

1 On September 10, 2010, the Board of Industrial Insurance Appeals
2 affirmed the decision of the Department of Labor and Industries. After
3 Plaintiff's appeal to Clark County Superior Court, a jury was empanelled
4 on March 7, 2011. Following the reading of the record of Plaintiff's case-
5 in-chief, the Defendant made a motion for directed verdict. The
6 Honorable Roger A. Bennett found that the decision of the HTACC that
7 spinal cord stimulators are not a covered benefit and RCW 70.14.120(3)
8 removed all issues of fact. The Motion for Directed Verdict was granted.

9 Finally, Plaintiff should be awarded attorney fees and costs, upon
10 prevailing, pursuant to RAP 18.1 and RCW 51.52.130.

11 IV. **ARGUMENT**

12 **Legal Criteria**

13 All issues regarding an injured worker's right to receive medical
14 treatment starts with RCW 51.36.010, which states:

15 Upon the occurrence of any injury to a worker entitled to
16 compensation under the provisions of this title, he or she
17 shall receive proper and necessary medical and surgical
18 services at the hands of a physician or licensed advanced
19 registered nurse practitioner of his or her own choice, if
conveniently located, and proper and necessary hospital
care and services during the period of his or her disability
from such injury.

20 On September 10, 2010, the Board of Industrial Insurance Appeals
21 affirmed the Department's decision to deny authorization of a spinal cord
22 stimulator on the basis that it was not proper and necessary medical and
23 surgical care. On appeal to Clark County Superior Court, the issue is
24 whether the Board was wrong in affirming the Department's September
25

1 24, 2009 order. RCW 51.52.115; *Layrite Products Co. v. Degenstein*, 74
2 Wn. App. 881 (1994).

3 However, the Legislature established the HTACC to “select the
4 health technologies to be reviewed by the committee under RCW
5 70.14.110.” RCW 70.14.100. Once a technology is selected, the
6 Committee shall determine “the conditions, if any, under which the health
7 technology will be included as a covered benefit in health care programs
8 of participating agencies.” RCW 70.14.110(1)(a). The Department of
9 Labor and Industries is a participating agency, but the Board of Industrial
10 Insurance Appeals is not. RCW 70.14.080(6).

11 On October 22, 2010, the HTACC determined that spinal cord
12 stimulators for chronic neuropathic pain were not a covered benefit. Once
13 the decision was made that spinal cord stimulators are not a covered
14 benefit, this Court must now decide how RCW 70.14.120 applies to
15 Plaintiff’s appeal of the Board of Industrial Insurance Appeals’ September
16 10, 2010 Decision and Order. RCW 70.14.120 states in relevant part:

- 17 (1) A participating agency shall comply with a
18 determination of the committee under RCW
19 70.14.110 unless:
20 (a) The determination conflicts with an
21 applicable federal statute or regulation, or
22 applicable state statute; or
23 (b) Reimbursement is provided under an agency
24 policy regarding experimental or
25 investigational treatment, services under a
clinical investigation approved by an
institutional review board, or health
technologies that have a humanitarian
device exemption from the federal food and
drug administration.

- 1
- 2 (3) A health technology not included as a covered
3 benefit under a state purchased health care program
4 pursuant to a determination of the health technology
5 clinical committee under RCW 70.14.110, or for
6 which a condition of coverage established by the
7 committee is not met, shall not be subject to a
8 determination in the case of an individual patient as
9 to whether it is medically necessary, or proper and
10 necessary treatment.
- 11 (4) Nothing in chapter 307, Laws of 2006 diminishes
12 an individual's right under existing law to appeal an
13 action or decision of a participating agency
14 regarding a state purchased health care program.
15 Appeals shall be governed by state and federal law
16 applicable to participating agency decisions.

17 When interpreting a statute, the Court's review is *de novo*. *State v.*
18 *Keller*, 143 Wn.2d 267, 276 (2001). The Court's objective is to determine
19 the Legislature's intent. *State v. Jacobs*, 154 Wn.2d 596, 600 (2005).

20 When determining the Legislature's intent, the Court shall first look to the
21 plain meaning of the statute. *Dep't of Ecology v. Campbell & Gwinn,*
22 *LLC*, 146 Wn.2d 1, 9-10 (2002). To determine the plain meaning, this
23 Court must look at the text and "the context of the statute in which that
24 provision is found, related provisions, and the statutory scheme as a
25 whole." *State v. Jacobs*, 154 Wn.2d at 600. If this reading of the statute
leads to more than one interpretation, then the statute is ambiguous and
this Court "may resort to statutory construction, legislative history, and
relevant case law for assistance in discerning legislative intent."

Christensen v. Ellsworth, 162 Wn.2d 365, 373 (2007).

There are no decisions of the Washington Courts, reported or
otherwise, interpreting the provisions of RCW 70.14.120.

1 **Plain Meaning of RCW 70.14.120**

2 Judge Bennett erred when he decided that Plaintiff had no right to
3 seek review of the Department's decision to deny authorization of a spinal
4 cord stimulator pursuant to RCW 70.14.120(3). Judge Bennett erred
5 because he failed to give effect to the plain meaning of RCW 70.14.120(4)
6 that allows Plaintiff to appeal the Department's decision under Title 51
7 RCW.

8 Under its plain meaning, RCW 70.14.120(1) requires the
9 Department of Labor and Industries to comply with coverage decisions of
10 the HTACC. RCW 70.14.120(3) limits a participating agency's ability in
11 making individual determinations whether the non-covered benefit is
12 proper and necessary treatment. Nothing in RCW 70.14.120(3) limits the
13 ability of reviewing agencies or the courts to make an individual
14 determination on whether the treatment is medically necessary and proper.
15 This is especially true in light RCW 70.14.120(4), which preserves an
16 injured worker's right to seek review of the Department's decisions under
17 51.52 RCW.

18 By interpreting RCW 70.14.120(3) as extinguishing an injured
19 worker's right to seek any review of the Department's decision not to
20 cover the spinal cord stimulator, Judge Bennett read out of existence the
21 plain language of RCW 70.14.120(4). The Legislature unambiguously
22 stated that nothing done under the auspices of Chapter 307, Laws of 2006
23 diminishes an injured worker's right under existing law (Title 51 RCW) to
24 appeal the decision of the Department regarding a state purchased health
25 care program (Title 51.36 RCW). RCW 70.14.120(4). Under its plain

1 meaning, this section must allow Plaintiff to appeal to the Board and the
2 Courts a decision of the Department to deny authorization of a spinal cord
3 stimulator.

4 Furthermore, the Governor exercised her veto power to eliminate a
5 specific provision of Chapter 307, Laws of 2006, which would have
6 established a separate appeal process for decisions by the HTACC.
7 Appendix D. In her veto message, Governor Gregoire states she supports
8 Section 5 (4) of the bill (later designated as RCW 70.14.120(4) because it
9 protects an individual's right to appeal. Appendix D, page 8. She
10 believed that Chapter 307, Laws of 2006 maintained an individual's right
11 to appeal under the existing appeal rights granted by the participating
12 agencies' authorizing statutes (in this case the Title 51 RCW). This
13 unambiguously establishes Plaintiff's right to continue to seek approval of
14 a spinal cord stimulator under the provisions of Title 51.52 RCW despite
15 the October 22, 2010 decision of the HTACC.

16 RCW 70.14.120(4) cannot mean, as Judge Bennett stated, that
17 injured workers' have the right to appeal other issues, but do not have the
18 right to appeal denials of coverage of specific health technologies.
19 (Report of Proceedings p. 15). Read as a whole, RCW 70.14.120
20 addresses solely the issue of what happens when a specific health
21 technology is determined to be not a covered benefit. It addresses the
22 obligations of participating state agencies. It addresses the rights of
23 individual citizens who are affected by the decisions of the participating
24 state agencies. Therefore, it was error to grant Defendant's Motion for
25 Directed Verdict.

1 **Effect of the October 22, 2010 HTACC Determination**

2 In the alternative, the October 22, 2010 determination by the
3 HTACC that spinal cord stimulators are not a covered benefit should not
4 be given a retroactive effect on Plaintiff's appeal. The general rule in
5 Washington is that "statutes will be construed to operate prospectively
6 only, unless an intent to the contrary clearly appears. It is said, 'that a law
7 will not be given a retrospective operation, unless the intention has been
8 manifested by the most clear and unequivocal expression.'" *Bodine v.*
9 *Dep't of Labor & Indus.*, 29 Wn. 2d 879, 888 (1948). Absent such an
10 expression, statutory changes affecting substantive or vested right cannot
11 be given retroactive effect. *Id.* at 887. The Court added, "all doubts are
12 resolved in favor of such a construction" that a statute operates
13 prospectively. *Id.* at 889.

14 While the provisions of 70.14 RCW at issue were enacted in 2006,
15 the question still remains as to what effect do subsequent decisions by the
16 HTACC have upon existing appeals before the Board of Industrial
17 Insurance Appeals and Washington Courts? With enactment of RCW
18 70.14.100 through 120, the Legislature has statutorily ceded to the
19 HTACC the right to change the substantive or vested rights of injured
20 workers. Absent a decision by the HTACC, the vested rights of injured
21 workers to receive treatment under RCW 51.36.010 proceeds under
22 existing statutory or regulatory authority.

23 ///

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1 But once the HTACC decides that a specific treatment modality
2 should not be a covered benefit, then injured workers' substantive or
3 vested rights are changed. There is no unequivocal language in either
4 Title 70.14 RCW or in Chapter 307, Laws of 2006 that states decisions of
5 the HTACC shall have retroactive effect. Appendix D.

6 To the contrary, the express language of RCW 70.14.120(4) limits
7 the effect of coverage decisions by the HTACC to prospective claims.
8 The statute states, "Nothing in chapter 307, Laws of 2006 diminishes an
9 individual's right under existing law to appeal an action or decision of a
10 participating agency." (emphasis added). At the time of the October 22,
11 2010 coverage decision, Plaintiff's right to appeal to Superior Court the
12 September 10, 2010 decision of the Board was in existence. But the plain
13 meaning of RCW 70.14.120(4), nothing done by the HTACC on October
14 22, 2010 could effect or change that right, contrary to the Judgment of the
15 Clark County Superior Court.

16 Furthermore, the Department argued below that even if the worker
17 has the right to appeal and the courts order it to authorize a spinal cord
18 stimulator it is prohibit from doing so by RCW 70.14.120(1). However,
19 the Department ignores RCW 70.14.120(1)(a), which requires it to
20 authorize the procedure to the extent required by applicable state statute.
21 The applicable state statutes include RCW 51.52.060 and RCW 51.52.110
22 which authorizes injured workers to seek review and the courts to reverse
23 decisions of the Department. Furthermore, once the decision of the courts
24 is final, the injured worker may seek a *writ of mandamus* enforcing the
25 Department's compliance pursuant to RCW 51.32.215. The Department's

1 position that it cannot comply with a court order under RCW 51.52.110 or
2 51.32 .215 is simply absurd.

3 **HTACC's October 22, 2010 Determination is not binding on the**
4 **Board or Courts**

5 It is important to note that decisions of the Health Technology
6 Assessment Committee are only binding upon participating state agencies.
7 The list of participating agencies is short and found in RCW 70.14.080(6)
8 and does not include the Board of Industrial Insurance Appeals. As noted
9 above, the issue before the Superior Court is whether the Board's
10 September 10, 2010 decision is correct based on the record before the
11 Board. The Industrial Insurance Act governs such appeals. The plain
12 language of RCW 70.14.120(4) exempts such appeals from its limitations.
13 Therefore, RCW 70.14.120 neither directly nor indirectly limits the right
14 of Plaintiff to seek judicial review of the Board's decision to affirm the
15 denial of the spinal cord stimulator. As such it was error to grant the
16 Defendant's Motion for Direct Verdict.

17 **Attorney Fees**

18 The award of attorney fees and costs in this appeal is controlled by
19 RCW 51.52.130, which applies to fees and costs in both the superior and
20 appellate courts when Board decisions are reviewed. *Hi-Way Fuel Co. v.*
21 *Estate of Allyn*, 128 Wn. App. 351, 363-64 (2005). Under RCW
22 51.52.130, Plaintiff is entitled to attorney fees and costs for this appeal if
23 her right to relief is sustained. *Brand v. Department of Labor and*
24 *Industries*, 139 Wn.2d 659, 669-70 (1999). Plaintiff's attorney fees and
25

1 costs are payable directly by the Department of Labor and Industries.
2 RCW 51.52.130.

3 **V. Conclusion**

4 Clark County Superior Court erred when it granted Defendant's
5 Motion for Directed Verdict. While RCW 70.14.120 may limit the
6 Department's authority to initial authorize a spinal cord stimulator,
7 nothing in that statute limits Plaintiff's right to seek judicial review.
8 Plaintiff presented evidence, if viewed in a light most favorable to her, is
9 sufficient to prove that a spinal cord stimulator is medically necessary and
10 proper treatment. It was error to dismiss claimant's appeal. This matter
11 should be remanded back to Clark County Superior Court with
12 instructions to begin a new trial.

13 Finally, Plaintiff petitions the Court to award attorney fees and
14 costs pursuant to RAP 18.1 and RCW 51.52.130.

15 DATED: July 27, 2011.

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19 Frances R. Hamrick, WSBA No. 31547
20 Douglas M. Palmer, WSBA No. 35198
21 Attorneys for Cheryl Joy,
22 Plaintiff/Appellant
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APPENDIX A

W 70.14.080
Definitions.

Definitions in this section apply throughout RCW 70.14.090 through 70.14.130 unless the context clearly requires otherwise.

- (1) "Administrator" means the administrator of the Washington state health care authority under chapter 41.05 RCW.
- (2) "Advisory group" means a group established under RCW 70.14.110(2)(c).
- (3) "Committee" means the health technology clinical committee established under RCW 70.14.090.
- (4) "Coverage determination" means a determination of the circumstances, if any, under which a health technology will be included as a covered benefit in a state purchased health care program.
- (5) "Health technology" means medical and surgical devices and procedures, medical equipment, and diagnostic tests. Health technologies does not include prescription drugs governed by RCW 70.14.050.
- (6) "Participating agency" means the department of social and health services, the state health care authority, and the department of labor and industries.
- (7) "Reimbursement determination" means a determination to provide or deny reimbursement for a health technology included as a covered benefit in a specific circumstance for an individual patient who is eligible to receive health care services from the state purchased health care program making the determination.

[2006 c 307 § 1.]

Notes:

Captions not law -- 2006 c 307: "Captions used in this act are not any part of the law." [2006 c 307 § 10.]

Conflict with federal requirements -- 2006 c 307: "If any part of this act is found to be in conflict with federal requirements that are a prescribed condition to the allocation of federal funds to the state, the conflicting part of this act is inoperative solely to the extent of the conflict and with respect to the agencies directly affected, and this finding does not affect the operation of the remainder of this act in its application to the agencies concerned. Rules adopted under this act must meet federal requirements that are a necessary condition to the receipt of federal funds by the state." [2006 c 307 § 11.]

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APPENDIX B

RCW 70.14.110
Health technology clinical committee determinations.

The committee shall determine, for each health technology selected for review under RCW 70.14.100: (a) The conditions, if any, under which the health technology will be included as a covered benefit in health care programs of participating agencies; and (b) if required, the criteria which the participating agency administering the program must use to decide whether the technology is medically necessary, or proper and necessary treatment.

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

(a) Shall consider, in an open and transparent process, evidence regarding the safety, efficacy, and cost-effectiveness of the technology as set forth in the systematic assessment conducted under RCW 70.14.100(4);

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

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

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

[2006 c 307 § 4.]

Notes:

Captions not law -- Conflict with federal requirements -- 2006 c 307: See notes following RCW 70.14.080.

APPENDIX C

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RCW 70.14.120

Agency compliance with committee determination — Coverage and reimbursement determinations for nonreviewed health technologies — Appeals.

A participating agency shall comply with a determination of the committee under RCW 70.14.110 unless:

- (a) The determination conflicts with an applicable federal statute or regulation, or applicable state statute; or
 - (b) Reimbursement is provided under an agency policy regarding experimental or investigational treatment, services under a clinical investigation approved by an institutional review board, or health technologies that have a humanitarian device exemption from the federal food and drug administration.
- (2) For a health technology not selected for review under RCW 70.14.100, a participating agency may use its existing statutory and administrative authority to make coverage and reimbursement determinations. Such determinations shall be shared among agencies, with a goal of maximizing each agency's understanding of the basis for the other's decisions and providing opportunities for agency collaboration.
- (3) A health technology not included as a covered benefit under a state purchased health care program pursuant to a determination of the health technology clinical committee under RCW 70.14.110, 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 chapter 307, Laws of 2006 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.

[RCW 307 c 307 § 5.]

Notes:

Captions not law -- Conflict with federal requirements -- 2006 c 307: See notes following RCW 70.14.080.

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APPENDIX D

CERTIFICATION OF ENROLLMENT
ENGROSSED SECOND SUBSTITUTE HOUSE BILL 2575

Chapter 307, Laws of 2006

(partial veto)

59th Legislature
2006 Regular Session

HEALTH TECHNOLOGY CLINICAL COMMITTEE

EFFECTIVE DATE: 6/7/06

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

FRANK CHOPP

Speaker of the House of Representatives

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

BRAD OWEN

President of the Senate

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

CHRISTINE GREGOIRE

Governor of the State of Washington

CERTIFICATE

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

RICHARD NAFZIGER

Chief Clerk

FILED

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

**Secretary of State
State of Washington**

ENGROSSED SECOND SUBSTITUTE HOUSE BILL 2575

AS AMENDED BY THE SENATE

Passed Legislature - 2006 Regular Session

State of Washington 59th Legislature 2006 Regular Session

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

READ FIRST TIME 02/07/06.

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

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

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

12 (2) "Advisory group" means a group established under section
13 4(2)(c) of this act.

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

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

·1 (5) "Health technology" means medical and surgical devices and
2 procedures, medical equipment, and diagnostic tests. Health
3 technologies does not include prescription drugs governed by RCW
4 70.14.050.

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

8 (7) "Reimbursement determination" means a determination to provide
9 or deny reimbursement for a health technology included as a covered
10 benefit in a specific circumstance for an individual patient who is
11 eligible to receive health care services from the state purchased
12 health care program making the determination.

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

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

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

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

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

26 (2) Members of the committee:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

36 (2) For a health technology not selected for review under section
37 3 of this act, a participating agency may use its existing statutory

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

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

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

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

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

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

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

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

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

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

35 (c) Access to the systematic assessment completed under section

1 3(4) of this act, and reports completed under subsection (2) of this
2 section.

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

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

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

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

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

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

27 (d) Exploration of common strategies for disease management and
28 demand management programs, including asthma, diabetes, heart disease,
29 and similar common chronic diseases. Strategies to be explored include
30 individual asthma management plans. On January 1, 2007, and January 1,
31 2009, the authority shall issue a status report to the legislature
32 summarizing any results it attains in exploring and coordinating
33 strategies for asthma, diabetes, heart disease, and other chronic
34 diseases.

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

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

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

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

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

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

Passed by the House March 6, 2006.

Passed by the Senate March 3, 2006.

Approved by the Governor March 29, 2006, with the exception of
certain items that were vetoed.

Filed in Office of Secretary of State March 29, 2006.

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

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

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

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

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

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

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

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

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

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

COURT OF APPEALS
DIVISION II
11 JUL 29 PM 2:10
STATE OF WASHINGTON
BY
DEPUTY

BEFORE THE COURT OF APPEALS, DIVISION II
STATE OF WASHINGTON

CHERYL JOY,) Case No. 42118-6-II
Appellant/Plaintiff)
v.) Proof of Mailing
DEP'T OF LABOR & INDUS.,)
Respondant/Defendant.)

The undersigned states that on Wednesday, the 27th day July 2011, I deposited in the United States Mail, with proper postage prepaid, Brief of the Appellant/Plaintiff as attached, addressed as follows:

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Assistant Attorney General
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J. Scott Timmons
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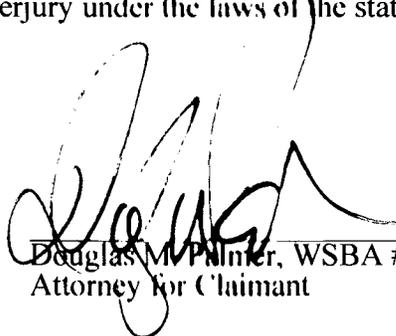
Director
Department of Labor and Industries
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Clerk of the Court
Court of Appeals, Division II
950 Broadway, Suite 300
Tacoma, WA 98402

I declare under penalty of perjury under the laws of the state of Washington that the foregoing is true and correct:

Dated: July 27, 2011.



Douglas M. Palmer, WSBA #35198
Attorney for Claimant