S-0985.2			

SENATE BILL 5619

State of Washington 60th Legislature 2007 Regular Session

By Senators Pflug, Keiser, Parlette, Marr, Weinstein, Fairley, Kastama, Kline and Kohl-Welles

Read first time 01/25/2007. Referred to Committee on Health & Long-Term Care.

- 1 AN ACT Relating to informed consent to health care; amending RCW
- 2 7.70.020, 7.70.040, 7.70.050, and 7.70.060; creating a new section; and
- 3 providing an effective date.

18

19

- 4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:
- 5 NEW SECTION. Sec. 1. (1) Our legal standard for informed consent must balance beneficence and respect for patient autonomy, should tip 6 in favor of autonomy in an equally balanced situation, 7 should strive 8 to protect patients' ability to obtain information and participate in treatment decision making, should permit health care providers to 9 10 present and support their medical opinions, as well as provide health care providers with a clear understanding of what other information 11 12 should be disclosed. Under such a standard, the health care providers should: (a) Provide the patient with unbiased information on the risk 13 and benefits of all treatment options; (b) give the patient the health 14 15 care provider's professional advice; (c) assist the patient in identifying the patient's own values; and (d) decide with the patient 16 which treatment choice is best. 17
 - (2) Shared decision making is a process in which the health care provider shares with the patient all relevant risk and benefit

p. 1 SB 5619

information on all treatment alternatives and the patient shares with the physician all relevant personal information that might make one treatment or side effect more or less tolerable than others. The goal of shared decision making is for the patient and physician to feel they fully understand the nature of the procedure, the risk and benefits, as well as the individual values and preferences that influence the treatment decision, such that both are willing to sign a statement of agreement that they both fully understand the treatment choice.

The legislature finds that shared decision making between providers and patients in the choice of health care treatments improves health outcomes, reduces medical errors, and better ensures the provision of cost-effective care. Although not all information is available with regard to all treatment options, all relevant and available treatment information must be shared with the patient to help with the patient's decision making. The legislature intends that a patient-oriented standard of disclosure means that the health care provider is required to engage in the process of shared decision making with the patient.

- (3) The legislature finds that widespread variation in medical practices and outcomes in seemingly similar populations has raised serious concerns about the quality of health care. The legislature further finds these variations also reflect inadequate appreciation for the importance of individual patients' well-informed preferences for care and subsequent health outcomes. The legislature finds that patient preference-sensitive care comprises treatments that involve significant trade-offs affecting the patient's quality and/or length of life. The legislature finds that decisions about these interventions ought to reflect patients' personal values and preferences, and ought to be made only after patients have enough information to make an informed choice. The legislature intends to empower patients and improve patient-centered decision quality.
- (4) The legislature finds that reasonable people may differ substantially on the amount and content of information they would find significant in deciding to undergo a specific treatment. The legislature finds that in order to ensure that patients have the information they require to make an informed patient choice, physicians should disclose all information that a reasonable person could consider significant in making a treatment decision.

SB 5619 p. 2

The legislature finds that one potential method for providing appropriate information to patients is via certified patient decision aids. Patient decision aids assist physicians to deliver: (a) High-quality, up-to-date information about the condition, including the risks and benefits of available options and, if appropriate, information on the limits of scientific knowledge about outcomes; (b) values clarification to help patients sort out their values and preferences, and (c) guidance or coaching in deliberation, designed to improve the patient's involvement in the decision process.

- (5) The legislature concludes that our state laws regarding informed consent must be modified to become more patient-oriented. The legislature believes that when patients are informed about treatment options and have reviewed patient information about their treatment, they are better able to choose and consent to or refuse a method of treatment. The legislature also finds that patients have a duty to be sure they understand the information they have been given, even if it means going over the information several times with their health care provider.
- **Sec. 2.** RCW 7.70.020 and 1995 c 323 s 3 are each amended to read 20 as follows:
- 21 (1) As used in this chapter "health care provider" means either:
 - $((\frac{1}{1}))$ (a) A person licensed by this state to provide health care or related services, including, but not limited to, a licensed acupuncturist, a physician, osteopathic physician, dentist, nurse, optometrist, podiatric physician and surgeon, chiropractor, physical therapist, psychologist, pharmacist, optician, physician($(\frac{1}{1})$) assistant, midwife, osteopathic physician's assistant, nurse practitioner, or physician's trained mobile intensive care paramedic, including, in the event such person is deceased, his or her estate or personal representative;
 - $((\frac{(2)}{(2)}))$ (b) An employee or agent of a person described in $(\frac{(part)}{(1) \text{ above}})$ (a) of this subsection, acting in the course and scope of his or her employment, including, in the event such employee or agent is deceased, his or her estate or personal representative; or
 - $((\frac{3}{2}))$ (c) An entity, whether or not incorporated, facility, or institution employing one or more persons described in $(\frac{part}{2})$ (a) of this subsection, including, but not limited to, a

p. 3 SB 5619

hospital, clinic, health maintenance organization, or nursing home; or an officer, director, employee, or agent thereof acting in the course and scope of his or her employment, including in the event such officer, director, employee, or agent is deceased, his or her estate or personal representative.

- (2) "Patient decision aid" means: (a) High-quality, up-to-date information about the condition, including risk and benefits of available options and, if appropriate, a discussion of the limits of scientific knowledge about outcomes; (b) values clarification to help patients sort out their values and preferences; and (c) guidance or coaching in deliberation, designed to improve the patient's involvement in the decision process. The patient decision aid must be credentialed by a national credentialing organization approved by the health care authority upon a demonstration that it is competently developed; that it provides a balanced presentation of treatment options benefits and harms; and that the patient decision aid is efficacious at improving decision making through a rigorous evaluation process.
- (3) "Shared decision making" means a process in which the physician discloses to the patient the risks and benefits associated with all treatment alternatives, including no treatment, that a reasonable person in the patient's situation could consider significant in selecting a particular path of medical care. The patient then shares with the physician all relevant personal information that might make one treatment or side effect more or less desirable than others.
- **Sec. 3.** RCW 7.70.040 and 1983 c 149 s 2 are each amended to read as follows:

The following shall be necessary elements of proof that injury resulted from the failure of the health care provider to follow the accepted standard of care:

- (1)(a) The health care provider failed to exercise that degree of care, skill, and learning expected of a reasonably prudent health care provider at that time in the profession or class to which he or she belongs, in the state of Washington, acting in the same or similar circumstances; and
- $((\frac{2}{2}))$ Such failure was a proximate cause of the injury 36 complained of: or

SB 5619 p. 4

- 1 (2)(a) The health care provider failed to engage in shared decision 2 making with the patient; and
 - (b) Such failure was the proximate cause of the injury.

3

6

7

8

9

10

13

1415

16

17

20

21

22

2324

2526

2728

31

32

33

34

35

36

- 4 **Sec. 4.** RCW 7.70.050 and 1975-'76 2nd ex.s. c 56 s 10 are each 5 amended to read as follows:
 - (1) The following shall be necessary elements of proof that injury resulted from health care in a civil negligence case or arbitration involving the issue of the alleged breach of the duty to secure an informed consent by a patient or his <u>or her</u> representatives against a health care provider:
- 11 (a) That the health care provider failed to inform the patient of 12 a ((material)) relevant fact or facts relating to the treatment;
 - (b) That the patient consented to the treatment without being aware of or fully informed of such ((material)) relevant fact or facts;
 - (c) That ((a reasonably prudent)) the patient ((under similar circumstances)) would not have consented to the treatment if informed of such ((material)) relevant fact or facts;
- 18 (d) That the treatment in question proximately caused injury to the patient.
 - (2) Under the provisions of this section a fact is defined as or considered to be a ((material)) relevant fact, if a reasonably prudent person in the position of the patient or his or her representative ((would)) could attach significance to it deciding whether or not to submit to the proposed treatment.
 - (3) ((Material)) Relevant facts under the provisions of this section which must be established by expert testimony shall be either:
 - (a) The nature and character of the treatment proposed and administered;
- 29 (b) The anticipated results of the treatment proposed and 30 administered;
 - (c) The recognized possible alternative forms of treatment; or
 - (d) The recognized serious possible risks, complications, and anticipated benefits involved in the treatment administered and in the recognized possible alternative forms of treatment, including nontreatment.
 - (4) If a recognized health care emergency exists and the patient is

p. 5 SB 5619

- not legally competent to give an informed consent and/or a person 1
- 2 legally authorized to consent on behalf of the patient is not readily
- 3 available, his or her consent to required treatment will be implied.
- **Sec. 5.** RCW 7.70.060 and 1975-'76 2nd ex.s. c 56 s 11 are each 4 5 amended to read as follows:
- 6 (1) Once the patient: (a) Understands the risk or seriousness of the disease or condition to be prevented; (b) understands the available 7 treatment alternatives, including the risks, benefits, and 8 uncertainties; and (c) has weighted his or her values regarding the 9
- potential benefits and harms associated with the services, then the 10
- 11 patient may engage in the treatment decision-making process at a level
- 12 he or she feels appropriate and select a final treatment plan.
- 13 (2) Both the physician and the patient must sign an informed consent form that sets forth that: (a) The patient and the physician 14
- engaged in shared decision making; (b) the patient acknowledges receipt 15
- of risk and benefit information on all treatment alternatives; (c) the 16
- patient has had the opportunity to ask questions and receive additional 17
- information; and (d) the patient and physician have agreed upon the 18
- <u>listed treatment option</u>. 19
- 20 (3) If a patient while legally competent, or his or her 21 representative if he or she is not competent, signs a consent form after participating in shared decision making in conjunction with the 22 23 use of a patient decision aid which sets forth the following, the 24 signed consent form shall constitute prima facie evidence that the
- patient gave his or her informed consent to the treatment administered 25
- 26 and the patient has the burden of rebutting this by a preponderance of
- 27 the evidence:
- (((1))) (a) A description, in language the patient could reasonably 28
- 29 be expected to understand, of:
- 30 $((\frac{a}{a}))$ (i) The diagnosis;
- (ii) The seriousness of the diagnosis; 31
- 32 (iii) The nature and character of ((the proposed)) methods of 33 treatment that were recommended;
- 34 (((b) The anticipated results of the proposed treatment;
- 35 (c))) (iv) The other recognized ((possible alternative forms of))
- 36 treatment options, including nontreatment; ((and

SB 5619 p. 6

1	(d))) (v) The benefits of the recommended and alternative				
2	treatments, including nontreatment;				
3	$\underline{\text{(vi)}}$ The recognized $((\frac{\text{serious possible}}{\text{possible}}))$ risks $((\frac{1}{7}))$ and				
4	complications((, and anticipated benefits involved in the treatment and				
5	in the recognized possible)) of the recommended and alternative ((forms				
6	of treatment, including nontreatment)) treatments;				
7	(vii) The discomforts associated with the treatments;				
8	(viii) The methods that will be used to prevent or relieve these				
9	discomforts;				
10	(ix) The recognized side effects of the treatment - immediate,				
11	short term, and long term;				
12	(x) The impact treatment, or not having treatment, will have on				
13	normal functions and activities;				
14	(xi) Length of treatment;				
15	(xii) Length of time before resumption of normal activities; and				
16	(xiii) Cost of treatment;				
17	$((\frac{(2)}{(2)}))$ Or as an alternative, a statement that the patient				
18	elects not to be informed of the elements set forth in (a) of this				
19	subsection $((\frac{1)}{1})$ of this section)).				
20	$\underline{(4)}$ Failure to use a form shall not be admissible as evidence of				
21	failure to obtain informed consent.				
22	NEW SECTION. Sec. 6. (1) This act takes effect January 1, 2009.				
23	(2) The health care authority may take steps before the effective				
24	date of this act to select and approve a patient decision aid so that				

it is available on the effective date of this act.

--- END ---

25

p. 7 SB 5619