S-1578.5		

SUBSTITUTE SENATE BILL 5619

State of Washington 60th Legislature 2007 Regular Session

By Senate Committee on Health & Long-Term Care (originally sponsored by Senators Pflug, Keiser, Parlette, Marr, Weinstein, Fairley, Kastama, Kline and Kohl-Welles)

READ FIRST TIME 02/22/07.

- AN ACT Relating to modifying unwarranted variation in health care; amending RCW 7.70.060; creating new sections; providing an effective date; and declaring an emergency.
- 4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:
- 5 NEW SECTION. Sec. 1. The legislature finds that unwarranted 6 variations in health care, variations not explained by illness, patient preference, or the dictates of evidence-based medicine, 7 are 8 significant feature of health care in Washington state. There is growing evidence that, for preference-sensitive care involving elective 9 10 surgery, the quality of patient-practitioner communication about the benefits, harms, and uncertainty of available treatment options can be 11 12 improved by introducing high-quality decision aids that encourage shared decision making. The international patient decision aid 13 standards collaboration, a network of over one hundred researchers, 14 practitioners, patients, and policy makers from fourteen countries, 15 have developed standards for constructing high-quality decision aids. 16 The legislature declares an intent to focus on improving the quality of 17 patient-practitioner communication and on increasing the extent to 18 19 which patients make genuinely informed, preference-based treatment

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decisions. Randomized clinical trial evidence indicates that effective 1 2 use of well designed decision aids is likely to improve the quality of patient decision making, reduce unwarranted variations in health care, 3 and result in lower health care costs overall. Despite this growing 4 5 body of evidence, widespread use of decision aids has yet to occur. Barriers include: (1) Lack of awareness of existing, appropriate, 6 7 high-quality decision aids; (2) poor accessibility to such decision aids; (3) low practitioner acceptance of decision aids in terms of 8 compatibility with their practice, ease of use, and expense to 9 10 incorporate into practice; (4) lack of incentives for use, such as reduced liability and reimbursement for their use; and (5) lack of a 11 12 process to certify that a decision aid meets the standards required of 13 a high-quality decision aid. The legislature intends to promote new public/private collaborative efforts to broaden the development, use, 14 evaluation, and certification of effective decision aids and intends to 15 support the collaborative through providing new recognition of the 16 17 shared decision-making process and patient decision aids in the state's laws on informed consent. The legislature also intends to establish a 18 process for certifying that a given decision aid meets the standards 19 20 required for a high-quality decision aid.

NEW SECTION. Sec. 2. The state health care authority shall work in collaboration with the health professions and quality improvement communities to increase awareness of appropriate, high-quality decision aids, and to train physicians and other practitioners in their use. The effort shall focus on one or more of the preference-sensitive conditions with high rates of unwarranted variation in Washington, and can include strategies such as prominent linkage to such decision aids in state web sites, and training/awareness programs in conjunction with professional and quality improvement groups. The state health care authority shall, in consultation with the national committee for quality assurance, identify a certification process for patient decision aids. The state health care authority may accept donations or grants to support such efforts.

NEW SECTION. Sec. 3. The state health care authority shall work with contracting health carriers and health care providers, and a nonproprietary public interest research group and/or university-based

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research group, to implement practical and usable models to demonstrate 1 2 shared decision making in everyday clinical practice. demonstrations shall be conducted at one or more multispecialty group 3 practice sites providing state purchased health care in the state of 4 Washington, and may include other practice sites providing state 5 purchased health care. The demonstrations must include the following 6 7 elements: Incorporation into clinical practice of one or more decision aids for one or more identified preference-sensitive care areas 8 combined with ongoing training and support of involved practitioners 9 10 and practice teams, preferably at sites with necessary supportive health information technology. The evaluation must include the 11 12 following elements: (1) A comparison between the demonstration sites 13 and, if appropriate, between the demonstration sites and a control 14 group, of the impact of the shared decision-making process employing the decision aids on: The use of preference-sensitive health care 15 services; and associated costs saved and/or expended; and (2) an 16 assessment of patient knowledge of the relevant health care choices, 17 benefits, harms, and uncertainties; concordance between patient values 18 and care received; and satisfaction with the decision-making process 19 and their health outcomes by patients and involved physicians and other 20 21 health care practitioners. The health care authority may solicit and 22 accept funding to support the demonstration and evaluation.

23 **Sec. 4.** RCW 7.70.060 and 1975-'76 2nd ex.s. c 56 s 11 are each 24 amended to read as follows:

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- (1) If a patient while legally competent, or his <u>or her</u> representative if he <u>or she</u> is not competent, signs a consent form which sets forth the following, the signed consent form shall constitute prima facie evidence that the patient gave his <u>or her</u> informed consent to the treatment administered and the patient has the burden of rebutting this by a preponderance of the evidence:
- 31 $((\frac{1}{1}))$ (a) A description, in language the patient could reasonably 32 be expected to understand, of:
- 33 $((\frac{a}{a}))$ (i) The nature and character of the proposed treatment;
- (((b))) (ii) The anticipated results of the proposed treatment;
- 35 (((+c))) (iii) The recognized possible alternative forms of 36 treatment; and

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(((d))) <u>(iv)</u> The recognized serious possible risks, complications, and anticipated benefits involved in the treatment and in the recognized possible alternative forms of treatment, including nontreatment;

- $((\frac{(2)}{(2)}))$ Or as an alternative, a statement that the patient elects not to be informed of the elements set forth in (a) of this subsection $((\frac{(1)}{(1)})$ of this section).
- (2) If a patient while legally competent, or his or her representative if he or she is not competent, signs an acknowledgement of shared decision making as described in subsection (3) of this section, such acknowledgement shall constitute prima facie evidence that the patient gave his or her informed consent to the treatment administered and the patient has the burden of rebutting this by clear and convincing evidence. An acknowledgement of shared decision making shall include:
- (a) A statement that the patient, or his or her representative, and the health care provider have engaged in shared decision making as an alternative means of meeting the informed consent requirements set forth by laws, accreditation standards, and other mandates;
- (b) A brief description of the services that the patient and provider jointly have agreed will be furnished;
 - (c) A brief description of the patient decision aid or aids that have been used by the patient and provider to address the needs for (i) 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; (ii) values clarification to help patients sort out their values and preferences; and (iii) guidance or coaching in deliberation, designed to improve the patient's involvement in the decision process;
 - (d) A statement that the patient or his or her representative understands: The risk or seriousness of the disease or condition to be prevented or treated; the available treatment alternatives, including nontreatment; and the risks, benefits, and uncertainties of the treatment alternatives, including nontreatment; and
- (e) A statement certifying that the patient or his or her representative has had the opportunity to ask the provider questions, and to have any questions answered to the patient's satisfaction, and indicating the patient's intent to receive the identified services.

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(3) "Shared decision making" means a process in which the physician or other health care practitioner discusses with the patient or his or her representative the information specified in subsection (1)(a) of this section, with or without the use of a patient decision aid, and the patient shares with the provider such relevant personal information as 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 or other health care practitioner to feel they appropriately understand the nature of the procedure, the risks and benefits, as well as the individual values and preferences that influence the treatment decision, such that both are willing to sign a statement acknowledging that they have engaged in shared decision making and setting forth the agreed treatment to be furnished.

(4) "Patient decision aid" means a written, audio-visual, or online tool that provides a balanced presentation of the condition and treatment options, benefits, and harms, including, if appropriate, a discussion of the limits of scientific knowledge about outcomes, and that is certified by one or more national certifying organizations approved by the health care authority. In order to be an approved national certifying organization, an organization must use a rigorous evaluation process to assure that decision aids are competently developed, provide a balanced presentation of treatment options, benefits, and harms, and are efficacious at improving decision making.

(5) Failure to use a form or to engage in shared decision making, with or without the use of a patient decision aid, shall not be admissible as evidence of failure to obtain informed consent. There shall be no liability, civil or otherwise, resulting from a health care provider choosing either the signed consent form set forth in subsection (1)(a) of this section or the signed acknowledgement of shared decision making as set forth in subsection (2) of this section.

<u>NEW SECTION.</u> **Sec. 5.** This act is necessary for the immediate preservation of the public peace, health, or safety, or support of the state government and its existing public institutions, and takes effect July 1, 2007.

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