H-4268.1

HOUSE BILL 2969

State of Washington 59th Legislature 2006 Regular Session

By Representatives Hinkle and Anderson

Read first time 01/17/2006. Referred to Committee on Health Care.

AN ACT Relating to evidence-based medicine; and adding a new chapter to Title 70 RCW.

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

NEW SECTION. **Sec. 1.** The legislature finds that individuals in state purchased health care programs need assurance that they will have access to the medically necessary care ordered by their physician. The best available clinical evidence should be used by the state to give patients access to medically necessary care in a cost-effective manner. Decisions for broad patient populations made by the state must not jeopardize the ability of the physician and patient to choose the medical items and services that best meet the needs of the individual. The state must use open, transparent decision-making processes to ensure individuals in state purchased health care programs have access to medically necessary care. The state has significant opportunities to improve the quality of health care received by citizens enrolled in state purchased health care programs. Quality improvement is a prerequisite for achieving more efficient utilization of health care and control of state health expenditures; improving patient access to medically necessary care in a cost-effective manner is an important

priority for the state. The state should use available, valid evidence to improve access to needed medicines and other health care items and services and improve the quality of care received by individuals in state purchased health care programs.

NEW SECTION. **Sec. 2.** The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "Evidence report" means any document assembled as a result of a systematic review of all evidence deemed relevant to a particular health care question or decision.

(2) "Guidelines" means clinical practice guidelines that are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.

(3) "Relevant evidence" means the entire body of available clinical, humanistic, and economic evidence that is considered by trained health care analysts as being scientifically valid and applicable to both real world medical practice patterns as well as to the target patient groups for which the product or service is being considered. This relevant body of evidence may include evidence from randomized clinical trials, meta-analyses, observational studies, and economic or epidemiologic models.

(4) "Systematic review" means an unbiased, comprehensive analysis of all evidence deemed relevant to a particular health care decision.

NEW SECTION. **Sec. 3.** The state shall ensure that there is broad and ongoing consultation with the public regarding its use of evidence, including its development and use of evidence reports, in making decisions related to coverage or payment for health care items and services. The consultation must include adequate public notice of proposed and final decisions, adequate explanation of the reasons for and evidence relied on in proposing and finalizing decisions, and adequate opportunity for input from the public, including input from patients and medical experts, including physicians licensed and practicing in the state and specializing in the treatment of the condition that is the subject of a report, on proposed and final decisions. The public consultation must include:

(1)(a) Review by an advisory committee: A medical quality advisory committee consists of members appointed by the governor and the legislature. For review of individual evidence reports, the state shall empanel members of the advisory committee as an advisory panel with nine members possessing expertise in the clinical area or areas represented in the report. Input from state medical and specialty organizations must be considered when empaneling experts. No specialist may be specifically excluded because of the nature or funding source of ongoing or previously conducted research, provided any and all conflicts are disclosed consistent with the manner described in section 505(n)(4) of the federal food, drug, and cosmetic act, and 18 U.S.C. Sec. 208. In the case of evidence reports on pharmaceuticals, five members must be physicians, licensed under chapter 18.71 RCW and four members must be pharmacists licensed under chapter 18.64 RCW. The members must be appointed to serve for terms of two years from the date of their appointment. Members may be appointed to more than one term. The health care authority shall serve as staff for the committee and assist them in their duties.

(b) The state shall ensure that a majority of advisory committee members possess experience evaluating the medical, pharmacology, and therapeutics literature and in treating the medical conditions for which evidence reports are prepared. The medical quality advisory committee shall take into consideration the unique characteristics and needs of relevant patient populations within the state when reviewing such reports. All evidence reports created or purchased must be reviewed and approved by the committee in order for the state to finalize and use them. In approving or rejecting a report for use by the state, the medical quality advisory committee shall consider and describe specific aspects of the report including methodology of data analysis, data collection, and strength and use of evidence.

(2) Open and public procedures. In establishing such open, public procedures, the state shall adhere to the open public meetings act, chapter 42.30 RCW, and provide at least thirty days' notice and adequate opportunity to comment on proposed questions to be addressed in evidence reports prior to initiation of their development.

(3) Open public meetings with thirty days' advance notice to the public must be held by the state on evidence reports that have been developed or purchased by the state. At the meetings, the state shall

provide a description of the methods used in developing the reports, the patient population studied, the intended use or uses of the reports, and the potential effect on the quality and efficiency of health care.

(4) Finalization of reports: No evidence report developed or purchased by the state may be considered final and available for use in the state until notice of at least thirty days and meetings have been held. In order to finalize evidence reports, the state shall announce through appropriate means, subsequent to the public meeting, availability of the evidence reports. The announcement must provide an adequate opportunity for public comment on evidence reports and their proposed use by the state. The state shall then publish the evidence report in final form taking into account input received on the report.

(5) Announcement of proposed decisions. In making coverage or payment decisions that make use of evidence reports or other relevant evidence as described in this section, the state shall announce proposed decisions to the public and provide a period of sixty days for public comment. The proposed decisions must describe the rationale, the evidence used, the methods employed in analyzing the evidence, and how different types of evidence were used in the proposed decision.

NEW SECTION. **Sec. 4.** (1) An evidence report must be used by the state for the purposes of improving health care quality, effectiveness, and efficiency. In making use of evidence reports, the state shall describe how the information will be used and how such use will improve health care quality, effectiveness, and efficiency.

(2) The state shall consider a broad range of evidence to improve the quality and appropriateness of health care. The state shall not specifically exclude nor consider any evidence report that specifically excludes any relevant evidence. The state shall make a good faith effort to identify, locate, and review all available evidence reports, including those that may be prepared by public stakeholders affected by the evidence reports.

(3) All reports considered and used by the state must be made available upon request to physicians, providers, patients, and other members of the public to improve health care decision making. To the extent that reports include confidential or proprietary data provided by manufacturers of other stakeholders, such data may not be disclosed

by a state agency, or contractor therewith, in a form that discloses the identity of the entity providing the data or the confidential or proprietary data. The data must be provided in a summary form that does not disclose confidential or proprietary information.

(4) Any evidence reports developed, purchased, or used by the state must: (a) Address a disease or condition that imposes a significant health burden on state purchased health care programs; (b) address health items or services for which utilization data or other information indicates a pattern of poor care or inappropriate utilization, including underuse, overuse, or misuse of items or services for the specified disease or condition; (c) provide a statement discussing both the strengths and limitations of the report's conclusions, including the strength of the evidence considered in the review and degree of uncertainty in the review results, the applicability of the review findings to individuals in state purchased health care programs, and the potential benefits and harm on the quality and efficiency of health care for the patients being served by the intervention/product; and (d) undergo review and approval by the medical quality advisory committee and reflect input received from the advisory committee and other members of the public. The description of the methods used should be inclusive enough that a member of the public wishing to replicate the review would have enough information to follow the same process and arrive at the same conclusion.

(5) An evidence report must demonstrate the clinical superiority of one item or service compared to alternatives in order for the state to use the evidence report as the basis for determinations regarding the relative effectiveness of alternative interventions. In the absence of such evidence, the state shall not use the evidence report to make determinations regarding the relative effectiveness of alternative interventions.

(6) Notwithstanding the findings of any evidence report, an individual enrolled in a state purchased health care program for whom coverage or payment is limited under this section shall have access to applicable appeal and hearing rights as afforded to them under state and federal laws.

(7) In using evidence reports, the state shall base decisions that affect payment or coverage of affected items, services, or modes of delivery on the strength of scientific evidence and on expert medical

opinion, including peer-reviewed medical literature such as randomized clinical trials, observational studies, health economics studies, medical consensus, and input from physicians, patients, and others received during public meetings and report finalization and such other information as deemed appropriate.

(8) A legislative oversight committee shall review and report at least yearly on the impact of evidence reports on patient access, treatment quality, and overall health care costs.

NEW SECTION. **Sec. 5.** Sections 1 through 4 of this act constitute a new chapter in Title 70 RCW.

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