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HOUSE BILL NO. 306

Offered January 13, 2010

Prefiled January 11, 2010

A BILL to amend the Code of Virginia by adding in Article 2 of Chapter 21.1 of Title 8.01 a section numbered 8.01-581.20:2, relating to disclosure of adverse medical outcomes; pilot program.

Patron—O'Bannon

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Article 2 of Chapter 21.1 of Title 8.01 a section numbered 8.01-581.20:2 as follows:

§ 8.01-581.20:2. Disclosure; pilot program.

A. For purposes of this section:

"Adverse medical outcome" means an outcome of health care that involves death or injury to the patient, irrespective or whether the adverse medical outcome was caused by a medical error, unreasonable care, or other factor.

"Commissioner" means the State Health Commissioner.

"Department" means the Department of Health.

"Disclosure" means communications from or to health care providers, their agents, or representatives in preparation for, execution of, or conclusion of a disclosure program involving an adverse medical outcome. As used in this section, communications shall include oral or written statements, recordings, or documentation prepared for use in a disclosure program under this section about an adverse medical outcome, its known or suspected cause, its impact on patient safety and health care providers, and actions taken to remediate the known or suspected cause, together with statements of admission.

"Disclosure program" means a specific policy and implementing protocols established within a health care facility under this section pursuant to guidelines promulgated by the Department, and designed to facilitate disclosures by health care providers, including independent medical staff, to patients and their representatives, and the conduct of a resolution process in the event of an adverse medical outcome.

"Health care" shall have the same meaning as in § 8.01-581.1.

"Health care facility" shall mean any health care provider licensed by the Board of Health under Article 1 (§ 32.1-123 et seq.) of Chapter 5 of Title 32.1, or any hospital owned or operated by an agency of the Commonwealth but exempt from licensure under § 32.1-124.

"Health care provider" shall have the same meaning as in § 8.01-581.1.

"Medical error" means a failure, in the course of provision of health care, of a planned action to be carried out as intended or use of a wrong plan to achieve an aim regardless of whether such error was a result of unreasonable care.

"Representative" means a legal guardian, attorney, or other person legally authorized to make decisions on behalf of a patient, or any person authorized by the patient to receive disclosure under the disclosure program.

"Resolution process" means a negotiation, mediation, or other voluntary process for resolving issues, including possible compensation, following an adverse medical outcome that is offered by a health care provider as part of a disclosure program, and that includes advising the patient of his right to counsel and his right to withdraw from the resolution process prior to its conclusion, and provides a reasonable period of time, in no event less than one week from the date such a process is offered, for a patient to consider whether to participate in a resolution process. The confidentiality terms of any resolution process employed by the facility and the patient or his representative, and the process for withdrawing from the resolution process, shall be specified in writing in the agreement to commence the resolution process.

"Unreasonable care" means health care that departs from accepted standards of medical practice.

B. A pilot program is hereby established under the oversight of the Commissioner within which the Department may authorize the creation and operation of disclosure programs by eligible health care facilities that have applied to participate in the pilot program.

C. Health care facilities selected by the Commissioner to participate in the pilot disclosure program shall, at a minimum, implement protocols of the health care facility's own design as approved by its governing body and consistent with the requirements of this section to: (i) facilitate compliance with ethical and regulatory mandates; (ii) facilitate accurate, timely, and complete communications, as known at the time of communication, with the patient or his representative about the patient's conditions, what

happened, how it happened, the patient's prognosis, and implications for future health care; (iii) evaluate and implement ways to avoid repetition of the adverse medical outcome to improve patient safety and encourage quality improvement; (iv) provide access to a pre-claim resolution process for achieving fair compensation for the patient in cases where the facility deems it appropriate; and (v) assess and report to the Department the benefits and costs of the disclosure program and the basis for the assessment.

D. The Department shall adopt guidelines to implement the pilot program, including (i) a process for application to the Commissioner to participate in the pilot program, including applicable fees and criteria for selection by the Commissioner, and (ii) standards for the implementation of the disclosure programs under this section, including resolution processes and the timing and substance of reports to the Commissioner on the benefits and costs of the disclosure programs required under subsection C. The Department shall have the discretion to close the application period for participation in the pilot program when the number of participants reaches the limit of the Department's ability to administer the pilot program, so long as diversity of geographic area and type of health care facility is not compromised by any such limitation. After consultation with the Board of Medicine, hospitals, other health care providers, interested bar associations, and other interested parties, the Department shall adopt its guidelines for the pilot program no later than September 30, 2010, and shall report on such to the Joint Commission on Health Care by October 31, 2010.

E. No person or liability insurer shall retaliate or discriminate against a health care provider who participates in the pilot program. Participation in such program shall not constitute a violation of an insured's duty to cooperate or constitute a failure to act in good faith under the terms of a liability insurance policy.

F. Reports to the Board of Medicine involving a licensee engaged in a disclosure program shall be made by the persons or entities set forth in §§ 54.1-2400.6, 54.1-2400.7, 54.1-2908, 54.1-2909, and 54.1-2910.1. Upon receipt of a required report or complaint, the Board shall review the report or complaint to determine if the licensee's continued practice constitutes a substantial danger to the public that warrants summary suspension. In the event that summary suspension is not warranted, the Board shall not initiate administrative proceedings until the disclosure and resolution processes regarding the subject of the report or complaint are concluded, provided the licensee or his designee reports to the Board at least monthly the status of the participation in the disclosure program under this section. Reports to the Board, including status reports, shall not constitute a waiver of any privilege, shall not be discoverable in any civil action and shall be deemed confidential pursuant to § 54.1-2400.2.

G. The following shall be privileged and inadmissible in a civil action, administrative action, or arbitration arising from an adverse medical outcome: (i) an offer to participate in a disclosure program or actual participation therein; (ii) a disclosure made as part of a disclosure program; and (iii) an offer of resolution, including compensation, made during a disclosure program. No disclosure made outside of a disclosure program by a health care provider, a patient, or a representative of a health care provider or patient shall be privileged or inadmissible under this section. This section shall not be construed to limit access to facts or information that is otherwise discoverable.

H. The provision of this section shall expire on December 31, 2015. However, any privileged disclosures made on or before the expiration of this section shall remain privileged. The Department shall report to the Joint Commission on Health Care annually on the effectiveness and value of the disclosure programs authorized under this section.

I. This section shall not affect or apply to disclosure programs and resolution processes undertaken outside of the disclosure programs implemented pursuant to this section.