Senate Bill 236

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SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure **as introduced.**

Makes participation in Oregon Patient Safety Reporting Program mandatory for hospitals and ambulatory surgical centers.

A BILL FOR AN ACT

Relating to patient safety reporting; amending ORS 442.819, 442.820, 442.831, 442.837, 442.846 and 442.850.

Be It Enacted by the People of the State of Oregon:

SECTION 1. ORS 442.819 is amended to read:

442.819. As used in ORS 442.819 to 442.851:

(1) "Participant" means an entity that reports patient safety data to the Oregon Patient Safety Reporting Program, and any agent, employee, consultant, representative, volunteer or medical staff member of the entity.

(2) "Patient safety activities" includes but is not limited to:

(a) The collection and analysis of patient safety data by a participant;

(b) The collection and analysis of patient safety data by the Oregon Patient Safety Commission established in ORS 442.820;

(c) The utilization of patient safety data by participants;

(d) The utilization of patient safety data by the Oregon Patient Safety Commission to improve the quality of care with respect to patient safety and to provide assistance to health care providers to minimize patient risk; and

(e) Oral and written communication regarding patient safety data among two or more participants with the intent of making a disclosure to or preparing a report to be submitted to the patient safety reporting program.

(3) "Patient safety data" means oral communication or written reports, data, records, memoranda, analyses, deliberative work, statements, root cause analyses or action plans that are collected or developed to improve patient safety or health care quality that:

(a) Are prepared by a participant for the purpose of reporting patient safety data [*voluntarily*] to the patient safety reporting program, or that are communicated among two or more participants with the intent of making a disclosure to or preparing a report to be submitted to the patient safety reporting program;

(b) Are collected or prepared by a patient safety organization certified by the United States Department of Health and Human Services under 42 U.S.C. 299b-24; or

(c) Are created by or at the direction of the patient safety reporting program, including com-

NOTE: Matter in **boldfaced** type in an amended section is new; matter [*italic and bracketed*] is existing law to be omitted. New sections are in **boldfaced** type.

munication, reports, notes or records created in the course of an investigation undertaken at the direction of the Oregon Patient Safety Commission.

(4) "Patient safety reporting program" means the Oregon Patient Safety Reporting Program created in ORS 442.837.

(5) "Serious adverse event" means an objective and definable negative consequence of patient care, or the risk thereof, that is unanticipated, usually preventable and results in, or presents a significant risk of, patient death or serious physical injury.

SECTION 2. ORS 442.820 is amended to read:

442.820. (1) The Oregon Patient Safety Commission is established as a semi-independent state agency subject to ORS 182.456 to 182.472. The commission shall exercise and carry out all powers, rights and privileges that are expressly conferred upon it, are implied by law or are incident to such powers.

(2) The mission of the commission is to improve patient safety by reducing the risk of serious adverse events occurring in Oregon's health care system and by encouraging a culture of patient safety in Oregon. To accomplish this mission, the commission shall:

(a) Establish a confidential[*, voluntary*] serious adverse event reporting system to identify serious adverse events;

(b) Establish quality improvement techniques to reduce systems' errors contributing to serious adverse events; and

(c) Disseminate evidence-based prevention practices to improve patient outcomes.

(3) ORS 192.410 to 192.505 do not apply to public records created or maintained by the commission that contain patient safety data or to reports obtained by the program.

(4) ORS 192.610 to 192.690 do not apply to portions of a meeting of the Oregon Patient Safety Commission Board of Directors, or subcommittees or advisory committees established by the board, to consider information that identifies a participant or patient and the written minutes of that portion of the meeting.

(5) Notwithstanding ORS 182.460, ORS 293.250 applies to the commission for the purpose of collecting unpaid fees established under ORS 442.850 that are owed to the commission and are past due.

SECTION 3. ORS 442.831 is amended to read:

442.831. (1) Except as otherwise provided in ORS 442.819 to 442.851, the Oregon Patient Safety Commission Board of Directors, or officials of the Oregon Patient Safety Commission acting under the authority of the board, shall exercise all the powers of the commission and shall govern the commission. The board shall adopt rules necessary for the implementation of the Oregon Patient Safety Reporting Program, including but not limited to:

(a) Developing a list of objective and definable serious adverse events to be reported by participants. In developing this list, the board shall consider similar lists developed in other states and nationally. The board may change the list from time to time. The first list developed by the board shall focus on serious adverse events that caused death or serious physical injury. Later lists may include, in the discretion of the board, serious adverse events that did not cause death or serious physical injury but posed a significant risk of death or a risk of significant physical injury.

(b) Developing a budget.

(c) Establishing a process to seek grants and other funding from federal and other sources.

(d) Establishing a method to determine participant fees, if necessary.

(e) Establishing auditing and oversight procedures, including a process to:

(A) Assess completeness of reports from participants;

(B) Assess credibility and thoroughness of root cause analyses submitted to the program;

(C) Assess the acceptability of action plans and participant follow-up on the action plan; and

(D) Obtain certification by the Public Health Officer on the completeness, credibility, thoroughness and acceptability of participant reports, root cause analyses and action plans.

(f) Establishing criteria for terminating a **voluntary** participant from the program. Incomplete reporting, failure to comply with ORS 442.837 [*(4)*] **(5)** or failure to adequately implement an action plan are grounds for termination from the program.

(2) The board may not use or disclose patient safety data reported, collected or developed pursuant to ORS 442.819 to 442.851 for purposes of any enforcement or regulatory action in relation to a participant.

(3) The board shall maintain the confidentiality of all patient safety data that identifies or could be reasonably used to identify a participant or an individual who is receiving or has received health care from the participant.

SECTION 4. ORS 442.837 is amended to read:

442.837. (1) The Oregon Patient Safety Reporting Program is created in the Oregon Patient Safety Commission to develop a serious adverse event reporting system. The program shall include but is not limited to:

(a) Reporting by participants, in a timely manner and in the form determined by the Oregon Patient Safety Commission Board of Directors established in ORS 442.830, of the following:

(A) Serious adverse events;

(B) Root cause analyses of serious adverse events;

(C) Action plans established to prevent similar serious adverse events; and

(D) Patient safety plans establishing procedures and protocols.

(b) Analyzing reported serious adverse events, root cause analyses and action plans to develop and disseminate information to improve the quality of care with respect to patient safety. This information shall be made available to participants and shall include but is not limited to:

(A) Statistical analyses;

(B) Recommendations regarding quality improvement techniques;

(C) Recommendations regarding standard protocols; and

(D) Recommendations regarding best patient safety practices.

(c) Providing technical assistance to participants, including but not limited to recommendations and advice regarding methodology, communication, dissemination of information, data collection, security and confidentiality.

(d) Auditing participant reporting to assess the level of reporting of serious adverse events, root cause analyses and action plans.

(e) Overseeing action plans to assess whether participants are taking sufficient steps to prevent the occurrence of serious adverse events.

(f) Creating incentives to improve and reward participation, including but not limited to providing:

(A) Feedback to participants; and

(B) Rewards and recognition to participants.

(g) Distributing written reports using aggregate, de-identified data from the program to describe statewide serious adverse event patterns and maintaining a website to facilitate public access to reports, as well as a list of names of participants. The reports shall include but are not limited to:

(A) The types and frequencies of serious adverse events;

(B) Yearly serious adverse event totals and trends;

(C) Clusters of serious adverse events;

(D) Demographics of patients involved in serious adverse events, including the frequency and types of serious adverse events associated with language barriers or ethnicity;

(E) Systems' factors associated with particular serious adverse events;

(F) Interventions to prevent frequent or high severity serious adverse events;

(G) Analyses of statewide patient safety data in Oregon and comparisons of that data to national patient safety data; and

(H) Appropriate consumer information regarding prevention of serious adverse events.

(2) Participation in the program is voluntary[.] **for** the following entities [*are eligible to participate*]:

[*(a) Hospitals as defined in ORS 442.015;*]

[*(b)*] **(a)** Long term care facilities as defined in ORS 442.015;

[*(c)*] **(b)** Pharmacies licensed under ORS chapter 689;

[*(d) Ambulatory surgical centers as defined in ORS 442.015;*]

[*(e)*] **(c)** Outpatient renal dialysis facilities as defined in ORS 442.015;

[*(f)*] **(d)** Freestanding birthing centers as defined in ORS 442.015; and

[*(g)*] **(e)** Independent professional health care societies or associations.

(3) Participation in the program is mandatory for the following entities:

(a) Hospitals as defined in ORS 442.015; and

(b) Ambulatory surgical centers as defined in ORS 442.015.

[*(3)*] **(4)** Reports or other information developed and disseminated by the program may not contain or reveal the name of or other identifiable information with respect to a particular participant providing information to the commission for the purposes of ORS 442.819 to 442.851, or to any individual identified in the report or information, and upon whose patient safety data, patient safety activities and reports the commission has relied in developing and disseminating information pursuant to this section.

[*(4)*] **(5)** After a serious adverse event occurs, a participant must provide written notification in a timely manner to each patient served by the participant who is affected by the event. Notice provided under this subsection may not be construed as an admission of liability in a civil action.

SECTION 5. ORS 442.850 is amended to read:

442.850. The Oregon Patient Safety Commission may assess fees on the entities described in ORS 442.837 [*(2)(a) to (f)*] **(2) and (3)** as determined by the Oregon Patient Safety Commission Board of Directors to fund the operating costs of the Oregon Patient Safety Reporting Program.

SECTION 6. ORS 442.846 is amended to read:

442.846. (1) Patient safety data and reports obtained by a patient safety reporting program from participants are confidential and privileged and are not admissible in evidence in any civil action, including but not limited to a judicial, administrative, arbitration or mediation proceeding. Patient safety data, patient safety activities and reports are not subject to:

(a) Civil or administrative subpoena;

(b) Discovery in connection with a civil action, including but not limited to a judicial, administrative, arbitration or mediation proceeding; or

(c) Disclosure under state public records law pursuant to ORS 442.820 (3) and, if permissible, federal public records laws.

(2) The privilege established under this section does not apply to records of a patient's medical diagnosis and treatment and to records of a participant created in the ordinary course of business.

(3) Patient safety data, collected or developed for the purpose of and with the intent to communicate with or to make a disclosure or report to the patient safety reporting program, that are contained in the business records of the participant are confidential and not subject to civil or administrative subpoena or to discovery in a civil action, including but not limited to a judicial, administrative, arbitration or mediation proceeding.

(4) The following persons are not subject to an action for civil damages for affirmative actions taken, acts of omission or statements made in good faith:

(a) A person serving on the Oregon Patient Safety Commission Board of Directors;

(b) A person serving on a committee established by the board;

(c) A person communicating information to the Oregon Patient Safety Reporting Program; or

(d) A person conducting a study or investigation on behalf of the program.

(5) A participant or a representative of the Oregon Patient Safety Reporting Program may not be examined in any civil action, including but not limited to a judicial, administrative, arbitration or mediation proceeding, as to whether a communication of any kind, including oral and written communication, has been made or shared with another participant or with the program regarding patient safety data, patient safety activities, reports, records, memoranda, analyses, deliberative work, statements or root cause analyses, provided the communication was made with the intent of making a disclosure to or preparing a report to be submitted to the Oregon Patient Safety Commission.

(6) Nothing in this section may be construed to:

(a) Limit or discourage patient safety activities of or among participants or the [*voluntary*] reporting of patient safety data by one or more participants, individually or jointly, to a patient safety reporting program;

(b) Affect other privileges that are available under federal or state laws that provide greater peer review or confidentiality protections than do the protections afforded under ORS 442.819 to 442.851;

(c) Preempt or otherwise affect mandatory reporting requirements under Oregon law or licensing or certification requirements of state or federal law; or

(d) Diminish obligations of participants to comply with state and federal laws pertaining to quality assurance, personnel management and infection control requirements.

(7) Reporting or sharing of patient safety data by a participant is not a waiver of any privilege or protection established under ORS 442.819 to 442.851 or other Oregon law.
