Senate Bill 229

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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.**

Updates terminology concerning reporting of serious adverse events. Modifies Oregon Patient Safety Reporting Program. Modifies qualification of members on Oregon Patient Safety Commission who are group purchasers of health care or consumers of health care, and modifies duties of commission.

A BILL FOR AN ACT

Relating to adverse event reporting program; amending ORS 442.819, 442.820, 442.830, 442.831, 442.837, 442.844 and 442.846.

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) "Adverse event" means an objective and definable negative consequence of patient care, or the risk of an objective and definable negative consequence of patient care, that:

(a) Is unanticipated and usually preventable; and

(b) Results in or presents a risk of resulting in physical injury to the patient.

[*(1)*] **(2)** "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)*] **(3)** "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[.]**; and**

(f) Collaboration between the Oregon Patient Safety Commission and participants on patient safety initiatives.

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

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.

(a) Are prepared by a participant for the purpose of reporting patient safety data voluntarily to **or otherwise working with** 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 communication, reports, notes or records created in the course of [*an investigation*] **a patient safety initiative** undertaken at the direction of **or in collaboration with** the Oregon Patient Safety Commission.

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

[*(5)*] **(6)** "Serious adverse event" means an objective and definable negative consequence of patient care, or the risk [*thereof*] **of an objective and definable negative consequence of patient care**, that**:**

(a) Is unanticipated[,] **and** usually preventable**;** and

(b) Results in, or presents a significant risk of, [*patient*] **the patient's** 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*] **to learn from adverse events**;

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

(c) Disseminate evidence-based prevention practices to improve patient [*outcomes*] **safety**.

(3) ORS 192.311 to 192.478 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 442.830 is amended to read:

442.830. (1) There is established the Oregon Patient Safety Commission Board of Directors consisting of 17 members, including the Public Health Officer and 16 directors who shall be appointed by the Governor and who shall be confirmed by the Senate in the manner prescribed in ORS 171.562 and 171.565.

(2) Membership on the board shall reflect the diversity of facilities, providers, insurers, purchasers and consumers that are involved in patient safety. Directors shall demonstrate interest, knowledge or experience in the area of patient safety.

(3) The membership of the board shall be as follows:

(a) The Public Health Officer or the officer's designee;

(b) One faculty member, who is not involved in the direct delivery of health care, of a public university listed in ORS 352.002 or a private Oregon university;

(c) Two representatives of group purchasers of health care, one of whom shall be employed by a state or other governmental entity and neither of whom may provide direct health care services [*or have an immediate family member who is involved in the delivery of health care*];

(d) Two representatives of health care consumers, neither of whom may provide direct health care services [*or have an immediate family member who is involved in the delivery of health care*];

(e) Two representatives of health insurers, including a representative of a domestic not-for-profit health care service contractor, a representative of a domestic insurance company licensed to transact health insurance or a representative of a health maintenance organization;

(f) One representative of a statewide or national labor organization;

(g) Two physicians licensed under ORS chapter 677 who are in active practice;

(h) Two hospital administrators or their designees;

(i) One pharmacist licensed under ORS chapter 689;

(j) One representative of an ambulatory surgical center or an outpatient renal dialysis facility;

(k) One nurse licensed under ORS chapter 678 who is in active clinical practice; and

(L) One nursing home administrator licensed under ORS chapter 678 or one nursing home director of nursing services.

(4) The term of office of each director appointed by the Governor is four years. Before the expiration of the term of a director, the Governor shall appoint a successor whose term begins on July 2 next following. A director is eligible for reappointment for an additional term. If there is a vacancy for any cause, the Governor shall make an appointment to become effective immediately for the unexpired term. [*The board shall nominate a slate of candidates whenever a vacancy occurs or is announced and shall forward the recommended candidates to the Governor for consideration.*]

(5) The board shall select one of its members as chairperson and another as vice chairperson for the terms and with the duties and powers as the board considers necessary for performance of the functions of those offices. The board shall adopt bylaws as necessary for the efficient and effective operation of the commission.

(6) The Governor may remove any member of the board at any time at the pleasure of the Governor, but not more than eight directors shall be removed within a period of four years, unless it is for corrupt conduct in office. The board may remove a director as specified in the commission bylaws.

(7) The board may appoint subcommittees and advisory groups as needed to assist the board, including but not limited to one or more consumer advisory groups and technical advisory groups. The technical advisory groups shall include physicians, nurses and other licensed or certified professionals with specialty knowledge and experience as necessary to assist the board.

(8) No voting member of the board may be an employee of the commission.

SECTION 4. 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.

(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*]

(A) Evaluate the effectiveness of the patient safety reporting program in advancing the mission of the commission described in ORS 442.820 (2);

(B) Update, as needed, the list of adverse events developed under paragraph (a) of this subsection; and

[*(D)*] **(C)** Obtain certification by the Public Health Officer [*on the completeness, credibility, thoroughness and acceptability of participant reports, root cause analyses and action plans*] **that the commission is administering the patient safety reporting program consistent with the mission described in ORS 442.820 (2) and the requirements of this section**.

[*(f) Establishing criteria for terminating a participant from the program. Incomplete reporting, failure to comply with ORS 442.837 (4) 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 5. 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*] **establish** a serious adverse event reporting system **to learn from adverse events**. 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) Systems and practices designed to learn from and prevent adverse events, which may include:

[*(B)*] **(i)** [*Root cause*] **Event investigations and** analyses of [*serious*] adverse events;

[*(C)*] **(ii)** Action plans [*established*] **developed and implemented** to prevent similar [*serious*] adverse events; [*and*]

(iii) Monitoring the effectiveness of patient safety or quality improvement efforts over time; and

(iv) Identifying and addressing the role of health equity in adverse events; and

[*(D)*] **(C)** Patient safety plans establishing procedures and protocols.

(b) Analyzing **information** reported [*serious adverse events, root cause analyses and action plans*] **under this subsection** 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 **recommendations regarding**:

[*(A) Statistical analyses;*]

(A) Systems and practices to support patient safety;

(B) [*Recommendations regarding*] Quality improvement techniques; **and**

[*(C) Recommendations regarding Standard protocols; and*]

[*(D)*] **(C)** [*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.*]

(d) Providing aggregate, deidentified information to the public on systems and practices participants have in place to learn from and prevent adverse events.

[*(f)*] **(e)** 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)*] **(f)** Distributing written reports using aggregate, deidentified data from the program to describe statewide [*serious*] adverse event [*patterns*] **reporting** 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*] **reported** adverse events;

(B) Yearly [*serious*] **reported** adverse event totals [*and trends*];

[*(C) Clusters of serious adverse events;*]

[*(D)*] **(C)** Demographics of patients involved in [*serious*] adverse events, including [*the frequency and types of serious adverse events associated with language barriers or*] **but not limited to race, gender, age, disability and** 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*]

(D) A summary of the analyses and recommendations described in paragraph (b) of this subsection; and

[*(H)*] **(E)** Appropriate consumer information regarding prevention of serious adverse events.

(2) Participation in the program is voluntary. The following entities are eligible to participate:

(a) Hospitals as defined in ORS 442.015;

(b) Long term care facilities as defined in ORS 442.015;

(c) Pharmacies licensed under ORS chapter 689;

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

(e) Outpatient renal dialysis facilities as defined in ORS 442.015;

(f) Freestanding birthing centers as defined in ORS 442.015;

(g) Independent professional health care societies or associations; and

(h) Extended stay centers licensed under ORS 441.026.

(3) 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) After a serious adverse event occurs, a participant must [*provide written notification in a timely manner to*] **notify, in a timely manner,** 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.

(5) The commission [*shall*] **may** collaborate with **organizations and** providers **across the continuum of health care, including but not limited to providers** of ambulatory health care**,** [*to develop initiatives to promote*] **on** patient safety [*in ambulatory health care*] **initiatives**.

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*] **event investigations and** 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.

SECTION 7. ORS 442.844 is amended to read:

442.844. (1) Patient safety data reported to the Oregon Patient Safety Commission [*and information developed pursuant to the auditing and oversight described in ORS 442.837 (1)*] may not be disclosed to, subject to subpoena by or used by any state agency for purposes of any enforcement or regulatory action in relation to a participant.

(2) Nothing in ORS 442.819 to 442.851 may be construed to limit the regulatory or enforcement authority of any state agency and, except for patient safety data, state agencies have the same authority to access participant records or other information in the same manner and to the same extent as if ORS 442.819 to 442.851 were not enacted.

(3) As used in this section, "state agency" has the meaning given that term in ORS 183.750.