

# Comparison of Proposed Patient Safety Legislation

## Prepared by the American Society for Clinical Pathology

| <p style="text-align: center;"><b>Subject</b></p>                           | <p style="text-align: center;"><b>HR 663</b><br/>(Bilirakis, Brown, Tauzin, Dingell)<br/><br/> <b>“Patient Safety and Quality Improvement Act”</b></p>  | <p style="text-align: center;"><b>S 720</b><br/>(Jeffords, Frist, Breau, and Gregg)<br/><br/> <b>“Patient Safety and Quality Improvement Act”</b></p>   |
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| <p style="text-align: center;"><b>Agency and Authority</b></p>              | <p>Amends title IX of the Public Health Service Act.</p>  | <p>Amends title IX of the Public Health Service Act.</p>  |
| <p style="text-align: center;"><b>Reporting</b></p>                         | <p>Provides for non-identifiable, voluntary reporting</p>   | <p>Provides for non-identifiable, voluntary reporting</p>   |
| <p style="text-align: center;"><b>Definition of Patient Safety Data</b></p> | <p>Calls data “patient safety work product.” Defines work products as any document or communication (including any information, report, record, memorandum, analysis, deliberative work, statement, or root cause analysis) that:</p> <ul style="list-style-type: none"> <li>• Developed by a provider for the purpose of reporting to a PSO, and is reported to a PSO</li> <li>• Is created by a PSO</li> <li>• Would reveal the deliberations or analytic process of a patient safety evaluation system</li> </ul> <p>Excluded is separate information submitted the PSO and not otherwise work product which is included with protected information submitted to the PSO.</p> <p>Also excluded is information available from other sources independent from the patient safety work product.</p> | <p>Defines patient safety data as any data, reports, records, memoranda, analyses, deliberative work, statements, root cause analyses, or quality improvement processes that could result in improved patient safety or health care quality, that [are]:</p> <ul style="list-style-type: none"> <li>• Collected or developed by a provider for the purpose of reporting to a PSO.</li> <li>• Reported to a PSO for patient safety or quality improvement processes.</li> <li>• Requested by a PSO (including the contents of such request);</li> <li>• Reported to a provider by a PSO.</li> <li>• Collected or developed by a PSO.</li> <li>• Reported among PSOs, after obtaining authorization; or</li> <li>• Information related to corrective actions taken in response to patient safety data.</li> </ul> |

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| <p><b>Definitions of Patient Safety Organization</b></p>                | <p>Defines a patient safety organization as a private or public organization or component thereof that performs the following activities:</p> <ul style="list-style-type: none"> <li>• The primary activity of the organization is to improve patient safety and the quality of health care delivery</li> </ul> <p>Additional activities include:</p> <ul style="list-style-type: none"> <li>• The collection and analysis of patient safety work products submitted by providers.</li> <li>• The development and dissemination of <u>evidence-based</u> information to providers regarding improving patient safety, including information regarding best practices.</li> <li>• The utilization of patient safety work product to encourage a culture of safety and to provide direct feedback and assistance to providers to minimize patient risk.</li> <li>• The maintenance of confidentiality with respect to identifiable information.</li> <li>• The provision of appropriate security measures.</li> <li>• The submission of non-identifiable information to the Agency consistent with the Secretary’s standards for any national patient safety database.</li> </ul> | <p>Defines a patient safety organization as a private or public organization or component thereof that performs the following activities:</p> <ul style="list-style-type: none"> <li>• The primary activity of the organization is to improve patient safety and the quality of health care delivery.</li> </ul> <p>Additional activities include:</p> <ul style="list-style-type: none"> <li>• The collection and analysis of patient safety data that are voluntarily submitted by a provider.</li> <li>• The development and dissemination of information to providers with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.</li> <li>• The utilization of patient safety data to carry out activities under this paragraph and for the purposes of encouraging a culture of safety and of providing direct feedback and assistance to providers to effectively minimize patient risk.</li> <li>• The maintenance of confidentiality with respect to individually identifiable health information.</li> <li>• The provision of appropriate security measures with respect to patient safety data.</li> <li>• The certification to the Agency that the patient safety organization satisfies the criteria of this paragraph for the period in which the organization is carrying out such duties.</li> </ul> |
| <p><b>Patient Safety Organization Conflict of Interest Standard</b></p> | <p>This § was in HR 877 but was not included in the version of HR 663 that passed the House March 12, 2003.</p>   |   |
| <p><b>Termination of a PSO</b></p>                                      | <p>This § was in HR 877 but was not included in the version of HR 663 that passed the House March 12, 2003.</p>   |   |

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| <p><b>Provider Definition</b></p> | <p><u>Includes any individual or entity licensed or otherwise authorized under state law to provide health care services including:</u> hospital, nursing facility, comprehensive outpatient rehabilitation center, home health agency, hospice program, physician, physician assistant, nurse practitioner, clinical nurse specialist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, or other individual health care provider, pharmacist, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner’s office, LTC facility, behavioral health residential treatment facility, clinical laboratory or community health center.</p>   | <p><u>Strictly follows the provider definition laid out in the Social Security Act including:</u> physicians, pharmacists, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office, long term care facility, behavioral health residential treatment facility, clinical laboratory, <i>or any other person or entity specified in regulations by the Secretary after public notice and comment.</i> (emphasis added)</p>  |
| <p><b>Scope of Privilege</b></p>  | <p>The scope of privilege requires that patient safety data shall not be:</p> <ul style="list-style-type: none"> <li>• Subject to civil, criminal, or administrative subpoena</li> <li>• Subject to discovery in connection with a civil, criminal, or administrative proceeding</li> <li>• Disclosed under the Freedom of Information Act or any other similar federal or state law</li> <li>• Admitted as evidence or disclosed in any state or federal civil or administrative proceeding</li> <li>• Used by a national accreditation organization in an accreditation action against the provider that reported the information, shared by such organization with its survey team; or required as a condition of accreditation by a national accreditation association.</li> </ul> | <p>The scope of privilege requires that patient safety data shall not be:</p> <ul style="list-style-type: none"> <li>• Subject to a civil, criminal, or administrative subpoena;</li> <li>• Subject to discovery in connection with a civil, criminal, or administrative proceeding;</li> <li>• Disclosed under the Freedom of Information Act or any other similar federal or state law;</li> <li>• Admitted as evidence or otherwise disclosed in any civil, criminal, or administrative proceeding; or</li> <li>• Utilized in an adverse employment action or in the evaluation of decisions made in relation to accreditation, certification, credentialing or licensing of an individual, that is based on such individual's participation in the development, collection, reporting, or storage of patient safety data in accordance with this part.</li> </ul> |

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| <p><b>Disclosure Not Subject to Protection</b></p> | <p>Patient safety data may still be disclosed in the following circumstances:</p> <ul style="list-style-type: none"> <li>• Voluntary disclosure of non-identifiable information</li> <li>• If it is authorized by the provider for the purposes of improving quality and safety.</li> </ul> <p>Patient safety data may also be disclosed in the following circumstances:</p> <ul style="list-style-type: none"> <li>• Required under the Health Insurance Portability and Accountability Act (HIPAA)</li> <li>• Disclosures can be made to the Food &amp; Drug Administration (FDA) or other administrations that are responsible for monitoring the quality, safety, or effectiveness of affected products or activities.</li> </ul> | <p>The following disclosures are NOT covered by privilege in this Act:</p> <ul style="list-style-type: none"> <li>▪ Privilege shall not apply to information (including a patient’s medical records or any other patient or hospital record) that is developed or maintained separately from information collected for reporting to a PSO.</li> <li>• Privilege shall not apply to patient safety data as part of a disciplinary proceeding relating to a provider, or a criminal proceeding, if such disclosure is--             <ul style="list-style-type: none"> <li>• material to the proceeding;</li> <li>• within the public interest; and</li> <li>• not available from any other source.</li> </ul> </li> <li>• Privilege shall not apply to patient safety data as to any FDA regulated product or activity, related to the quality, safety, or effectiveness of the product or activity in question.</li> <li>• Privilege shall not apply to patient safety data collected or used by a PSO as defined in § 921 (patient safety data defined).</li> </ul> |
| <p><b>Reporter Protection</b></p>                  | <p>Employers may not use the reporting of patient safety data to the provider with the intention of having it reported to a PSO or the direct reporting of information to a PSO against an individual in an adverse employment action.</p>  | <p>Employers may not use the reporting of patient safety data to the provider with the intention of having it reported to a PSO or the direct reporting of information to a PSO against an individual in an adverse employment action or with regard to decisions about accreditation, certification, credentialing, or licensing of an individual.</p>  |

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| <p><b>Disclosure Requirements</b></p>                 | <p>Patient safety data may still be disclosed in the following circumstances:</p> <ul style="list-style-type: none"> <li>• Voluntary disclosure of non-identifiable information</li> <li>• If it is authorized by the provider for the purposes of improving quality and safety.</li> </ul> <p>Patient safety data may still be disclosed in the following circumstances:</p> <ul style="list-style-type: none"> <li>• Required under HIPAA</li> <li>• Disclosures can be made to the FDA or other administrations that are responsible for monitoring the quality, safety, or effectiveness of affected products or activities.</li> </ul> | <p>See description of “Information not subject to Disclosure.</p>   |
| <p><b>Transfer of Information</b></p>                 | <p>Transfer of patient safety work product between a provider and PSO is NOT treated a waiver of patient privacy protection.</p> <p>Unauthorized disclosure of patient safety work product does not lose the privacy protection under this Act.</p>   | <p>The transfer of any patient safety data by a provider to a PSO is not a waiver of any privilege or protection under this Act or established under State law.</p> |
| <p><b>Punishment for Confidentiality Breaches</b></p> | <p>Confidentiality violations are punishable by \$10,000 civil monetary penalty, but no jail time, unless the disclosure was in violation of HIPAA, in which case HIPAA penalties would apply.</p>  | <p>Confidentiality violations are punishable by \$10,000 civil monetary penalty.</p>  |
| <p><b>Limitation of Outside Privileges</b></p>        | <p>This Act does not limit other privileges that are available under federal or state laws that provide greater peer review or confidentiality protections</p>  | <p>This Act does not limit other privileges that are available under federal or state laws that provide greater peer review or confidentiality protections</p>      |

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| <p><b>Relation to State Reporting Requirements</b></p> | <p>This Act shall not preempt or otherwise affect any state law requiring a provider to report.</p>   | <p>Requires the Attorney General of the US to conduct a survey of state laws that relate to patient safety data peer review systems, including laws that establish an evidentiary privilege applicable to data developed by such systems, and review the manner in which the courts have interpreted such laws.</p> <p>Survey results must be reported to the Senate Committee on Health, Education, Labor, and Pensions and the House Committee on Energy and Commerce within 9 months of enactment.</p> |
| <p><b>Continuation of Privilege</b></p>                | <p>Patient safety data shall continue to be privileged and confidential even if the PSO’s certification is terminated, revoked, or if the organization no longer operates as a PSO.</p>   |   |
| <p><b>HIPAA</b></p>                                    | <p>For the purposes of applying HIPAA standards:</p> <ul style="list-style-type: none"> <li>• Patient safety organizations shall be treated as business associates.</li> <li>• Activities of PSOs in relation to a health care provider are deemed to be health care operations of the provider.</li> </ul> |   |

**H.R. 663** ←

**S. 720** ←

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| <p><b>Surveying and Reporting</b></p>                           | <p>Requires the Secretary to prepare a draft report on effective strategies for reducing medical errors within 18 months of the creation of the National Patient Safety Database.</p> <p>Requires that no later than 1 year after the release of the draft report, a final report shall be submitted to Congress.</p> | <p>Requires the Secretary to prepare within 18 months of enactment a report on the impact of medical technologies and therapies on patient safety, patient benefit, health care quality, and the costs of care as well as productivity growth.</p> <p>The study is required to “determine:”</p> <ul style="list-style-type: none"> <li>• the extent to which labor versus technology contributes to increases in the GDP devoted to health care and the impact of medical technologies and therapies on such increases;</li> <li>• the extent to which early and appropriate introduction and integration of innovative medical technologies and therapies may affect the overall productivity and quality of the health care delivery systems of the United States; and</li> <li>• the relationship of such medical technologies and therapies to patient safety, patient benefit, health care quality, and cost of care.</li> </ul> |
| <p><b>Center for Quality Improvement and Patient Safety</b></p> | <p>This § was in HR 877 but was not included in the version of HR 663 that passed the House March 12, 2003.</p>   |   |

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| <p><b>National Database</b></p>    | <ul style="list-style-type: none"> <li>• The Secretary shall establish and maintain a database to receive non-identifiable patient safety work product.</li> <li>• The database shall be used to analyze national and regional statistics, including trends and patterns of health care errors.</li> <li>• The Secretary shall develop the database in conjunction with PSOs, the provider community, and the health information technology community.</li> <li>• In consultation with stakeholders, the Secretary shall determine common formats for the voluntary reporting of nonidentifiable patient safety work product.</li> <li>• Only non-identifiable information may be transferred to the database.</li> </ul> | <ul style="list-style-type: none"> <li>• The Secretary <i>may</i> establish a database to receive relevant non-identifiable patient safety data, or <i>may</i> designate entities to collect relevant non-identifiable patient safety data, that is voluntarily reported by PSOs at the Secretary ’s request. (emphasis added)             <ul style="list-style-type: none"> <li>• Data reported to this database <i>shall</i> be used to analyze regional variations and national statistics related to patient safety and health care quality. The information resulting from such analyses may be included in the annual quality reports prepared under section 913(b)(2). (emphasis added)</li> </ul> </li> <li>• In developing or designating this database, the Secretary may determine common formats for voluntarily reporting of non-identifiable patient safety data, including necessary data elements, common and consistent definitions, and a standardized computer interface for the processing of such data. To the extent practicable, such standards shall be consistent with the administrative simplification provisions of part C of title XI of the Social Security Act.</li> <li>• Any non-identifiable patient safety data that is transferred to the database under this section shall be privileged and confidential.</li> </ul> |
| <p><b>Technical Assistance</b></p> | <p>The Secretary, acting through the Director, may provide technical assistance to PSOs, and to states with reporting systems. The Secretary may also provide guidance on the type of data to be submitted to the database and may hold annual meetings to discuss methodology, communication, data collection or privacy concerns.</p>   | <p>The Secretary, acting through the Director, may provide technical assistance to patient safety organizations. Such assistance shall include annual meetings for patient safety organizations to discuss methodology, communication, data collection, or privacy concerns</p>   |

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| <p><b>Certification of Patient Safety Organizations</b></p> | <p>No later than 6 months after the passage of this act, the Secretary shall develop a process to certify PSOs.</p> <ul style="list-style-type: none"> <li>• Certification may fall under the Secretary or under state governmental organizations.</li> </ul> <p>The PSO must meet the following criteria as a condition of certification:</p> <ul style="list-style-type: none"> <li>• The mission of the PSO must not be in conflict with the interest of providers.</li> <li>• The PSO has qualified staff, including licensed and certified medical professionals</li> <li>• During any 2-year period the PSO must contract with more than one provider.</li> <li>• The PSO is not a component of a health insurer.</li> <li>• The PSO is managed, controlled and operated independently of any provider it contracts with.</li> <li>• The PSO must collect data in a standardized manner, that allows for comparisons with data from other PSOs.</li> </ul> <p>Includes additional standards for PSOs that are a component of other organizations:</p> <ul style="list-style-type: none"> <li>• The PSO must maintain the patient safety work product separately from the rest of the organization and establish appropriate security measures to maintain confidentiality.</li> <li>• The PSO may not make unauthorized disclosures to the rest of the organization.</li> <li>• The mission of the PSO doesn't create a conflict of interest with the rest of the organization.</li> </ul> |  |
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| <p><b>Inter-operability Standards for Health Care Information Technology Systems</b></p> | <p>The Secretary has 18 months to develop voluntary national standards that promote the interoperability of information technology systems across all health care settings.</p> <p>Makes specific reference to the need for computerized physician order entry.</p> <p>The Secretary shall take into account the cost that meeting such standards would have on providing health care. The Secretary shall also assess the ability of such systems to enable evidence-based medicine and other applications that promote the electronic exchange of patient medical information.</p> <p>The Secretary shall develop such standards in consultation with the National Committee for Vital and Health Statistics.</p> <p>The Secretary shall submit a report to Congress containing recommendations on these standards.</p> | <p>The Secretary has 36 months from enactment to develop or adopt voluntary national standards that promote the integration of health care information technology systems.</p> <ul style="list-style-type: none"> <li>• The Secretary is charged with providing for the ongoing review and periodic updating of the standards developed or adopted under this section of the bill.</li> <li>• Without a proscribed timetable, the Secretary is directed to provide for the dissemination of the standards developed and updated under this section.</li> </ul> |
| <p><b>Product Identification Technology</b></p>  | <p>The Secretary shall issue regulations requiring manufacturers, labelers, or packagers of any drug or biological product subject to FDA regulation to include a unique product identifier on the packaging.</p> <p>The product identifier must be able to be read by a scanning device or other technology the Secretary deems acceptable.</p>  |  |
| <p><b>Grants for Electronic Prescription Programs</b></p>                                | <p>The Secretary may make grants to qualified practitioners for the purpose of establishing electronic prescription programs.</p> <p>The grants must be at least equally matched by the practitioner through non-federal funds, may be cash or in-kind, and are subject to the usual prohibitions on “double dipping” of federal funds for matching purposes.</p>   |  |

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| <p><b>Information Technology</b></p>                       | <p>Authorizes the Secretary to provide grants to hospitals and other health care providers for IT to improve quality of care and patient safety.</p> <p>Special consideration shall go to grant applicants seeking to:</p> <ul style="list-style-type: none"> <li>• Promote interoperability across hospital services and departments</li> <li>• Increase electronic communication of patient data</li> <li>• Employ computerized physician order entry or bar coding applications.</li> <li>• Increase electronic communication of patient data in hospitals providing services to low-income or underserved populations.</li> </ul>  |  |
| <p><b>Medical Information Technology Board (MITAB)</b></p> | <p>Provides that the Secretary shall appoint MITAB within 3 months of enactment. The Secretary shall designate one member as chairman who must be with an organization with expertise in creating American National Standards Institute (ANSI) accepted standards in health care information technology and a member of the National Committee for Vital and Health Statistics.</p> <p>Within 18 months of enactment, MITAB shall make an initial report to Congress on:</p> <ul style="list-style-type: none"> <li>• Status of health care information technology currently at use in the public and private sectors</li> <li>• Recommendations for accelerating the development of common health care terminology standards</li> </ul> <p>For the following 2 years, MITAB shall report annually to Congress on recommendations and progress of the mission goals listed below. MITAB terminates 30 days after submitting this report.</p> <p>MITAB is charged with advising the Secretary on:</p> <ul style="list-style-type: none"> <li>• Best practices in medical technology</li> <li>• Methods for transitioning from old to new health care computer systems</li> <li>• Methods for implementing standardization and records security</li> </ul> |  |

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| <p><b>Medical Information Technology Board (cont'd)</b></p> | <ul style="list-style-type: none"> <li>• Methods to promote uniformity of terminology and technology to facilitate improving patient safety</li> <li>• Reducing inefficiencies in record keeping and minimization of medical errors due to record keeping</li> <li>• Ensuring cost effective technologies are developed in concert with currently used technologies</li> </ul> <p>Membership is capped at 17, to include:</p> <ul style="list-style-type: none"> <li>• Experts in medical &amp; information technology, medical records and health care</li> <li>• One or more each from:             <ul style="list-style-type: none"> <li>○ Centers for Medicare &amp; Medicaid Services (CMMS)</li> <li>○ Agency for Healthcare Research and Quality (AHRQ)</li> <li>○ Institute of Medicine of the National Academy of Sciences (IOM-NAS)</li> </ul> </li> <li>• Terms are life appointments</li> <li>• MITAB meetings are at the call of the Chair or a majority of members</li> <li>• Vacancies are to be filled within 30 days of notification</li> <li>• MITAB members receive no compensation for Board service</li> </ul> |  |
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