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Patient Safety and Quality Improvement Act (S. 720 and HR 663)

BACKGROUND ON THE LEGISLATION

The "Patient Safety and Quality Improvement Act (S.720 and HR663) could preempt state laws on hospital quality and patient safety laws. There are basically three categories of relevant state reporting laws:
(1) hospital-acquired infection reporting laws;
(2) medical errors/adverse event reporting laws and
(3) medical outcomes reporting laws.

The federal bills ostensibly deal with the second category, medical errors, but, as explained below, their definitions appear broad enough to sweep in the other categories as well.

S.720: "Patient safety data"

Definitions

The definition of "patient safety data" in S.720 (Sec. 921(2)(A)) is incredibly broad. It includes "any data, reports, records, memoranda, analyses or statements that could result in improved patient safety or health care or health care outcomes, that are--

> *(I) collected or developed by a provider for reporting to a patient safety organization. . . .*
>
> *(II) requested by a patient safety organization. . . .*
>
> *(IV) collected from a provider or patient safety organization or developed by patient safety organization;"* [Note: this seems to be a catchall category that covers any and all data from a hospital or doctor or at the patient safety organization. This category does not even require submission to a patient safety organization, it simply includes all data from a provider.]

The bill states that "patient safety data" shall not include "information (including a patient's medical record) that is collected or developed separately from and that exists separately from patient safety data. Such separate information or a copy thereof submitted to a patient safety organization shall not itself be considered as patient safety data." This "separate information" exception is not clear. Interpreted narrowly, it could exclude only things like patient medical records that are clearly not developed for patient safety reasons. However, other kinds of data used for patient safety reasons, such as medical outcomes or infection rate data, would still seem to qualify as "patient safety data" (see discussion of state laws below). The problem here is the

broad definition of "patient safety data" as anything "that could result in improved patient safety or health care quality. . .that is collected from a [hospital or doctor]."

At the very least, the "separate information" exception must be redrafted, and other specific examples of quality data that should be publicly available (like infection rates, outcomes, etc.) should be excluded from "patient safety data." Or, the bill should be more narrowly drafted to refer only to medical errors/adverse event reporting by hospitals. This would make clear that the bill does not affect non-incident specific quality data reporting. Medical errors and adverse events are examples of mistakes on specific patients by hospitals or doctors. However, other types of quality measures aggregate such incidents into general rates and should be publicly available.

"Patient safety organization" (PSO) is another important definition in the bill. These organizations may be private organizations, ranging from the existing Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to entities newly created by one or more hospital corporations. Hospital-owned PSOs would obviously create conflict-of-interest issues. At the least, the bill needs much stronger conflicts provisions. The PSO definition would also include state agencies that currently collect hospital data.

Confidentiality

The bill provides a sweeping privilege from disclosure for patient safety data (Sec. 922). The data cannot be revealed to the general public, except in a form that does not identify any specific hospital or health care provider. So, for example, there could be a report indicating that 20 medication errors occurred in the state of Vermont in 2003, but nothing to indicate the hospital in which they occurred.

The data cannot be disclosed pursuant to state and federal Freedom of Information Act-type laws. It is not discoverable in any criminal, civil or administrative proceeding. It cannot be admitted as evidence in any criminal, civil or administrative proceeding. It cannot be used in any disciplinary proceeding against a doctor or hospital (or other provider). There are limited exceptions, the main one being for criminal proceedings where there is evidence of an "intentional at to directly harm the patient." That will almost never occur. Other exceptions mostly allow voluntary disclosure of data by the hospital.

H. R. 663: "Patient safety work product"

Definitions

The House bill uses the term "patient safety work product" (Sec. 921(5)). The preemption problem with this definition is more subtle and complicated than that in S. 720. Work product includes:

> *(A) "any document or communication (including any information, report, record. . .) that--*

(i) except as provided in subparagraph (B), is developed by a provider for the purpose of reporting to a patient safety organization, and is reported to a patient safety organization;

. . .

H.R. 663 also has a "separate information" clause (Sec. 921(5)(B) that appears more preemptive of state laws that the Senate bill:

(B)(i) Patient safety work product. . .

(I) does not include any separate information described in clause (ii); and

(II) shall not be construed to include such separate information merely by reason of inclusion of a copy of the document or communication involved in a submission to, or the fact of submission of such a copy to, a patient safety organization.

(ii) Separate information described in this clause is a document or communication (including a patient's medical record or any other patient or hospital record) that is developed or maintained, or exists, separately from any patient safety evaluation system."

H.R. 663 also includes a PSO definition similar to S.720.

Confidentiality

The House bill has similar nondisclosure and confidentiality privileges as the Senate bill. "Patient safety work product" is not subject to civil subpoenas, discovery in civil or administrative proceedings, and FOIA-type laws. The House bill, unlike the Senate, does not specifically prohibit use of the data in disciplinary proceedings. However, the House bill simply says data cannot be used in "any" civil or administrative proceeding, which would seem broad enough to include disciplinary proceedings. Also, the House bill, unlike the Senate bill, specifically prohibits use of data by organizations, like JCAHO, that accredit hospitals or doctors.

"Preservation" of state laws

To make things a little more complicated, H.R. 663 has a provision that purports to preserve state reporting laws, however that provision only applies to information "that is not patient safety work product." Thus, the key question is can hospitals claim data they submit to state agencies qualifies as "patient safety work product" and thus not subject to the public disclosure provisions of state law? At best, H.R. 663 is unclear on this point, but I believe the current language is loose enough to allow hospitals to claim any quality and safety-related data they collect is "patient safety work product." See examples below of specific state laws.

MORE BACKGROUND ON SPECIFIC STATE REPORTING LAWS

Some existing state laws could be preempted by the federal bills. Any future state laws on these subjects would also be precluded.

State Hospital-Acquired Infection Reporting: Illinois

Earlier this year, in response to a major expose on hospital infections by the Chicago Tribune, Illinois enacted a mandatory hospital-acquired infections reporting bill, SB 59 (Illinois Public Act 93-0563). SB 59 requires hospitals to report quarterly hospital-acquired infection rates to the state Department of Public Health. These quarterly reports will be publicly available at the hospital and through the Department. The agency will issue an annual public report listing summarizing the quarterly reports by listing individual hospitals and their infection rates.

S. 720's broad definition of "patient safety data" includes data which "result in improved patient safety or health care or health care outcomes." This definition clearly would cover hospital infection rates, thereby preempting this important new law. The Illinois Department of Public Health would clearly qualify as a "patient safety organization" (PSO). The "separate information" exception may not apply to infection data because a hospital could always argue that infection data are patient safety data and if it submits infection data to a PSO, then those data become confidential.

State Medical Errors/Adverse Event Reporting Laws

According to the National Academy for State Health Policy (NASHP), as of April 2000 about 15 states have mandatory reporting laws. NASHP issued its report after surveying all 50 states regarding medical error reporting laws. In general, most of the state laws require reporting to a state agency of serious or "sentinel" adverse events (death or serious injury).

Enforcement and Confidentiality

According to the NASHP report, nine states use event reports as a basis for administering sanctions against providers, and for taking corrective action. This type of enforcement would appear to be preempted by both S. 720 and its House counterpart. State laws also differ from the federal bill in the scope of their confidentiality privilege. Several states are not as restrictive as the federal bills, and might, therefore, be preempted.

For example:

Colorado: occurrence reports may be transmitted to "an appropriate regulatory agency having jurisdiction for disciplinary or license sanctions" (Colo. Stats. 25-1-124(4)).

Florida:
(a) incident reports discoverable in litigation relating to the facility, but not admissible in court (Title XXIX Fla. Stats., §395.0197(4)).
(b) annual reports submitted to the state agency by a hospital may be discoverable or admissible in a disciplinary proceeding by the appropriate regulating or licensing agency (Title XXIX Fla. Stats., §395.0197(6)(c)).

Rhode Island: reportable event reports entitled to same privileges and immunities as for peer review records, meaning that they be admissible in a proceeding imposing sanctions on a physician (Title 23 R.I Stats. § 23-17-40(g) and 23-27-25(a)).

Public Reporting

Colorado regularly issues a public report naming individual hospitals (Colo. Stats. 25-1-124(6)(b)). The report consists of a summary of the agency's investigation of an adverse event, including whether there was violation of licensing or safety requirements. The reports do not identify the patient or the health care provider. The report is available on the Internet. Minnesota enacted earlier this year a bill on adverse hospital events that requires the Commissioner of Health to issue an annual report listing adverse events by institution Ch. 99 - S.F. No. 1019, Minn. Sess. Laws 2003). S. 720 would appear to preempt these reporting requirements in Colorado and Minnesota. Kansas, Massachusetts, New York and Florida also appear to issue regular or periodic reports of adverse events, which would likewise be preempted under S. 720.

State Medical Outcomes Reporting Laws

Several states develop reports on hospital performance on various conditions and procedures. Examples of such reports include: heart attack, coronary artery bypass graft surgery (CABG), and stroke. These reports typically rate hospital performance in *Consumer Reports*-like charts/tables that indicate whether a hospital's risk-adjusted mortality rates are "better than expected", "expected," or "worse than expected." The data for each hospital are "risk-adjusted," meaning that hospitals receive extra credit for treating sicker patients or those with more complex medical problems. Some of the CABG reports even compare the performance of individual surgeons performing CABGs. By naming hospitals and doctors publicly, these reports encourage self-improvement by providers and facilities; give better information to consumers, health insurers, employers and other puchasers of health insurance; and promote public accountability. Studies have shown such reporting results in lower death rates and higher quality care for patients.

Medical outcomes data would appear to fall squarely within S. 720's definition of "patient safety data." The purpose of collecting medical outcomes data is to allow hospitals to improve their performance by reducing mortality rates. The state agencies receiving the data would fall under the definitions of "patient safety organizations" and thus would not be permitted in the Senate bill.

States with medical outcomes reporting statutes and programs include: California, New York, New Jersey, Pennsylvania, Texas, Virginia, and Maryland. Examples of state medical outcome reports can be found at the following websites:

1. California: http://www.oshpd.ca.gov/. Scroll down under "Featured Topics" to "Outcome Studies" (CABG and heart attack)

2. New York: http://www.health.state.ny.us/nysdoh/heart/heart_disease.htm (CABG and angioplasty reports with data by individual hospital and physician).

3. Texas: http://www.thcic.state.tx.us/IQIReport2001/IQIReport2001.htm (quality data for many different conditions and procedures)

4. Pennsylvania: (a) http://www.phc4.org/reports/hospitals.htm (quality data for many different conditions and procedures); (b) http://www.phc4.org/idb/Cabg/default.cfm (CABG data by individual hospital and surgeon)

5. New Jersey: http://www.health.state.ny.us/nysdoh/heart/heart_disease.htm (CABG data by hospital).