

Swimming in Murky Waters: Thoughts on "Safe Harbor" Legislation

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Background

At the April 2010 CFHHS meeting, the committee received a briefing paper on defensive medicine. As a reminder, defensive medicine can be described as a process of treating patients in which doctors authorize tests in part to reduce the risk that they will be sued. Dr. Carter Beck, the presenter in the defensive medicine segment of the April meeting, suggested that the committee look into some type of "safe harbor" legislation. This memo is an attempt to provide the committee with a bit more information on the issue of safe harbors, a concept which has been addressed at the state level in a few states, none of which appear to have been greatly successful, and is currently being looked at nationally.

Basic Idea

As discussed at the April meeting, the concept of a "safe harbor" with regard to defensive medicine may involve some type of disclaimer on a patient's chart or a change in Montana's statutes stating that the doctor has chosen not to order, based on evidence-based medical (EBM) guidelines, a particular test and can't be held liable for failure to do so, absent some type of negligent act on the part of the doctor. In other words, if a doctor follows established medical guidelines that say a given test is unnecessary, the doctor cannot be sued for failing to order the test. The idea would be to lower costs of medical procedures by cutting down on defensive medicine practices (ordering tests so as not to get sued later).

Several States Have Tried Safe Harbor Laws

It appears that a few states have had this type of safe harbor legislation on the books. A sampling of these states include Connecticut, Maine, Minnesota, Florida, and Vermont. The Maine program was established in 1990.¹ It focused on a handful of practice parameters from four specialties: anesthesiology, emergency medicine, obstetrics/gynecology, and radiology. The goal was to eliminate litigation over the standard of care in medical liability claims by providing physicians with an affirmative defense if they followed the guidelines. A majority of physicians in each of the four specialties had to enroll in order to trigger the start of the program, which they did. While the program was successful in enrolling sufficient numbers of physicians, it was unsuccessful in finding a test case that would have measured the effectiveness of the affirmative defense, so it went unutilized while the program was in existence and was eventually sunset.

While Florida, Maryland, Minnesota, and Vermont also attempted to implement similar programs, they did not proceed as far as Maine on this issue. Minnesota enacted legislation in 1992 that would have created a safe harbor for the use of EBM guidelines.² However, like Maine, the provision was not used in a legal proceeding. The Minnesota legislature established an advisory committee to develop statewide practice parameters. The committee met for over

¹Maine Medical Liability Demonstration Project, 24 M.R.S. Section 2971 (repealed).

²Minnesota Statutes, 1992, 62J.34 Outcome-based Practice Parameters (repealed).

two years and developed a few parameters, but they were not helpful in providing liability protection. Minnesota repealed the statute in 1995.

As part of Vermont's efforts to enact universal healthcare access in the early 1990s, the state passed a contingent amendment that would have allowed state-sanctioned practice guidelines to be used as a standard of care in medical liability cases. Apparently, the provision never went into effect. Florida and Maryland also attempted to address EBM guidelines and medical liability, but these programs were not pursued after initial implementation efforts.

AMA Supports Concept of Safe Harbor for Physicians

At the national level, in 2009 the American Medical Association (AMA) adopted principles related to liability safe harbors for physicians when they practiced in accordance with EBM guidelines. Some of these guidelines include:

- each program should start out as a pilot program and would be voluntary for patients and physicians;
- physicians who elect to participate in the program would utilize EBM guidelines that could include a decision support process/application based on the guidelines. If the physician decides the EBM guidelines are inapplicable in a case, then there should not be any legal penalty for this conclusion;
- participating physicians who follow EBM guidelines should receive liability protections for diagnosis and treatment in compliance with the guidelines;
- such liability protections could include, but are not limited to:
 - civil immunity related to the claims;
 - an affirmative defense to the claims; or
 - higher burden of proof for plaintiffs; and
- there would be no presumption of negligence if a participating physician does not adhere to the guidelines.³

Reflecting these principles on the national scene, the AMA is working to amend the federal healthcare bill to address the unnecessary costs of additional tests or therapies that are being done in the practice of defensive medicine. Jeffrey Segal, a board-certified neurosurgeon, discussed more specifics regarding this safe harbor concept in the American People's Online Health Summit.⁴ "Clinicians should be shielded from liability if they document their use of evidence based medicine and/or clinical best practices. Such documentation would be presumptive evidence that the standard of care was followed. This would translate into 'safe harbor' immunity." Segal goes on to say that "no less important is preserving the right of

³This language was included in a recent federal bill, H.R. 3400, 111th Congress, 1st Session which was not enacted. H.R. 3400 would also have permitted states to revise their medical liability statutes to include an affirmative defense if a physician follows certain EBM guidelines.

⁴<http://cht.typepad.com/hbhr/health-justice>.

physicians to exercise their clinical judgment to make personalized decisions based on the circumstances of the patient and the patient's condition. The physicians may choose to deviate from accepted algorithms, if in that case, it makes better clinical sense. In this situation, the doctor would document that the doctor was aware of algorithms recommended by evidence-based medicine but consciously chose a different path for specific reasons. This documentation would provide qualified safe harbor immunity."

Oregon Receives Federal Grant To Try Out Safe Harbors

Coinciding with the arrival of federal healthcare reform legislation, the Secretary of Health and Human Services (HHS) launched a Patient Safety and Medical Liability Initiative with the availability of \$25 million in funding to address four goals: Put patient safety first and work to reduce preventable injuries; foster better communication between doctors and their patients; ensure that patients are compensated in a fair and timely manner for medical injuries, while also reducing the incidence of frivolous lawsuits; and reduce liability premiums. This initiative includes the following components: Grants to jump start and evaluate efforts, planning grants, and review of existing initiatives. Of particular interest: The Office for Oregon Health Policy and Research received a planning grant of \$299,458 to develop and implement a method for setting priorities for developing evidence-based practice guidelines, craft a broadly supported safe harbor legislative proposal that will define the legal standard of care, and develop a plan to evaluate the effectiveness of the legislative proposal, if enacted.

Possible Safe Harbor Language⁵

Because this is a relatively untested area, it is difficult to determine whether implementing a safe harbor clause would lower the costs of healthcare. However, should the CFHHS Interim Committee wish to consider possible safe harbor legislation, below may be possible language that could be utilized within Montana's statutes:

- Notwithstanding any provision of the general statutes, there shall be no monetary liability on the part of, and no cause of action for damages shall arise against, a participating healthcare provider for a patient's injury caused by the provider's provision of care when such care was consistent with guidelines approved by the governing entity [Board of Medical Examiners, Medical Legal Panel?].
- The governing entity shall establish and implement a process for providing a patient with no-fault compensation for injuries sustained by the patient notwithstanding the fact that the provider's provision of care was consistent with guidelines approved by the governing entity.
- Exemption from liability shall not apply to injuries that result from: (1) A mistaken determination by the provider that a particular guideline applied to a particular patient, where such mistaken determination is caused by the provider's negligence or intentional

⁵Based on language contained in H.B. 6600, Connecticut, 2009, which was not enacted.

misconduct, or (2) a failure to properly follow a particular guideline where such failure is caused by the provider's negligence or intentional misconduct.

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