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Safe Harbors: A Port in the Storm of Malpractice?

An Information Paper

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There is a new war brewing on the horizon for the heart and soul of medicine. As a country we are moving rapidly into a pay for quality and evidence-based model. Yet the medical malpractice system remains as antiquated as ever relying on *experts* and eschewing data driven protocols. How are we to encourage physicians to use guidelines that *accept* a 1% margin of error when our malpractice system requires 0.00%? The answer may just lay in an old concept in health law called Safe Harbors. In case that term is too controversial, new catchphrases including Evidence-Based Patient Safety Measures are being used to describe the concept as it relates as much to patient safety as to physician protection.

Why Not More of the Same?

The traditional methods of caps on damages and tightening of the statute of limitations is coming under increasing fire. Eight states have found state level caps on non-economic damages unconstitutional.[1] There is also increasing scholarly attention to the impact of these reforms that demonstrate, in some cases, increasing rates of medical board complaints,[2] little impact on defensive medicine,[3] and no arrest of the climb in health care costs.[4]These findings, coupled with high political costs, have resulted in bipartisan failure, with various forms of national tort reform failing to pass despite annual introduction for over 15 years.

"New" Hope on the Horizon?

Discussions about the adoption of clinical practice guidelines as medical malpractice "safe harbors" have been around since the 1990s. Recently proposed legislation, the rising costs of healthcare, and the adoption of campaigns such as Choosing Wisely® are bringing these discussions back to the forefront. The theoretical benefits of a Safe Harbors Program are significant:

Driving Higher Quality Care. Narrowing practice deviation across a group of clinicians is a good concept, particularly with high-risk diagnoses like chest pain or abdominal pain in the elderly. From a patient safety perspective, standardization can reduce medical errors and adverse outcomes, which theoretically should reduce malpractice exposure.[5] For instance, use of guidelines like the PECARN criteria for pediatric head injury can help not only identify those at risk for serious intracranial injury, but also prevent unnecessary radiation known to cause malignancies. Yet we continue to see practice variations due to a fear of litigation over a one in a several thousand case, despite evidence of greater patient safety by avoiding radiation.

*Incentivize and Align with Payment Reform***.** The move to pay for performance and quality is at odds in many ways with the current expert-based system of malpractice. If quality metrics were focused on appropriate use of guidelines coupled with safe harbor protection, it is possible to drive even greater adoption and greater potential patient safety. While CMS and insurers have believed that a monetary penalty will motivate physicians, many would argue that the risk of a malpractice claim outweighs any individual financial harm from a small reduction in payment. As a result, a system that provides a strong carrot to go along with the stick of financial reform might have more significant effects on overall health delivery costs.

Reducing Defensive Medicine. A survey in 2009 showed that physicians attributed as much as 34% of the overall health care costs to defensive medicine.[6] These tests lead to increased costs and may expose patients to potential complications. In that same study, emergency medicine was identified as one of the most likely specialties to practice defensive medicine along with obstetrics and primary care. Theoretically, the protection of safe harbors would reduce utilization of unnecessary laboratory testing, imaging, and admissions by following guidelines such as PECARN, NEXUS, and ACEP Clinical Policies. However in the current risk environment, there are some providers who find the acceptance of an unknown risk of litigation higher than the known risk of radiation.

New Storm Clouds On That Horizon?

While many have heralded the promise of Safe Harbors, the reality is that danger lies around the corner with the hope for protection. It is important to understand some of the potential complications that could come from a Safe Harbor Program including:

Creating a Standard of Care to Violate. One of the cardinal sins of adopting best practice guidelines is failing to follow them. This failure can provide the plaintiffs' bar with strong "failure to follow" arguments that greatly resonate with juries. One can practically hear the siren's song of the plaintiff's bar, "*if only the doctor had followed the guidelines, Ms. Jones would still be alive."*

Conflicting guidelines between specialties and groups. An issue with the safe harbor concept is the existence of conflicting clinical practice guidelines in the medical literature. The lack of consensus across guidelines may present the plaintiffs' bar with the opportunity to establish doubt regarding the appropriate safe harbor to apply to a case. One need only look at the guidelines for breast cancer screening to see major parties with significant disagreement on when to start screening that exposes providers to risk.[7] As emergency physicians we have many other specialties that feel the need to opine on our practices; what would happen if theirs was the only guideline? These types of issues have the potential to pose significant risk to the individual provider.

Timely, Costly, and Limited Guidelines. The investment in strong evidence-based guidelines is not insignificant, even for an organization of the size of the American College of Emergency Physicians. Effective guidelines take expert panels that take time and costs to review the literature and create a synthesis of the available data.[5] Additionally, the need for constant review of published guidelines compounds the ongoing cost to organizations that can be prohibitive. It is also unlikely that guidelines will apply to every case. In fact in one study, only 1in 266 claims would have been covered by a theoretical safe harbor program.[5] Thus if measured by litigation rates alone, the impact may not be as significant as hoped.

A New Triple Aim?

While there are significant challenges to any proposed safe harbors, the reality is that our current system is not working well for anyone in the system. The trifecta of patient, provider, and attorney involved in the current medical malpractice environment is rarely served on the whole. Safe harbors have the potential to be the true win-win-win solution for the other triple aim.

Patients. We know from the Institute of Medicine "*To Err is Human"* report that only a small fraction of patients will seek compensation for injuries and that harm is still far too prevalent in our health care system. Following evidence based guidelines that have the potential to reduce the rate of medical error could improve health care outcomes and reduce the rate of harm that results in litigation.

Attorneys. While physicians remember "that one case" in the news, the reality is that on the whole physicians have more success than attorneys. In one study, only 55.2% of claims filed resulted in litigation. Of those claims that became litigation, 54.1% were dismissed by the court. Finally, in the 4.5% of cases with a jury verdict, physicians prevailed 79.6% of the time.[8] Put another way, of all claims filed, physicians prevailed on 78.2% of claims. Attorneys have a significant amount of costs to investigate and pursue claims. There is the potential that clear guidelines could help streamline their process for review and help them avoid some of these costly unsuccessful pursuits.

Physicians. While the use of safe harbors will not impact all lawsuits, there is the potential to reduce provider anxiety regarding possible litigation, increase compliance with guidelines, and improve the practice of defensive medicine.

Future Advocacy Efforts

The future of safe harbors legislation may lie in bills like HR 4106 introduced in the 113th Session of Congress by Reps. Barr and Bera. This legislation would have led to the development of safe harbors for guidelines produced by a multitude of groups including specialty societies that were certified by the Secretary of Health and Human Services. The bill would have moved cases from state court to federal courts for application of the appropriate guidelines and expert review of the litigation. ACEP will continue to work with sponsors of this type of legislation to ensure it is provider and patient safe.

New Wave with a New Name

While legislation has recently been introduced, opposition to it has again risen in political circles, likely making the issue dead on arrival. As we have moved toward Patient Safety Organizations, driving quality care, and other initiatives focused on practicing what our research teaches, there is a move to rebrand the safe harbor initiatives. New names such as "Evidence-Based Patient Safety Measures" are being developed and promoted in some advocacy circles. Much like safe harbors was a rebranding of various concepts from the 1990s, there will likely be a similar move with safe harbors given the political stigma attached to them. Regardless, the concepts of safe harbors, and the benefits to the parties remain regardless of the name. Keep informed and keep up to date on the name to stay engaged as a successful advocate.

Conclusion

The concept of safe harbors is not new or novel, but it is possible that the timing and drive toward evidence-based quality payments will align the stars to help pass this type of legislation. While no solution will be perfect for everyone, there is reason for optimism that promotion of applicable, safe, and evidence-based guidelines might meet the needs of everyone involved in the process. Ongoing advocacy and engagement will be critical, so join in the conversation!

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