

2012

Physicians and Safe Harbor Legal Immunity

Thaddeus Mason Pope
Widener University School of Law and Albany Medical College

Follow this and additional works at: <http://lawcommons.luc.edu/annals>



Part of the [Health Law and Policy Commons](#)

Recommended Citation

Thaddeus M. Pope *Physicians and Safe Harbor Legal Immunity*, 21 *Annals Health L.* 121 (2012).
Available at: <http://lawcommons.luc.edu/annals/vol21/iss1/12>

This Article is brought to you for free and open access by LAW eCommons. It has been accepted for inclusion in *Annals of Health Law* by an authorized administrator of LAW eCommons. For more information, please contact law-library@luc.edu.

Physicians and Safe Harbor Legal Immunity

Thaddeus Mason Pope^{*}

I. INTRODUCTION

Professor Sandra Johnson has identified what she calls physician's "bad law" claims.¹ In some circumstances, physicians perceive that there is significant legal risk in doing what they think is clinically appropriate. In response, physicians sometimes take a medically inappropriate course of action, because it appears safer.² For example, physicians might feel intimidated by aggressively enforced drug control laws.³ In response, they may under-treat patients' pain to avoid perceived (and real) threats of investigation, discipline, or criminal prosecution.⁴ In short, well-meaning laws sometimes have the unintended side effect of incentivizing physicians to do "bad" things.

Johnson identifies three responses to physicians' "bad law" claims. Each of these is aimed at "relieving [physicians'] fears and reducing or managing the legal risk, real or perceived, so that doctors can freely engage in the socially desirable behaviors threatened by the operation of the putative bad law."⁵ The first response is education. To the extent that physicians' fears

^{*} Associate Professor of Law, Widener University School of Law; Adjunct Associate Professor of Medical Education, Albany Medical College. Effective January 2011, Professor Pope will be Director of the Health Law Institute at Hamline University School of Law. A version of this Article was presented at the 34th Annual ASLME Health Law Professors Conference at Loyola University School of Law in June 2011.

1. Sandra H. Johnson, *Regulating Physician Behavior: Taking Doctors' 'Bad Law' Claims Seriously*, 53 ST. LOUIS U. L.J. 973 (2009) [hereinafter *Regulating Physician Behavior*].

2. Sandra H. Johnson, *Test-Driving "Patient-Centered Health Law,"* 45 WAKE FOREST L. REV. 1475, 1483 (2010) ("Doctors . . . claim . . . that fear of legal penalties . . . causes them to under-treat patients in pain.") [hereinafter *Test-Driving*]. Johnson rightly explains that not all "bad law" claims are valid or honest. *Regulating Physician Behavior*, *supra* note 1, at 993-1005. See also Robert Schwartz, *End-of-Life Care: Doctors' Complaints and Legal Restraints*, 53 ST. LOUIS U. L.J. 1155 (2009).

3. *Test-Driving*, *supra* note 2, at 1479 (citing Diane E. Hoffman, *Treating Pain v. Reducing Drug Diversion and Abuse: Recalibrating the Balance in Our Drug Control Laws and Policies*, 1 ST. LOUIS U. J. HEALTH L. & POL'Y 231 (2008)).

4. See, e.g., Kathryn L. Tucker, *Improving Pain Care: A Safe Harbor Is Not Enough; the Sea Outside the Harbor Must Be Rough*, HEALTH LAW, May 1999, at 15.

5. *Regulating Physician Behavior*, *supra* note 1, at 1009. In fact, Johnson divides the responses into four categories, separating "immunity" from "safe harbors." *Id.* at 1014-22. I

of the law are based on misinformation or misunderstanding, it might seem that they could be educated about the actual (often low or virtually non-existent) legal risk.⁶ The second response is equalizing the risk from all alternatives. If physicians perceive a particular desirable course of action as too risky, asymmetrical incentives might be eliminated by making inappropriate alternatives equally (or more) risky.⁷ But Johnson explains that these two responses are typically unlikely to be effective.

The third response to “bad law” claims is safe harbor legal immunity. Johnson observes that this is one of “the more familiar legislative responses to physician-reported fears of legal risks.”⁸ Indeed, it would seem to be the strongest legal weapon in quelling physicians’ fears of legal risk. Immunity, after all, is a classic mechanism for encouraging legally fearful individuals to do their job.⁹ But Johnson concludes that “the evidence seems to indicate otherwise.”¹⁰

When does safe harbor legal immunity work to dispel physicians’ legal fears? When does it fail? What are the essential attributes of an effective safe harbor? What are the limitations? These are the question that I will address in this article. In section I, I provide a brief taxonomy of medical safe harbors. In section II, I outline the essential attributes of an effective safe harbor. Finally, in section III, I discuss three key limitations of medical safe harbors. Notwithstanding these limitations, I conclude that safe harbors can be an efficacious mechanism for addressing physicians’ “bad law” claims.¹¹

II. TAXONOMY OF MEDICAL SAFE HARBORS

There are four main types of medical safe harbors. The first type

treat these together because they similarly operate as “immunizers.” Lee H. Rosenthal, *Managing Electronic Discovery: Views from the Judges*, 76 *FORDHAM L. REV.* 1, 16 (2007); Schwartz, *supra* note 2, at 1160 (“Safe harbors are another form of immunity, although the term “safe harbor” is more likely to be found in an administrative code, and the term “immunity” is more likely to apply in cases with potential exposure to tort liability.”); Schwartz, *supra* note 2, at 1165 (“[I]t is not always so easy to distinguish one from the other”).

6. *Test-Driving*, *supra* note 2, at 1485; *Regulating Physician Behavior*, *supra* note 1, at 1009-14.

7. *Regulating Physician Behavior*, *supra* note 1, at 1022-24.

8. *Id.* at 1014.

9. *Cf. Boice v. Unisys Corp.*, 50 F.3d 1145, 1148 (2d Cir. 1995).

10. *Regulating Physician Behavior*, *supra* note 1, at 1015.

11. I focus only on the effectiveness of safe harbors. I do not examine the broader policy question of whether the safe harbor produces bad results on balance by, for example, impeding fair compensation or physician accountability. *Cf. Regulating Physician Behavior*, *supra* note 1, at 1018-22; *Test-Drive*, *supra* note 2, at 1486; John E. Calfee & Richard Craswell, *Some Effects of Uncertainty on Compliance with Legal Standards*, 70 *V.A. L. REV.* 965, 1000 (1984).

describes and defines conduct that poses little or no risk of harm. It confirms that such low-risk conduct is secure from sanctions. Second, a closely-related type of safe harbor also protects low-risk conduct. But the conduct protected by this type of safe harbor cannot be substantively defined *ex ante*. Instead this type of safe harbor specifies procedures. Compliance with these procedures assures low-risk and, therefore, protection. In contrast to the first two types of safe harbor, the third type protects potentially risky conduct. Protection is afforded, despite the risk, because the conduct is considered necessary or desirable on balance. Finally, the fourth type of safe harbor protects certain conduct for no other reason than self-protection of the parties engaged in that conduct.

A. *Substantively-Defined Low Risk Conduct*

Sometimes, safe harbors expressly describe and define the conduct that they protect. They draw reasonably bright lines around the protected conduct. Two examples are the safe harbors in federal fraud and abuse laws and those increasingly defined by clinical practice guidelines.¹²

1. Fraud and Abuse Safe Harbors

Both the Medicare Anti-Kickback Statute and the Stark Anti-Referral Laws include a number of safe harbors.¹³ Regulators were concerned that the anti-fraud provisions in these statutes were so broad that they could cover even “innocuous” conduct.¹⁴ For example, there is little risk of inducing referrals by paying for space or equipment rentals pursuant to a written contract of at least one year in duration at fair market value. And since such rentals are common and necessary, Congress provided a safe harbor. This and other fraud and abuse safe harbors specify arrangements pursuant to which payments will not be the basis of prosecution.¹⁵

12. Another example might be antitrust “safety zones” for integrations that are deemed beneficial. See DEPT. OF JUSTICE (DOJ) & FED. TRADE COMM’N (FTC), STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTHCARE 64-70 (Aug. 1996), available at <http://www.justice.gov/atr/public/guidelines/0000.pdf>; DOJ & FTC, ANTITRUST GUIDELINES FOR COLLABORATIONS AMONG COMPETITORS 25-27 (Apr. 2000), available at <http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf>.

13. 42 U.S.C. § 1395nn(b)-(e) (2010); 42 C.F.R. § 1001.952 (2010).

14. See Dept. Health & Human Serv. (DHHS), *Medicare and Medicaid Programs: Fraud and Abuse Anti-Kickback Provision*, 54 Fed. Reg. 3088, 3090 (Jan. 23, 1989); DHHS, *Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors for Federally Qualified Health Centers*, 72 Fed. Reg. 56,632, 56,632 (Oct. 4, 2007).

15. The Anti-Kickback Law also provides for advisory opinions. 42 C.F.R. §§ 1008.1-.59 (2010). These might be considered as “essentially case-specific safe harbors.” James F. Blumstein, *Of Doctors and Hospitals: Setting the Analytical Framework for Managing and Regulating the Relationship*, 4 IND. HEALTH L. REV. 211, 219 (2007).

2. Clinical Practice Guidelines

While fraud and abuse safe harbors focus on physicians' financial arrangements, clinical practice guidelines ("CPGs") focus on physicians' medical judgment and performance. A number of studies have demonstrated that physicians practice substantial amounts of defensive medicine. Nearly 90 percent of physicians have ordered extra tests and procedures solely to protect themselves from liability,¹⁶ and almost one in four healthcare dollars is spent on legally-, not medically-indicated medicine.¹⁷ The adverse effects of defensive medicine are not limited to costs. Defensive medicine also has a significant negative impact on healthcare quality and safety.

Clinical practice guidelines have been increasingly recommended as a response.¹⁸ Defensive medicine results from uncertainty over what exactly the standard of care requires. Offering immunity for adherence to evidence-based CPGs dispels this uncertainty. Several states experimented with CPG safe harbors in the early 1990s.¹⁹ While those pilot projects produced mixed or uncertain results, there has been significant rejuvenated interest.²⁰ The science of guideline development has improved²¹ and many are now at work developing and implementing CPG safe harbors.²²

16. See Tara F. Bishop et al., *Physicians' Views on Defensive Medicine: A National Survey*, 170 ARCHIVES INTERNAL MED. 1081 (2010).

17. See Emily R. Carrier, *Physicians' Fears of Malpractice Lawsuits Are Not Assuaged by Tort Reforms*, 29 HEALTH AFF. 1585 (2010); MASSACHUSETTS MED. SOC'Y, INVESTIGATION OF DEFENSIVE MEDICINE IN MASSACHUSETTS (Nov. 2008), available at http://www.massmed.org/AM/Template.cfm?Section=Research_Reports_and_Studies2&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=27797.

18. See generally Jennifer Begel, *Maine Physician Practice Guidelines: Implications for Medical Malpractice Litigation*, 47 MAINE L. REV. 69 (1995); J. Rosser Matthews, *Practice Guidelines and Tort Reform: The Legal System Confronts the Technocratic Wish*, 24 J HEALTH POL. POL'Y & L. 275 (1999); Michelle M. Mello, *Of Swords and Shields: The Use of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PENN. L. REV. 645 (2001); Arnold J. Rosoff, *Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines*, 26 J. HEALTH POL. POL'Y & L. 327 (2001); Daniel W. Shuman, *The Standard of Care in Medical Malpractice Claims, Clinical Practice Guidelines, and Managed Care: Towards a Therapeutic Harmony?* 34 CAL. W. L. REV. 99 (1997).

19. MICHELLE M. MELLO & ALLAN KACHALIA, EVALUATION OF OPTIONS FOR MEDICAL MALPRACTICE SYSTEM REFORM 42-47 (April 2010), available at http://www.medpac.gov/documents/Apr10_MedicalMalpractice_CONTRACTOR.pdf.

20. See, e.g., Peter R. Orszag, *How Healthcare Can Save or Sink America: The Case for Reform and Fiscal Sustainability*, 90 FOREIGN AFF. 42 (2011).

21. William M. Sage & David A. Hyman, *Do Health Reform and Malpractice Reform Fit Together?* (U. Texas L., L. & Econ. Res. Paper No. 203; Ill. Program in L., Behav. & Soc. Sci. Paper No. LBSS11-13, 2011), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1785796.

22. See, e.g., Texas informed consent works much like a clinical practice guideline. Using the disclosures and forms specified for some interventions is deemed sufficient. TEX.

B. *Procedurally-Defined Low Risk Conduct*

While some safe harbors like CPGs specify substantive standards, others specify only procedures.²³ Like substantively-defined safe harbors, procedurally-defined safe harbors also protect low-risk conduct, but they cannot specify that conduct *ex ante* because it cannot be described in the text of a statute. Instead, this type of safe harbor specifies a process, adherence to which assures that the conduct is low-risk, and thus worthy of protection. Two examples are peer review immunity and immunity for the unilateral refusal of life-sustaining treatment in Texas.²⁴

1. Peer Review Immunity

Peer review is an important quality-assuring mechanism in medicine. However, the success of the peer review process depends entirely upon the participation of physicians and their open and candid assessments. Researchers have demonstrated that a lack of immunity from civil suit stifles the process and the quality of the results.²⁵ Physicians are reluctant to discipline their colleagues, especially when that exposes them to the risk of retaliatory legal action by those colleagues. Consequently, safe harbor protection is afforded, even though physicians may take some adverse professional review actions in bad faith.²⁶

While most states afford this protection,²⁷ the keystone of peer review immunity is the Health Care Quality Improvement Act of 1986 (“HCQIA”).²⁸ This statute provides immunity from damages, so long as the professional review action is taken: (1) in a reasonable belief that the action was in furtherance of quality health care, (2) after a reasonable effort to obtain the facts of the matter, (3) after adequate notice and hearing

CIV. PRAC. & REM. CODE § 74.106 (2011); Thaddeus M. Pope, *Legal Briefing: Informed Consent*, 21 J. CLINICAL ETHICS 72 (2010); OREGON HEALTH POLICY BOARD, OFFICE FOR HEALTH POLICY AND RESEARCH, OREGON MEDICAL LIABILITY TASK FORCE REPORT 20-21 (Dec. 2010), available at <http://www.oregon.gov/OHA/action-plan/med-liability-report.pdf?ga=t>.

23. See Tamar Frankel, *Corporate Directors’ Duty of Care: The American Law Institute’s Project on Corporate Governance*, 52 GEO. WASH. L. REV. 705, 707 (1984) (“[S]ubject matter specificity is not the only way to provide . . . a safe harbor; specific process is another”).

24. A third example might be the documentation requirements for pain management safe harbors. See, e.g., ARK. CODE ANN. § 17-95-707 (2011); TENN. COMP. R. & REGS. 0880-2-14(6)(e) (2011).

25. See John F. Watson & J. Matthew Anderson, *The Medical Peer Review Privilege: Illustrative Cases of the Public Policy Supporting the Privilege and A Practical Approach to Presenting the Case for Protection*, 46 TORT TRIAL & INS. PRAC. L.J. 95 (2010).

26. See, e.g., *Poliner v. Texas Health Systems*, 537 F.3d 368, 380 (5th Cir. 2008).

27. See, e.g., 225 ILL. COMP. STAT. § 60/5 (2011); IOWA CODE § 147.135 (2011); S.D. CODIFIED LAWS § 36-4-25 (2011); VA. CODE § 8.01-581.16 (2011).

28. 42 U.S.C. §§ 11101-11152 (2011).

procedures, and (4) in the reasonable belief that the action was warranted by the facts known after a reasonable effort to obtain such facts.²⁹ Compliance with these measures earns the participating providers immunity because this procedural due process minimizes the risk of error.

2. Texas Advance Directives Act

The Texas Advance Directives Act (“TADA”) similarly provides a process-defined safe harbor. It offers a unique mechanism for resolving intractable medical futility disputes.³⁰ When a Texas physician refuses to honor a surrogate’s request to continue a patient’s life-sustaining treatment, the physician must commence a multi-stage review process. The first stage entails giving the surrogate at least 48-hours notice of a hospital committee meeting. Second, the committee reviews the treating physician’s determination. Third, if the committee agrees that the disputed treatment is inappropriate, the surrogate is given the committee’s written decision. This decision is final and unreviewable in court.

Fourth, the physician is obligated to continue providing the disputed treatment for ten days, during which time the provider must attempt to transfer the patient to another provider that is willing to comply with the surrogate’s treatment request. Fifth, if the patient has not been transferred, then the physician may unilaterally stop treatment on the eleventh day. Providers who follow TADA’s prescribed notice and meeting procedures are immune both from disciplinary action and from civil and criminal liability.³¹ Compliance with these measures earns the participating providers immunity because the supposed expertise of the hospital ethics committee minimizes the risk of error.

C. *Potentially Risky but Worthwhile Conduct*

In contrast to the first two types of safe harbor that protect conduct because it is either substantively or procedurally defined as low-risk, the third type of safe harbor protects even conduct that poses significant risk. This third type of safe harbor affords legal immunity, despite the risk, because the protected conduct is deemed socially desirable.³² There is a community interest in ensuring that physicians are not legally chilled from

29. 42 U.S.C. § 11112(a) (2011).

30. TEX. HEALTH & SAFETY CODE ANN. § 166.046 (2011).

31. *Id.* § 166.045 (2011).

32. *United Mine Workers v. Pennington*, 381 U.S. 657, 670 (1965); There are many such safe harbors outside medicine. For example, private entities are immune from liability under the antitrust laws for attempts to influence the passage or enforcement of laws, even if the laws they advocate for would have anticompetitive effects. *E. R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 135 (1961).

engaging in worthwhile activity such as rendering emergency aid, reporting public health threats, and honoring end-of-life decisions.³³ So, immunity is afforded to incentivize participation and furtherance of these important objectives.

1. Emergency Health Care

During catastrophic disasters and emergencies, it is neither possible nor appropriate to deliver medicine according to the customary standard of care. With limited staff and supplies, health goals must be refocused from the individual patient to the wider population.³⁴ Because the threat of liability could deter physicians from participating in emergency response activities, policymakers have devoted significant efforts to expanding immunity and developing crisis standards of care.³⁵

For example, the federal First Responders Fighting Terrorism Protection Act of 2011 would provide civil immunity to any “first responder who takes reasonable action to prevent an act of terrorism” or who “takes reasonable action to respond to” terrorist activity.³⁶ Unfortunately, disaster immunity law remains largely “a patchwork with many gaps and inconsistencies,”³⁷

While policymakers have been devoting significant attention to the crisis and disaster situation, physicians are often protected in even routine emergency situations.³⁸ In the early 2000s, five states enacted legislation

33. Since their involvement may be required by the Eighth Amendment, safe harbor protection is also extended to physicians participating in capital punishment. See generally Ty Alper, *The Role of State Medical Boards in Regulating Physician Participation in Executions*, J. MED. LICENSURE & DISCIPLINE 2009, at 1, 5-6; Nadia Sawicki, *Doctors, Discipline, and the Death Penalty: Professional Implications of Safe Harbor Policies*, 27 YALE L. & POL’Y REV. 107 (2008). Similarly, in *Hui v. Castaneda*, the Supreme Court held that U.S. Public Health Service physicians are immune even though that could adversely impact the standard of care in federal detention facilities. 130 S. Ct. 1845 (2010). Congress had made the judgment that this was necessary to encourage people to join the PHS. 42 U.S.C. § 233(a) (2011). A third, and more controversial, example is conscientious objection. Without such protection, the medical profession might be unable to attract individuals from some religions and cultures. See Thaddeus M. Pope, *Legal Briefing: Conscience Clauses and Conscientious Refusal*, 21(2) J. CLINICAL ETHICS 163 (2010). Such principles have long been included in common law. For example, the necessity privilege permits the destruction of property for the common good. And the negligence standard of care takes the relevant circumstances into consideration.

34. See Kristi L. Koenig et al., *Crisis Standards of Care: Refocusing Health Care Goals During Catastrophic Disasters and Emergencies*, J. EXPERIMENTAL & CLINICAL MED. (forthcoming 2011).

35. See Thaddeus M. Pope & Mitchell Palazzo, *Legal Briefing: Crisis Standards of Care and Legal Protections during Disasters and Emergencies*, 21 J. CLINICAL ETHICS 358 (2010).

36. H.R. 504, 112th Cong., 1st Sess. (2011).

37. Koenig et al., *supra* note 34.

38. For example, states often extend immunity to those providing advanced life support services. See, e.g., *Garry v. UMDNJ Hosp.*, 2011 WL 1261113 (N.J. Super. A.D. 2011) (construing N.J. STAT. ANN. § 26:2H-14 (2010)).

immunizing physicians providing emergency medicine.³⁹ A number of other states have introduced and considered similar legislation.⁴⁰ This safe harbor protection encourages the rendering of emergency medical services and enables emergency physicians to stop practicing defensive medicine.⁴¹ Moreover, eliminating the fear of lawsuits is expected to have a positive impact on emergency department crowding and on the lack of on-call specialists.

Liability protection for providing emergency medicine extends even outside the hospital. All fifty states have Good Samaritan statutes⁴² and pending federal legislation provides that a “health care practitioner or health care institution that provides emergency health care on a Good Samaritan basis is not liable for damages caused by that care except for willful or wanton negligence or more culpable misconduct.”⁴³

Deviating from the customary standard of care exposes the patient to physical risk and the physician to potential litigation and liability. Yet, deviating from the customary standard of care may be ethically appropriate or mandatory in crisis surge circumstances. Consequently, the law extends various forms of immunity to encourage physician participation in this socially desirable conduct.

2. Mandatory Reporting of Health Threats

State public health codes require physicians to report suspected cases of certain communicable diseases and health conditions.⁴⁴ For example, physicians must report patients with driving impairments,⁴⁵ AIDS,⁴⁶ and suspected cases of child abuse⁴⁷ and elder abuse.⁴⁸ Typically, the same

39. American College of Emergency Physicians, Sample Legislation, (2011), <http://www.acep.org/content.aspx?id=33178> (collecting authority).

40. See, e.g., Ohio S.B. 129, 129th Gen. Assembly (2011).

41. Cf. *Van Horn v. Watson*, 197 P.3d 164, 170 (Cal. 2008).

42. See, e.g., ARK. CODE ANN. § 17-95-101 (2011); STEVEN E. PEGALIS, AMERICAN LAW OF MEDICAL MALPRACTICE § 7.13 (3d ed.); Victoria Sutton, *Is There a Doctor (and a Lawyer) in the House? Why Our Good Samaritans Laws Are Doing More Harm Than Good for a National Public Health Security Strategy: A Fifty-State Survey*, 6 J. HEALTH & BIOMEDICAL L. 261 (2010).

43. H.R. 896, 112th Cong., 1st Sess. (2011).

44. See, e.g., 405 ILL. COMP. STAT. § 5/6-103 (2011); IND. STAT. ANN. § 34-30-16-3 (2011); MONT. CODE ANN. § 27-1-1103 (2011).

45. See, e.g., ALASKA STAT. § 08.64.336(e) (2011).

46. See, e.g., ARIZ. REV. STAT. § 32-1860 (2011).

47. See, e.g., *Id.* § 13-3620 (2011); COLO. REV. STAT. § 19-3-304 (2011); MASS. GEN. LAWS ch. 119 § 51A (2011).

48. See, e.g., MASS. GEN. LAWS ch. 19A § 15 (2011); ECRI Institute, *Elder Abuse Reporting*, 4 HEALTHCARE RISK CONTROL (Jan. 2008), available at http://aliciakraig.weebly.com/uploads/6/0/6/4/6064219/emercare3_elder_abuse.pdf.

statute that requires the report also affords immunity for making it.⁴⁹

While physician reporting of these conditions poses risks, such as breach of confidentiality, it is desirable on balance. This reporting enables the relevant authorities to take action either to protect the patient or to protect others from the patient. Because of the strong public policy interest in protecting innocent parties, physicians are afforded immunity for making these reports. Otherwise, they might be discouraged from doing so by the prospect of litigation and liability.

3. End-of-Life Decision Making

Historically, physicians have been reluctant to be involved in medical interventions that hasten a patient's death.⁵⁰ They are concerned that facilitating or failing to forestall death will get them into legal trouble. Yet, there is a strong public policy interest in honoring patient autonomy and permitting individuals to forgo life-sustaining treatment when they determine that the burdens outweigh the benefits. Accordingly, the healthcare decisions acts of most states grant physicians immunity for complying with advance directives.⁵¹ Similar immunity is provided to encourage compliance with the newer Physician Orders for Life-Sustaining Treatment ("POLST").⁵² Similarly, to encourage the procurement of organs after death, the Uniform Determination of Death Act⁵³ and the Uniform Anatomical Gift Act,⁵⁴ each adopted in almost every state, afford immunity.

D. *Blatant Protectionism*

We have seen that some safe harbors are justified on the basis of the protected conduct's low risk and others on the basis of the protected conduct's social value. But the justification for still other safe harbors is

49. See, e.g., ALA. CODE § 38-9-9 (2011) ("Any person . . . making of a report pursuant to this chapter . . . shall in so doing be immune from any liability, civil or criminal, that might otherwise be incurred or imposed."); ALA. CODE § 22-11A-2 (2011) ("Any physician . . . making any report required by this article . . . shall, in so doing, be immune from any civil or criminal liability, that might otherwise be incurred or imposed.")

50. See Schwartz, *supra* note 2; Henry S. Perkins et al., *Impact of Legal Liability, Family Wishes and Other 'External' Factors on Physicians' Life Support Decisions*, 89 AM. J. MED. 185 (1990); Irene M. Spinello, *End-of-Life Care in ICU: A Practical Guide*, 26 J. INTENSIVE CARE MED. 295 (2011).

51. See, e.g., DEL. CODE tit. 16 § 2510(a) (2011); Uniform Health Care Decisions Act § 9.

52. See, e.g., CAL. PROB. CODE § 4782 (2011).

53. See *In re Bowman*, 617 P.2d 731, 738 (Wash. 1980) ("Adoption of [a legislative] standard will alleviate concern among medical practitioners that legal liability will be imposed when life support systems are withdrawn . . ."); Christopher Burkle et al., *Brain Death and the Courts*, 76 NEUROLOGY 837 (2011).

54. Uniform Anatomical Gift Act § 18; Kristin Cook, *Familial Conflict for Registered Organ Donors: A Legally Rejected Concept*, 17 HEALTH MATRIX 117, 132-36 (2007).

wholly unrelated to the protected conduct. Instead, these safe harbors are best explained by the political and lobbying power of those whom they protect.

A paradigm example of this blatant protectionism is the state and federal introduction of “cheeseburger bills” in the mid-2000s.⁵⁵ These bills purported to ban lawsuits that blame the food industry for health conditions related to obesity. Supporters explained that exposing the food industry to suits similar to those used against the tobacco industry could bankrupt fast-food chains and restaurants.⁵⁶

For physicians, the classic example of a blatantly protective safe harbor is the statutes of repose. In response to the medical malpractice crisis of the 1970s, many states enacted statutes of repose. These statutes require plaintiffs to file their lawsuits within a certain time period. Since the time period is measured from the date of the negligent act, statutes of repose significantly reduce the uncertainty associated with the “long tail” effect of the discovery rule applicable to statutes of limitation. This, in turn, permitted malpractice liability carriers to lower premiums.⁵⁷

III. THE ESSENTIAL ATTRIBUTES OF A SAFE HARBOR

Now that we have reviewed the four types of medical safe harbors, we can examine how they should be designed to operate effectively. The essential attributes of a safe harbor vary according to whether the safe harbor is substantively- or procedurally- defined. Substantively-defined safe harbors require certainty, clarity, and concreteness. Procedurally-defined safe harbors must minimize the duration, distance, and demands of the process.

A. *Certainty, Clarity, and Concrete*

The prospect of liability, especially tort liability, is uncertain. The standards of care against which potential defendants’ conduct is measured

55. See H.R. 339, 108th Cong. (2004); Amy Winterfeld, Food Vendor Lawsuit Immunity (Feb, 2005), <http://www.ncsl.org/default.aspx?tabid=13869>. During this same time, a majority of states introduced, and more than a dozen enacted, legislation to limit the liability of food manufacturers, sellers, and others in the food distribution and marketing industry for claims resulting from health conditions related to obesity as a result of food consumption.

56. Similar bills have been proposed to protect other businesses, like the gun industry. See, e.g., Protection of Lawful Commerce in Arms Act, H.R. 1036, 108th Cong., 1st Sess. (2003). Congress cited as cause for the bill, a need to “prevent State courts from bankrupting the national firearms industry.” H.R. Rep. No. 108-59, at 4. These safe harbors did not protect specific conduct as much as they protected the entire industry.

57. See Martin H. Redish, *Legislative Response to the Medical Malpractice Insurance Crisis: Constitutional Implications*, 55 TEX. L. REV. 759 (1977).

are both *ad hoc* and *ex post*.⁵⁸ They are set by selectively drawn expert witness testimony after a lawsuit has already been filed. The primary value of safe harbors comes in eliminating or reducing this uncertainty.⁵⁹

To provide the intended and necessary certainty, substantively-defined safe harbors must be clear⁶⁰ and precise.⁶¹ “In order to be effective, a safe harbor must have a bright line that is unmistakable to all parties.”⁶² Clarity and concreteness reduce uncertainty and increase predictability.⁶³ Physicians cannot or will not undertake protected conduct unless they are able to confidently identify it as protected.

B. Duration, Distance, and Demands

Like a substantively-defined safe harbor, the core value of a procedurally-defined safe harbor lies in providing certainty and predictability. Just as substantive standards must be clear and precise, so too must the steps of the required process.

But, in addition, the process cannot be too elaborate. It must be easy to access. It must not last too long. And it must not demand too much time from the physician. In other words, unless the safe harbor minimizes the duration, distance, and demands of the process, physicians will be unwilling to utilize it.

IV. THE LIMITATIONS OF SAFE HARBORS

By comparing the essential attributes of safe harbors to the track record

58. James F. Blumstein, *Medical Malpractice Standard-Setting: Developing Malpractice “Safe Harbors” as a New Role for QIOs?* 59 VAND. L. REV. 1017, 1026-29 (2006); Mark A. Hall, *The Defensive Effect of Medical Practice Policies in Malpractice Litigation*, 54 L. & CONTEMP. PROBLEMS 119, 126-28 (1991). Still, there are some hard limits to the uncertainty of the standard of care. For example, almost every state has rejected a subjective disclosure standard for informed consent. *Canterbury v. Spence*, 464 F.2d 772, 790-91 (D.C. Cir.1972) (holding that such a standard “places the physician in jeopardy of the patient’s hindsight and bitterness”).

59. Cf. Jeffrey C.J. Lee, *The Ongoing Design Duty in Universal Music Australia Pty Ltd v. Sharman License Holdings Ltd: Casting the Scope of Copyright Infringement Even Wider*, 15 INT’L J. L. & INFO. TECH. 275, 282 (2006); Alison R. Watkins, *The Family Movie Act and the Future of Fair Use Legislation*, 21 BERKELEY TECH. L.J. 241, 258-59 (2006). Some safe harbors extend immunity to suit and not just to liability. See, e.g., ME. REV. STAT. tit. 14 § 8103 (government entities); ME. REV. STAT. tit. 39A § 104 (worker’s compensation); DEL. CODE tit. 24 § 1768(a) (“[M]embers of other peer review committees . . . are immune from claim, suit, liability, damages, or any other recourse, civil or criminal . . .”).

60. Blumstein, *supra* note 58, at 1049.

61. Hall, *supra* note 58, at 133-34, 142.

62. *Private Securities Litigation Reform Act of 1995; Report of the Committee on Banking, Housing, and Urban Affairs United States Senate*, Senate Report 104-98, at 35 (June 19, 1995). See also Gideon Parchomovsky & Keith A. Goodman, *Fair Use Harbors*, 93 VA. L. REV. 101, 127 (2007) (“bright-line rules”).

63. Parchomovsky & A. Goodman, *supra* note 62, at 127.

of actual safe harbors, it becomes evident that medical safe harbors suffer from several serious limitations. First, given the variability and complexity of medicine, it is difficult to state specific, precise substantive standards. Second, it is difficult to state procedural standards that are fair yet not too burdensome.

A. Substantively-Defined Standards: Discretion vs. Specificity

Legislators have been able to specify some safe harbors in a way that provides sufficient notice to physicians. Most of the fraud and abuse safe harbors, for example, are specific and predictable. In contrast, legislators have had significant trouble writing clear and concrete safe harbors in other areas like clinical practice guidelines and medical futility.

The development of clinical practice guidelines has been hampered by a number of obstacles. Their development has been decentralized and it is unclear which guidelines should be authoritative.⁶⁴ Some are contradictory and many more are plagued with conflicts of interest. Moreover, even if a particular guideline were identified as authoritative, there would still be “battle of the expert” debates over whether it applied to the circumstances at hand.⁶⁵ After all, with any substantively-defined safe harbor, “some qualified decision maker” must determine whether that CPG applies to the “clinical situation in the case.”⁶⁶

Like CPG safe harbors, medical futility safe harbors are similarly troubled. Medical treatment at the end of life is the subject of significant conflict. One type of conflict, a medical futility dispute, arises when a healthcare provider wants to refuse treatment (usually life-sustaining treatment) that the patient or surrogate wants. Fortunately, most futility disputes are resolved consensually and informally. Only rarely do they become intractable.

For the subset of irreconcilable disputes, a majority of states provide safe harbors that purport to allow physicians to refuse life-sustaining treatment they judge medically inappropriate.⁶⁷ California, for example, provides that a “health care provider . . . may decline to comply with an individual health care instruction or health care decision that requires . . . health care contrary

64. Ronen Avraham, *Clinical Practice Guidelines-The Warped Incentives in the U.S. Healthcare System*, 37 AM. J. L. & MED. 7 (2011); Inst. of Med., Standards for Developing Trustworthy Clinical Practice Guidelines (Mar. 2011), [http://iom.edu/~media/Files/Report%20Files/2011/Clinical-Practice-Guidelines-We-Can Trust/Clinical%20Practice%20Guidelines%202011%20Insert.pdf](http://iom.edu/~media/Files/Report%20Files/2011/Clinical-Practice-Guidelines-We-Can%20Trust/Clinical%20Practice%20Guidelines%202011%20Insert.pdf).

65. C.J. Stimson et al., *Health Care Reform 2010: A Fresh View on Tort Reform*, 184 J. UROLOGY 1840, 1844 (2010).

66. Mello & Kachalia, *supra* note 19, at 43.

67. See Thaddeus M. Pope, *Medical Futility Statutes: No Safe Harbor to Unilaterally Refuse Life-Sustaining Treatment*, 75 TENN. L. REV. 1 (2007).

to generally accepted health care standards”⁶⁸

But the California statute, like most safe harbors, is ineffective, because it is linked to the standard of care. This makes any protection vague and uncertain.⁶⁹ Since the determination of the standard of care is set *ex post*, the safe harbor adds little or nothing in terms of predictability.⁷⁰ So, this hardly even counts as a safe harbor.⁷¹ If it does count, the linkage to the standard of care makes it inoperative.⁷² New Mexico tried to address this problem by permitting the physician to decline treatment that would not “offer the patient any significant benefit *as determined by a physician*.”⁷³ But the separate immunity section still requires that the physician act “in accordance with generally accepted healthcare standards.”⁷⁴ The New Mexico legislation was not careless. Policymakers are unable to write more precise statutory language because neither the medical profession nor society can agree on the relevant standards.

The safe harbor limitations exhibited by CPGs and medical futility are not unique to those contexts. As Mark Hall observes, in very few areas of medicine do we find professional standards that are “sufficiently mandatory and concrete” to operate as a safe harbor.⁷⁵ Rarely do we have what is necessary for immunity, “a precise and plain statement of the acceptable medical practice.”⁷⁶ Medicine is, after all, often too variable or too subtle to be captured in concrete standards.⁷⁷

68. CAL. PROB. CODE §§ 4735 & 4740 (2011).

69. See generally Anne L. Flamm, *The Texas ‘Futility’ Procedure: No Such Thing as a Fairy Tale Ending*, LAHEY CLINIC MED. ETHICS J., Spring 2004, at 4 (“The promise of immunity, of course, is not guaranteed; patients can challenge a provider’s adherence to [the statute.]”); Thaddeus M. Pope & Ellen A. Waldman, *Mediation at the End-of-Life: Getting Beyond the Limits of the Talking Cure*, 23 OHIO ST. J. ON DISP. RESOL. 143 (2007).

70. Malpractice law is itself a sort of safe harbor: “Comply with the standard of care and there is no liability.”

71. Stimson et al, *supra* note 65, at 1843 (“Whereas current medical malpractice negligence determinations are entirely an *ex post* (after the injury) analysis, safe harbors introduce *ex ante* (before the injury) standards that prospectively distinguish negligent from non-negligent health care.”).

72. Clark C. Havighurst, *Practice Guidelines as Legal Standards Governing Physician Liability*, 54 L. & CONTEMP. PROBLEMS 87, 106 (1991); Hall, *supra* note 58, at 138 & n.81 (“immunity is undermined by the statute itself”).

73. N.M. STAT. § 24-7A-7(F) (2011) (emphasis added).

74. *Id.* § 24-7A-9(A)(4) (2011).

75. Hall, *supra* note 58, at 121, 127-28, 144-45.

76. *Id.* at 134.

77. *Id.* at 127-28, 143. In some cases this is mitigated by requiring only the physician’s “good faith” compliance with the safe harbor. But this often introduces uncertainty over what constitutes good faith. See, e.g., *Perry v. St. Francis Hosp.*, 886 F. Supp. 1551 (D. Kan. 1995); *Geary v. Stanley Med. Res. Inst.*, 939 A.2d 86 (Me. 2008); *Maxey v. Davis*, 187 P.3d 144, 151-52 (Nev. 2008) (construing NEV. REV. STAT. § 449.630(2)); *Ballensky v. Fattum-Riemers*, 716 N.W.2d 110 (N.D. 2006) (denying summary judgment); *Sattler v. Nw. Tissue Ctr.*, 42 P.3d 440 (Wash. Ct. App. 2002); *Test-Drive*, *supra* note 2, at 1486 (“[I]ndeterminate

B. *Procedurally-Defined Standards: Fairness vs. Speed*

While procedurally-defined safe harbors overcome some of the obstacles facing substantively-defined safe harbors, they have their own limitations. For example, in contrast to most states' healthcare decisions statutes, which specify vague substantive standards for resolving medical futility disputes, the TADA safe harbor is defined solely in terms of process. Because TADA's requirements are concrete and measurable, there is little, if any, uncertainty of compliance. Indeed, providers have used TADA numerous times to unilaterally withdraw life-sustaining treatment over surrogate objections.⁷⁸

However, the TADA Act has proven very controversial and was the subject of significant legislative activity during the 2007, 2009, and 2011 sessions of the Texas Legislature.⁷⁹ Among other problems, the statute arguably fails to afford patients and surrogates with adequate procedural due process. The ultimate life-and-death decision rests in the hands of an institutional committee comprised of physicians and administrators who look to the hospital for their economic livelihood, and there is no judicial review of the committee's decision. But a more elaborate process with longer notice periods and an independent, neutral committee would, for many physicians, make the mechanism more trouble than it would be worth.

Canada also has a special adjudicative mechanism for the resolution of medical futility disputes: the Ontario Consent and Capacity Board ("CCB").⁸⁰ Notably, however, there are two important distinctions between the TADA and the CCB that make the latter fairer. First, unlike TADA committees which are part of the hospital, the CCB is "an independent, quasi-judicial tribunal;" a "neutral, expert board." Second, unlike a TADA committee's decision, which is unreviewable, even a "legal and binding" CCB decision can be reversed on appeal through the courts.⁸¹

But the additional due process in the CCB mechanism comes at a steep price. A recent survey of physician attitudes toward the CCB indicates that the appeals process is perceived as a substantial obstacle. It extends the

standards, such as good faith or reasonableness . . . shed the shield they offer because they are fact-sensitive and litigable").

78. Robert D. Truog & Christine Mitchell, *Futility – From Hospital Policies to State Laws*, AM. J. BIOETHICS, Sept./Oct. 2006, at 19, 20 ("Clinicians in Texas may also be much more confident and bold in applying the policy, knowing that they are protected by the law.").

79. Thaddeus M. Pope, *Legal Briefing: Futile or Non-Beneficial Treatment*, 22 J. CLINICAL ETHICS 277 (2011).

80. Consent and Capacity Board (Aug. 25, 2010) <http://www.ccboard.on.ca/scripts/english/index.asp>.

81. Mark Handelman & Bob Parke, *The Beneficial Role of a Judicial Process When 'Everything' Is Too Much*, HEALTHCARE Q., Winter 2008, at 46.

process for an indefinite period of time, making it so lengthy that it negates any perceived benefit of the process. Indeed, some respondents indicated that the appeal results in more harm to the patient than if no application had been made to the CCB in the first place.⁸² Indeed, physicians are asking the Supreme Court of Canada to declare that they need not use the CCB.⁸³ The duration and demands of the process undermine the attractiveness, and thus the effectiveness, of the safe harbor.

V. CONCLUSION

While safe harbor legal immunity has not always been an entirely effective, trouble-free response, there is reason for optimism. The development of CPGs is more sophisticated and more supported than ever before. Similarly, greater experience with and evaluations of procedurally-defined safe harbors can help policymakers tweak the balance between fairness and expedition.

Because they may “influence doctors to alter their practices in undesirable ways,” Professor Johnson rightly urges that we seriously attend to physicians’ “fears over the prospect of legal entanglement and potential sanctions.”⁸⁴ Safe harbor legal immunity remains an appropriate response to physicians’ “bad law” claims.

82. Paula Chidwick & Robert Sibbald, *Physician Perspectives on Legal Processes for Resolving End-of-Life Disputes*, HEALTHCARE Q., 2011, at 69.

83. *Cuthbertson v. Rasouli*, No. 34362 (Supreme Court of Canada Aug. 5, 2011) (Application for Leave).

84. *Regulating Physician Behavior*, *supra* note 1, at 1024.