I. INTRODUCTION

The intersection of law and information technology (IT) holds profound implications for healthcare, one of the great social policy subjects of our time. As an unacceptably high rate of medical errors continues unabated and double-digit increases in costs make healthcare affordability increasingly problematic, old and new forces are combining to create an imperative for a national-level system of medical information connectivity that would improve healthcare quality and reduce medical malpractice costs.¹ These forces and the opportunities and obstacles they create have spawned a growing national debate, a key but insufficiently discussed facet of which pertains to the enormous potential of information technology to reduce medical errors and their

¹ See, e.g., Volker Pfahlert & Hamid Emminger, Future Prospects In Medical Diagnostics, 27 J. MED. ENG’G & TECH. 109, 109-10 (2003) (discussing doctor and patient interest in diagnostic procedures aligned with the latest scientific findings).
attendant malpractice costs. This article examines the potential just noted and considers
the need to modify or eliminate legal barriers to the full realization of that potential.

Medical malpractice cases and the costs thereof are not new topics of public
discourse. Such issues re-emerged in the 2004 presidential campaign, when an alleged
malpractice liability “crisis” became a political football and healthcare providers’ liability
insurance premiums were asserted to have reached unacceptably high levels. The Bush
Administration's proposed solution to the supposed crisis, offered during the 2004
campaign and reiterated since the election, centered on capping non-economic damages
in malpractice cases at $250,000. Such caps are anything but novel and are premised on

---

2 See, e.g., Mark D. Hiatt, Caps on Damages Awards in Medical Malpractice Cases: Constitutional
(discussing judicial challenges to capping damages in medical malpractice claims).

3 Brandon Van Grack, Recent Development: The Medical Malpractice Liability Limitation Bill, 42 HARV. J.
ON LEGIS. 299, 300 (2005). This crisis may well have become a subject of discussion in the 2004 campaign
even if the Democratic ticket had not featured a vice-presidential candidate with a background as a highly
successful plaintiffs’ attorney in medical malpractice and other tort cases, but the selection of John
Edwards effectively guaranteed that medical malpractice-related matters would be high on Republicans’
list of campaign issues. See generally Hillary for Tort Reform, WALL ST. J., Nov. 20, 2001, at A18
(discussing Clinton’s support of a tort reform provision in an aviation security bill). During campaign
appearances and after the election, President Bush frequently spoke about large damage awards in
malpractice cases and a supposed epidemic of frivolous cases against healthcare providers. He also
lamented skyrocketing malpractice insurance premiums that were allegedly having the effect of driving
some physicians from practice. Press Release, White House, President Discusses Lawsuit Abuse at White
House Economic Conference (Dec. 15, 2004), available at

4 Van Grack, supra note 3, at 300.
the assumption—whose validity is contested by critics—that big damage awards and
monetary settlements in malpractice cases have caused malpractice insurance premiums
to rise drastically.\textsuperscript{5}

Yet even if one assumes for the sake of argument that large malpractice damage
awards and settlements are the sole reason why medical malpractice insurance is so
expensive and that a reduction in insurers' payouts in malpractice cases should lead to
lower malpractice insurance premiums, non-economic-damages caps are incomplete
solutions to the multi-faceted healthcare cost crisis.\textsuperscript{6} Such caps would do nothing to
improve the quality of patient care.\textsuperscript{7} Worse yet, they could lead to reduced attention to
patient safety, thereby increasing medical errors.\textsuperscript{8}

\textsuperscript{5} Hiatt, \textit{supra} note 2, at 87. This assumption matches the insurance industry's explanation for why
malpractice premiums have risen so high. Catherine M. Sharkey, \textit{Unintended Consequences of Medical
Malpractice Damages}, 80 N.Y.U. L. Rev. 391, 405 (2005). Critics of this argument point to other
explanations such as insurers' desire to make up for investment income they had become accustomed to
receiving during better economic times before it diminished in recent years.\textit{Id. See also}, David A. Hyman
& Charles Silver, \textit{The Poor State of Health Care Quality in the U.S.: Is Malpractice Liability Part of the
Problem or Part of the Solution?}, 90 CORNELL L. REV. 893, 899 (2005) (arguing that tort reform is more
likely to reduce health care quality than improve it).

\textsuperscript{6} Bryan A. Liang & LiLan Ren, \textit{Medical Liability Insurance and Damage Caps: Getting Beyond Band Aids
to Substantive Systems Treatment to Improve Quality and Safety in Healthcare}, 30 AM. J. L. & MED. 501,

\textsuperscript{7} E.g., Edward J. Kionka, \textit{Things to Do (or Not) to Address the Medical Malpractice Insurance Problem}, 26

\textsuperscript{8} Hyman & Silver, \textit{supra} note 5, at 897, 899. Statutory ceilings on the amount of recoverable damages
would of course limit what insurers would pay out in jury awards or settlements regardless of the strength
of the case and the extent of the harm allegedly experienced by the plaintiff, but the ceiling's real impact
In this article, we maintain that meaningful malpractice reform requires a new direction--treating the disease rather than its symptoms. Instead of tinkering with malpractice-related legal rules through largely ineffective measures such as caps on damages, malpractice reform should focus on a fundamental underlying concern: the need to reduce the number and frequency of medical errors. Medical errors result in more than 90,000 patient deaths per year and similar numbers of instances of physical harm short of death. Reduction of medical errors is a direction to be pursued in malpractice reform because if errors are reduced, less litigation would be triggered and fewer damage awards and settlements of huge magnitude would be expected.

would be on the strongest cases in which the harm suffered by the plaintiffs was quite extensive. See infra text accompanying notes 139-42.

9 See Liang & Ren, supra note 6, at 502.

10 When the term “medical error” is used herein, we generally are referring to instances in which harm comes to a patient as the result of a health care professional’s failure to meet the reasonable care standard discussed later in this article. As will be seen, a bad outcome for a patient does not necessarily mean that there was any failure to use reasonable care on the part of the health care professional. See infra text accompanying notes 36-49. Information technology-based measures of the sort discussed in this article are likely to reduce not only the number and frequency of medical errors but also the number and frequency of bad outcomes that may not have involved any failure to use reasonable care. See infra text accompanying notes 50-54.


12 Liang & Ren, supra note 6, at 540.
malpractice litigation is the premium-raising culprit physicians and insurance companies assert it is, a reduction in litigation volume should lead to decreases in premiums.\textsuperscript{13}

Further reason to make medical error reduction the focus of malpractice reform stems from the likelihood that without real changes in the manner in which medicine is practiced, the frequency of medical errors will increase.\textsuperscript{14} As healthcare and life sciences advancements add to the complexity of diagnoses and treatments and simultaneously enhance patient longevity, the need for ever more treatments arises.\textsuperscript{15} Absent new safeguards, however, the opportunities for medical errors will increase as well.\textsuperscript{16} A complex interplay among a growing array of diagnostic tests, treatments, and patient characteristics will serve to multiply the number of information cues physicians will need to process.\textsuperscript{17} Today, however, many physicians collect and process patient information in an antediluvian manner, much as physicians did fifty years ago without the benefit of

\begin{itemize}
  \item \textsuperscript{13} Marilyn M. Rosenthal, \textit{Medical Errors and Medical Narcissism}, 353 NEW ENG. J. MED. 324, 324 (2005) (reviewing JOHN D. BANJA, \textit{MEDICAL ERRORS AND MEDICAL NARCISSISM} (2005)).
  \item \textsuperscript{14} Pfahlert & Emminger, \textit{supra} note 1, at 109-12. For a discussion of the increasing complexity of medical information and the implications for treatment standards, see id.
  \item \textsuperscript{15} I.D. Montoya et al., \textit{Drug Abuse, AIDS, And The Coming Crisis In Long-Term Care}, 4 J. NURSING MGMT. 151, 151 (1996). \textit{See generally COPING WITH METHUSELAH} (Henry J. Aaron & William B. Schwartz eds., 2004) (discussing implications of longevity for the economy and the quality of the services of the health care industry).
  \item \textsuperscript{17} Pfahlert & Emminger, \textit{supra} note 1, at 109-12. Longstanding evidence from cognitive research, however, reveals there are finite limits on the number of cues that can be processed effectively by intelligent decision makers. \textit{Id.}
\end{itemize}
information-systems decision aids and prompts--a recipe for an explosion of medical errors in light of burgeoning healthcare knowledge.\textsuperscript{18}

We contend not only that medical error reduction should be the focus of a new type of malpractice reform, but also that increased use of healthcare information technology (IT) should be the primary method of implementing this error-reduction focus. Recent advancements in IT furnish considerable potential for reducing medical errors, and thus could play key roles in meaningful malpractice reform and in lessening malpractice costs.\textsuperscript{19} Appropriate use of electronic medical records (EMRs) has been shown to reduce significantly the number and frequency of medical errors by providing healthcare professionals superior information to that afforded by traditional, often incomplete, and less accessible charting.\textsuperscript{20} Evidence also suggests that reduction in


\textsuperscript{19} Pfahler & Emminger, supra note 1, at 109-12. \textit{See President to Push Medical Record Computerization}, N.Y. SUN, Jan. 6, 2006, at 1.

\textsuperscript{20} Robert Badgett & Cynthia Mulrow, \textit{Using Information Technology to Transfer Knowledge: A Medical Institution Steps Up to the Plate}, 142 ANNALS INTERNAL MED. 220, 220-21 (2005). For an example of a hospital touting improvement in the quality of care and a reduction of medical errors resulting from the use of EMR, see Hogstrom, supra note 18, at A3.
medical errors results from the use of IT prompting tools that aid physicians in diagnosing health problems and selecting appropriate courses of treatment.  

Notwithstanding IT’s potential efficacy in reducing medical errors, the number of physicians using EMR and related IT diagnostic and treatment aids remains small. The very physicians who have embraced technological advancements in the performance of clinical procedures have predominantly continued to "rely on pen and paper to record and track their patients' medical histories.” Various factors, including concern over possible costs and fears of increased legal liability, have made many physicians hesitant to use EMR and related diagnostic/prompting aids.

There are signs, however, that the tide may be turning. The office of the National Coordinator for Health Information Technology is leading a still-fledgling but promising effort to promote EMR use. Congress has begun to consider legislation intended to increase EMR use and electronic sharing of medical information among

---


25 See, e.g., CR Investigates: The New Threat to Your Privacy; You Need to Know, CONSUMER REPORTS, Mar. 2006, at 39 (“So far, the development of medical information networks has been sporadic, but those in operation are already offering advantages to both doctors and patients.”).

26 See Brailer, supra note 22 (discussing the increasing use of IT in the healthcare industry).
healthcare providers. This proposed legislation has bipartisan support.\textsuperscript{27} Private organizations led by physicians favorably disposed to EMR are actively engaged in educational efforts highlighting the error-reduction potential of such systems.\textsuperscript{28}

Furthermore, healthcare consumers seem likely to play an important two-part role in persuading healthcare providers to adopt EMR. First, consumers are far more empowered to participate in their healthcare decisions than in the past,\textsuperscript{29} a fact that will logically give rise to increased expectations regarding the availability of health and

\textsuperscript{27}Although unlikely political allies, Sen. Hillary Clinton (D-N.Y.) and former Rep. Newt Gingrich (R-Ga.) are among the high-profile individuals who have jointly expressed their support for the legislative effort. So has former Senate Majority Leader Bill Frist (R-Tenn.). Sens. Clinton, Frist Push Medical-Records Bill, http://www.msnbc.msn.com/id/8242127/.


patient information. Second, as patient safeguards present in medical IT systems become more widely publicized, patients will logically prefer those healthcare providers who utilize such leading-edge safeguards.


With these governmental and private sector influences operating in conjunction with legal incentives and a moral imperative on the part of healthcare providers to safeguard patients, it seems that increased use of EMR and IT systems should occur. In this article, therefore, we propose promotion of the use of healthcare IT as a cornerstone of a fundamentally different type of medical malpractice reform--one that emphasizes the common interest of patients, healthcare providers, insurers, and the government in reducing medical errors. Significant obstacles exist, however, to the use of healthcare IT on a national level sufficient to effect a realization of its full potential in furthering patients’ welfare and reducing medical errors.32 These obstacles include the cost of acquiring and implementing the systems, legal and operational issues associated with systems integration, patient privacy concerns, and, in some cases, increased legal liability resulting from a failure to act following receipt of patient information.33 We argue later in the article that to realize the full benefits of a national-level healthcare IT system, certain legal obstacles must be minimized or removed.

---


33 Id.
Section II of the article furnishes necessary background by addressing fundamental legal issues in medical malpractice cases and, in particular, the reasonable care standard. As will be seen, use of EMR and similar tools seems destined to become a factor that courts will consider in determining whether a healthcare provider has met the reasonable care standard. Section III provides background on the current malpractice "crisis" (including the malpractice insurance dimension) and on the tort and medical malpractice reforms instituted by certain states in response to earlier crises of a similar nature. As will be seen, the insufficient effectiveness of these reforms (which typically have targeted certain legal rules discussed in Section II) serves as a reason for shifting to an error-reduction-focused response to the malpractice crisis. Because medical information privacy concerns may serve as an obstacle to more widespread adoption of EMR, Section IV furnishes background on laws and regulations that affect the collection, dissemination, and use of medical information.

Section V adds another dimension to the article’s medical error-reduction thesis by exploring the current state of IT in the healthcare industry. Emphasis is placed on various types of applications presently available or likely to be available in the near future, and on the potential of EMR and related tools for reducing medical errors. Section VI follows suit by examining the need for a national healthcare information network (NHIN), its characteristics, and its potential benefits. In Section VII, we address legal barriers to implementation of a NHIN and provide recommendations for a legal environment that would be necessary for the maximum success of a NHIH. Section VIII

34 See David W. Bates et al., A Proposal for Electronic Medical Records in U.S. Primary Care, 10 J. AM. MED. INFORMATICS ASS’N 4, 4 (2003) (arguing that the use of EMRs should be increased).
summarizes our arguments for achieving the broader goal of reduction of medical errors through the use of IT as the centerpiece of a new and more fruitful type of malpractice reform.

II. FUNDAMENTAL LEGAL ISSUES IN MEDICAL MALPRACTICE CASES

 Failures to Use Reasonable Care

Medical malpractice litigation normally presents the basic question of whether the healthcare provider (hereinafter "HCP") being sued exercised reasonable care—the degree of care that a reasonable provider of ordinary prudence would have exercised under the circumstances. This focus on the reasonable care standard means that medical malpractice cases fit under the broader heading of *negligence* litigation.

---

35 As used herein, *healthcare provider* (HCP) refers to physicians, nurses, other medical professionals, hospitals, medical clinics, and other similarly situated parties.


37 SHOWALTER, supra note 36, at 39; WING, supra note 36, at 287, 290. The special name *malpractice* becomes attached to these cases because they arise in the context of treatment administered by professionals—here, medical professionals. See, e.g., id. at 290-91. Cases in which the patient claims a lack of informed consent to a medical procedure have effectively become another subset of negligence cases.
Malpractice cases typically necessitate asking whether a defendant physician provided medical care that a reasonable physician would have provided, whether a defendant nurse acted as a reasonable nurse would have acted in furnishing treatment, whether a defendant medical clinic or hospital provided healthcare services that a reasonable clinic or hospital would have supplied, and so forth. If the defendant failed to live up to the

See SMITH, supra note 36, §§ 12.04, 12.05. For a discussion of physicians’ obligation to obtain informed consent from their patients, see id. Informed consent cases will not receive further discussion here.

E.g., SHOWALTER, supra note 36, at 40-43. Some jurisdictions compare the defendant physician's actions (or failures to act) with those of the hypothetical reasonable physician in the same geographic locality. E.g., Leazer v. Kiefer, 821 P.2d 957, 960 (Idaho 1991). Others broaden the inquiry by considering what a reasonable physician in the same community or a similar community would have done, e.g., Purtill v. Hess, 489 N.E.2d 867, 874 (Ill. 1986), or by taking into account the course of action that a reasonable physician in the defendant's state would have pursued. E.g., Vasquez v. Markin, 731 P.2d 510, 517 (Wash. Ct. App. 1986). Still other jurisdictions go further, employing effectively a national standard in deciding whether the defendant measured up. E.g., Hall v. Hilburn, 466 So. 2d 856 (Miss. 1985). The trend appears to be in favor of broader statewide or national standards, especially when the defendant is a specialist with board certification in a particular specialty. See SHOWALTER, supra note 36, at 41. Moreover, in a case involving a specialist, the relevant comparison is between the defendant and reasonable physicians of the same specialty, as opposed to reasonable physicians generally. E.g., Riggins v. Mauriello, 603 A.2d 827 (Del. 1992).

SMITH, supra note 36, §§ 11.02[2], [3].

See, e.g., Darling v. Charleston Mem’l Hosp., 211 N.E.2d 253 (Ill. 1965). Darling was instrumental in establishing the "corporate negligence" doctrine, which is now recognized in a significant number of states as a basis for holding hospitals liable. SMITH, supra note 36, § 3.03[1]. The hospital's failure to use reasonable care may have taken a variety of forms, including such errors as not providing adequate training or instruction to employees, not engaging in appropriate supervision of physicians and employees, negligently credentialing physicians who should not have been credentialed, and failing to furnish adequate
reasonable care standard and that failure caused or helped to cause the physical harm experienced by the plaintiff, the defendant is liable despite the lack of any intent to inflict harm.\footnote{41}

Accordingly, the mere fact that a patient experiences a bad outcome as a result of medical treatment does not mean that the patient will be a successful plaintiff in a malpractice case. Only if the bad outcome-producing treatment amounted to a failure to use due care would the HCP be liable to the patient. If the hypothetical reasonable HCP would have done--or not done--the same things that the defendant HCP did or failed to do, the harmed plaintiff does not have a meritorious legal claim.\footnote{42}

\footnote{41}E.g., \textit{Wing}, \textit{supra} note 36, at 292. The elements of a malpractice claimed based on supposed professional negligence are the existence of a duty on the part of the defendant(s), the breach of that duty, and a sufficient causation link between the breach of duty and the plaintiff's harm or injury. \textit{E.g., id.} The duty element normally will be present, in view of the reasonable care standard discussed above. \textit{See supra} text accompanying notes 35-40. As a result, the case typically will hinge on whether the breach of duty and causation elements are also present. \textit{See, e.g., Wing, supra} note 36, at 291-92.

\footnote{42}E.g., \textit{Wing, supra} note 36, at 291-92. Of course, there is no guarantee that litigation will not be instituted regarding the bad outcome, even if it is ultimately determined that the defendant is not liable. Increased use of information technology, as proposed herein, should lead not only to reduction of true medical errors...
Alleged failures to use due care on the part of the HCP frequently take the form of some inappropriate action. Perhaps a surgeon performed a procedure without the degree of skill that a reasonable surgeon would have displayed, or a physician ordered a particular treatment regimen that a reasonable physician would have rejected under the circumstances.\textsuperscript{43} Perhaps the physician prescribed a certain medication that interacted with other medications being taken by the patient and caused severe harm to the patient--harm that accessible published studies had shown to be a serious interaction risk in regard to the drugs involved.\textsuperscript{44} What if the physician prescribed a suitable medication and an appropriate dose thereof, but hospital nurses departed from the standard of reasonable care by mistakenly giving the patient a significantly heavier dose than the proper one (i.e., actions or failures to act that violate the reasonable care standard) but also to the reduction of bad outcomes that did not involve a failure to use reasonable care. See infra text accompanying notes 50-54.

Establishing that the physician or other HCP failed to use reasonable care will normally require expert testimony. SHOWALTER, supra note 36, at 45-47. Plaintiffs sometimes experience difficulty obtaining physicians who are willing to testify as experts against defendant physicians. This difficulty can present a significant obstacle to plaintiffs' ability to win their cases. See id. at 45.

\textsuperscript{43} E.g., Esfandiari v. United States, 810 F. Supp. 1 (D.D.C. 1992); Riggins v. Mauriello, 603 A.2d 827 (Del. 1992). Of course, liability would result only if the physician's failure to use reasonable care resulted in injury to the patient. See supra text accompanying note 41.

\textsuperscript{44} See, e.g., Incollingo v. Ewing, 282 A.2d 206 (Pa. 1971) (holding that in all survivor actions, damages are properly measured by decedent's pain and suffering and loss of gross earning potential from the date of injury until death and loss of earning potential less personal maintenance expenses from the time of death through decedent's estimated working life span). See also SMITH, supra note 36, § 10.08 (discussing physician's responsibility when he or she issues improper medication order).
actually prescribed? The physician would not be liable, but the nurses and their employer, the hospital, could be if the overdose resulted in harm to the patient.\textsuperscript{45}

An omission to act may also constitute the alleged failure to use reasonable care. For instance, assume that a physician did not pick up on signs of likely cancer in a patient until it was too late to help the patient. If a reasonable physician would have recognized these signs much sooner and would have acted accordingly, the physician who failed to act in a timely manner may have been negligent.\textsuperscript{46} Similarly, hospital employees who failed to check for long periods of time on a severely ill patient may have been negligent if the failure was inconsistent with reasonable treatment protocols under such circumstances.\textsuperscript{47}

\begin{flushright}
\end{flushright}

\begin{flushright}
\textsuperscript{46} See., e.g., -Georgetown Cmty. Health Plan, Inc. v. Stutsman, 491 A.2d 502 (D.C. App. 1985) (holding that District of Columbia law would apply to malpractice action, because District’s interest in holding its corporations liable for negligence and in protecting members of its work force who contracted for health services with District corporations would be advanced by application of such law, and Virginia policy of limiting malpractice liability to lower malpractice premium for Virginia health care providers would not be contravened); Jones v. Speed, 577 A.2d 64 (Md. 1990); Kaiser.
\end{flushright}

\begin{flushright}
\textsuperscript{47} SMITH, supra note 36, §§ 4.02(2), 4.04(2), 11.04(2).
\end{flushright}
existed between that failure and the harm experienced by the plaintiff.\textsuperscript{48} To demonstrate this causal link, the plaintiff must show that the HCP’s having fallen below the standard of due care either was the "but for" cause of the plaintiff’s harm or was a substantial factor in the production of the harm.\textsuperscript{49}

Later sections of this article will explore how increased use of electronic medical records and similar technological advances would be likely to reduce significantly the

\begin{footnotesize}
\textsuperscript{48} Showalter, supra note 36, at 51; Wing, supra note 36, at 292. Consider, for instance, a case in which the defendant physician fell below the standard of care by failing to recognize that a piece of steel had become lodged in the plaintiff’s eye. Shortly thereafter, another physician spotted the piece of steel and administered treatment. The plaintiff experienced a loss of vision because his eye had become infected, but the defendant physician was not held liable because the plaintiff would have sustained those harms even if the defendant had diagnosed the problem correctly and provided appropriate treatment sooner than it actually was provided. Hence, there was not an adequate causal link between the defendant’s breach of duty and the harm experienced by the plaintiff. Henderson v. Mason, 386 S.W.2d 879 (Tex. Civ. App. 1964).

\textsuperscript{49} Wing, supra note 36, at 292-93; Showalter, supra note 36, at 51. The causation requirement has two parts: actual cause and proximate cause. Both parts must be established. Actual cause is established under the “but for” or substantial factor tests noted in the text. Id. at 51. Depending upon the test used in the jurisdiction whose law controls, proximate cause exists if the harm experienced by the plaintiff was a foreseeable consequence of the defendant’s breach or was a natural and probable consequence of the breach. Wing, supra note 36, at 292-93. If actual cause exists in a medical malpractice case, proximate cause is likely to exist as well. See id. With HCPs typically furnishing medical treatment to persons who were already ill or injured, the patient whose condition was worsened as a result of negligent medical treatment may have a valid malpractice claim for the harm associated with the worsened condition, even though the HCP was neither the initial nor sole cause of the condition that warranted treatment. E.g., Lanzet v. Greenburg, 594 A.2d 1309 (N.J. 1991); Mitzelfelt v. Kamrin, 584 A.2d 888 (Pa. 1990).
\end{footnotesize}
number of medical errors and bad outcomes that commonly have given rise to malpractice cases.\textsuperscript{50} Some examples are worth noting at this juncture, however. For instance, computerized drug order entry systems and access to the Physician’s Desk Reference through handheld wireless devices hold considerable potential for reducing medication-related errors.\textsuperscript{51} Electronic health records and patient monitoring devices can provide the physician and other medical personnel up-to-date and readily accessible patient information to facilitate correct diagnoses and decisions on appropriate courses of treatment.\textsuperscript{52} Fewer medical errors should mean fewer lawsuits.\textsuperscript{53} Moreover, when litigation does arise, HCPs utilizing electronic medical records and similar technological advances are likely to find that such advances better enable them to argue that they exercised reasonable care and thus should not be held liable.\textsuperscript{54}

\textsuperscript{50} See infra text accompanying notes 168-75, 233-51, 291-92, 294-304, 314-60.

\textsuperscript{51} See infra text accompanying notes 248-51. As noted earlier, see supra note 45, the Institute of Medicine recently concluded that at least 1.5 million preventable medication errors occur each year in the United States. *Inst. of Med., Preventing Medication Errors*, supra note 45, at 112. The IOM recommends greatly expanded use of computerized drug order entry systems, electronic records, and similar technological advancements as ways of preventing medication errors. *See id.* at 200, 201, 204, 209, 211-13, 215, 217-18.

\textsuperscript{52} See infra text accompanying notes 246-51, 318-22.

\textsuperscript{53} Liang and Ren, supra note 6, at 503.

\textsuperscript{54} See infra text accompanying notes 237-38, 368-78. There is a flipside, however, to the implications for the reasonable care standard in malpractice cases. As use of electronic medical records and similar advances becomes more prevalent, HCPs not utilizing them could be at risk of liability if their failure to use them is factored into what constitutes reasonable care. *See George J. Annas, The Patient’s Right to Safety--Improving the Quality of Care Through Litigation Against Hospitals*, 354 New Eng. J. Med. 2063, 2064
Recoverable Damages and Responsibility Among Defendants

Another key aspect of medical malpractice cases is the assessment of money damages when the plaintiff establishes that the defendant (or defendants’) breach of duty caused her to experience injury. Such a plaintiff is entitled to recover *compensatory damages*, which are designed to compensate the plaintiff for the harm she experienced. This compensation is meant to make the plaintiff "whole" without providing a windfall.\(^5\)

Making the plaintiff whole necessitates consideration of two varieties of compensatory damages: special damages and general damages.\(^6\) Special damages are awarded to compensate the plaintiff for losses that are fairly readily quantifiable. Examples would include medical bills and lost earnings associated directly with the incident of malpractice.\(^5\) Because the losses accounted for in special damages have an obvious economic character to them, these damages are often referred to by an alternate name: *economic damages*.\(^5\)

General damages are designed to compensate the plaintiff for harms that are not necessarily easy to value monetarily, even though the judge or jury deciding the case is

---


\(^6\) E.g., Sharkey, *supra* note 5, at 398.

\(^5\) E.g., *id*. In wrongful death cases, the financial support of which surviving heirs were deprived may be an item of special damages if the survivors were financially dependent on the decedent. *Id.*

\(^5\) *Id.; Showalter, supra* note 36, at 53.
expected to assign a dollar figure to them. These harms include physical pain and suffering, emotional distress, and other harms such as loss of quality of life. 59 The appropriate amount of general damages may be small or large, depending to a great extent on the severity and duration of the intangible harm experienced by the plaintiff. Except for the rule that a damages award cannot be clearly excessive in light of the evidence, definitive guidelines for amounts of general damages awards do not exist. 60

Because the harms that give rise to general damages are intangible and less readily quantifiable than the losses triggering special damages, general damages are sometimes referred to as non-economic damages. 61 By their very nature, general damages awards hold the potential to be large in absolute amount and in relation to the amount of special damages. This potential is not always realized, of course, but it serves as a major reason why proponents of tort reform have often singled out these supposed non-economic damages as targets of reform efforts. 62 Such efforts will be examined later in the article. 63


60 See Priest, supra note 55, at 10; Amanda Edwards, Recent Development: Medical Malpractice Non-Economic Damages Caps, 43 HARV. J. ON LEGIS. 213, 215 (2006); Goldberg, supra note 36, at 621; Sharkey, supra note 5, at 403; Vidmar, supra note 59, at 1224-25.

61 Sharkey, supra note 5, at 398; Vidmar, supra note 59, at 1225.

62 See Sharkey, supra note 5, at 402-03, 404-05; Vidmar, supra note 59, at 1225-26; Hyman & Silver, supra note 5, at 893, 895, 899, 927.
It is possible, of course, that more than one HCP may be held liable to the plaintiff in a medical malpractice case. The extent to which each defendant bears responsibility for the damages awarded to the plaintiff depends in large part on whether applicable state law calls for use of the *joint and several liability* principle.\textsuperscript{64} Under joint and several liability, each defendant is potentially responsible for the full damages award regardless of the extent of his or her fault.\textsuperscript{63}

\textsuperscript{63} See infra text accompanying notes 105-14, 133-57 (explaining why reform is targeted at special damages). Although a plaintiff who wins a medical malpractice case can expect to receive awards of special and general damages, he or she normally cannot expect an additional award of punitive damages to be assessed. Sharkey, supra note 5, at 393, 415-16; Neil Vidmar, Medical Malpractice and the American Jury: Confronting the Myths About Jury Incompetence, Deep Pockets, and Outrageous Damage Awards 169-71 (1995). Punitive damages are ordinarily reserved for instances in which the defendant's action or inaction was flagrantly wrongful and far worse in culpability than the failure to use reasonable care that lies at the heart of most malpractice litigation and other cases brought on a negligence theory. Cass R. Sunstein et al., Punitive Damages: How Juries Decide 75 (2002). The punishment and deterrence rationales underlying punitive damages are ill-fitting in regard to a defendant who merely failed to use reasonable care. See Restatement (Second) of Torts § 908 cmt. b (1979). To justify an assessment of punitive damages, the defendant's wrongdoing must normally be shown to have been intentional and egregious or to have consisted of a conscious disregard for, or willful indifference to, a known danger. Id. § 908(2); Sunstein et al., supra, at 75. Medical errors that give rise to malpractice liability are just that--errors--rather than actions meant to harm a patient or decisions made in deliberate disregard of the probability of severe harm to the patient. See Sharkey, supra note 5, at 393, 415-16; Van Grack, supra note 3, at 306 n.51.

\textsuperscript{64} See Restatement (Third) of Torts: Apportionment of Liability §§ 10, 17 (2000) [hereinafter Restatement (Third)]. After the implementation of tort reform measures in many states during the past three decades, no more than 15 states remain on the list of those adhering to pure joint and several liability. Id. §§ 10 cmt. a, 17 cmt. a & reporters' note.
of that defendant's respective degree of fault in relation to the degrees of fault of the other defendants. The plaintiff thus has the options to look to a single liable defendant, or to some combination of the liable defendants, for payment of the full damages award to which the plaintiff has been held entitled. Once the plaintiff has collected the full damages award—whether from one defendant or from some combination of the defendants—the plaintiff's recovery options have been exhausted.

States that do not apply joint and several liability extend successful plaintiffs less latitude in how they choose to collect the damages awarded to them. Some states have opted for several liability, which requires the setting of individual limits on each defendant's respective extent of responsibility for the damages awarded. In a several liability regime, the jury determines each defendant's respective percentage of responsibility for the harm experienced by the plaintiff. The same percentage is then used to establish the portion of the damages award that a given defendant is obligated to

65 Restatement (Third) § 10; Wing, supra note 36, at 295, 296-97. The collection options afforded the plaintiff under joint and several liability mean that if a liable defendant has no assets, the plaintiff can look to the other defendants for payment. Joint and several liability thus places the risk of uncollectibility from a given defendant on the remaining defendants rather than on the plaintiff. Kionka, supra note 7, at 491.

66 Wing, supra note 36, at 296-97. For example, assume that HCP #1, HCP #2, and HCP #3 are held jointly and severally liable, that the amount of damages awarded is $450,000, and that HCP #1 was probably more at fault than HCPs #2 and #3. The collection options afforded the plaintiff by joint and several liability would allow the plaintiff to demand the full $450,000 from HCP #3, or the full $450,000 from either of the other defendants, or $150,000 from each defendant, or any combination of amounts totaling $450,000 from any combination of the defendants. If one of the jointly and severally liable defendants is compelled to pay the plaintiff more than that defendant's fair share (as among the defendants), that defendant would have contribution claims against the others. Restatement (Third) § 23.
pay. More common than a pure several liability regime today, however, is a hybrid approach that applies several liability in certain situations but joint and several liability in others. Some states, for instance, adhere to several liability principles as a general rule but allow joint and several liability to be imposed on a defendant whose degree of responsibility exceeds a threshold percentage such as 50 percent.

When an HCP is sued for malpractice, the HCP's professional liability insurance carrier of course furnishes a defense, makes a settlement payment to the plaintiff if an agreement is reached, and pays the necessary damages if the HCP is held liable at trial.

In recent years, applications of the liability and damages rules discussed above have

---

67 Restatement (Third) §§ 11, 17. See id. § 17 cmt. a & reporters' note (discussing apportionment of liability); Kionka, supra note 7, at 491 (examining joint and several liability). For example, if the total damages award is $450,000, the jury's verdict may establish degrees of relative fault and responsibility to pay damages in a manner such as this: HCP #1, 50 percent; HCP #2, 30 percent; and HCP #3, 20 percent. In this example, several liability would dictate that HCP #1 cannot be compelled to pay the plaintiff anything more than $225,000 even if the other defendants prove to be insolvent. Several liability thus assigns the plaintiff the risk of uncollectibility from insolvent defendants, in contrast with joint and several liability's assignment of that risk to the solvent defendants. Id. See supra note 65.

68 Restatement (Third) § 17 cmt. a; id., reporters' note; Kionka, supra note 7, at 491.


caused critics to assert the existence of a crisis in which malpractice insurance has become prohibitively expensive or unavailable and certain HCPs have therefore effectively been forced out of the practice of medicine.\textsuperscript{71} We now turn, in Section III, to the issues raised by these assertions and to the reform efforts that states have implemented in response to the supposed crisis and earlier crises of a similar nature. As will be seen, most reform efforts undertaken or advocated thus far have focused on modifying the legal rules governing malpractice cases\textsuperscript{72} instead of pursuing the fundamentally different type of reform called for in this article: reform that reduces the amount of malpractice litigation by focusing on reduction of medical errors through more widespread use of healthcare information technology.

\textbf{III. CURRENT AND PAST MALPRACTICE CRISIS AND REFORM EFFORTS}

Do plaintiffs (a) bring malpractice cases too frequently (and too often frivolously), (b) win malpractice cases too often, and (c) recover excessive amounts of damages when they win? Those who sense a crisis atmosphere surrounding medical malpractice answer "yes" to at least one, if not all three, of the questions just posed. These persons also tend to assert that as a result, malpractice insurance premiums have risen to unacceptably high levels.\textsuperscript{73}

\textsuperscript{71} See, e.g., Gunnar, supra note 70, at 465-66, 470-71, 473-74 (examining the effect of rising insurance rates on HCP’s).

\textsuperscript{72} See infra text accompanying notes 168-71 (discussing trends in liability standards).

Plaintiffs' Success Rates and Trends in Verdict and Settlement Amounts

Would-be defendants may naturally be inclined to say too many malpractice cases are filed, whereas potential plaintiffs and those aligned with their interests may regard the number of filed cases as about right or even too low. Whatever the "correct" number of filed cases should be, recent studies indicate that the amount of malpractice litigation has been generally stable during the past two decades. Further, most patients injured by


74 See Gunnar, supra note 70, at 476-77; Kionka, supra note 7, at 470-72. This disagreement seems fundamentally a political and philosophical one in which beliefs are strongly held and neither side's invocation of supposed supporting evidence (whether anecdotal or statistical) is likely to convince the other. See Gunnar, supra note 70, at 466; Kionka, supra note 7, at 473-74.

75 See, e.g., THOMAS H. COHEN, U.S. DEP'T OF JUSTICE, NCJ No. 203098, MEDICAL MALPRACTICE TRIALS AND VERDICTS IN LARGE COUNTIES, 2001 (2004), available at http://www.ojp.usdoj.gov/bjs/pub/pdf/mmtvlco1.pdf (noting nationally, a generally consistent number of jury trials in medical malpractice cases each year from 1992 through 2001); Black et al., supra note 73, at 209, 221, 231, 233, 235 (noting stable numbers of medical malpractice claims disposed of in Texas by insurers during years from 1988 though 2002); Neil Vidmar et al., Uncovering the "Invisible" Profile of Medical Malpractice Litigation: Insights from Florida, 54 DEPAUL L. REV. 315, 333 (2005) (stating that there was no upward trend in number of malpractice claims in Florida during 1990s) [hereinafter Uncovering]; Vidmar, supra note 59, at 1248-49 (explaining that there was perhaps a moderate increase in number of Florida filings from 2000 to 2003).
medical errors never file claims.\textsuperscript{76} Concerning the related question of whether plaintiffs win malpractice cases too often, studies show that plaintiffs win malpractice trials approximately 25 percent of the time.\textsuperscript{77} This is a far lower winning percentage than plaintiffs manage in other tort cases.\textsuperscript{78}

\textsuperscript{76} David M. Studdert et al., \textit{Claims, Errors, and Compensation Payments in Medical Malpractice Litigation}, 354 NEW ENGL. J. MED. 2024, 2025 (2006); Hyman & Silver, \textit{supra} note 5, at 976; Michael J. Saks et al., \textit{A Multiattribute Utility Analysis of Legal System Responses to Medical Injuries}, 54 DEPAUL L. REV. 277, 277-78 (2005). Studies dealing with patients harmed by medical errors indicate that the percentage of such patients who sue is as low as 3 to 6 percent. Sharkey, \textit{supra} note 5, at 399 n.26. Other studies suggest that this percentage is 10 to 14 percent. Vidmar, \textit{supra} note 59, at 1226-27. In any event, the harmed patient who institutes litigation is the exception, not the rule. See \textit{id.} at 1227-28. Studies indicate that physicians tend to overestimate by a considerable degree the actual risk of being sued. \textit{E.g.}, Gunnar, \textit{supra} note 70, at 476 (“[P]hysician perception of the risk of being sued is three times the actual risk.”).


What victorious plaintiffs recover in damages becomes the next question to be considered. A Department of Justice study revealed that plaintiffs who won malpractice trials in 2001 recovered a median damages award of $431,000, as compared with the 1992 median verdict of $253,000. 79 When adjusted for inflation and recent years' significant increases in the costs of medical care--costs that would be reflected in the economic damages portion of the awards--the more recent median figure represents a fairly modest increase. 80 There is no denying, however, that when a plaintiff wins a malpractice case, the damages award can be quite large. 81 Very large verdicts attract

79 COHEN, supra note 75 at 9. Other studies have yielded similar figures. Based on verdict information compiled by the National Center for State Courts concerning 46 of the nation's 75 most populous counties, the median verdicts for 1992, 1996, and 2001 were $251,600, $324,601, and $529,034, respectively. Sharkey, supra note 5, at 446-451.

80 Vidmar, supra note 59, at 1240; Sharkey, supra note 5, at 481, 484-87; Kenneth C. Chessick and Matthew D. Robinson, Medical Negligence Litigation Is Not the Problem, 26 N. ILL. L. REV. 563, 569-70 (2006); see Amitabh Chandra et al., The Growth of Physician Medical Malpractice Payments: Evidence From the National Practitioner Data Bank, HEALTH AFF., May 31, 2005, at W5-240, W5-243, W5-247, available at http://content.healthaffairs.org. Recall that any median figure for damages awarded takes into account only those cases in which the plaintiff prevails. It does not take into account the 75 percent of malpractice trials in which the plaintiff loses. See supra note 77. Of course, the defendants and their insurers will still incur significant defense costs in these cases. E.g., Vidmar, supra note 59, at 1234.

81 See Vidmar, supra note 59, at 1240-42. The obstacles to obtaining any award of damages--let alone a large award--in malpractice cases are considerable, however. See id. at 1229-39. The potential for large verdicts is as it should be, some commentators contend, because they see the liability system as furnishing necessary incentives for healthcare providers to improve the quality of their services. See, e.g., Hyman & Silver, supra note 5, at 917, 991; Chessick & Robertson, supra note 80, at 574, 585.
media attention and the watchful eye of those who favor reform measures such as caps on damages.\textsuperscript{82}

Focusing exclusively on trends in dollar amounts of plaintiffs’ verdicts does not provide a complete understanding of monetary compensation issues in malpractice cases, however. When plaintiffs receive payment in such cases, it is nearly always by way of a settlement agreement rather than a jury verdict.\textsuperscript{83} Approximately 25 percent of pursued malpractice claims result in settlement agreements under which the plaintiff receives payment from the defendant, usually through the defendant's insurer.\textsuperscript{84} Far more cases--another 60 or more percent--are either dismissed at a pre-trial stage or are dropped by the claimant after the defendant and the defendant's insurer refuse to settle with the

\textsuperscript{82}See, e.g., Lohr, \textit{supra} note 77; Treaster & Brinkley, \textit{supra} note 73.

\textsuperscript{83}Chandra et al., \textit{supra} note 80, at W5-240, 246-47. According to Chandra et al.’s study of malpractice payments made to injured patients, only 4 percent of the payments stemmed from jury verdicts, with the other 96 percent resulting from settlement agreements. \textit{Id.} This study relied on figures obtained from the National Practitioner Data Bank, to which malpractice payments made on behalf of physicians must be reported in accordance with federal law. \textit{Id.} at W5-241; see Health Care Quality Improvement Act of 1986, 42 U.S.C. §§ 11101-52 (2005). Other estimates similarly indicate that settlements much more frequently account for payments to patients in malpractice cases than do trial verdicts. See, e.g., Vidmar, \textit{supra} note 59, at 1245-46 (noting that when malpractice payments are made, settlements are the reason approximately 97 percent of the time).

In the end, then, not quite 30 percent of pursued claims result in payment to the patient. With settlement payments occurring much more frequently than payments pursuant to trial verdicts, it becomes important to consider verdict and settlement amounts together in order to obtain a more complete perspective on how payments have trended. Recent studies of malpractice payments by way of settlements and verdicts in Texas, Florida, and throughout the United States have revealed mean and median

---

85 See Gunnar, supra note 70, at 477 (“67.7% were dropped or dismissed”); Vidmar, supra note 59, at 1228, 1246-47, 1250-51.

86 This estimate takes into account the roughly 25 percent of claims in which payment is made under a settlement agreement. See Gunnar, supra note 70, at 477 (summarizing how various cases were resolved). It then factors in plaintiffs' likely one-fourth success rate in cases that proceed to trial. See supra text accompanying note 77, in the 7 to 10 percent of claims that proceed to trial. See Vidmar, supra note 59, at 1228.

87 A study conducted by Professors Black, Silver, Hyman, and Sage (hereinafter "Texas Study") focused on a Texas Department of Insurance database that dealt with malpractice claims from 1988 through 2002. Black et al., supra note 73 at 207-10 (finding that claims did not change significantly over that time period when adjusted for inflation).

88 In what will be referred to hereinafter as the “Florida Study,” Professor Vidmar and his co-authors studied malpractice payments by insurers in tried and settled cases in Florida from 1990 through 2003. Vidmar, supra note 75 at 323-48.

89 In what will be referred to hereinafter as the "NPDB Study", Professor Chandra and his co-authors took into account more than 184,000 malpractice payments made between 1991 and 2003, as reported to the National Practitioner Data Bank. Chandra, supra note 80 at W5-241.
dollar amounts lower than the median verdict amount\textsuperscript{90} revealed by the previously noted Justice Department study.\textsuperscript{91} Moreover, malpractice payments have remained generally stable over time, when adjusted for inflation and increases in the costs of obtaining medical treatment.\textsuperscript{92}

\textsuperscript{90} The Texas Study revealed that when converted to 1988 dollars, mean payments per large claim (those exceeding $25,000 in 1988 dollars) went from $300,000 in 1988 to $401,000 in 1990 and then back down to $347,000 in 2002. Black et al., \textit{supra} note 73, at 238. Because mean figures can be influenced by extremely large or very small payments, median figures are therefore a useful alternative way of examining payment trends. Vidmar et al., \textit{supra} note 75, at 337. In the Texas Study, median payments for 1988, 1990, and 2002 were $120,000, $145,000, and $132,000, respectively (again in 1988 dollars). Black et al., \textit{supra} note 73, at 238. The Florida Study revealed that mean payments (converted to 2003 dollars) went from $177,000 in 1990 to $300,000 in 2003. Vidmar et al., \textit{supra} note 75, at 336, 338, tbl. 6. Median payments for 1990 and 2003 were $49,000 and $150,000, respectively. \textit{Id.} The NPDB study demonstrated that the average payment increased from $173,000 in 1991 to $263,000 in 2003. Chandra et al., \textit{supra} note 80, at W5-242 to 243, exhibit 1. The increase over the full period translated into an average annual average annual growth rate of 4 percent. \textit{Id.} at W5-243.

\textsuperscript{91} See \textit{supra} text accompanying notes 79-80 (discussing similarities between the Justice Department study and other studies).

\textsuperscript{92} See Black et al., \textit{supra} note 73, at 209-10, 238, fig. 9. The authors of the Texas Study characterized this stability as "remarkable given that health-care costs account for a significant fraction of the harm from medical malpractice, and these costs rose significantly faster than overall prices" between 1988 and 2002. \textit{Id.} at 238-39. In the Florida Study, the rate of increase was greater than that revealed in the Texas Study. \textit{Compare} Vidmar et al., \textit{supra} note 75, at 336,338, tbl. 6, 337 (Florida numbers) \textit{with} Black et al., \textit{supra} note 73, at 209, 238 (Texas numbers). The authors of the Florida Study noted that the very significant rise in costs of medical care was a likely contributing factor in the upward trend in malpractice payment amounts. Vidmar et al., \textit{supra} note 75, at 338, 344. According to the NPDB Study's authors, the malpractice payment growth rate during the studied period was proportionate to increases in national
**Malpractice Insurance Costs**

The perceived medical malpractice crisis has a further dimension whose causes are debated: the expensive nature of malpractice insurance and the consequences that may flow when insurance effectively becomes unaffordable. Critics of the liability and damages rules applicable to malpractice cases typically argue, as do the liability insurers themselves, that significant increases in the amounts of insurance premiums are the healthcare spending--suggesting that rising costs of medical treatment would help explain the increase in malpractice payment amounts. Chandra et al., supra note 80, at W5-243, 245, exhibit 3, W5-247.

93 See Gunnar, supra note 70, at 466, 470-71, 473-75 (discussing the relationship between expensive malpractice insurance and affordable healthcare); Kionka, supra note 7, at 472-73; Van Grack, supra note 3, at 299. An American Medical Association report classified 20 states as supposedly experiencing a "full-blown medical liability crisis"--with numerous other states showing signs of such a problem--because of very substantial increases in the amounts of malpractice insurance premiums. AM. MED. ASS'N, AMERICA'S MEDICAL LIABILITY CRISIS: A NATIONAL VIEW (2004), http://www.ama-assn.org/ama/noindex/category/11871.html.

94 During the past few years, malpractice premium amounts in a significant number of states have increased dramatically--especially for specialties perceived as high-risk in nature. Sharkey, supra note 5, at 409. In some states, specialties such as obstetrics and gynecology, neurosurgery, and general surgery have been hit with rate hikes of 19 to 56 percent over one to two years. Gunnar, supra note 70, at 471. Malpractice premiums are set according to the physician's specialty, the geographic location of his or her practice, and his or her years in practice. They are not individual experience-rated--i.e., they do not vary depending upon whether the insurer has or has not had to pay out sums because of malpractice claims against the individual physician. Id. at 471; Hyman & Silver, supra note 6, at 981-82 (commenting on the generalized nature of malpractice insurance rates); Daniel P. Kessler et al., Impact of Malpractice Reforms on the Supply of Physician Services, 293 JAMA 2618, 2624 (2005) (relating malpractice reform to physician supply); William L. Sage, Understanding the First Malpractice Crisis of the 21st Century, in HEALTH LAW
direct result of too many large awards of damages in favor of plaintiffs. Curtailing awards of damages in terms of frequency and amounts would supposedly enable insurers to bring premiums down from their lofty heights\textsuperscript{95} and would alter a blame-focused environment in which physicians feel compelled to engage in so-called "defensive medicine."\textsuperscript{96} Plaintiffs' attorneys and other commentators concede the existence of

\begin{quote}
\textsc{Handbook} 1, 20-21 (Alice Gosfield ed., 2003). Roughly 54 percent of paid malpractice claims since 1990 have been based on medical errors committed by approximately 5 percent of physicians. Gunnar, \textit{supra} note 70, at 471-72 (discussing the relationship between malpractice insurance costs and healthcare availability).
\end{quote}

\textsuperscript{95} \textit{E.g.}, Vidmar, \textit{supra} note 59, at 1218-19 (noting this argument). \textit{See} Treaster & Brinkley, \textit{supra} note 73 (quoting January 2005 speech by President Bush, in which he commented on spikes in malpractice insurance premiums, asserted that high premiums "'don't start in an examining room or an operating room [but] in a courtroom," and blamed the "'skyrocketing'" costs of "'junk lawsuits'" against physicians and hospitals). \textit{But see} Black et al., \textit{supra} note 73, at 210, 221, 223, 249-52 (concluding that malpractice claims outcomes in Texas from 1988 through 2002 would not have caused the insurance premium hikes that led Texas to enact a package of tort reforms); \textit{id.} at 252 (observing that "'runaway med mal litigation' makes a poor poster child for the cause of tort reform"); Chandra et al., \textit{supra} note 80, W5-247 (expressing doubt that recent years' considerable hikes in malpractice insurance premiums could be credibly attributed to large jury verdicts or to increases in average amounts of malpractice payments).

\textsuperscript{96} "Defensive medicine" may be defined as departing from sound medical practice--perhaps by ordering needless, costly tests and procedures--because of a fear of potential liability. David M. Studdert et al., \textit{Defensive Medicine Among High-Risk Specialist Physicians in a Volatile Malpractice Environment}, 293 JAMA 2609, 2609 (2005). Commentators have noted the defensive medicine concerns raised by critics of existing malpractice liability rules. \textit{See}, \textit{e.g.}, Gunnar, \textit{supra} note 70, at 466, 476-77. \textit{See also} Studdert et al., \textit{supra}, at 2609, 2616-17 (concluding that vast majority of Pennsylvania physicians who participated in study believed they had engaged in defensive medicine). Other commentators regard the defensive
overly high liability insurance premiums but place most of the blame on the insurance companies. Those who hold this view regard huge premiums as less a result of insurers' financial exposure and more an attempt by insurers to make up for the loss of income they had become used to receiving when investment yields were better in previous years.97

Regardless of the cause or causes of the high insurance premiums, it is a serious problem when premiums reach a level at which physicians find themselves wondering how long they can continue to take the substantial financial "hit."98 If the costs of liability insurance become too great, some physicians may face the dilemma of deciding

---

97 See, e.g., Chessick & Robinson, supra note 80, at 570, 574; Hyman & Silver, supra note 5, at 937-38.
98 Kionka, supra note 7, at 473-74; Vidmar, supra note 59, at 1218. Efforts to achieve savings in insurance premiums have made self-insurance in organizations and risk-retention groups more common than they once were, but a meaningful group size is necessary in order to make such options viable alternatives to conventional malpractice insurance. See Shefali Anand, Doctors' Creed: Insure Thyself, WALL ST. J., Aug. 17, 2005, at C1.
whether to relocate, scale back their practices, or even leave practice altogether. During the 2004 election campaign and in speeches since then, President Bush referred repeatedly to anecdotal evidence of instances in which high insurance premiums presumably forced obstetricians, cardiologists, neurosurgeons, and other specialists to decide to relocate, scale back, or retire. Commentators disagree on whether the anecdotal evidence has been confirmed by statistical evidence of a broader physician supply problem, or whether the seriousness of the supposed problem is less than as billed.

99 See Gunnar, supra note 70, at 471, 473-76 (discussing the burden of high malpractice insurance costs on physicians); Sharkey, supra note 5, at 410-12; Liang & Ren, supra note 6, at 501-02, 514-15. According to studies, physicians have made such decisions often enough in 18 states that those states face physician supply shortages and problems with patients' access to medical care. Gunnar, supra note 70, at 473. But see id. at 467, 474 (indicating that lowered Medicare and Medicaid payments to physicians may also have played role in decisions by physicians to alter their practices or discontinue practicing); Marc A. Rodwin et al., Malpractice Premiums and Physicians' Income: Perceptions of a Crisis Conflict With Empirical Evidence, 25 HEALTH AFF. 750, 757 (2006) (concluding that recent years' income loss by physicians stemmed mainly from declining revenue and increases in other practice expenses instead of from increases in malpractice premiums).


101 See Kessler et al., supra note 94, at 2620-21, 2623-24 (study finding physician supply growth exceeded national growth rate in states that had implemented malpractice reform measures, but acknowledging that factors other than malpractice climate could help explain results); Doctors Gravitate to States With
The amount of public attention devoted to the malpractice crisis of recent years seems to match the amount devoted to similar perceived crises during the past three decades. At varying times during the 1970s and 1980s, premiums for malpractice insurance and other liability insurance became uncomfortably large. Then, as now, healthcare providers, other businesses, and insurers cited tort litigation generally and malpractice cases specifically as the culprits, with contrary explanations offered by those who sought to lay the blame at insurers' feet.\(^{102}\) Then, as now, calls for tort reform--and especially medical malpractice reform--have been issued and sometimes heeded.\(^{103}\) We therefore turn to an examination of typical reform measures and then to an assessment of their effectiveness.

**Malpractice Reform Measures**

---

\(^{102}\) See Gunnar, *supra* note 70, at 484 (discussing the first generation of medical malpractice statutes); Liang & Ren, *supra* note 6, at 504; Vidmar et al., *supra* note 75, at 315.

\(^{103}\) Gunnar, *supra* note 70, at 484; Vidmar et al., *supra* note 75, at 315-16; Kionka, *supra* note 7, at 479.
Almost all tort reform measures over the past three decades have come from the states rather than from the federal government. Legislative caps on medical malpractice damages are a frequently employed measure, with approximately 25 states having enacted them since the 1970s on the assumption that reduced damages payouts in malpractice cases would lead to lower malpractice insurance premiums. Roughly ten other states have enacted damages caps that go beyond malpractice cases and apply to other tort cases as well. With several states’ damages caps having been struck down as unconstitutional, damages caps remain in effect in nearly 30 states. These limitations on damages almost always apply only to non-economic damages and not to economic damages. Caps on non-economic damages thus restrict awards for

104 See Gunnar, supra note 70, at 484, 492-93 (outlining failed attempts at passing federal malpractice reform); Kionka, supra note 7, at 479.

105 E.g., Sharkey, supra note 5, at 405, 412-13; Gunnar, supra note 70, at 484; Liang & Ren, supra note 6, at 505. The assumption’s validity, or lack thereof, will be addressed later. See supra text accompanying notes 133-42.

106 Sharkey, supra note 5, at 412.

107 Id. at 413; Gunnar, supra note 70, at 484-86. Consideration of the specifics of the constitutional challenges is beyond the scope of this article. For discussion of the constitutional issues, see id; Hiatt, supra note 2, at 86-87; Kionka, supra note 7, at 492-95.

108 Sharkey, supra note 5, at 412-13. E.g., CAL. CIV. CODE § 3333.2 (West 1997); FLA. STAT. ANN. § 766.118 (West Supp. 2005); GA. CODE ANN. § 51-13-1 (2005); OHIO REV. CODE ANN. § 2323.43 (West 2004); TEX. CIV. PRAC. & REM. CODE ANN. § 74.301 (Vernon Supp. 2004-05). For a listing of the states that have caps, see Sharkey, supra note 5, Appendix I.

109 This is true of the caps in approximately 25 states, when caps restricted to malpractice cases and caps applicable to tort cases generally are considered together. Sharkey, supra note 5, at 412-13. See id., Appendix I.
intangible harms such as pain and suffering, mental anguish, and the like, but not awards for more readily quantifiable harms such as medical expenses and lost wages.\textsuperscript{110} A handful of states, however, have capped total compensatory damages (economic and non-economic).\textsuperscript{111}

When caps on non-economic damages exist under state law, the specific amounts of the limits vary from state to state. The sum of $250,000 has a long malpractice reform pedigree, however, and has tended to be a fairly typical limit.\textsuperscript{112} A $250,000 ceiling

\textsuperscript{110} See id. at 414; Vidmar, supra note 59, at 1252. For further discussion of non-economic damages, see supra text accompanying notes 59-62. Economic damages are discussed at supra text accompanying notes 56-58.

\textsuperscript{111} Sharkey, supra note 5, at 414. \textit{E.g.}, COLO. REV. STAT. § 13-64-302 (2003); IND. CODE § 34-18-4-3 (2003); NEB. REV. STAT. § 44-2825(1) (Supp. 2003). Most of the states that cap total compensatory damages in malpractice cases have implemented a special feature, the patient compensation fund (PCF). In these states, when a qualifying healthcare provider is held liable, the provider is obligated to pay the plaintiff only up to a certain amount established by law even if the total damages award is higher. The PCF will pay the difference between the designated limit of the provider's obligation and the plaintiff's damages award (subject, of course to the overall cap). See Sharkey, supra note 5, at 414, 459-60. \textit{E.g.}, IND. CODE §§ 34-18-4-1, 34-18-6-1, 34-18-6-2, 34-18-6-6, 34-18-14-3. The limit of the provider's obligation is usually the same amount as the minimum limits of the malpractice insurance policy that the provider must have in order to qualify for the benefits of the PCF statute. \textit{E.g.}, id. §§ 34-18-4-1, 34-18-14-3. Surcharges assessed on healthcare providers in the state typically provide the PCF the financial resources necessary for its operation. \textit{E.g.}, id. §§ 34-18-6-1.

\textsuperscript{112} See Sharkey, supra note 5, Appendix I; Vidmar, supra note 59, at 1252. An influential California statute, the Medical Injury Compensation Reform Act (MICRA), CAL. CIV. CODE § 3333.2 (West 1997), was enacted in the 1970s and was an early leader in the movement to cap non-economic damages in malpractice cases. It established a still-existing $250,000 cap. \textit{Id.} For discussion of MICRA's influential
happens to be the same cap called for by President Bush and set forth in a recent bill that, if enacted, would have established a federal limitation on non-economic damages.\footnote{Medical Care Access Protection Act of 2006, S. 22, 109th Cong. § 5(b)(1) (2006). The bill also would have eliminated joint and several liability in malpractice cases. See id. at §5(d). See also Lohr, supra note 77 (quoting President Bush's call for "a hard cap of $250,000" on non-economic damages in malpractice cases).} The bill failed to advance in the Senate, however.\footnote{Sheryl Gay Stolberg, Senate Rejects Award Limits in Malpractice, N.Y. TIMES, May 9, 2006, http://www.nytimes.com/2q006/05/09/washington/09malpractice.html. Similar bills have met the same fate in Congress over the past decade. Dana Milbank, Take Two of These and Call Us Next Year, WASH. POST, May 9, 2006, at A2. See, e.g., Kionka, supra note 7, at 477-80; Van Grack, supra note 3, at 299-311.}

Laws requiring the use of medical review panels constitute another malpractice reform measure adopted by states with reasonable frequency.\footnote{Catherine T. Struve, Doctors, The Adversary System, and Procedural Reform in Medical Liability Litigation, 72 FORDHAM L. REV. 943, 988-90 (2004). Twenty states have medical review panel laws, but more than 30 once did. Some states repealed their review panel statutes, and some such laws were invalidated. Id. at 990. For a list of states that have review panel statutes in force, see id. nn. 249-50.} This reform measure utilizes the review panel as a device for screening malpractice claims and presumably identifying those of questionable validity.\footnote{Id. at 988-89. See SHOWALTER, supra note 36, at 63-64.} Although the details vary from state to state, this approach calls for malpractice claims to be submitted to a review panel, made up of doctors and other health professionals.
primarily or exclusively of physicians, before the claims can be pursued in court.\textsuperscript{117} The review panel considers evidence presented to it and makes a finding concerning whether the relevant healthcare providers met the reasonable care standard in connection with the medical treatment at issue.\textsuperscript{118} The patient who believes she was a victim of malpractice may pursue her case in court regardless of the review panel's finding.\textsuperscript{119} Thus, the patient who "loses" before the panel--the probable outcome much of the time--could still win in court. In reality, however, such a plaintiff faces an uphill battle to win the case.\textsuperscript{120}

\begin{footnotesize}
\begin{enumerate}
\item Struve, supra note 115, at 991. The review panel process is generally mandatory. See id. See also, e.g., IND. CODE §§ 34-18-8-4 to -6 (making the process mandatory unless all parties waive or plaintiff seeks no more than $15,000 in damages). In other states, however, the review panel step is optional. See Struve, supra note 115, at 991. Some states call for all panel members to be physicians, whereas other states require that most members be physicians, with attorneys or laypersons making up the remainder of the panel. Id. See, e.g., IND. CODE § 34-18-10-3 (providing for a panel consisting of one non-voting attorney who serves as the chair, plus three voting physicians). Panel size depends on state law but tends to range from three to seven members. See, e.g., id.; Struve, supra note 115, at 991.
\item Struve, supra note 115, at 991; SHOWALTER, supra note 36, at 63. See, e.g., IND. CODE §§ 34-18-10-19, 34-18-10-21, 34-18-10-22.
\item Struve, supra note 115, at 991. In some states, the review panel’s finding cannot be admitted into evidence at trial or in summary judgment proceedings. In other states, however, the panel's finding is admissible evidence but is not binding on the court. Id. Panel members may be called to testify at trial in some states. Id. See, e.g., IND. CODE § 34-18-10-23 (making the panel's opinion admissible but not conclusive, and panel members may be called to testify at trial).
\item See SHOWALTER, supra note 36, at 64; Struve, supra note 115, at 994-95. Conversely, when the review panel finds that the healthcare providers fell short of the reasonable care standard, the plaintiff's chances of prevailing in a lawsuit are enhanced considerably. See SHOWALTER, supra note 36, at 64. In such an
\end{enumerate}
\end{footnotesize}
Although medical review panel statutes do not effect a substantive change in the legal standard for whether healthcare providers are liable, their requirement of panel review as a procedural prerequisite to filing a lawsuit could operate as a check on unmeritorious and frivolous cases. Because some of the patients who receive an unfavorable ruling from the review panel presumably would decide not to proceed in court, the amount of malpractice litigation could be lessened. Critics of review panel laws assert, however, that the required procedural step of going to the panel sometimes operates to the detriment of patients who probably have meritorious claims. The review panel step is time-consuming and costly, and plaintiffs who have legitimate claims may decide they cannot afford to do what effectively amounts to trying the case twice.

instance, the panel opinion in favor of the plaintiff would seem especially likely to be persuasive if it is received into evidence at trial.

121 See Struve, supra note 115, at 988-89, 991, 993-94.

122 See id. at 988-89, 991, 993-94. Review panel proponents would consider this a positive outcome. See Van Grack, supra note 3, at 316-17. But see Struve, supra note 115, at 991-92 (noting some indications that review panel system may increase, rather than decrease, frequency with which claims are brought). It is also possible that even if fewer malpractice payouts are made because the review panel process screens out weaker cases, the remaining presumably stronger cases that continue after the panel review is completed could trigger bigger awards of damages or more substantial settlements. See Sharkey, supra note 5, at 459.

123 See Struve, supra note 115, at 990, 991, 992-93. Professor Struve regards medical review panel systems as an inefficient and ineffective way to resolve cases without trial and bring medical expertise to cases that do require trial. Id. at 994-95.
Moreover, according to critics, review panels consisting largely of physicians may be reluctant to rule against a physician defendant.\textsuperscript{124}

Other tort reform enactments in some states have included abolition of joint and several liability.\textsuperscript{125} States that have eliminated joint and several liability have substituted proportional liability rules of the sort discussed earlier.\textsuperscript{126} These measures, which typically apply to tort cases generally and not merely to malpractice cases, tie a particular defendant's responsibility to pay a portion of the awarded damages to that defendant's degree of responsibility for the harm experienced by the plaintiff.\textsuperscript{127}

Although political figures make considerable mention of an asserted epidemic of frivolous malpractice claims,\textsuperscript{128} the states and the federal government have not made

\begin{footnotesize}
\textsuperscript{124} E.g., \textit{id.} at 995. That supposed reluctance could lead to erroneous rulings in favor of healthcare providers and to instances in which patients with valid claims abandon them or go on to lose in court because of the influential effect of the review panel’s finding. \textit{Id.} at 996.

\textsuperscript{125} Kionka, \textit{supra} note 7, at 490-91, 496; Kessler et al., \textit{supra} note 94, at 2619 & Table 1. The failed efforts to impose a federal cap on non-economic damages, discussed earlier in the article, also included unsuccessful efforts to eliminate joint and several liability from medical malpractice cases as a matter of federal law. \textit{See supra} notes 113-14. For discussion of joint and several liability, see \textit{supra} text accompanying notes 64-66.

\textsuperscript{126} Kionka, \textit{supra} note 7, at 490-91, 496. \textit{See Kessler et al., supra} note 94, at 2619 & Table 1.

\textsuperscript{127} Kionka, \textit{supra} note 7, at 490-91. \textit{See supra} text accompanying notes 67-69.

\textsuperscript{128} \textit{See, e.g.,} Treaster & Brinkley, \textit{supra} note 73 (quoting President Bush’s complaint about "junk lawsuits"); Chessick & Robinson, \textit{supra} note 80, at 565 (quoting President Bush’s complaint about "baseless suits against doctors and hospitals"). Commentators, however, consistently reject the notion that an epidemic of frivolous cases plagues the medical malpractice system. \textit{E.g., id.} at 566-69; Kionka, \textit{supra} note 7, at 476, 511. For further discussion of the frivolous cases argument and the importance of
\end{footnotesize}
direct, malpractice case-specific attacks on this supposed problem. Medical review panel laws address the matter only indirectly. Otherwise, instances of frivolous

---

129 In late 2005, the U.S. House of Representatives approved a bill that would cause an attorney to be suspended from practice for a year if a court determined that he or she had filed three frivolous cases. Susan Cornwall, *House Passes Crackdown on "Junk" Lawsuits*, RED ORBIT NEWS, Oct. 27, 2005, http://redorbit.com/news/politics/286843/house_approves_crackdown_on_junk_lawsuits/index.html. Opponents maintained that courts already have inherent powers to impose sanctions when frivolous cases are filed, see id., and that the bill’s proponents had made unsupported arguments about a connection between frivolous case filings and high malpractice insurance premiums. *House Republicans Target Lawyers of Frivolous Suits*, WALL ST. J., Oct. 27, 2005, http://online.wsj.com/article/SB113042745014181361.html. As of mid-2007, it appeared doubtful that a bill matching the one passed by the House would be introduced and passed in the Senate. See *House Passes Crackdown on "Junk" Lawsuits, supra.*

130 A recent study provided not only a further basis for doubting the existence of a severe frivolous cases problem but also strong indications that the existing system reliably distinguishes meritorious malpractice cases from unmeritorious ones. See Studdert et al., supra note 76, at 2027-28, 2031 (“The malpractice system performs reasonably well in its function of separating claims without merit from those with merit and compensating the latter”). The authors had teams of trained physicians review the files of closed malpractice claims from five insurers, in order to see whether the physicians concluded that medical error occurred. *Id.* at 2024-26. The reviewing physicians identified an injury-producing medical error in 73 percent of the cases in which the plaintiff won at trial or received a settlement payment. They found no medical error in 72 percent of the cases in which no settlement was reached or the plaintiff lost the case. *Id.* at 2024, 2027-28. These results caused the authors to conclude that the existing system of deciding and settling cases does a generally effective job of sorting out meritorious cases from unmeritorious ones and that arguments asserting the existence of a frivolous cases problem are “overblown.” *Id.* at 2031.
litigation have been dealt with on a case-by-case basis by courts under their longstanding authority to impose sanctions on the plaintiff who brings a frivolous case and the attorneys who represent him.\textsuperscript{132}

\textit{Assessing Existing Malpractice Reform Measures' Effectiveness--or Lack Thereof}

Attempts to assess the effectiveness of the tort reform measures described above have not produced clear and consistent answers. Caps on damages in some states have been credited not only with lowering average awards of damages in malpractice cases\textsuperscript{133} but also with spurring a decrease in the size of malpractice insurance premiums.\textsuperscript{134} In other states, however, damages caps appear to have had little or no downward effect on premiums.\textsuperscript{135} Moreover, when states that have imposed damages caps have witnessed

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{131} See supra text accompanying notes 115-24 (discussing review panel laws and the significance of review panel findings).
\item \textsuperscript{132} Kionka, supra note 7, at 476. See Fed.R.Civ.P 11.
\item \textsuperscript{133} See W. Kip Viscusi & Patricia H. Born, \textit{Damages Caps, Insurability, and the Performance of Medical Malpractice Insurance}, 72 J. Risk & Ins. 23, 25, 36 (2005). But see Sharkey, supra note 5, at 445, 469 (finding non-economic damages caps had little to no effect on size of compensatory damages awards).
\item \textsuperscript{134} See Viscusi & Born, supra note 133, at 38 (downward effects on premiums seemingly present but not as substantial as downward effects on amounts of damages awarded); Liang & Ren, supra note 6, at 521 (some evidence of downward effects on premiums, though such effects debatable); GAO-03-836, supra note 101, at 32, 37 (some indications that caps lower premiums, but other factors may help explain).
\item \textsuperscript{135} See Gunnar, supra note 70, at 491, 493 (The Weiss Ratings . . . concluded that medical malpractice insurers were . . . not passing a benefit of lower premiums on to the physicians.”). See also Martin D. Weiss et al., \textit{Medical Malpractice Caps: The Impact of Noneconomic Damage Caps on Physician Premiums, Claims Payout Levels, and Availability of Coverage} 7-8 (2003), available at http://www.weissratings.com/malpracticecap.asp (insurance analyst's conclusion that caps do not lead to
\end{itemize}
\end{footnotesize}
lowered premiums, it has not been clear whether the real reason was the damages cap or, instead, direct insurance rate regulation.\footnote{136}{This mixed record of success leaves open reduction in premiums}. In addition, some states that do not have damages caps have lower malpractice insurance rates than states that have caps. See Vidmar, supra note 59, at 1253, 1262.

\footnote{136}{For instance, reduced malpractice insurance premiums occurred after California enacted MICRA, which capped non-economic damages at $250,000. Supra note 112. MICRA therefore tends to be cited as an example of a damages cap that led to lower premiums. E.g., Liang & Ren, supra note 6, at 505-06 (noting this, but recognizing there may be questions about MICRA’s real impact). Commentators have noted that premium reductions were slow to come about after MICRA’s enactment and did not actually occur until a decade later, when California implemented direct regulation of insurance rates. Chessick & Robinson, supra note 80, at 575-76. See Kionka, supra note 7, at 514-15 (“[W]hile California is often cited . . . to prove that caps are effective in reducing medical malpractice insurance premiums, it is more likely that the reduction in medical malpractice insurance rates . . . is attributable to the insurance regulation and restrictions that accompanied the enactment of the caps, and not to the caps themselves.”). The California experience has led damages cap opponents to propose careful government regulation of malpractice insurance rates as a more effective way to bring about lower premiums. See, e.g., Chessick & Robinson, supra note 80 (proposing three methods of insurance reform), at 592-93; Kionka, supra note 7, at 505, 511, 514-15 (discussing Public Act 94-677 as effective reform to the medical malpractice insurance problem).}

\footnote{137}{See Sharkey, supra note 5, at 407-08 (discussing that reports differ in their conclusions on whether caps on medical malpractice damages lower insurance premiums). See also Vidmar, supra note 59, at 1253 (observing that "the evidence that caps reduce or slow doctors' premium increases is at best unclear"), 1262 (noting that in view of unclear evidence that caps might lead to lower premiums and other evidence indicating they would not, caps on non-economic damages "do not appear to be the answer to lowering doctors' liability insurance premiums"). On the question whether damages caps have played a positive role in increasing physician supply and reducing physicians' decisions to retire or relocate to another state, there are studies indicating such a possible effect from malpractice reforms of that nature. E.g., Kessler et al., supra note 94, at 2620-21, 2623, 2624. But see Kessler et al., supra note 94, at 2623, 2624 (acknowledging...}}
the previously raised questions concerning what really causes high malpractice insurance premiums.\textsuperscript{138}

Even if damages caps worked exactly as designed and clearly led to a lowering of insurance costs for healthcare providers, they would be only a partial, less-than-satisfactory solution to the malpractice crisis. Damages caps address only the "plaintiffs win too much money" aspect of the problem, and they do so in a way that most strongly disadvantages those plaintiffs who seem most likely to have the best claims for large amounts of damages.\textsuperscript{139} Consider the cases of hypothetical Plaintiffs A and B, each of whom proves that malpractice occurred. Plaintiff A demonstrates fairly short-term harms and no permanent disability. Plaintiff B demonstrates permanently disabling harms that will cause her to experience considerable pain and a greatly diminished quality of life for the remainder of her existence. A $250,000 damages cap probably will not operate to the detriment of Plaintiff A, because his award of non-economic damages would likely be less than $250,000 anyway. Such a damages cap, however, would operate to the profound detriment of the far more severely harmed Plaintiff B, whose award of non-

\textsuperscript{138} See supra text accompanying notes 93-97.

\textsuperscript{139} See Kionka, supra note 7, at 479 ("[C]aps do not discriminate against weak claims but rather tend to discourage meritorious claims with substantial non-economic loss where the economic damages are small."); Vidmar, supra note 59, at 1254 (discussing that the most severely injured may “be at the highest risk for inadequate compensation.”).
economic damages would almost certainly exceed $250,000.\textsuperscript{140} Damages caps may offer financial relief for defendants and their insurers in cases such as Plaintiff B's, but that relief raises substantive fairness concerns when it comes at the expense of those who seem most deserving of recovery.\textsuperscript{141} It may be argued, too, that damages caps do not furnish incentives to improve the quality of healthcare and that they even create the danger of lowering its quality.\textsuperscript{142}

Damages caps, moreover, do nothing meaningful to address the supposed frivolous claims component of the malpractice crisis.\textsuperscript{143} Although plaintiffs lose roughly three-fourths of the malpractice cases that go to trial,\textsuperscript{144} that fact does not mean three-fourths of tried malpractice cases are frivolous. In cases the plaintiff loses, there nearly always was a plausible basis for bringing the lawsuit even though it ultimately was

\textsuperscript{140} See Vidmar, supra note 59, at 1241-42, 1254, 1261 (discussing that a damage cap harms severely injured plaintiffs the most); Kionka, supra note 7, at 479 (discussing the fact that damages caps hurt those with the most serious injuries with little economic loss to show for it).

\textsuperscript{141} See Vidmar, supra note 59, at 1261; Gunnar, supra note 70, at 493. Not believing that caps on non-economic damages translate into lower malpractice insurance premiums, Professor Gunnar regards such caps as a "windfall" for insurance companies. Gunnar, supra note 70, at 493

\textsuperscript{142} See Hyman & Silver, supra note 5, at 897, 899 (discussing liability and the quality of care); Chessick & Robinson, supra note 80, at 585 (discussing medical liability insurance). Cf. Annas, supra note 54, at 2066 (commenting on risk of liability as a motivation for improving quality of medical care).

\textsuperscript{143} Advocates of malpractice reform often assert that frivolous cases are filed in significant numbers. E.g., Treaster & Brinkley, supra note 73. Contra Studdert et al., supra note 76, at 2027-28, 2031 (calling frivolous cases arguments "overblown").

\textsuperscript{144} See supra accompanying text and sources cited at note 77.
determined to lack sufficient merit.\textsuperscript{145} Hence, the truly frivolous case is a rare commodity.\textsuperscript{146}

The rarity of the frivolous case stems largely from plaintiffs’ attorneys' lack of incentive to litigate such cases. The contingency fee arrangement typically used in malpractice cases makes frivolous cases unattractive.\textsuperscript{147} Because of the risks inherent in

\textsuperscript{145} See Kionka, supra note 7, at 476 (discussing the fact that claims with merit may still fail because the plaintiff must meet his/her burden of proof); Vidmar, supra note 59, at 1249, 1251 (noting when partial evidence shows a case is not winnable is settled and that only those cases go to trial). A frivolous case is one in which the plaintiff sues despite having no plausible basis under the facts and existing law (and possible reasonable extensions thereof) for believing he could win the case. Studdert et al., supra note 76, at 2025. See also Vidmar, supra note 59, at 1251 (noting that cases in which the defendant's liability is quite clear tend to be settled, whereas cases more likely to go to trial are ones in which there is close call concerning whether defendants were negligent).

\textsuperscript{146} “The data is overwhelming, and . . . every practicing tort lawyer knows to a certainty from personal experience--a truly frivolous medical malpractice lawsuit is as rare as Oprah in a Wal-Mart.” Kionka, supra note 7, at 476.

\textsuperscript{147} Chessick & Robinson, supra note 80, at 567-69; Gunnar, supra note 70, at 478-79; Vidmar, supra note 59, at 1233, 1250. Under such an arrangement, the plaintiff's attorney receives a fee only if the plaintiff wins the case, in which event the fee is an agreed percentage of the damages recovery. If the plaintiff loses, her attorney receives no fee despite the hours the attorney devoted to the case. Gunnar, supra note 70, at 478-79. When malpractice victims' cases appear to have significant merit, plaintiffs' attorneys may be willing to take the risk that they will not be paid if the seemingly meritorious cases turn out not to be. A frivolous case, however, is essentially guaranteed to be a losing case if it is litigated. The contingency fee arrangement serves as a major deterrent to the filing of frivolous cases because plaintiffs' attorneys have little inclination to spend many uncompensated-for hours working on a case they will lose. \textit{E.g.}, \textit{id.}
the contingency fee arrangement, plaintiffs' attorneys are extremely careful in choosing which cases to take.\footnote{E.g., Chessick & Robinson, supra note 80, at 567-69; Gunnar, supra note 70, at 478-79; Vidmar, supra note 59, at 1233, 1250. The caution exercised by plaintiffs' attorneys results not only in decisions not to take frivolous cases but also in decisions not to take certain cases that could be meritorious. Chessick & Robinson, supra note 80, at 567-68. This selectivity almost certainly helps explain why malpractice claims are pursued in such a small percentage of the instances in which harm resulted from medical errors. See id. at 568; Hyman & Silver, supra note 5, at 982.}

With experts consistently rejecting the notion that a "junk lawsuits" epidemic has permeated the medical malpractice liability and insurance system,\footnote{E.g., Studdert et al., supra note 76, at 2027-28, 2031; Chessick & Robinson, supra note 80, at 566, 567-69; Gunnar, supra note 70, at 478-79; Vidmar, supra note 59, at 1233, 1250-51; Kionka, supra note 7, at 476. The "junk lawsuits" phrasing is President Bush's. See Treaster & Brinkley, supra note 73 (noting that malpractice suits have risen only modestly, and less than insurance rates); Lohr, supra note 77 (noting lawyer's own incentive to weed out bad cases in a contingency fee regime).} frivolous cases do not appear to pose an ever-present, system-threatening danger that must be eradicated through reform measures. In the absence of a frivolous cases epidemic, the argument that a cap on non-economic damages is needed to deter frivolous cases\footnote{See Treaster & Brinkley, supra note 73 (noting insurers like caps due to their more predictable nature); Lohr, supra note 77 (noting that health care analysts generally agree that damage caps only address one part of the problem); Chessick & Robinson, supra note 80, at 565-66 (each referring to speeches in which President Bush made such an argument).} rests on a thin reed: the outside chance that a rare frivolous case will somehow make it through the system and temporarily yield an erroneous damages award in excess of the cap amount.\footnote{If an occasional frivolous claim slips past the case-selection checks provided by the contingency fee strategy, survives the defendant's motion for summary judgment, and goes to trial, a cap on non-economic}
reed seems especially thin when one recalls the previously noted effect that a non-economic damages cap would likely have on the most meritorious of cases.\textsuperscript{152}

In making the "junk lawsuits" pitch for a cap on non-economic damages, however, the proponents add the argument that attorneys routinely file "baseless suits," not because they expect to take the cases to trial but because they expect to get quick settlements from insurers that decide to settle in order to avoid high defense costs.\textsuperscript{153}

damages (say, $250,000) will do nothing about the isolated problem such a rare case presents. The case is very unlikely to produce any award of damages--let alone an award of non-economic damages large enough to trigger a $250,000 cap--because if the claim truly is frivolous, the plaintiff presumably will lose the case. See Studdert et al., \textit{supra} note 76, at 2031 (noting that false positives, claims without merit receiving compensation, are far less common than false negatives, cases with merit not receiving any compensation); Vidmar, \textit{supra} note 59, at 1236-38 (noting juries tend to be skeptical of claims and that their determinations tend to be consistent with that of neutral experts). If the jury erroneously returns a verdict for the plaintiff, any non-economic damages awarded would seem likely to be below the cap amount. Only if the non-economic damages awarded were in excess of $250,000 would the cap come into play, but other existing legal devices would afford better and more appropriate relief to the defendant anyway. The frivolous nature of the case would make the jury's clearly erroneous verdict vulnerable to a motion for judgment notwithstanding the verdict or a motion for new trial (not to mention appeal). \textit{Cf.} Vidmar, \textit{supra} note 59, at 1244-45 (noting role of post-trial proceedings in reducing "outlier" awards of damages, but similar treatment should be extended to clearly erroneous determination of liability in frivolous case).

\textsuperscript{152} See \textit{supra} text accompanying notes 141-42 (noting impact damage caps have on both quality of care and the insurance industry).

\textsuperscript{153} Chessick & Robinson, \textit{supra} note 80, at 565 (quoting a speech in which President Bush asserted that "all across this country . . . lawyers are filing baseless suits against doctors and hospitals," that "the medical liability system is tilted in their [plaintiffs' and plaintiffs' attorneys'] favor," that because jury
Therefore, the argument goes, a cap on non-economic damages is needed to curb this strategy of plaintiffs' attorneys. Once again, however, the argument does not withstand analysis. A ceiling of, say, $250,000 on non-economic damages will not have the effect of lessening the amounts insurers pay out in settlement of frivolous claims because a truly frivolous claim does not have the potential to generate a settlement large enough to make the $250,000 cap meaningful as a negotiating tool for the insurer. This discussion assumes, of course, that malpractice insurers are inclined to consider settling frivolous cases in some instances in order to save on defense costs. Such an assumption may not

---

awards had "skyrocketed" recently, "every claim filed by a personal injury lawyer brings the chance of a huge payoff or a profitable settlement out of court," with settlements often occurring because physicians and hospitals "know it's expensive to fight a lawsuit, even if it doesn't have any merit" and because "the system is so unpredictable [that] there is a constant risk of being hit by a massive jury award" if the case is not settled. Contra Kionka, supra note 7, at 476 (also noting this argument but disagreeing that frivolous cases are often filed and that insurance companies settle where liability is highly doubtful); Vidmar, supra note 59, at 1249 (noting this argument but disagreeing with it because such claims are not “supported by research evidence”). See also Chessick & Robinson, supra note 80, at 566 (calling the "baseless suits" assertion "Myth #1" in a list of myths disseminated by malpractice reform advocates).

154 See Vidmar, supra note 59, at 1249 (stating that the average payment to claimants could be the reason for the sharp increase in claims).

155 See Kionka, supra note 7, at 476 (stating that the evidence would probably have to at least weigh 51% in favor of the plaintiff to win); Vidmar, supra note 59, at 1249 (arguing that medical costs could be the reason). A cap on non-economic damages could furnish an insurer negotiating leverage, however, not in cases that appear to be meritorious and present indications of potentially very substantial non-economic harms. See Sharkey, supra note 5, at 423 (citing an experiment that showed awards were higher where caps were implemented).
be valid, as malpractice insurers report that they routinely refuse to extend settlement offers regarding claims they perceive to be frivolous.\textsuperscript{156}

No attempt is made here to assert that frivolous malpractice cases are never filed or that it is not an undesirable occurrence if an insurer, even on rare occasions, decides to settle such a case for "nuisance value" in order to avoid the costs of defending against it. It seems clear, however, that the supposed frivolous cases problem is not of epidemic proportions, that verdicts and settlements in favor of plaintiffs in frivolous cases are infrequent and isolated in nature, and that in any event, damages caps are poorly suited mechanisms for combating the relatively minor problem that frivolous litigation poses.\textsuperscript{157}

As noted earlier, medical review panel statutes deal indirectly with the seldom-encountered frivolous claim insofar as a panel finding of no failure to use reasonable care may cause the patient with such a claim to be less likely to pursue it in court.\textsuperscript{158} There is no guarantee, of course, that this effect will be achieved in the truly frivolous case or in

\begin{itemize}
\item[\textsuperscript{156}] Kionka, supra note 7, at 476; Vidmar, supra note 59, at 1250. Although insurers may make occasional exceptions, their usual policy against settling frivolous cases is "based on the belief that, if they ever begin to settle cases just to make them go away, their credibility will be destroyed, and this in turn will encourage more litigation." \textit{Id.}
\item[\textsuperscript{157}] See Saks et al., \textit{supra} note 76, at 277 (observing that the "most serious problem[s]" in the malpractice arena "[are] not that plaintiffs bring claims too readily and too often, or that the system affords relief too easily, or that the relief granted is overly generous," but that "medical treatment is a widespread cause of avoidable injuries and deaths, that very few victims with an actionable injury bring claims," and that when valid claims are brought, "the system typically fails to compensate losses fully or . . . fails to provide any compensation at all").
\item[\textsuperscript{158}] See \textit{supra} text accompanying notes 118-22 (arguing that malpractice litigation could be lessened because patients are less likely to pursue a suit if they receive an unfavorable review by the panel).
\end{itemize}
cases that are probably unmeritorious but not frivolous.\textsuperscript{159} Such cases may still end up in court, along with the strong ones.\textsuperscript{160} The flipside should not be ignored, however. The cases that do not show up in court after a review panel’s ruling against the patient may include those in which the patient's claim probably has merit but the panel’s ruling, though questionable, deterred the patient from continuing with the case.\textsuperscript{161} Review panel statutes thus may reduce the number of malpractice case pursued in court,\textsuperscript{162} but probably not meaningfully, and almost certainly in a way that falls well short of a genuine "weed out the bad cases" goal. Some of the "bad" cases are weeded out, but in all likelihood, so are some of the "good" ones.\textsuperscript{163}

The full consequences of moves by states to modify or abolish joint and several liability\textsuperscript{164} are uncertain. In theory, such moves could reduce the amount of malpractice litigation and help insurers determine risks more reliably, and could therefore operate to keep premium amounts down.\textsuperscript{165} Elimination of joint and several liability might also

\textsuperscript{159} \textit{See} Struve, \textit{supra} note 115, at 991 (stating that the panels that weed out all frivolous claims may prevent plaintiffs from recovering on valid claims).

\textsuperscript{160} \textit{Id}.

\textsuperscript{161} \textit{See id} (stating that panels that deter valid claims are undesirable in terms of public policy).

\textsuperscript{162} This supposed effect is far from certain, as there are indications that review panel statutes may even increase the frequency with which claims are brought, \textit{id}. at 991-92, or least that such statutes have no meaningful effect on claim frequency. Gunnar, \textit{supra} note 70, at 490.

\textsuperscript{163} \textit{See} Struve, \textit{supra} note 115, at 991-93.

\textsuperscript{164} \textit{See supra} text accompanying notes 125-27 (noting that some states have abolished joint and several liability as a form of tort reform).

\textsuperscript{165} \textit{See} Van Grack, \textit{supra} note 3, at 307-08 (discussing bill proponents’ contention that the rule of joint and several liability “galvanizes attorneys to bring frivolous lawsuits . . .”). \textit{But see id.} (noting that such effects have not been demonstrated).
have positive effects on physician retention,¹⁶⁶ if one believes significant numbers of physicians pay attention to what rule his or her state follows on this subject.¹⁶⁷ Reliably tracing effects of modification or abolition of joint and several liability is complicated further by the likelihood that any such action by a state is likely to have been accompanied by other more widely publicized and more easily understood reform measures such as caps on damages.¹⁶⁸

¹⁶⁶ Kessler et al., supra note 94, at 2620, 2623. The Kessler et al. study revealed an apparent positive relationship between malpractice reform measures implemented by a state and that state's physician supply. Id. The appearance of such a relationship depended significantly on whether direct reform measures such as caps on non-economic damages were part of the reform package enacted, either with other direct measures or with indirect measures. Id. In the authors' classification scheme, joint and several liability elimination was considered an indirect reform measure. Id. at 2619, Table 1. The study stressed the important role of direct reform measures and did not involve an attempt to measure separately the effects of indirect measures. See id. at 2619, 2620, 2623. The authors were also careful to note that various factors other than malpractice reform measures may play a role in physicians' decisions on the geographic area in which to practice. Id. at 2623-24.

¹⁶⁷ Some commentators maintain that physicians often are unfamiliar with the basic negligence concept of failure to use reasonable care and the role it plays in the determination of whether a defendant is liable. Liang & Ren, supra note 6, at 528; Kionka, supra note 7, at 513-14. If this is so, it seems difficult to believe that many physicians are familiar with the details of joint and several liability and have given careful consideration to a particular state's adherence or non-adherence to that rule when they decide whether to practice in the state.

¹⁶⁸ Cf. Kessler et al., supra note 94, at 2619-20, 2623 (classifying joint and several liability elimination as an indirect reform measure and stressing importance, to effect on physician supply, of direct reform measures such as damages caps among enacted reform measures). See Liang & Ren, supra note 6, at 505-13 (discussing components in packages of malpractice reform measures enacted in various states). Even if
The Need for a New Direction in Malpractice Reform

Medical malpractice reform efforts to this point have nibbled around the edges of the legal rules on liability and damages and have done so with limited effectiveness. Caps on non-economic damages, often promoted by means of an unsound argument that they are necessary to deter the pursuit of frivolous cases, reduce the financial exposure of defendants and their insurers but raise fundamental fairness concerns by having their greatest adverse impact on the plaintiffs who experienced the most severe harms as a result of malpractice. Review panel statutes and eliminations of joint and several liability have yielded results that are mixed at best. Despite these malpractice reform measures, the amount of malpractice litigation remains as significant as ever and malpractice insurance premiums remain unacceptably high for many healthcare providers.

---

positive premium-reduction or physician-retention effects could be documented, the apparent fairness of tying a particular defendant's damages exposure to that defendant's degree of responsibility for causing the plaintiff's harm may be undercut by the potential unfairness to certain harmed plaintiffs when the collection options afforded by joint and several liability are taken away. See supra text accompanying notes 64-69 (discussing joint and several liability and states' decisions to opt out).

169 See supra text accompanying notes 149-57 (arguing that frivolous suits are very unlikely to yield a frivolous ruling).

170 See supra text accompanying notes 139-42 (arguing that damage caps may be fair to plaintiffs suffering minimal injury, but unfair to plaintiffs suffering long-term disabling injury).

171 See supra text accompanying notes 158-67 (arguing that panels may “weed out” the “good” cases).
Reform efforts so far have not targeted, and therefore have left largely unchecked, the critical underlying problem of medical errors.\textsuperscript{172} Despite the best intentions of healthcare providers, medical errors lead to an estimated 98,000 patient deaths per year\textsuperscript{173} and to even larger numbers of incidents in which patients are harmed but do not die.\textsuperscript{174} Meaningfully reducing the volume and costs of malpractice litigation will require a fundamentally different type of malpractice reform--one that makes reduction of medical errors its centerpiece. If errors are substantially reduced in number and malpractice claims accordingly become less frequently brought, the common interest patients and healthcare providers have in high-quality care would be better protected, and insurers presumably should be well-positioned to bring premiums down from crisis levels.\textsuperscript{175}

\textsuperscript{172} Chessick & Robinson, supra note 80, at 564, 582-83; Kionka, supra note 7, at 518; Vidmar, supra note 59, at 1220. The existing federal requirement that malpractice payments on behalf of physicians be reported to the National Practitioner Data Bank is a positive measure that touches on the subject of medical errors. See supra note 83 (discussing rates of settlements versus jury verdicts). It must be supplemented, however, with other efforts that more directly and aggressively make error reduction a priority.

\textsuperscript{173} INST. OF MED., supra note 11, at 26, 31. This means that "the risk of dying as a result of a medical error far surpasses the risk of dying in an airline accident, [yet] a good deal more public attention has been focused on improving safety in the airline industry than in the healthcare industry." Id. at 42. Some estimates place the number of medical error-related deaths much higher than the Institute of Medicine's estimate. See Vidmar, supra note 59, at 1222 (stating that deaths may reach 195,000 per year); Hyman & Silver, supra note 5, at 901-02.

\textsuperscript{174} See Hyman & Silver, supra note 5, at 903. The Institute of Medicine recently issued a report concluding that 1.5 million preventable medication errors occur each year. INSTITUTE OF MEDICINE, supra note 45, at 112. Fortunately, not all of those errors result in injury or death. Id.

\textsuperscript{175} Liang & Ren, supra note 6, at 522. See also Hyman & Silver, supra note 5, at 917-23 (discussing experience of anesthesiologists who adopted a strategy focused on preventing errors and ended up
Significantly expanded use of electronic medical records and similar advancements in medical information technology under a national health information network (NHIN) holds tremendous potential for reducing medical error frequency and thus can play a vital role in an error-reduction-based approach to malpractice reform.\textsuperscript{176} Later sections of the article will more fully explore this potential, the barriers to its realization, and ways of overcoming those barriers.\textsuperscript{177} However, to lay a foundation for those sections and for the later discussion of privacy concerns that may accompany increased use of electronic medical records, we must first consider how the current legal framework addresses the exchange and use of patients' medical information. The following section does so.

IV. LEGAL RULES CONCERNING DISSEMINATION AND USE OF PATIENTS' MEDICAL INFORMATION

*Medical Records and State Laws: Content, Ownership, Access, and Privacy*

Healthcare providers' medical records regarding patients contain a broad range of information collected and inserted by physicians, nurses, and other medical professionals. This information furnishes support for the physicians' diagnoses and prescribed treatments. The specific content of medical records varies, depending upon the nature of obtaining significant reductions in insurance premiums); Stokely Baksh & Stefan Nicola, *Online Services Put Patients in Charge*, UPI, May 11, 2005, available at LEXIS, Nexis Library, UPI File (citing anecdotal evidence of a 10% reduction in medical liability costs in one family practitioner’s practice).

\textsuperscript{176} INST. OF MED., *supra* note 45, at 200, 201, 204, 209, 211-13, 215, 217-18; INST. OF MED., *supra* note 11, at 40. See *supra* text accompanying notes 19-21, 50-54 (discussing the impact of technological advances on reducing medical errors).

\textsuperscript{177} See infra Parts V-VIII.
the healthcare provider, the type of patient receiving care, and the state or federal regulations that may apply.\textsuperscript{178}

As a general rule, the healthcare provider is considered the legal owner of the medical record regarding a patient.\textsuperscript{179} In many states, however, the patient has a statutory or common law right of access to most, if not all, of the information contained in the record regarding him or her.\textsuperscript{180} If medical records are the healthcare provider’s property but the patient has a right of access, is the healthcare provider to disclose the contents of records to third parties? Codes of medical ethics speak to this question in a general way by establishing that when the physician acquires information about a patient, the

\begin{flushright}
\textsuperscript{178} See SMITH, supra note 36, § 14.01[4]; JOINT COMMISSION ON ACCREDITATION OF HOSPITALS, ACCREDITATION MANUAL FOR HOSPITALS 64 (1985) (hereinafter "JCAH MANUAL"). Medical records concerning a patient in a hospital setting typically contain the nine sections called for by the Joint Commission for Accreditation of Hospitals: (1) patient identification information; (2) medical history; (3) summary of physical examination; (4) notations reflecting initial conclusions based on history and physical examination, as well as notations stating course of action to be taken; (5) physicians’ orders of a diagnostic and therapeutic nature; (6) information establishing patient’s informed consent; (7) summaries of clinical observations, including progress notes and reports provided by consulting physicians; (8) reports and results regarding tests conducted and procedures performed; and (9) discharge summaries or other entries setting forth conclusions at end of hospitalization or period of evaluation and treatment. JCAH MANUAL, supra, at 86; SMITH, supra note 36, § 14.01[4]. Other healthcare providers such as medical clinics keep patient records containing the same types of information just noted. See id. §§ 14.01[2], [3], 14.03.
\textsuperscript{179} SMITH, supra note 36, § 14.04[2]; JCAH MANUAL, supra note 177, at 68. This prevailing rule, established during the era of paper records, should be no different in the emerging era of electronic records.
\textsuperscript{180} SMITH, supra note 36, § 14.04[2]. The federal Privacy Act speaks to the right of access issue in a limited sense by establishing that patients may inspect medical records maintained about them by federal agencies, including federal hospitals. 5 U.S.C. § 552a (2005).
\end{flushright}
physician is ethically obligated not to disclose the information to third parties except when disclosure is necessary for the furnishing of care to the patient or for the furtherance of important societal interests.\textsuperscript{181}

Various states have seen the need for laws barring healthcare providers from revealing the contents of medical records to third parties.\textsuperscript{182} However, these statutes have varied in terms of the range of healthcare providers subject to them.\textsuperscript{183} The statutes also have not been consistent on the types of disclosures that amount to violations, and on whether the patient has a private right of enforcement.\textsuperscript{184} These inconsistencies, coupled with other states’ lack of specific medical records laws, created an incomplete patchwork quilt of rules regarding medical information privacy. The stage was thus set for federal action to establish a national rule.\textsuperscript{185}

\textit{HIPAA: Federal Protection of Medical Information Privacy}

\textsuperscript{181} DEAN M. HARRIS, CONTEMPORARY ISSUES IN HEALTHCARE LAW AND ETHICS 102, 107 (2d ed. 2003).

This same basic ethical precept binds entities such as hospitals and healthcare workers. SMITH, \textit{supra} note 36, § 14.04[1]. Statutes and court decisions in a number of states have given this ethical rule a legal grounding, often by establishment of a patient-physician evidentiary privilege that generally applies in judicial and other legal proceedings. HARRIS, \textit{supra}, at 104; SMITH, \textit{supra} note 36, § 14.04[2][a].

\textsuperscript{182} HARRIS, \textit{supra} note 180, at 104.

\textsuperscript{183} \textit{See id.}

\textsuperscript{184} \textit{See id.} at 104-07; Peter A. Winn, \textit{Confidentiality in Cyberspace: The HIPAA Privacy Rules and the Common Law}, 33 RUTGERS L.J. 617, 654 (2002) (discussing the tort of breach of confidentiality between physicians and patients).

\textsuperscript{185} HARRIS, \textit{supra} note 180, at 104. As will be seen, however, the national rule that was set does not preempt state privacy laws if they provide patients more protection than the federal rule does. \textit{See infra} text accompanying notes 216-18.
With the Health Insurance Portability and Accountability Act of 1996 (HIPAA)\textsuperscript{186} and regulations promulgated pursuant to it, the federal government entered the medical information privacy arena. HIPAA largely delegated to the Department of Health and Human Services (HHS) the authority to adopt standards concerning the protection, use, and disclosure of patients' health information by certain entities specified in the statute.\textsuperscript{187} In making this delegation, Congress listed, as covered entities to which the HHS standards would apply, "health plan[s],” “healthcare clearinghouse[s],” and “healthcare provider[s] who transmit[] any health information in electronic form” in connection with specified financial and administrative transactions.\textsuperscript{188}


\textsuperscript{187} 42 U.S.C. §§ 1320d-1, 1320d-2, 1320d-3. HIPAA also directed HHS to formulate standards requiring these entities to implement appropriate safeguards to preserve the confidentiality and integrity of patients' health information. 42 U.S.C. § 1320d-2(d)(2).

\textsuperscript{188} 42 U.S.C. § 1320d-1(a). HIPAA’s broad definition of \textit{health plan} applies to essentially all types of health insurance offered by private insurers, coverage afforded by health maintenance organizations, and specialized healthcare programs of a governmental nature, including Medicare and Medicaid. § 1320d(5). A \textit{healthcare clearinghouse} is a public or private entity that obtains patients' health-related data in contexts such as insurance claims processing. § 1320d(2); SMITH, \textit{supra} note 36, § 14.04[3]. HIPAA also broadly defined \textit{healthcare provider}, with any "provider of medical or other health services [as defined in other federal statutes] and any other person furnishing healthcare services or supplies” being covered. 42 U.S.C. § 1320d(3). Physicians, nurses, pharmacists, dentists, clinics, and hospitals thus would be among the entities falling within the requirements of HIPAA and the related regulations--if these parties "transmit[] any health information in electronic form” in connection with financial or administrative transactions. 42 U.S.C. § 1320d-1(a).
After setting general parameters and establishing which entities would be covered by the then-forthcoming standards concerning medical information privacy, HIPAA left the task of crafting many of the details to HHS. In response, HHS promulgated regulations that will be referred to collectively as the "Privacy Rule" in this discussion.

The Privacy Rule provides the specific obligations and duties imposed on covered entities with regard to the safeguarding of protected health information (PHI), which the Privacy Rule defines as medical information that is "individually identifiable" in regard to a particular patient. This "individually identifiable information" includes health information that "(1) is maintained in any form or medium, (2) relates to, identifies, or could identify the person that the health information concerns, and (3) is transmitted or maintained by a covered entity."

---


191 45 C.F.R. § 160.103.

192 See 42 U.S.C. § 1320d(6) (defining individually identifiable health information). This definition obviously sweeps in much information typically contained in medical records. See supra note 177. The Privacy Rule's general prohibition against disclosure does not apply to medical information that is not "individually identifiable" and thus falls short of being PHI. See 45 C.F.R. § 164.501. If medical information is "de-identified" through removal of names, addresses, telephone numbers, social security numbers, and various other facts that would tend to identify a particular patient, the information does not constitute PHI. Id. § 164.514. See SMITH, supra note 36, § 14.04[3].
Covered entities must keep PHI confidential to the greatest extent reasonably possible.\textsuperscript{193} Although it imposes on covered entities this general duty not to disclose PHI, the Privacy Rule recognizes a number of purposes for which disclosure is lawful if the covered entities adhere to a "minimum necessary" standard\textsuperscript{194} when making such a disclosure. For instance, a covered entity's disclosure of PHI may generally occur without any need to obtain consent from the patient if the disclosure is for purposes of "treatment, payment, or healthcare operations."\textsuperscript{195} Healthcare providers, health plans, and healthcare clearinghouses thus have fairly wide latitude to disclose PHI in the course of key aspects of their day-to-day operations.\textsuperscript{196} The Privacy Rule recognizes various other

\textsuperscript{193} See 42 U.S.C. § 1320d-2(d)(2); 45 C.F.R. §§ 164.502, 164.514 (outlining safeguards, rules, and requirements for use of health information). Along the way, the Privacy Rule defines and addresses "business associate" status, which applies to outside parties that receive protected health information when performing important services for covered entities. Id. § 160.103. Examples include accounting, law, and consulting firms. See id.; Smith, supra note 36, § 14.04[3]. A covered entity may lawfully disclose protected health information to a business associate only if the covered entity obtains satisfactory written assurances that the information will be safeguarded. 45 C.F.R. § 164.502(e). Such assurances also are necessary if the business associate is authorized to receive or create protected health information on behalf of the covered entity. Id. § 164.502(e)(1). If a covered entity becomes aware that a business associate has repeatedly violated the privacy-preservation obligation, the covered entity must remedy the violations or cease dealing with the business associate. Id. § 164.504(e)(1)(ii).

\textsuperscript{194} 45 C.F.R. §§ 164.502, 164.514. The "minimum necessary" standard will receive further discussion at infra text accompanying notes 294-96.

\textsuperscript{195} 45 C.F.R. § 164.506.

\textsuperscript{196} See id. (discussing disclosures to health care providers and other covered entities). Psychotherapy notes are treated differently, however. If the PHI includes psychotherapy notes, a consent requirement applies to
purposes for which covered entities may disclose PHI without first giving the patient an opportunity to object to the disclosure. 197 In other instances, however, disclosure of PHI cannot occur without the patient’s consent. 198

When a covered entity discloses PHI for a permissible purpose, the "minimum necessary" standard limits the amount of information to be disclosed. 199 The covered

197 See § 164.512(a)-(l). These purposes are: making disclosures required by law; furthering public health activities such as the recording of deaths, births, and disease incidents; providing information regarding abuse or domestic violence victims; aiding in health oversight activities; fulfilling obligations in legal proceedings; aiding in law enforcement purposes; providing information regarding deceased persons; assisting with organ donation programs; furthering research purposes; guarding against significant threats to public health or safety; aiding military operations and other specialized government functions; and providing information relevant to workers' compensation matters. § 164.512(a)-(l).

198 See § 164.510. One such instance concerns hospitals’ patient directories, which historically have been publicly available. The Privacy Rule establishes that the patient’s name cannot appear in such a directory unless she consents. Id. Assuming the patient furnishes the necessary consent, the Privacy Rule permits the healthcare provider to reveal PHI to the patient's family member or friend or to some other party designated by the patient, if the person to whom disclosure is made has involvement with the patient’s medical treatment or carries financial responsibility for the services provided, § 164.510(b)(2), or if the disclosure is designed to provide notification of the patient's general condition or location. § 164.510(b)(2), (3). If a covered entity will be making any disclosure of PHI for purposes other than those explained in this section of the article, the patient’s written authorization will normally be required. See § 164.502(a).

199 §§ 164.502, 164.516. See SMITH, supra note 36, § 14.04[3][c]. This is true whether the purpose is one for which the patient’s consent is unnecessary or for which the patient’s consent is necessary. See 45 C.F.R. §§ 164.502, 164.516 (**164.516 isn’t a CFR section?**).
entity should pass along only the amount of PHI reasonably needed to accomplish the purpose of the disclosure. If only certain information in a patient's medical record relates to the purpose of the disclosure, the full record should not be disclosed.\textsuperscript{200}

In order to increase the likelihood that patients will be aware of their HIPAA rights, the Privacy Rule requires covered entities to provide patients a written notice of such rights.\textsuperscript{201} The notice must inform patients of the above-described instances in which their PHI may be disclosed (both those in which the patient's consent is unnecessary and those in which the patient must give approval).\textsuperscript{202} In addition, the notice must provide the patient information on how to complain about supposedly improper disclosures of her PHI.\textsuperscript{203}

\textsuperscript{200} SMITH, supra note 36, § 14.04[3][c]. Highlighting the importance of the “minimum necessary” standard, the Privacy Rule directs covered entities to develop policies and procedures regarding application of the standard. 45 C.F.R. § 164.514(d)(5).

\textsuperscript{201} 45 C.F.R. § 164.520.

\textsuperscript{202} Id. The notice must also inform the patient that she has the right to inspect her PHI and request amendments or corrections to it, and that she is entitled upon request to an accounting of instances in which her PHI has been disclosed to third parties. §§ 164.520, 164.528. See id. §§ 164.524, 164.526; SMITH, supra note 36, § 14.04[3][c][vi]. The Privacy Rule further requires covered entities to inform the patient of her right to request that her PHI not be disclosed for certain purposes and in certain contexts. However, the covered entity is not obligated to honor those requests if the Privacy Rule otherwise allows the covered entity to make such disclosures. 45 C.F.R. § 164.522. See § 164.506.

\textsuperscript{203} § 164.520. Someone must be designated by the entity to receive patients' complaints about possible violations, with all such complaints being documented. § 164.530(a)(1)(ii). Among various measures that further emphasize the importance of keeping PHI confidential, the Privacy Rule requires covered entities to designate a privacy officer who is in charge of the entity's policies and procedures regarding such matters. § 164.530(a)(1)(i). In addition, HHS has adopted complementary regulations requiring covered entities to
Another important aspect of the Privacy Rule is its provision that patients have a right of access to their PHI. This right includes an entitlement to inspect and copy a "designated record set."²⁰⁴ The Privacy Rule defines designated record set as a group of "medical records and billing records about individuals maintained by or for a covered healthcare provider[,]" a health plan's "enrollment, payment, claims adjudication, and case or medical management records systems[,]" or records "[u]sed . . . by or for the covered entity to make decisions about individuals."²⁰⁵

Patients have substantial rights under HIPAA and the Privacy Rule but cannot initiate litigation against covered entities that commit violations. Instead, HIPAA and the Privacy Rule provide enforcement authority to the Department of Health and Human Services (HHS) and the Department of Justice.²⁰⁶ Patients who believe violations have occurred are entitled to complain to HHS, which may investigate and initiate civil administrative proceedings.²⁰⁷ The Privacy Rule empowers HHS to engage in informal resolution of complaints--a frequently utilized approach in which HHS obtains assurances from the covered entity that the alleged problem complained about will be eliminated and implement specific security measures to safeguard PHI during its electronic transmission and use. See §§ 164.306, 164.308, 164.312.

²⁰⁴ § 164.524.

²⁰⁵ § 164.501. This definition and the patient’s right of access carry obvious implications for electronic medical records systems.


²⁰⁷ 45 C.F.R. § 164.306(a).
If the case proceeds through the full administrative process and violations are found to have occurred, civil penalties of not more than $100 per violation may be assessed against the violators. However, even when an administrative proceeding leads to the conclusion that a violation occurred, the Privacy Rule gives HHS latitude to waive the civil penalty.

In addition to outlining the potential civil penalties, HIPAA criminalizes the knowing disclosure or obtaining of individually identifiable health information in violation of the statute and the Privacy Rule. The civil and criminal penalties

---

208 See Rob Stein, Medical Privacy Law Nets No Fines, WASH. POST, June 5, 2006, at A1 (noting that from 2003 to 2006--the first three years of privacy protections put in place by HIPAA and the Privacy Rule--HHS nearly always engaged in informal resolution if it concluded there were indications of a violation).

209 §§ 160.300-160.316, 160.400-160.426 (containing the codified administrative provisions).


211 45 C.F.R. § 412. HIPAA and the Privacy Rule, moreover, establish a $25,000 limit on the total civil penalties that may be imposed on the same violator for all violations of the same requirement or prohibition during the same calendar year. 42 U.S.C. § 1320d-5(a); 45 C.F.R. § 404. HIPAA also provides that no civil penalty is to be imposed if a criminal violation is established. 42 U.S.C. § 1320d-5(b). The criminal liability provision is § 1320d-6. In addition, no civil penalty is to be imposed if the person who committed a violation did not know, and had no reason to know, that a violation occurred, if the failure to comply stemmed from "reasonable cause and not . . . willful neglect," or if the failure to comply was corrected promptly. § 1320d-5(b).

212 42 U.S.C. § 1320d-6(a). Fines of up to $50,000 and a maximum of one year of imprisonment may be imposed as penalties for such criminal violations. The maximum fine and term of imprisonment increase to $100,000 and five years, respectively, if the violation consists of disclosing or obtaining individually identifiable health information "under false pretenses." § 1320d-6(b). When the offense is "committed
established in HIPAA and detailed in the Privacy Rule have not been extensively employed, however, during the roughly four years the Privacy Rule has been in effect. As of June 2006, no civil penalties had been imposed by HHS. Concerning approximately 14,000 complaints lodged by patients, HHS found no violation, resolved the matter informally upon an assurance of future compliance by the covered entity, or found a violation but did not impose a civil penalty. HHS's clear preference so far has been to resolve complaints informally and encourage voluntary compliance.

Covered entities have tended to applaud HHS's preference for encouraging voluntary compliance instead of imposing civil penalties after full-blown administrative proceedings. Privacy advocates, however, have faulted HHS's enforcement efforts. They see HHS's failure to impose civil penalties as a signal to covered entities that violations of the Privacy Rule will not be dealt with harshly and that the obligations set forth in HIPAA and the Privacy Rule therefore need not be taken especially seriously. This debate seems likely to take on heightened significance as the use of electronic medical records becomes more widespread.

with intent to sell, transfer, or use" such information "for commercial advantage, personal gain, or malicious harm," the maximum fine becomes $250,000 and the maximum term of imprisonment becomes ten years. 

213 Stein, supra note 207.

214 Id.

215 Id. As for the criminal aspect of HIPAA, little enforcement action has occurred so far. HHS had referred approximately 300 cases to the Justice Department for possible criminal prosecution as of June 2006, but the Justice Department had instituted only two actual prosecutions. Id.

216 See id (explaining how the HHS informally settles complaints and rarely imposes real penalties).
In establishing federal standards for keeping PHI private, HIPAA and the Privacy Rule generally supersede state laws that contradict the federal requirements.\textsuperscript{217} If state laws furnish more protection to the privacy interests of patients than do HIPAA and the Privacy Rule, however, the state provisions are not preempted.\textsuperscript{218} As will be seen, states’ ability to provide greater privacy protections may need to be revisited so that privacy concerns, despite their importance, do not become an undue barrier to widespread adoption of medical-error-reducing healthcare information technology.\textsuperscript{219}

Now that relevant legal rules regarding medical information privacy have been explored, it becomes necessary to consider the range of healthcare information systems and technologies that may play a role in a National Healthcare Information Network and may help fulfill its medical-error-reduction potential. We do so in the following section.

V. THE STATE OF HEALTHCARE INFORMATION SYSTEMS AND TECHNOLOGIES

\textsuperscript{217} 42 U.S.C. § 1320d-7(a)(1); 45 C.F.R. § 160.203. If HHS determines, however, that certain state laws prevent fraud or are important aspects of the state's regulation of insurance, the federal provisions do not preempt the state provisions. There is also no preemption of state laws pertaining to controlled substances and to the reporting of injuries, diseases, other public health matters, and vital statistics. 42 U.S.C. § 1320d-7(a)(2), (b); 45 C.F.R. § 160.203.

\textsuperscript{218} 42 U.S.C. § 1320d-7(a)(2), (b); 45 C.F.R. § 160.203. Neither are state standards and information-gathering efforts in the context of audits, licensure, or certification. 42 U.S.C. § 1320d-7(a)(2), (b); 45 C.F.R. § 160.203.

\textsuperscript{219} See infra text accompanying notes 495-517.
Healthcare is one of the most technologically intense\textsuperscript{220} and data-rich industries.\textsuperscript{221} There are few areas in which information technology (IT) has been applied with greater benefits and success than in treatment processes at the local level.\textsuperscript{222} Despite the national goals for improving healthcare quality and availability, patient safety, and cost effectiveness,\textsuperscript{223} and the potential for increased adoption of IT to enhance the effectiveness and efficiency of healthcare by facilitating the flow of patient-related information,\textsuperscript{224} the industry invests only about 2 percent of its revenues in IT, compared with 10 percent for other information-intensive industries.\textsuperscript{225}

\textit{EMRs and Other Emerging Forms of Technology}

Traditional technology components that have played a role in healthcare delivery include diagnostic systems used to identify the nature of an illness (e.g., imaging systems), therapeutic systems involved in the treatment of disease (e.g., pacemakers), and clinical decision support systems used to integrate clinical and patient information and

\textsuperscript{220} See, e.g., Rainu Kaushal et al., \textit{The Costs of a National Health Information Network}, 143 ANNALS INTERNAL MED. 165, 165 (2005) (summarizing the perceived need for more IT in health care).

\textsuperscript{221} See, e.g., Jacqueline Palank, \textit{Microsoft Purchases Patient-Data Tracker}, WASH. TIMES, July 27, 2006, at C8 (describing various data involved in the health-care industry).

\textsuperscript{222} See generally INST. OF MED., CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE TWENTY-FIRST CENTURY (2001).

\textsuperscript{223} See H.R. 534, 109th Cong. (1st Sess. 2005) (intending to “improve patient access to health care . . . by reducing the excessive burden [of] the liability system . . .”).

\textsuperscript{224} See Shortliffe, supra note 30, at 1227 (describing potential for the “role that IT could be playing in addressing their fiscal, quality, and organizational challenges.”).

\textsuperscript{225} The No-Computer Virus - IT in the Health-Care Industry, ECONOMIST, Apr. 30, 2005, at 65.
provide decision support for care.\textsuperscript{226} Today, newer forms of technology that leverage advanced information and communications networks including the public Internet are being introduced.\textsuperscript{227} Examples are secure electronic mail that facilitates clinician-patient communication, patient portals that enable remote monitoring via alerts and reminders, personal health records controlled by patients themselves,\textsuperscript{228} and computerized provider order entry (CPOE).\textsuperscript{229} Patients' participation in the maintenance of their health records may lead to the collection of useful information regarding a variety of medical and psychological illnesses, and interactive computers could replace telephone consultations for some simple medical problems.\textsuperscript{230}

In the realm of emerging health information technologies, electronic medical records (EMRs) will serve as a key component central to the future of healthcare systems. Although potentially encompassing all of the technologies previously enumerated, a system constitutes an EMR only if it is able to integrate information from multiple

\begin{footnotesize}
\begin{enumerate}
\item One of the more intriguing recent such technologies is the radio-frequency-identification-tag-embedded sponge, which alerts medical personnel if it is left in a patient following surgery. \textit{‘Tagged’ Sponge Beeps If Doctors Leave It Behind}, WALL ST. J., Jul. 18, 2006, at D3.
\item For an in-depth assessment of the capabilities and value of CPOE, see Douglas Johnston et al., \textit{The Value of Computerized Provider Order Entry in Ambulatory Settings: Executive Preview}, CENTER FOR INFO. TECH. LEADERSHIP (2003), \textit{at} http://www.citl.org/research/ACPOE_Executive_Preview.pdf.
\end{enumerate}
\end{footnotesize}
sources, capture data at the point of encounter, and support caregiver decision-making.\textsuperscript{231} The Institute of Medicine (IOM) has identified several critical capabilities of an EMR. These include clinical documentation, results management, order entry management, decision support, electronic communication and connectivity, patient support, administrative process support, and population health reporting.\textsuperscript{232} Fundamentally, the goal of an EMR is to move patient information from paper files and into electronic databases that are connected to and interoperable with one another.\textsuperscript{233} Such connectivity should link systems of clinicians, hospitals, laboratories, pharmacies and insurers so that patient information is accessible from “anywhere” at “anytime.”\textsuperscript{234}

As noted earlier, a 1999 IOM report cited as many as 98,000 deaths annually due to medical errors.\textsuperscript{235} A 2006 IOM report suggested that medication errors alone harm 1.5 million people and kill several thousand each year in the U.S., at a cost of at least $3.5 billion annually.\textsuperscript{236} The IOM therefore has urged widespread adoption of EMRs as a key

\textsuperscript{231} Open Clinical, \textit{Electronic Medical Records} (citing definition offered by Linda Kloss, Executive Vice-President and CEO, American Health Info. Mgmt. Ass'n), at http://www.openclinical.org/emr.html.

\textsuperscript{232} \textsc{Inst. of Med.}, \textsc{Key Capabilities of an Electronic Health Record System} \textsc{7} (2003), http://www.nap.edu/catalog/10781.html.

\textsuperscript{233} Gale Wilson-Steele, \textit{Transforming Healthcare Through Patient Empowerment}, \textsc{Health Mgmt. Tech.}, Apr. 2006, at 44, 44.

\textsuperscript{234} Bates et al., \textit{supra} note 34, at 4. \textit{See} Slack, \textit{supra} note 228, at 2258 (describing users’ ability to connect at any time of the day).

\textsuperscript{235} \textsc{Inst. of Med.}, \textit{supra} note 11, at 26, 31.

\textsuperscript{236} \textsc{Inst. of Med.}, \textit{supra} note 45, at 124, 132; Press Release, Committee on Identifying and Preventing Medication Errors, Institute of Medicine, Medication Errors Injure 1.5 Million People and Cost Billions of Dollars Annually (July 20, 2006),
means to improve quality and continuity of care, enhance patient safety, contain costs, and fill gaps in clinical and public health data.\textsuperscript{237} Despite this call for an IT-based partial solution to the medical error problem, the state of healthcare IT remains fragmented and adoption of EMRs is still in a relatively primitive phase.\textsuperscript{238} Adoption of EMRs, however, is expected to boom\textsuperscript{239} and play a role in whether healthcare providers have adhered to the reasonable care standard.\textsuperscript{240}

Why so much focus on EMRs? Empirical evidence strongly suggests that the incidence of medical errors can be reduced through EMRs' ability to provide more complete, current, and integrated healthcare information to HCPs.\textsuperscript{241} EMRs provide a longitudinal repository of patient health information generated by one or more encounters in any care delivery setting, such as physician offices, emergency rooms, chronic care

\begin{footnotes}
\item[237] Inst. of Med., supra note 45, at 203-04, 222; Inst. of Med., supra note 11, at 40;
\item[239] See Boulton, supra note 28.
\item[240] Doctors at SIU Medical School to Use Computers to Keep Records, AP, Apr. 26, 2005, LEXIS, Nexis Library, AP File. For discussion of the reasonable care standard and its role in malpractice cases, see supra text accompanying notes 35-49.
\item[241] See, e.g., Jim Grogan, EHRs and Information Availability: Are You at Risk?, Health Mgmt. Tech., May 2006, at 16 (“[T]he effective use of automation can allow practitioners at every level to make decisions and treat patients to the best of their abilities.”).
\end{footnotes}
facilities, and the like. In the current state, typically an EMR is installed on a central server and connected via a network to access devices such as personal computers (PCs), tablet PCs, and personal digital assistants (PDAs) used by caregivers and administrative staff to input clinical, financial, and administrative data. Patient demographics and past medical history, progress notes, problems, medications, vital signs, immunizations, laboratory data, and radiology reports are examples of information that can be collected in an EMR. More powerful and flexible than paper-based systems, EMRs offer new methods of storing, manipulating and communicating medical information of all kinds, including text, images, sound, and video. Pressure to adopt EMRs is increasing, in part because "high-quality patient care relies upon careful documentation of each patient’s

---

242 Bates et al., supra note 34, at 7.

243 Id.

244 Hillestad et al., supra note 236, at 1110.

245 Simon Rogerson, Electronic Patient Records, 10 INST. FOR MGMT. INFO. SYS., 1 (2000), available at http://www.ccsr.cse.dmu.ac.uk/resources/general/ethicol/Ecv10no5.pdf. Commentators have also noted the following specific benefits associated with EMRs: (1) they establish criteria and display alerts at time of visit for wellness and disease management based upon age, gender, past problems, and medications; (2) they identify preventive services between visits and provide alerts when counseling is due; (3) they generate population management reports (e.g., rosters of patients with diabetes); (4) they generate reports based upon the absence of critical data elements; (5) they create, assign, reassign, and escalate tasks to HCPs; (6) they integrate, store, and display text-based external reports, results, images, and data; (7) they refer or transfer clinical care; (8) they enable patient and user identity correlation; and (9) they receive federal authorization for treatment. Erica Drazen & Keith MacDonald, Workshop Presentation, “Selecting the Right Electronic Health Record for Care and Quality Management,” Harvard Seminar, supra note 30.
medical history, health status, current medical conditions, and treatment plans.\textsuperscript{246} Because they provide the means to store and retrieve patient information from different locations, EMRs can be used to monitor patient status, support care decisions with evidence-based guidelines, expedite referrals to specialists and other caregivers, and computerize the ordering of prescription drugs, laboratory tests, and images.\textsuperscript{247}

The electronic flow of patient information--via connected, interoperable EMRs--offers several potential clinical, financial, and administrative benefits that can improve the overall quality of healthcare. For example, interoperability among hospitals, outpatient clinics, and external laboratories could reduce redundant tests, as well as the delays and costs associated with paper-based ordering and results reporting.\textsuperscript{248} Clinicians could also have access to patients’ longitudinal test results on a 24-hour/7-days-a-week basis from office, hospital, or home.\textsuperscript{249} Errors associated with oral reporting would be reduced.\textsuperscript{250} Interoperability with pharmacies would also enable the formation of complete medication lists and reduce duplicate therapy, drug interactions, and other

\begin{flushright}
\textsuperscript{246} \textit{CHARLES J. AUSTIN & STUART B. BOXERMAN, INFORMATION SYSTEMS FOR HEALTH SERVICES ADMINISTRATION} 3 (5th ed. 1998).
\end{flushright}

\begin{flushright}
\end{flushright}

\begin{flushright}
\end{flushright}

\begin{flushright}
\end{flushright}

\begin{flushright}
\textsuperscript{250} Walker et al., \textit{supra} note 248, at W5-10, W5-13.
\end{flushright}
adverse drug events, with the attendant benefits of automated refill alerts, easy clinician access to information regarding patients' of refilling prescriptions, identification of patients affected in the event of drug recalls, and detection of new drug side effects across a broader patient population. Provider-provider interoperability would save time associated with the handling of referrals and chart requests, and interoperable EMRs could become the building blocks in a nationwide network for assembling and distributing up-to-the-minute health studies showing researchers and physicians what treatments work best for patients with similar characteristics.

Levels of EMR Use and Barriers to Broader Adoption

Despite these potential benefits of EMR, the adoption rate remains relatively low, and a disproportionate amount of literature regarding realized benefits of healthcare IT, including EMRs, has come from a small number of early-adopting institutions with internal systems only. Some evidence exists, however, that patient safety has been improved due to alerts, reminders, and other components related to

251 Id. at W5-14.


254 See Blackford Middleton et al., Accelerating U.S. EHR Adoption: How to Get There From Here; Recommendations Based on the 2004 ACMI Retreat, 12 J. AM. MED. INFORMATICS ASS’N 13, 14-15 (2005) (noting reasons for limited adoption of EMR system).

255 See Chaudhry et al., supra note 236, at 749.
electronic order entry. Beyond patient safety issues, however, the literature to date provides limited evidence about the effectiveness of EMRs on such health matters as disease prevention and chronic disease management.

When restricted only to primary providers such as individual physicians and hospitals, however, the promise of EMRs remains unfulfilled because medical records stored on paper cannot be used effectively to coordinate care, measure quality, reduce medical errors, or assist patients in making informed decisions about their care. If the goal of creating a life-long medical record that moves with the patient and is accessible by all authorized participants in the healthcare process is to be realized, a distinctly different system of EMRs is needed. This system must provide connectivity and interoperability with other systems that will capture whatever data are needed to

256 David W. Bates et al., *The Impact of Computerized Physician Order Entry on Medication Error Prevention*, 6 J. AM. INFORMATICS ASS’N 313, 313 (1999). See Wang et al., *supra* note 250, at 401; Chaudhry et al., *supra* note 236, at 746, 748 (for example, with information available to physicians at the time they enter an order, physicians can be warned about potential drug interactions with a patient’s other drugs); Katerina Pesheva, *Tracking Computer-Based Error Reports Improves Patient Safety, Hopkins Study Finds--Physicians, Nurses, Pharmacists Equally Prone to Fault*, Johns Hopkins Medicine Media Relations, at www.hopkinschildrens.org.


258 See id. (noting low percentage of adopters).

259 Id. at 1103; Bates et al., *supra* note 34, at 4.

260 See generally RUDI VAN DE VELDE & PATRICE DEGOULET, *CLINICAL INFORMATION SYSTEMS: A COMPONENT-BASED APPROACH* (2005) (looking at clinical information systems, which are used to directly manage patients).
accomplish any EMR task, including interfacing with pharmacy systems, specialists, hospitals, insurance billing systems, and even government agencies--entities engaged in the clinical and administrative care of individual patients as well as the clinical care of practice populations. Such connectivity between networks is essential for rapid coordination of care and the seamless sharing of healthcare information. Interoperability of healthcare data is required so that connected data are accessible and

---

261 McDonald, supra note 32, at 219.

262 Mary Mosquera, HHS Proposes Health IT Exception to Anti-Kickback Laws, NEWSBYTES NEWS NETWORK, Oct. 5, 2005 (citing Michael Leavitt, Secretary of U.S. Department of Health and Human Services, the author notes that computer-assisted drug prescriptions result in a 70 percent reduction in prescription errors versus handwritten prescriptions).

263 See id. The author describes one anecdotal instance of the manner in which such systems can interact to benefit patient care:

[HHS Secretary] Leavitt watched a physician use an electronic health record to assist in conducting cholesterol and blood pressure screenings for a patient with heart disease, with the patient’s permission. The blood pressure apparatus automatically transmitted the data to the physician’s laptop as he was speaking with the patient. The patient provided information about his diet and exercise, which the physician then entered into the record. The physician clicked on a variety of clinical categories, such as lab results and medications, to view the patient’s history, make changes to medication dosages, look at trend data and enter new orders for treatment.

Id.

264 Rogerson, supra note 243, at 2000; Walker et al., supra note 248, at W5-14.

265 Charles M. Kilo, Transforming Care: Medical Practice Design and Information Technology, 24 HEALTH AFF. 1296, 1300 (2005).
consistent in meaning whenever and wherever approved access is warranted on a need-to-know basis.\textsuperscript{266}

In spite of a recent report estimating that widespread use of EMRs could save $77.8 billion annually, or 5 percent of total healthcare expenditures in the US,\textsuperscript{267} policymakers and healthcare officials counting on EMRs to improve healthcare quality may be disappointed given the current adoption rate. Although the benefits of EMRs and the appropriate sharing of health information are nearly universally acknowledged,\textsuperscript{268} adoption has been slow--particularly in the U.S., which trails a number of other countries.\textsuperscript{269} Evidence suggests that large physician groups (nine or more physicians).

\begin{flushleft}
\textsuperscript{266} John Halamka et al., \textit{Exchanging Health Information: Local Distribution, National Coordination}, 24 HEALTH AFF. 1170, 1171-72 (2005). “Many medical errors are traced to gaps in the flows of necessary information.” Sidney Taurel, Chairman & CEO, Eli Lilly & Co., Remarks, Healthcare Conundrum Conference, supra note 29 (notes on file with authors).
\textsuperscript{267} Richard J. Baron et al., \textit{Electronic Health Records: Just Around the Corner? Or Over the Cliff?}, 143 ANNALS INTERNAL MED. 222, 222, 226 n.5 (2005).
\textsuperscript{268} Glenn A. Lomis et al., \textit{If Electronic Medical Records Are So Great, Why Aren’t Family Physicians Using Them?} 51 J. FAM. PRAC. 636, 636 (2002). “The benefits of using electronic medical records (EMRs) instead of paper have been well documented [, but] the current use (5% to 10%) falls very short of the 100% by the year 2000 recommended by [the] Institute of Medicine [in 1991]; furthermore, the rate of EMR use has remained relatively unchanged . . . over the past decade.” \textit{Id}.
\end{flushleft}
and hospitals are at the forefront of using EMRs. However, just 3 percent of hospitals have EMRs in place today, and only 6 percent of physician offices are even connected to hospital EMR systems. Although it is difficult to obtain an accurate figure regarding EMR use by primary care physicians, estimates range from 5 percent to 13 percent. Often-cited financial and technology-related barriers to widespread EMR adoption include cost, incomplete interoperability with other systems, difficulties in assessing product quality, concerns about medical information privacy, and slow and uncertain financial payoffs. Start-up costs can include hardware, software (e.g., EMR, security, and interoperability software), training, installation, and ongoing support and maintenance, as well as expenses associated with redesigning work processes. High bandwidth network services, internally and externally, are also needed to allow efficient data transmission. Induced costs may include provider downtime and temporary decreases in productivity during the transition from paper to electronic systems.

---


271 Harris, supra note 45.


275 Wang et al., supra note 250, at 398.
also need to be integrated from several internal and external systems.\textsuperscript{276} Currently lacking, however, are data standards\textsuperscript{277} that would greatly reduce, if not eliminate, the need for and costs associated with custom-built interfaces between disparate systems.\textsuperscript{278} Although standards-setting has been a relatively slow process,\textsuperscript{279} a number of bodies are involved in different aspects of the standardization/interoperability process in the U.S.\textsuperscript{280}

In order to address difficulties in assessing the efficacy and reliability of various IT products, the Certification Commission for Healthcare Information Technology

\textsuperscript{276} Kaushal et al., \textit{supra} note 219, at 167. For example, large institutions, such as hospitals, need to integrate pharmacy records and laboratory records, as well as patient information. Depending on the number of healthcare entities (e.g., physician offices, hospitals, pharmacies, laboratories, and imaging centers) that will be connected, interoperability costs will vary. \textit{See id.}

\textsuperscript{277} \textit{See, e.g.}, Middleton et al., \textit{supra} note 249, at 13.

\textsuperscript{278} \textit{See COMM'N ON SYSTEMIC INTEROPERABILITY, ENDING THE DOCUMENT GAME: CONNECTING AND TRANSFORMING YOUR HEALTHCARE THROUGH INFORMATION TECHNOLOGY} 90-91 (2005), \textit{available at http://endingthedocumentgame.gov/PDFs/entireReport.pdf.}

\textsuperscript{279} \textit{See} Middleton et al., \textit{supra} note 249, at 13.

\textsuperscript{280} For instance, Health Level Seven (HL7), an international community of healthcare and information technology experts who work together to develop standards regarding management and exchange of medical information in electronic contexts, has set what amounts to “accepted messaging standard for communicating clinical data”. National Health Information Infrastructure, U.S. Dep't of Health & Human Services, \textit{http://aspe.hhs.gov/sp/NHII/standards.html#ASC. See also} Health Level Seven (HL7), \textit{http://www.hl7.org/} (HL7 site). Also, the American National Standards Institute Accredited Standards Committee selected X12N as the standard for electronic data interchange in HIPAA-compliant administrative and financial transactions in compliance with HIPAA. National Health Information Infrastructure, U.S. Dep't of Health & Human Services, \textit{http://aspe.hhs.gov/sp/NHII/standards.html. See also} Accredited Standards Committee (ASC) X12, \textit{http://www.x12.org/x12org/index.cfm} (ASCX12 site).
(CCHIT) is engaged in developing certification criteria and a certification process to ensure that electronic health records products meet baseline functionality, interoperability, and security standards. Awarded a contract by the U.S. Department of Health and Human Services (HHS) in 2005, the CCHIT is in the process of certifying electronic record products in three phases: (1) outpatient or ambulatory; (2) inpatient or hospital; and (3) EMR systems that enable the exchange of information between and among healthcare providers and institutions. Further, despite some concerns to the contrary, there is little evidence that the use of IT in healthcare introduces errors.

Although HIPAA offers privacy protections, consumers remain very concerned about the privacy of personal health information. Other than HIPAA requirements, 

---

281 Accelerating the Adoption of Health Information Technology: Hearing Before the Senate Comm. on Commerce (June 21, 2006) (Statement of Mark Leavitt, Chair, Certification Commission Healthcare Information Technology).


285 See supra Section IV.
there are no uniform agreements about security or privacy of health information.\textsuperscript{286} Security efforts are necessary, however, to help alleviate these concerns and assure confidentiality, integrity, and availability of health information stored in EMRs.\textsuperscript{287} Advocates of IT in medicine are confident that interoperable EMR systems can be designed to provide persistent, reliable access for authorized users\textsuperscript{288} despite concerns on the part of opponents about hacking, application failures, infrastructure failures, and natural disasters.\textsuperscript{289}

Finally, despite the purported benefits of EMRs, the absence of solid evidence regarding the financial impact from a cost/benefit perspective has also hindered adoption.\textsuperscript{290} Moreover, there appears to be a misalignment of incentives between those

\textsuperscript{286} Halamka et al., \textit{supra} note 264, at 1172.

\textsuperscript{287} COMM'N ON SYSTEMIC INTEROPERABILITY, \textit{supra} note 276, at 31-32; Lawrence Gostin, \textit{Health Care Information and the Protection of Personal Privacy: Ethical and Legal Considerations}, 127 \textit{ANNALS INTERNAL MED.} 683, 684-85 (1997).

\textsuperscript{288} See COMM'N ON SYSTEMIC INTEROPERABILITY, \textit{supra} note 276, at 96-99. Specifically, confidentiality defines which people are authorized to access health information and under what conditions. EMRs can provide more consistent and measurable security than paper-based records by implementing tools such as tracking system log-ins. Integrity ensures that the health information will only be modified in appropriate ways by appropriate people, i.e., the information is trustworthy. For example, a physician should be able to trust that allergy information is correct and up-to-date. Finally, availability represents the requirement that health information be accessible to authorized persons, devices, and/or other systems.

\textsuperscript{289} Grogan, \textit{supra} note 239.

\textsuperscript{290} Hillestad, et al., \textit{supra} note 236, at 1115; Kaushal et al., \textit{supra} note 219, at 172; Wang et al., \textit{supra} note 250, at 397. There is some evidence, however, that the benefits of EMRs are being recognized to a limited extent in the insurance markets. Some malpractice insurers are offering premium discounts to physicians who utilize EMRs. Medical Malpractice Discount, \textit{RISK MGMT.}, Apr. 1995, at 18.
investing in EMRs (and health information technologies, in general) and those who fund healthcare.\textsuperscript{291} For example, patient safety and quality benefits accrue to the purchaser of services, whereas providers have limited incentives unless EMRs improve practice efficiency or revenues.\textsuperscript{292} Given the aforementioned slow progress in adopting EMR systems \textit{within} individual HCPs’ own domains, these factors can only serve as a warning regarding some of the difficulties likely to be encountered in attempts to fully leverage healthcare IT at a national level.

The foregoing issues notwithstanding, there remains substantial evidence that healthcare IT has very positive effects on the quality of patient care, with the 100 “most wired” hospitals and health systems having risk-adjusted mortality rates that are 7.2 percent lower than those of their least-wired counterparts.\textsuperscript{293} Hence, significantly expanded use of healthcare IT should hold considerable potential for reducing medical errors and bad medical outcomes, and thus for reducing the amount of malpractice litigation. Lessened amounts of malpractice litigation should lead to a lowering of malpractice insurance premiums, if insurance companies’ standard explanations of high premiums levels are to be believed.\textsuperscript{294} In order for the effects suggested here to be realized on a widespread basis, the expanded use of healthcare IT must be truly national. We therefore turn to consideration of the architecture, features, and benefits of a proposed national Healthcare Information Network.

\textsuperscript{291} Eta S. Berner et al., \textit{Will the Wave Finally Break? A Brief Review of the Adoption of Electronic Medical Records in the United States}, 12 J. AM. MED. INFORMATICS ASS’N 3, 6 (2005).

\textsuperscript{292} Middleton et al., \textit{supra} note 249, at 14.

\textsuperscript{293} Solovy, \textit{supra} note 281, at 39.

\textsuperscript{294} See \textit{supra} text accompanying notes 94-96, 174.
VI. TOWARD A NATIONAL HEALTHCARE INFORMATION NETWORK

Failures of the Status Quo

The aforementioned existing and evolving capabilities inherent in EMR notwithstanding, the U.S. healthcare industry has been described as "arguably the world’s largest, most inefficient information enterprise." Despite an annual expenditure of $1.7 trillion, or twice the Organization for Economic Cooperation and Development (OECD) average for a member nation, premature mortality in the U.S. is much higher than OECD averages and the potential benefits of EMR in reducing medical malpractice go largely unrealized. Even in the face of the vast potential of IT to improve communication among HCPs, a lack of such communication among HCPs--together with a lack of understanding of patterns of error resulting from shared information--is often the culprit in causing medical errors, as opposed to purely individual human mistakes. Additionally, other potential forces (including government regulation) that might logically reduce medical errors do not appear to be effective enough to prevent the

295 Hereinafter, for purposes of simplicity, we use "EMR" to refer collectively to electronic medical records containing historical and current patient information, computerized physician order entry, clinical decision support systems, and central data repositories.

296 Hillestad et al., supra note 236, at 1103.

297 Id. The authors note that “[m]ost medical records are still stored on paper, which means that they cannot be used to coordinate care, routinely measure quality, or reduce medical errors.”

298 Rosenthal, supra note 13. (“A close examination of empirical studies shows that many such [errors] are more preventable than is commonly perceived.”)

299 Tom Murphy, Clarian Plans Training Center, INDIANAPOLIS BUS. J., Apr. 3, 2006, at 46A.
current, unacceptably high rate of mortality from such errors. For example, despite the one notable exception of anesthesiology, it seems evident that industry self-regulation has had limited effectiveness in reducing the rate of medical errors. As previously


The Patient Safety Act is built on the false premise that goodwill alone is sufficient to motivate healthcare providers to study their mistakes and improve their systems. Health care workers can complain to regulators already, and sometimes they do. Generally speaking, however, it is more profitable for them to participate in the “conspiracy of silence” that allows errors to continue than to report them. Hyman & Silver, supra note 5, at 988.

Anesthesiology provides some evidence that appropriate self-imposed standards can reduce medical errors. E.g., Hyman & Silver, supra note 5, at 985. (“Anesthesia safety improved dramatically and quickly after the ASA promulgated guidelines for patient monitoring,” with the result that “[u]nlike rates for other medical professionals, anesthesiologists’ insurance premiums have remained relatively flat, reflecting the fact that anesthesia delivery continues to be safe.”). There remains a question, however, as to why other medical specialties have not been able to achieve similar benefits from self-regulation. Hyman & Silver note that “[m]any providers have failed to adopt patient safety measures of proven effectiveness, and they have similarly failed to use information already in their possession to protect patients from harm.” Id. at 991.

302 For a discussion of the practice of allowing HCPs to exempt themselves from government inspections based on self-regulation--a practice that would be inconceivable in other industries in which human lives
noted, patients victimized by medical errors often fail to file suit, thereby limiting the effectiveness of the tort system in reducing errors beyond existing levels\(^3\) with the result that “[m]edical liability is an extraordinarily inefficient mechanism for encouraging the delivery of high-quality care and for transferring resources from negligent providers to injured patients.”\(^4\) Further, consumers often lack the necessary information about HCP,

\(^3\) HARRIS, supra note 180, at 69, 253; see supra text accompanying note 76; see also Hyman & Silver, supra note 5, at 978-79 (observing that “[p]laintiffs with serious injuries (whether stemming from medical malpractice or other causes) tend to be under-compensated, not overpaid,” that ”[w]hen one considers that plaintiffs have to pay their attorneys, defray expert fees and other costs, and reimburse Medicare, Medicaid, and other payers from these sums, even these trial recoveries seem inadequate,” that ”[o]verpayments thus do not offset under-claiming,” and that ”[m]any commentators agree that under-claiming weakens providers’ incentives to invest in patient safety”); Rosenthal, supra note 13, at 324 (noting that current ideas of tort reform better reflect the needs of the insurance industry than those of patients and physicians).

\(^4\) Hyman & Silver, supra note 5, at 992. The authors also cite evidence that patients who are least likely to sue (the aged and poor) are the most likely to suffer from medical negligence. Id. at 916. See HARRIS, supra note 180, at 252-53 (noting that the vast majority of patients injured as a result of medical negligence do not pursue malpractice claims). Moreover,
treatments, and costs\textsuperscript{305} to make informed decisions necessary for market competition to function effectively in disciplining those HCPs that commit the greatest number and most egregious of medical errors.\textsuperscript{306} Moreover, extant and proposed government regulation also appears inadequate to this task.\textsuperscript{307}

Given (a) that government regulation, industry self-regulation, market competition, and tort law have all apparently failed to ensure a healthcare environment in which medical errors in the U.S. are contained at acceptable levels,\textsuperscript{308} (b) that delivery of excellent primary care (central to overall medical care) demands that providers have the necessary information when they give care,\textsuperscript{309} and (c) that “health care lags behind other [information-intensive] industries in investment in and use of IT in [\ldots] frontline

Legal scholars point out that although one of the aims of the tort system is deterrence, there is virtually no evidence that parties who are sued go on to substantially change their practice styles. One reason for this is that most physicians who are sued are sued very infrequently. And because their malpractice carrier pays for any eventual settlement or jury award, neither the physician nor his or her hospital experiences an immediate or direct financial loss, unless the physician or hospital has assumed a deductible.


\textsuperscript{305}Bush Seeks Health Care Cost Transparency, USA TODAY, Aug. 22, 2006, at B1. (Health and Human Services Secretary Michael Leavitt has stated that "when it comes to healthcare, we lack the tools to compare either quality or the costs.") Information on cost and quality needs to be presented in a way that consumers will use it in order for a market system to work effectively. Larry C. Glasscock, Chairman, President, & CEO, WellPoint, Inc, Remarks, Healthcare Conundrum Conference, \textit{supra} note 29.

\textsuperscript{306}Hillestad et al., \textit{supra} note 236, at 1103. \textit{See} HARRIS, \textit{supra} note 180, at 69.

\textsuperscript{307}\textit{See} HARRIS, note 180, at 69-79.

\textsuperscript{308}\textit{See} \textit{supra} text accompanying notes 9-18, 50-54, 168-75.

\textsuperscript{309}Bates et al., \textit{supra} note 34, at 4.
processes," the best hope for a significant reduction in the high mortality rate due to medical errors in the U.S. would appear to rest elsewhere--in part with a NHIN such as proposed by Walker et al. If some form of NHIN thus offers hope for a significant reduction in medical errors, what are the desirable characteristics of this network?

In order to realize the full benefits of healthcare IT systems from the standpoint of reducing both medical errors and their attendant costs, a desirable NHIN should involve six groups of major stakeholders: HCPs, independent laboratories, pharmacies, payers, public health departments, and other providers of healthcare services. Moreover, it should connect these parties in such a manner that they can access patients’ individual health information on a need-to-know basis, thereby yielding an estimated $142-$371 billion in efficiency and safety savings. Chaundry et al. detail the types of healthcare information technologies that should be part of a NHIN as including not only EHRs with computerized physician order entry (CPOE) capability but also decision support systems, electronic results reporting, electronic prescribing, consumer health informatics, mobile computing, telemedicine, electronic health communication, data exchange networks, and knowledge retrieval systems. These technologies would encompass a spectrum of functional capabilities that would include clinical documentation, results management,

310 Kaushal et al., supra note 219, at 165.

311 See Walker et al., supra note 248, at W5-11, W5-16 - W5-18.

312 Id. More specifically, Kaushal et al. propose that a model NHIN should include six major stakeholders: physician office practices, hospitals, skilled nursing facilities, home health agencies, laboratories, and pharmacies. Kaushal et al., supra note 219, at 168.

313 Hillestad et al., supra note 236, at 1103.

314 Chaudhry et al., supra note 236, at 742 n.13, 744, 744 (table), 748.
order entry management, decision support, patient support, administrative processes, and reporting on patient population health. 315

**Error-Reduction Benefits of a NHIN**

What would be the likely impact of a NHIN structured as previously described with respect to reducing medical errors? Walker et al. develop a functional taxonomy of electronic healthcare information exchange and interoperability characterized by four levels. 316 The highest (fourth) level envisions a ten-year national rollout scenario, with benefits increasing by ten percent per annum during the rollout period. 317 Such a system would have many benefits, including: (a) interoperability between freestanding and outpatient clinicians and external laboratories--reducing delays in getting lab results to clinicians; (b) connectivity between office-based clinicians, hospital-based ambulatory practices, and radiology centers for the electronic transmission of imagery--helping ensure that imagery is available for diagnoses on close to a real-time basis; and (c) interoperability between outpatient providers and pharmacies--lessening the fill time for prescriptions and facilitating complete medical lists, reducing duplicate therapies, drug

---

315 *Id.*

316 Walker et al., *supra* note 248, at W5-11. In this taxonomy, Level 1 represents a paper-based system in which there is no shared use of electronic data; Level 2 represents a machine-transportable data system in which transmission of data is by basic IT such as fax; Level 3 represents a system of machine-organizable data in which there is transmission of structured messages containing non-standardized data; and Level 4 represents a system of machine-interpretable data in which structured messages contain standardized and coded data, and all systems exchange information by employing the same formats and vocabularies. *Id.*

317 *Id.* at W5-12.
interactions, adverse drug events, and drug abuse, better identifying side effects, and facilitating drug recalls.\textsuperscript{318}

Perhaps the closest existing example of a NHIN-like architecture can be seen in the Veterans Administration (VA) hospitals. The VA has in place one of the few networked, complex healthcare IT systems. It provides physicians access to "layers of information, including notes from office visits, hospital admissions and discharge notes, special patient problems, allergies, diagnostic test results, and a list of patient medications."\textsuperscript{319}

A NHIN would also address the fact that physicians are often pushed into treating inappropriately without adequate patient information,\textsuperscript{320} in part because when patients move or travel, "the challenge of getting to the critical health information starts over."\textsuperscript{321} Access to complete patient medical histories regardless of where the patient is treated will help relieve time constraints on physicians who are now required to duplicate medical records when seeing patients on a first-time basis because they are away from their home area.\textsuperscript{322} Further, patients follow prescribed protocols more closely with

\textsuperscript{318} Id. at W5-14 - W5-15

\textsuperscript{319} CR Investigates the New Threat to Your Privacy, supra note 25, at 39. See David Stires, How the VA Healed Itself, FORTUNE, May 15, 2006, at 131 (discussing recent advances at VA hospitals which resulted from the use of technology); BERTELSMANN FOUND., 5 HEALTH POLICY DEVELOPMENTS 35 (Reinhard Busse et al. eds., vol. 5, 2006).

\textsuperscript{320} Blackford Middleton, Keynote Presentation, “The Value of Information Technology in Clinical practice,” Harvard Seminar, supra note 30 (notes on file with authors).

\textsuperscript{321} Wilson-Steele, supra note 231, at 44.

\textsuperscript{322} See Slack, supra note 228, at 2259. (discussing incomplete patient histories).
electronic monitoring, and patients with chronic illnesses can be better served by having continuous access to their medical records.

Another major contributing factor in error reduction from a NHIN would likely come from far greater adherence to guideline-and-protocol-based care, especially with respect to IT-supported diagnostics available through such a network. With the increasing complexity of medicine, it appears probable that physicians will become

---

323 Joseph Kvedar, Panel Discussion Remarks, “Bringing Care to the Patient: Real-Time Use of eHealth Monitoring and Feedback Applications,” Harvard Seminar, supra note 30 (notes on file with authors). The panelist noted that telemedicine is now reaching remote areas in Canada, but the major benefit in the U.S. will be less in regard to geography and more in regard to greater patient involvement. Tim Kenealy et al., *Patients and Computers as Reminders to Screen for Diabetes in Family Practice*, 20 J. GEN. INTERNAL MED. 916, 920 (2005). (discussing how computer reminders doubled the rate of screening for diabetes).


325 See, e.g., Chaudhry et al., supra note 236, at E14.

326 Pfahlert & Emminger, supra note 1, at 109-12. “Both physicians and patients are demanding increasingly intelligent diagnostic procedures which allow reliable and standardized comparison and interpretation of data aligned with the very latest and most comprehensive scientific findings in an intuitive and universally available form.” *Id.* at 109. Such diagnostics include and integrate sensory, physiological, imaging, and biochemical diagnostics. Electronification of data will include far more than simple data storage and warehousing and will permit use of diagnostic tools such as diagrams using time series patient data, parallel retrieval of data from multiple sources, and exchange of data for case-based management. Patient outcome forecasting can be greatly enhanced by assessment of outcome probabilities using empirically based algorithms. Such systems are currently being used on a limited basis with significant success. *Id.*
overwhelmed with more data than unaided human cognition can process.\textsuperscript{327} As the number of treatments and cures increases due to advances in molecular medicine, the number of cues that need to be incorporated into HCPs’ decision processes will also increase dramatically.\textsuperscript{328} Experiments conducted as far back as the 1950s suggest that the number of cues intelligent humans can incorporate into a decision is quite limited.\textsuperscript{329}

\textsuperscript{327} See Bates et al., supra note 34, at 4 (stating that the “unaided human mind simply cannot process the current volume of clinical data required for practice," that "[a]s information becomes obsolete, it is not refreshed, and new knowledge cannot be integrated," and that "[t]he advent of genomics will only make this problem worse”); Marc Overhage, Associate Professor of Medicine & Investigator, Regenstrief Institute for Healthcare, Indiana University, Remarks, IHI05, supra note 29 (notes on file with authors) (observing that the amount of information physicians are asked to process is "phenomenal.”).

\textsuperscript{328} Bates et al., supra note 34, at 4.

\textsuperscript{329} See, e.g., George A. Miller, The Magical Number Seven, Plus or Minus Two: Some Limits on Our Capacity for Processing Information, 63 PSYCHOL. REV. 81, 81 (1956). See K. Anders Ericsson & Walter Kintsch, Long-Term Working Memory (undated working paper), http://www.ecs.soton.ac.uk/~harnad/Papers/Py104/ericsson.long.html (detailed review of cognitive literature related to decision makers’ ability to extract information from long-term memory when provided cues) (last visited Oct. 10, 2007). For a discussion of the issue of temporal separation distinguishing between previously stored information and more recent, presumably revised and improved, information, see id. “As long as the temporal separation between the most recent encoding and the previous encodings is sufficient to make it distinctive, retrieval is accurate [i.e., ‘temporal interference’ is reduced as temporal separation increases].” Id. The implication of the foregoing statement, in light of an enhanced rate of medical innovation with increasingly smaller temporal increments between innovations, is that HCPs will experience an increasing rate of difficulty in sorting out the most currently valid information with which to make diagnoses. See id. Furthermore, the authors note that “[t]he mechanism of STM [short-term memory] accounts for working memory in unfamiliar activities, but does not appear to provide sufficient storage capacity for working memory in skilled complex activities. One possible explanation is that the
despite the fact that patients are complex and care solutions often do not lend themselves to simple answers.\textsuperscript{330} Moreover, the rate of advance in medical innovation will mean that HCPs will have increased difficulty in staying abreast of the latest diagnostic tests and treatments.\textsuperscript{331} Paper records slow the flow of information between HCPs,\textsuperscript{332} and obtaining data faster results in better decisions for patients.\textsuperscript{333} Taken together with the feeling expressed by some physicians that the science and art of most diagnosis rests more in patient history than with examination\textsuperscript{334}--and the fact that patient history is captured far better in one comprehensive EMR than in individual physicians files to which only they have access--the foregoing points make a convincing case for the type of medical decision support that could be provided by a NHIN.\textsuperscript{335}

\textsuperscript{330} Murphy, \textit{supra} note 297, at 46A (quoting the Dean of the Indiana University School of Nursing as saying that “[y]ou have to have a lot of people’s heads together to get the best solution”).

\textsuperscript{331} See, \textit{e.g.}, Pfahlert & Emminger, \textit{supra} note 1, at 109 (noting that “[t]he sheer volume of information means that doctors will find it increasingly difficult to keep up with the latest developments in their own field”).

\textsuperscript{332} Schmit, \textit{supra} note 18.

\textsuperscript{333} Hogstrom, \textit{supra} note 18, at A3.

\textsuperscript{334} Kilo, \textit{supra} note 30.

\textsuperscript{335} See Kilo, \textit{supra} note 263, at 1300. Thus,

\[ \text{[k]nowledge management, not electronic record keeping, should become the primary capability of our electronic systems. Most EHRs available today are focused primarily on creating a record and} \]
An additional benefit from a NHIN will emanate from embedded programs that expand the capabilities for HCPs to function as teams despite team members not being collocated.\textsuperscript{336} The interdependencies that exist within the processes of patient receiving, diagnosis, treatment, and follow-up logically suggest the need for team-situated decision making. In many ways this decision making is similar to that required in some military environments, in which decisions must be made by teams in a real-time environment punctuated by conditions of risk of loss of life or injury, information overload, and integration of a spectrum of functions--with the collateral benefit of a greater likelihood that system-related medical errors will be detected and corrected.\textsuperscript{337} For example, most laboratory testing and imaging are performed in radiology centers that are not collocated with the physicians ordering the diagnostics. Connectivity among physicians, laboratories, radiology centers, and treatment facilities would reduce redundant tests and save time that could be critical in patient care.\textsuperscript{338} A high degree of interoperability would permit appropriate treatment to begin sooner in some critical situations, especially documenting compliance with ‘evaluation and management’ standards for billing purposes.

Although these are important functions, they should in fact be secondary to clinical knowledge development.

\textit{Id.}

\textsuperscript{336} NAT'L COMM. FOR QUALITY HEALTHCARE, CEO SURVIVAL GUIDE TO ELECTRONIC HEALTH RECORD SYSTEMS 50 (2006).

\textsuperscript{337} See JULIUS B. RICHMOND & RASHI FEIN, THE HEALTH CARE MESS 212 (2005). “Evidence suggests that a significant proportion of medical errors are system rather than individual errors. If so, the inhibitions to effective communication serve to reduce the probability that system errors will be uncovered and dealt with to the benefit of future patients.” \textit{Id.}

\textsuperscript{338} Walker et al., \textit{supra} note 248, at W5-14.
when physicians live an hour or more from hospitals.\textsuperscript{339} There is evidence that decision outcomes in such environments can be greatly enhanced through the use of integrative IT.\textsuperscript{340}

Data-intensive functions such as quality of care would also be improved through clinical monitoring based on large-scale screening and aggregation of data in which such concerns as the frequency of adverse drug events, which alone result in an estimated 7,000 fatalities\textsuperscript{341} and 1.5 million injuries per annum,\textsuperscript{342} could be tracked and interventions initiated when such frequencies exceed proscribed thresholds.\textsuperscript{343} A substantial reduction in medication errors would be a likely result,\textsuperscript{344} together with

\begin{itemize}
  \item \textsuperscript{339} McEachern, \textit{supra} note 28, at 63.
  \item \textsuperscript{340} See, e.g., Wayne W. Zachary et al., Cognitive Task Analysis and Modeling of Decision Making in Complex Environments 16 (undated) (working paper, on file with authors).
  \item \textsuperscript{341} \textsc{Institute of Medicine}, \textit{To Err is Human: Building a Safer Health System}, \textit{supra} note 11, at 27.
  \item \textsuperscript{342} Lauran Neergaard, \textit{Report Finds Drug Errors Hurt 1.5 Million}, AP, July 20, 2006, http://abclocal.go.com/wpvi/story?section=healthcheck&id=4384833. “[A] preventable drug error can add more than $5,800 to the hospital bill of a single patient. Assuming that hospitals commit 400,000 preventable drug errors each year, that’s $3.5 billion--not counting lost productivity and other costs--from hospitals alone.” \textit{Id.}
  \item \textsuperscript{343} Bates et al., \textit{supra} note 34, at 4 (citing study in which medication errors were reduced by more than 80 percent through use of IT).
  \item \textsuperscript{344} Bates et al., \textit{supra} note 34, at 4.
  \item \textsuperscript{344} \textit{Id.} One hospital reported that a major cause of patient drug medication errors was the combination of pharmacists being unable to read prescriptions written by physicians, the need for immediate administration of medication when waiting presented risks, and the non-availability of physicians to clarify the prescriptions due to other commitments. Interview with C. Lynne Rover-Willoughby, Director of Medical Informatics, Community Health Network, Indianapolis, IN (Oct. 19, 2004). Such difficulties would be eliminated with a NHIN. Bar coding of prescriptions and patients (using armbands) has been suggested as
\end{itemize}
substantial cost savings. Lessons learned from medical errors could be elevated to a national policy level, and would improve the quality of care for large patient populations. Some suggest a national database for physician performance to better inform consumers about quality of care. Also, medical research, such as modern molecular biology research—another data-intensive activity—would be significantly


345 Walker et al., *supra* note 248, at W5-13 - W5-15. With a NHIN, estimated cost savings of $2.71 billion annually could stem from physician and pharmacy time savings, in addition to the medical-error-reducing benefits from the reduction of duplicate therapies, drug interactions, and other adverse drug events. *Id.* at W5-14.

346 Middleton et al., *supra* note 249, at 17. “In the absence of such risk-stratification and population-monitoring capabilities, many low-risk patients receive treatment when it is not indicated, and many high-risk patients remain untreated.” Kilo, *supra* note 263, at 1299.

347 William T. Lester et al., *Randomized Controlled Trial of an Informatics-based Intervention to Increase Statin Prescription for Secondary Prevention of Coronary Disease*, 20 J. GEN. INTERNAL MED. 1, 7 (2005). *See* Overhage, *supra* note 325. *See also* David K. Ahern et al., *What Is e-Health (6): Perspectives on the Evolution of eHealth Research*, 8 J. MED. INTERNET RES. 9, 9 (2006) (“e-Health has the capacity to address health disparities among traditionally underserved populations due to its scalability, potential to target specific groups and conditions, and ability to be tailored and customized to culturally and linguistically diverse users”).

348 Interview with Todd Rowland, MD, Leader, Bloomington e-Health Collaborative, Bloomington, IN (Apr. 5, 2005) [hereinafter, "Rowland Interview"] (notes on file with authors).
enhanced as a result of far greater availability of patient data. Tracking and reporting of vital statistics would make treatment of certain diseases more efficient and complete, resulting in an estimated annual savings of $195 million.

Finally, a collateral benefit likely to result from NHIN implementation is that of much-needed process improvements within HCPs’ facilities and in regard to communication with patients. For example, Evanston Northwestern Healthcare

---

349 See, e.g., Shortliffe, supra note 30, at 1227. “The human genome project clearly demonstrated that modern molecular biology research has become impossible, given the amount of data that must be gathered, managed, and analyzed, without major computational support.” Id. W. Wesley Marshall & Robert W. Haley, *Use of Secure Internet Web Site for Collaborative Medical Research*, 284 JAMA 1843, 1843-44 (2000).

350 Walker et al., supra note 248, at W5-14. One physician reported that persons possibly suffering with clinical depression were more likely to undergo screening online than when they had to appear in person for reasons of both convenience and greater anonymity. Floor comment, Harvard Seminar, supra note 30 (notes on file with authors).

351 Some argue that to make significant inroads into improving the quality of healthcare, the healthcare industry must make transformational changes in its organizational structure and improvements in its treatment and administrative processes. See Naresh Khatri et al., *Medical Errors and Quality of Care*, 48 CAL. MGMT. REV. 115, 134-135 (2006). This need was underscored by Ronald Dollens, former CEO of Guidant Corp., who commented that fundamental process change was a prerequisite for healthcare improvement and successful large-scale IT implementation within healthcare. Interview with Ronald W. Dollens, former President and CEO, Guidant Corp., and past Chairman, Healthcare Leadership Council, Bloomington, IN (Feb. 1, 2006) [hereinafter, Dollens Interview] (notes on file with authors). He noted the importance of being “careful not to pave over cart paths.” Id. See Solovy, supra note 281, at 39 (noting that “[m]ost chief information officers and chief medical officers say that, to be effective, adoption of information technology must be combined with clinical process improvements and a culture of safety”).
executives report that implementation of its EMR system led its hospitals to engage in a streamlining of healthcare processes, with substantial savings in time and money resulting from process improvements considered to be a necessary prerequisite to fully successful EMR implementation. Further, a great deal of care could be delivered

---

352 Evanston Northwestern Healthcare, Evanston, IL, located in Chicago’s northern suburbs, is an academic healthcare system that includes a 476-bed hospital, a 136-bed hospital, a 239-bed hospital, ENH Medical group, ENH Home Services, ENH Foundation, and ENH Research Institute. In addition, it also provides care in 50 other locations. A single, unified staff is in place for the system. For eleven consecutive years, the organization Evanston Northwestern Healthcare has been named among the Top 100 General Hospitals and Top 15 Major Teaching Hospitals in the nation. It has also been at the forefront of health IT and has been named among the 100 Most Wired medical institutions in the nation. Evanston Northwestern Healthcare, Threshold Application for the Davies Award (undated) (on file with authors)

353 Interviews with Mark R. Neaman CEO, Jeffrey H. Hillebrand COO, Thomas H. Hodges CFO, Joseph Golbus President, ENH Medical Group, Peggy King Senior Vice President, Quality and Risk Management, and Dr. Ned Wagner Medical Director of Medical Informatics, Evanston Northwestern Healthcare, Evanston, IL (April 19, 2006) [hereinafter, "Evanston Northwestern Interviews"] (notes on file with authors). If such process improvements can have such a significant effect on one facility’s costs, the implication for process improvement on a national scale are profound. See Ross Koppel et al., Role of Computerized Physician Order Entry Systems in Facilitating Medication Errors, 293 J. AM. MED. ASS’N. 1197, 1197 (2005). (computerized physician order entry systems may save hundreds of billions in annual costs). The authors note the need to be attentive to errors that can be increased by health IT in addition to those IT reduces. Of particular interest are human-machine interface flaws that do not correspond to the existing organization of work flows. Id. at 1199-1201. Concerning the need for additional information regarding the benefits to be obtained from workflow redesign associated with medical IT, see Chaudhry et al., supra note 236, at 748-49. See also Overhage, supra note 455 (stressing a need for process improvement by noting that “[n]ot only did different doctors make different decisions on different days, different doctors made different decisions on the same day”).
without office visits when electronic communication is supported by an appropriate IT structure such as that offered by a NHIN, thereby reducing strain on personnel and facilities.\textsuperscript{354} Communication linkages that prompt patients to schedule routine medical tests for such illnesses as breast and prostate cancer would permit closer patient tracking and encourage patients to seek care on schedule.\textsuperscript{355}

Although almost all of these error-reduction aspects of IT could be implemented to a limited extent with less than a NHIN, an effective national network would go far in ensuring that health information would be accessible regardless of where patient information resided, so that HCPs could access patient history, current medications, and other patient-specific information when applying protocols and prescribing medications.\textsuperscript{356} As one healthcare IT visionary has suggested, it is not just the individual

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{354} Kilo, \textit{supra} note 263, at 1298-1301. A potential collateral benefit would be an automatic electronic record of patient communication that could reduce medical error--and under some circumstances, physicians’ legal risk as well--due to better documentation of physician/patient exchanges. \textit{Id.} at 1298-99.
\item \textsuperscript{355} Callahan, \textit{supra} note 24.
\item \textsuperscript{356} Walker et al., \textit{supra} note 248, at W5-13 - W5-14. Walker et al. offer the following additional insights: With national standards today neither completely defined nor adopted, it is tempting to develop a nonstandardized Level 3 system. Level 3 systems can indeed aggregate information from remote sources. However, they must reconcile diverse codes, data structures, and terminologies. Through such inevitably imprecise processes, Level 3 systems may generate errors and redundant information, limit the efficacy of clinical decision support, and create information and cognitive overload for clinicians. A Level 4 system, with on-demand, seamless integration of local and remote records, is far more likely to offer clinicians the integrated information the need for providing optimal care.
\end{itemize}
\end{footnotesize}
components of a healthcare IT system that increase the quality of healthcare, it is also the synergies gained through the interconnectivity of all the components.\textsuperscript{357} Unfortunately, notwithstanding significant interest on the part of the medical community\textsuperscript{358} and the expressed desire of HHS officials to resolve obstacles to widespread use of IT in the national healthcare system,\textsuperscript{359} the barriers to the creation of an effective NHIN are daunting.\textsuperscript{360} In addition to the need to integrate four basic categories of network components,\textsuperscript{361} many financial, IT interoperability, and HCP acceptance barriers exist.\textsuperscript{362}

\textit{Id.} at W5-16 - W5-17.

\textsuperscript{357} Kilo, \textit{supra} note 263, at 1298. As a healthcare executive has observed, there are three basic elements to improving healthcare: (1) broad adoption of advanced information technology, (2) interoperability of disparate systems, and (3) patients becoming active and knowledgeable consumers of healthcare. Sachs, \textit{supra} note 29.

\textsuperscript{358} Loomis et al., \textit{supra} note 266, at 638. In one survey, over 75 percent of 611 physicians surveyed answered yes to this statement: “I am interested in an EMR that would connect all physician practices, labs, x-ray facilities, and hospitals in my area securely for the exchange of patient data.” \textit{Id.}


\textsuperscript{360} See Walker et al., \textit{supra} note 248, at W5-17 (discussing limitations with implementing such systems). A NHIN will require “strong policy incentives, federal leadership, and possibly state and federal legislative mandates.” \textit{Id.}

\textsuperscript{361} Chaudhry, et al., \textit{supra} note 236, at 749. The components of an HIT implementation can be categorized as technological (e.g., systems applications), organizational process change (e.g., workflow design), human factors (e.g., user friendliness), and project management (e.g., achieving project milestones). \textit{Id.}

\textsuperscript{362} MARKLE FOUND, WORKING GROUP ON FIN., ORG., & LEGAL SUSTAINABILITY OF HEALTH INFO. EXCHANGE, FINANCIAL LEGAL AND ORGANIZATIONAL APPROACHES TO ACHIEVING ELECTRONIC
One of the least discussed--yet most critical--of these barriers, however, is the absence of a legal framework in which the establishment of a NHIN can proceed unfettered by such legal concerns as incompatibility with existing federal laws, frictions arising from state regulation and licensing requirements, and new issues regarding responsible parties with attendant malpractice liability implications. The following section outlines these issues and proposes an agenda for establishing such a framework.

VII. LEGAL BARRIERS TO IMPLEMENTATION OF A NHIN

Formidable legal obstacles\textsuperscript{363} threaten to impede the implementation of a fully effective NHIN and the medical-error-reduction potential it holds.\textsuperscript{364} The most important of these obstacles can be roughly divided into the following three categories: (1) professional liability issues associated with potentially greater exposure of HCPs to malpractice lawsuits arising from participation in a NHIN; (2) physician anti-kickback and anti-self-referral laws that may restrict the development of health IT networks necessary for a NHIN to be fully successful; and (3) various data issues that (a) create a

\textsuperscript{363} In this section's focus on legal barriers, we will identify numerous issues that form the basis of an agenda for future research. This article explores general contours, with more detailed analysis of the legal barriers being left to future scholarly analyses by the authors of this article or by other authors.

\textsuperscript{364} See, e.g., Joseph Goedert, \textit{The Politics of Electronic Medical Records}, \textit{Health Data Mgmt.}, Feb. 2005, at 44. Although the top barrier to the full implementation of a NHIN is funding, legal barriers are also important. Appearing to underscore the difficulty of overcoming these barriers, former Speaker of the House of Representatives Newt Gingrich has noted that “[y]ou are dealing with a federal bureaucracy that does not move at the speed of the modern world.” \textit{Id.}
tension between interoperability requirements and patient privacy sensitivities, (b) give rise to new opportunities for widespread divulgence of sensitive patient data\textsuperscript{365} (thereby potentially increasing lawsuits against HCPs), and (c) generate conflicts among disparate state laws that govern disclosure.\textsuperscript{366} Although federal and state legislative initiatives aimed at facilitating adoption of healthcare IT are becoming more common,\textsuperscript{367} such initiatives appear fragmented and fall short of overcoming the legal barriers\textsuperscript{368} necessary to create a framework within which a NHIN will thrive.\textsuperscript{369}

**Possible Increase in Physician Exposure to Malpractice Suits**

Field study suggests that the proliferation of information complexities associated with a NHIN gives rise to concerns about a host of unanswered questions with negligence

\textsuperscript{365} Working Group, supra note 359, at 39, 40.

\textsuperscript{366} See Bob Dart, Panel Weighs Patient Privacy Rights, Cox News Service, Mar. 16, 2006, http://www.coxwashington.com/reporters/content/reporters/stories/2006/03/17/BC_PATIENTS_PRIVACY17_Cox.html (quoting president of American Medical Informatics Association as saying that “‘I do not see how we can get to common standards and interoperability that underlie the widespread adoption of electronic health records without federal pre-emption of conflicting state laws,’” and Rep. Nathan Deal (R-Ga.) as saying that “‘some degree of uniformity on privacy rules seems necessary in setting up a national network’”).

\textsuperscript{367} Chaudhry et al., supra note 236, at 749.

\textsuperscript{368} In order to develop information beyond published sources with respect to these barriers, the authors conducted field study as follows: (1) Dollens Interview, supra note 349; (2) Evanston Northwestern Interviews, supra note 350; (3) Attendance at Harvard Seminar, supra note 30; (4) Attendance at IHI05, supra note 29; (5) Attendance at Health Care Conundrum Conference, supra note 29; (6) Rowland Interview, supra note 346.

\textsuperscript{369} Kilo, supra note 263. “Current legislation will fail to deliver on its promises.”
liability and insurance implications for physicians. 370 Electronic communication involving patients creates new fears among physicians about their legal liability for a variety of reasons. 371 Patients’ expectations concerning communications with their physicians are already changing with the medical knowledge available in lay terms and readily accessible via the Internet. 372 There is strong interest among patients in using health IT to participate more in their healthcare. 373 Many patients actually prefer the more convenient and rapid communications with physicians via email, 374 and it is estimated that as many as 50 percent of ambulatory care visits are unnecessary and could be handed via email. 375 Email has several benefits for physicians, including

370 Tom Delbanco, Keynote Presentation, “Through the Patient’s Eyes: Time, Secrets, and Flickering Screens,” Harvard Seminar, supra note 30. The speaker noted that there has been no evidence of increased malpractice lawsuits to date as a result of healthcare IT. Id. However, it remains to be seen whether patients detecting and correcting errors in EMRs will lead to more lawsuits, fewer medical errors, or both. Id. For a discussion of whether shared EMRs could serve as a protection against unwarranted lawsuits, see Slack, supra note 228, at 2229. See also Daniel C. Judge & Daniel Z. Sands, Panel Discussion Remarks, “Using Secure Messaging and E-Mail to Support and Enhance Patient-Provider Communication,” Harvard Seminar, supra note 30 (noting that “medical malpractice cases drop through better communication”).

371 Floor comments, Harvard Seminar, supra note 30 (notes on file with authors).

372 Pfahlert & Emminger, supra note 1, at 109. See Slack, supra note 228, at 2225-29.


374 Harvard Seminar, supra note 30 (notes on file with authors).

asynchronous physician-patient communication, written records that can be part of medical records, and ease of forwarding to other HCPs. Electronic remote patient monitoring that would permit shorter hospital stays and fewer office visits appears likely in the not-too-distant future. Such electronic communications between HCPs and patients already raise liability concerns. If a NHIN is characterized by synchronous

378 Slack, supra note 228, at 2257. The following questions illustrate physician concerns about legal liability resulting from a failure to answer email in a timely manner due to other responsibilities. What is the physician’s liability if a patient emails a physician regarding an urgent matter, but the busy physician does not become aware of the email message until after the patient experiences harm? Similarly, is the physician obligated to respond to all patient emails? Harvard Seminar, supra note 30 (notes on file with authors). Some legal commentators argue, however, that email provides a better paper trail to be used in malpractice litigation, as well as improved credibility in court. Peter Basch et al., Workshop Presentation at Harvard Seminar: Costs and Benefits of Implementing eHealth Solutions into Practice Settings (Apr. 28-30), Harvard Seminar, supra note 30. See Reni Gertner, Doctors & e-Mail: Lawyers Helping Establish Guidelines to Prevent Suits, ST. LOUIS DAILY RECORD/ST. LOUIS COUNTYAN, June 24, 2006, at 1 available at http://proquest.umi.com/pqdweb?did=1071931251&sid+2&Fmt=3&clientId=12010&RQT=309&VName=PQD (some attorneys believe that the careful use of email can actually reduce liability). But see Reni Gertner, Policies, Procedures for Attorneys Advising Doctor Clients about e-Mail Use with Patients, ST. LOUIS DAILY RECORD/ST. LOUIS COUNTYAN, June 24, 2006, at 1, available at http://proquest.umi.com/pqdweb?did=1071931251&sid+2&Fmt
and asynchronous electronic encounters with patients, video conferencing and messaging, connectivity to multiple data sources, data sent from home-based diagnostic technology, and full patient access to notes and reports.\textsuperscript{379} Professional liability issues associated with cybermedicine become potentially more prominent due to the mismatch between extant practice and that contemplated with a NHIN.\textsuperscript{380}

For example, current state licensing places restrictions on the interstate practice of medicine despite the need to treat patients wherever they are.\textsuperscript{381} Most malpractice insurance covers only face-to-face encounters within the state where a physician practices


\textsuperscript{380} Slack, \textit{supra} note 228, at 2259. \textit{See} Gertner, \textit{supra} note 376, at 1 (noting that using email can lower risk of litigation).

\textsuperscript{381} Middleton et al., \textit{supra} note 249, at 18.

[W]ith the advent of ‘wired’ clinical care environments and their emerging interconnectivity, and an increasingly mobile patient, we suggest that soon it will be advantageous for . . . licensure in the health professions [to] be provided at the federal level. Providers should be able to act on behalf on their patients even remotely. \textit{Id.}

The general principle is that physicians can give advice to out-of-state physicians but cannot give advice directly to out-of-state patients. Warner V. Slack, Keynote Presentation at Harvard Seminar: Cybermedicine: Computing to Enhance Communication in the Field of Medicine (Apr. 28-30), Harvard Seminar, \textit{supra} note 30.
and is licensed.\footnote{Julius A. Karash, \textit{Patients' E-records Facing Legal Hurdles}, KAN. CITY STAR, Feb. 28, 2006, at 1, available at http://proquest.umi.com/pqdweb?did=994869971&sid=12&Fmt=3&clinetid=120010&RQT=309&VName=PQD.} This means that physicians who provide telemedicine services to patients in other states could be exposed to liability from malpractice claims for which they would not be insured.\footnote{Id.} Practicing within a NHIN has the obvious effect of transcending state boundaries because, when a physician consults electronically with a patient or with other physicians who are communicating with a patient, the physician may have little or no idea as to the patient’s present location; nor does it seem that this should logically bear upon treatment in many cases. Consequently, federal legislative and regulatory attention should be given to the present state of malpractice insurance and physician licensing, with a goal of removing electronic and geographic barriers to physicians’ ability to obtain malpractice coverage in all jurisdictions within a NHIN.\footnote{See Middleton et al., supra note 249, at 17; Middleton, supra note 318 (calling for national licensure of healthcare professionals).}

**Emerging Malpractice Issues**

New questions of legal responsibility also arise, in view of the potentially far greater number of HCPs who could be involved in a given patient’s healthcare under a NHIN. A major issue is who takes responsibility for maintaining and ensuring that EMRs are up to date, given the necessity of shared records.\footnote{Emma Vere-Jones, \textit{Confidentiality Divides Doctors}, HOSPITAL DOCTOR, July 14, 2005, at 9, available at http://proquest.umi.com/pqdweb?did=874923791&sid=16&Fmt=3&clientid=12010&RQT=309&VName=PQD.} Do physicians have
responsibility for acting upon information supplied electronically by a patient and, if so, under what circumstances?\textsuperscript{386} Which physician, among various sets of physicians providing care for various ailments, has responsibility for taking action in the event that evidence indicating a potential health-threatening issue is placed in a patient’s EMR by one of the physicians?\textsuperscript{387} Who is responsible for ensuring patient information is current and correct,\textsuperscript{388} and who, if anyone, has the responsibility for periodically updating the system with current patient data, reconciling conflicting data, and deciding on the disposition of information that arrives after a patient is discharged?\textsuperscript{389} Which physician

\textsuperscript{386} One physician gave the example of an important email message being received from a patient on Friday but not read until Monday. The physician asked, “If I open the door to electronic communication with a patient, am I responsible for reading email as it arrives?” Harvard Seminar, supra note 30 (notes on file with authors). The discussion of potential liability issues in this paragraph and those that immediately follow is presented in a manner consistent with our previously identified objective of identifying numerous issues that form the basis of an agenda for future research. As noted earlier, supra note 361, we outline the general contours here, with more detailed analysis being left to future research efforts on our part or on the part of other authors.

\textsuperscript{387} Rowland Interview, supra note 346 (notes on file with authors). Take, for example, a situation in which a patient-remote-monitoring device sends signals indicating a possible increased probability of heart attack or perhaps simply a gastrointestinal disturbance. Which physician should be notified: the primary-care-physician, the cardiologist, the gastroenterologist, or all three? If the answer is all three, then who has the responsibility to initiate action? If coordination in diagnosis and treatment is required, who is responsible for effecting the coordination? Dollens Interview, supra note 349 (notes on file with authors).

\textsuperscript{388} One physician concern relates to the fact that once an error is introduced in to an EMR and signed off on, it cannot be erased. Harvard Seminar, supra note 30 (notes on file with authors).

\textsuperscript{389} An example of this type of question posed by one physician related to assignment of responsibility for laboratory reports and imagery that come into the file after a patient has been treated and discharged.
among various sets of physicians providing care for specific ailments has responsibility for taking action evidence indicating a potential health-threatening issue is placed in a patient’s EMR?³⁹⁰ How far should legal liability extend in a chain of providers? Should joint and several liability rules be abolished in those states that have not done so, in order to avoid having an exponentially greater number of HCPs, many of whom may have little association with the plaintiff patient’s care, being named as defendants?³⁹¹


³⁹¹ Evanston Northwestern Interviews, supra note 351. See Glascock, supra note 30 (noting that Kaiser Permanente insureds in Georgia "can now e-mail their doctor’s office with questions, view lab test results, and review past office visit information online at their convenience"). For example, physicians expressed concerns over the possibility of being added to lawsuits under joint and several liability rules because they were mentioned in a patient's EMR but were no longer a primary provider of healthcare to that patient. Due to the far more extensive data that would be contained in networked EMRs, some physicians were concerned that access to EMRs obtained during discovery would used for purposes of “fishing” for other potential lawsuits. Floor comments, Harvard Seminar, supra note 30 (notes on file with authors).
Yet another set of professional liability questions emanates from the notion that patients should have access to their EMRs.\textsuperscript{392} Some health experts consider patients to be important contributors to their medical records because only they know which prescribed and over-the-counter drugs they actually use and what home care they perform.\textsuperscript{393} Should patients be able to annotate their EMRs, and, if so, must a physician respond to statements placed in EMRs by patients if the physician disagrees with the statements?\textsuperscript{394} Do physicians have responsibility for acting upon information supplied electronically by a patient and, if so, under what circumstances?\textsuperscript{395} To what extent should patients share in the responsibility for the information contained in EMRs?\textsuperscript{396} Should there be a section of

\textsuperscript{392} Mandl et al., \textit{supra} note 31, at 283-86. There is a need to combine patients’ unique knowledge about themselves with physicians’ knowledge of medicine. Delbanco, \textit{supra} note 368.

\textsuperscript{393} Wilson-Steele, \textit{supra} note 231, at 44.

\textsuperscript{394} This issue was raised by a physician whose concern is illustrated by the following scenario: A patient is seen by a physician in the office and given a diagnosis and prescription. The patient returns home and emails the physician with additional information that, in the patient’s--but not the physician’s--mind, possibly changes the diagnosis and prescription. Must the physician engage in an email dialogue with the patient? Harvard Seminar, \textit{supra} note 30 (notes on file with authors).

\textsuperscript{395} One physician noted that “if a patient mentions suicide it is always a legal issue,” implying a legal responsibility to act upon this patient comment. In an environment in which physicians could conceivably receive hundreds of emails each day, what is the physician’s responsibility to read these emails in a timely manner in order to identify such comments and intervene on a timely basis? Floor comments, Harvard Seminar, \textit{supra} note 30 (notes on file with authors).

\textsuperscript{396} Noting that EMRs can create electronic records indicating who makes entries and when, a commentator observed that this would enable users of EMRs to know who had provided the information and therefore make some assessment regarding its reliability. Another commentator noted that EMRs could actually facilitate a legal defense by providing a more accurate and detailed record of who supplied what
an EMR that is reserved for physician notes and to which the patient cannot gain access except through discovery? One healthcare IT proponent hopes that patients will be more willing to share the responsibility for medical decisions if their medical records are shared with them. Although this is an empirical question and many patients may be

information and when, and, more generally, by providing evidence of sequence of care and timeliness of response by HCPs. Floor comments at Harvard Medical School Seminar “Patient-Centered Computing and eHealth: State of the Field” (Apr. 28-30) [hereinafter Floor Comments] (notes on file with authors).

397 Evanston Northwestern Interviews, supra note 351. Warner Slack, Harvard physician and noted pioneer in healthcare IT, suggests the creation of an “uncertainty folder,” accessible only to the physician and containing essentially the physician’s notes to himself or herself on pending matters. A major reason for such a folder is that although physicians are often uncertain about medical diagnoses and treatments, patients do not like uncertainty. Dr. Slack would prefer that this folder not be part of the official medical record and not be subject to discovery in the event of litigation. Slack, supra note 228, at 2260. Although the notion of a fire-walled electronic suspense file within the EMR for physician use only has some intuitive appeal, it also suggests the morass of legal issues that attend the general area of healthcare IT in a network environment. If “uncertainty folders” were permitted under the conditions preferred by Dr. Slack, would physicians be allowed to introduce the contents into evidence in their own defense in malpractice suits? If so, then a fairness asymmetry is seemingly created. Further, would physicians be inclined to place important but potentially controversial patient information in “uncertainty folders” in perpetuity in an attempt to shield information from patient and/or legal discovery? As one physician noted wryly, “People don’t get put in prison for not sharing data.” Floor comments, supra note 394. Should other physicians have access to “uncertainty folders” and be able to annotate notes therein with their own observations? If so, who has the power to transfer the notes to the accessible portion of the record, and who has the power to erase the notes?

398 Slack, supra note 228, at 2259. (“Perhaps the more we welcome our patients as colleagues, and the more they participate in medical decisions, the more they will share with us the responsibility for those
willing to accept more responsibility as a result of shared EMRs, we remain skeptical that patient goodwill alone will resolve all physicians’ concerns regarding malpractice liability.  

One facet of a NHIN that seems destined to generate unwarranted physician concerns over increased legal risk is the use of computer-based models for diagnosis and treatment. The use of such models appears likely to expand exponentially under a NHIN, wherein physicians gain broader, easier, and timelier access to artificial intelligence capable of aiding in diagnosis and disease-forecasting. With the advance

399 One reason for such doubt is the medical information asymmetry that exists between physicians and patients. See HEALTH LAW SECTION, AM. BAR ASS’N, E-HEALTH BUSINESS & TRANSACTIONAL LAW 120-123 (Barbara Bennett ed., 2002) [hereinafter E-HEALTH BUSINESS].


401 Pfahlert & Emminger, supra note 1, at 109,-10, 112. For instance:

The recording and archiving of patient data using electronic systems in hospitals and in general practice can already be regarded as a standard in many cases. The opportunities arising out of data electronification (such as the generation of diagrams from series of data, the parallel retrieval of the applied treatment or the exchange of data as the basis for evidenced-based disease or case management) will in the future be much more in focus that the mere warehousing of data.

Id. at 110. Medical forecasting also “uses various artificial intelligence methods by means of which algorithms and available data (e.g., details of life cycle, patient history, pathological medical parameters, etc.) can be used to give a reliable forecast” a disease’s likely progression. Id. In addition, a review of studies dealing with the impact such decision support systems on clinical decisions indicated that
of such systems, questions of physicians’ liability from not using such decision aids will logically arise.\textsuperscript{402} Medical diagnostic suppliers are the most promising vendors of such decision support capabilities,\textsuperscript{403} and will no doubt face liability if their products do not reflect the current state of the medical art. Physicians, however, will increasingly be faced with the choice of whether to use artificial diagnostic and forecasting intelligence in treatment of patients. This choice seems likely to generate concerns about computers practicing medicine and about physicians being forced to practice defensive medicine by accepting the IT diagnosis or by forecasting against their better instincts because of fear

\hspace{1cm}

\footnotesize{practitioner decisions were significantly improved in 62 of the 97 studies analyzed. Amit x. Garg et al., \textit{Effects of Computerized Clinical Decision Support Systems on Practitioner Performance and Patient Outcomes: A Systematic Review}. 293 JAMA 1223, 1223 (2005).}

\footnotesize{\textsuperscript{402} It does not stretch the imagination far to foresee an environment in which physicians are held accountable for not consulting with diagnostic aids when an incorrect diagnosis results in harm to a patient. For example, consider the occurrence of a low probability but high-damage event such as the rare-but-potentially-fatal scarring of lung tissue from the use of medication used to treat heart arrhythmia. Such a dire side effect could go undiagnosed until too late. If such a case were to occur in the future when diagnosis via artificial intelligence becomes more pervasive, and if a lawsuit were to result, it seems likely that astute plaintiff’s attorneys would ask whether or not artificial intelligence was consulted before the incorrect diagnosis was made. That said, physicians may well argue that the sword cuts both ways with artificial diagnostic intelligence. That is, physicians may profess that they are reluctant to go against predictions from algorithms in the diagnostic models even when their experience and instincts suggest they should. On average, however, diagnostic models should logically result in better forecasts because they will be built upon empirically derived probabilities of disease occurrence.}

\footnotesize{\textsuperscript{403} Pfahlert & Emminger, \textit{supra} note 1, at 112.}
of legal liability.\textsuperscript{404} Lawmakers and judges who remain unconvinced by the evidence against superficial malpractice liability arguments presented earlier may be tempted to embrace such assertions, which we regard as a red herring. However, “[t]he rapid and reliable interpretation of medical data in the light of the latest medical information and the individual patient situation is becoming increasingly the minimum . . . required of a doctor,”\textsuperscript{405} and that seems exactly as it should be.\textsuperscript{406} Lawmakers and judges should resist shallow arguments for legal protection against

\textsuperscript{404} See Legal Issues Related to Medical Decision Support Systems, J. CLINICAL MONITORING & COMPUTING, April 1989, at 75. For a discussion of contentions that concern how the possibility of legal liability forces physicians to practice defensive medicine, see Hyman & Silver, supra note 5, at 915-17. “Often-heard complaints about ‘defensive medicine’ only make sense if providers actually are deterred [from committing medical errors--] in fact, only if they are over-deterred [--] by the risk of liability.” Id. The authors note that none of the empirical evidence generated by a Harvard medical study, see PAUL C. WEILER ET AL., A MEASURE OF MALPRACTICE: MEDICAL INJURY, MALPRACTICE LITIGATION AND PATIENT COMPENSATION (1993) (providing result of malpractice study), supports the notion that legal liability undermines the quality of healthcare. Hyman & Silver, supra note 5, at 917. “Instead, the best available evidence shows that liability makes a modest positive contribution to patient safety despite the definitive and unqualified claims to the contrary made by patient safety advocates and other critics of the tort system.” Id.

\textsuperscript{405} Pfahler & Emminger, supra note 1, at 109.

\textsuperscript{406} Id. Despite the positive nature of “the rapid increase in medical knowledge based on published scientific literature,” it seems “increasingly unlikely that such information will be quickly and fully absorbed and applied in everyday practice in [the] future. The sheer volume of information means that doctors will find it increasingly difficult to keep up with the latest developments in their own field.” Id. This exponential increase in medical information means that the limitations on human cognition described elsewhere in this study, see supra Miller note 327, at 81, will be increasingly tested. It seems logical,
the use of artificial intelligence in medical treatment.\footnote{407}

Historically, anti-self-referral\footnote{408} and anti-kickback laws\footnote{409} have contributed to the development of

therefore, that patient safety concerns dictate the widespread use of artificial intelligence in diagnosis and forecasting.

\footnote{407} An analogy can once again be drawn to the airline industry, which relies heavily on artificial intelligence to steer and navigate aircraft. Some pilots might prefer “flying by stick” to “flying by wire,” but arguments for “winging it” fail the safety sniff test. See KEN FUNK ET AL., ALTERNATE TAXONOMY OF FLIGHTDECK AUTOMATION PROBLEMS AND CONCERNS (1996), http://www.flightdeckautomation.com/phase1/phase1alttaxonomy.aspx#pc163 (identifying various dangers that automation poses to human pilot performance). In a somewhat similar vein, some physicians express concern about patterns of their practice becoming more discernible in an electronic network, thereby making discovery of such practices far easier in malpractice lawsuits. Harvard Seminar, \supra\ note 30; Floor comments, \supra\ note 394. Again, we see no fundamental fairness issue associated with this concern. Making patterns of practice more discernible should have the effects of improving practice processes, identifying physicians who commit medical errors recurrently, better enabling best-practices information to be collected, analyzed, and disseminated, and, through all these means, reducing medical errors.

\footnote{408} The federal anti-self-referral statute known as the Stark Law, 42 U.S.C. § 1395nn (2006), provides that a physician generally cannot refer patients to a healthcare entity with which the referring physician has a financial relationship, if payment for the relevant healthcare services is to be made through the Medicare and Medicaid programs. § 1395nn(a)(1)(A). Entities that have furnished healthcare services pursuant to an unlawful referral are prohibited from seeking and obtaining Medicare and Medicaid payment for those services. § 1395nn(g). In the event of submission of a bill requesting Medicare or Medicaid payment for a service resulting from a prohibited referral, any party submitting such a bill or causing it to be submitted may be assessed a civil monetary penalty of up to $15,000 per service, assuming the party knew or should have known that the performance of the service resulted from a prohibited referral. § 1395nn(g)(3) Civil
penalties as high as $100,000 may be assessed on any participant in an ongoing scheme such as a cross-referral arrangement, if the participant knew or should have known that prohibited self-referrals led to the furnishing of the relevant healthcare services. § 1395nn(g)(4) In addition, healthcare providers can be barred from the Medicare and Medicaid programs for knowing violations of the Stark Law. See 60 Fed. Reg. 16,580-16,584 (Mar. 31, 1995) (codified at 42 C.F.R. pt. 1003). There are several exceptions, however, to the Stark Law’s ban on physicians’ referrals to entities with which they have a financial relationship. Among the various exceptions are ones allowing self-referrals when the physician is employed by the entity to which he makes a referral, 42 U.S.C. § 1395nn(e)(2), when certain other types of personal services arrangements exist between the referring physician and the referred-to entity, § 1395nn(e)(3), when the referred-to entity is the same medical group with which the physician practices, § 1395nn(b)(1), (2), and when certain arrangements involving rental of space or equipment exist between the referring physician and the referred-to entity, § 1395nn(e)(1). Unless an exception applies, any referral otherwise prohibited constitutes a violation of the Stark Law. § 1395nn(a)(1)(A). For useful overviews of the Stark Law, its considerable breadth and ambiguities, the exceptions to its application, and the controversy it has generated, see E-HEALTH BUSINESS, supra note 397, at 120-23; SHOWALTER supra note 36, at 242-46.

The federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b) (2006), prohibits the knowing and willful solicitation, receipt, offer, or payment of remuneration of any sort in an effort to induce a healthcare services referral for which payment is made under a federally funded healthcare program. §§ 1320a-7b(b)(1), (2). This statute and the Stark Law, see supra note 406, rest on the apparent rationale that consumers of healthcare services are at a significant disadvantage compared to providers because of a material and unfavorable information asymmetry, and that there must be checks against providers whose financial motivations might induce them to make referrals for self-interested reasons rather than on the basis of what is best for the patient. See E-HEALTH BUSINESS, supra note 397, at 114-15. Because it may be violated by any person or entity, the anti-kickback statute sweeps even more broadly than the Stark Law, which addresses self-referral by physicians. Compare 42 U.S.C. §§ 1320a-7b(b)(1), (2) (anti-kickback statute’s applicability to “[w]hoever knowingly and willfully solicits or receives . . . ” and “[w]hoever knowingly and willfully offers or pays . . . ”) with 42 U.S.C. § 1395nn(a)(1)(A) (Stark Law’s ban on self-
healthcare IT in a fragmented manner that has led, in turn, to poor coordination and a lack of standardization. HCPs are governed by both types of statutes, with violations being quite serious from a monetary standpoint, and, in some instances, even a criminal standpoint. In 2004, the Government Accountability Office (GAO) identified both

referral by a "physician"). A violation of the anti-kickback law can lead to a felony criminal prosecution in which fines of up to $25,000 and imprisonment for a maximum of five years can be imposed. 42 U.S.C. §§ 1320a-7(b)(1), (2). The statute and regulations promulgated by the Department of Health and Human Services allow for numerous exceptions and safe harbors that classify particular arrangements and relationships as permissible and non-violative of the anti-kickback law. See id. § 1320a-7(b)(3); 42 C.F.R. § 1001.952 (2006). Among these exceptions and safe harbors are ones providing protection for remuneration furnished pursuant to an employment relationship, see 42 U.S.C § 1320a-7(b)(3)(B), an independent contractor relationship that meets certain conditions, 42 C.F.R. § 1001.952(d), and certain qualifying space and equipment rental contacts, see id. § 1001.952(c). For an overview of the anti-kickback statute, its exceptions and safe harbors, and other federal laws dealing with fraud and abuse in regard to federally funded healthcare programs, see E-HEALTH BUSINESS, supra note 397, at 114-20, 126-27. For a history of the development of Medicare and Medicaid-related anti-kickback law, see WING, supra note 36, at 206-14.

410 Shortliffe, supra note 30, at 1228.

411 See SHOWALTER, supra note 36, at 235; see also supra notes 406-07 (discussing the potential financial consequences associated with violations of the Stark Law and the anti-kickback statute). Qui tam suits filed under the civil False Claims Act, 31 U.S.C. §§ 3729-3731 (2006), have been a major weapon in the pursuit of HCPs who violate the Stark and anti-kickback laws and other similar statutes. Such suits are brought by “whistle-blower” third-parties (“relators” who are often employees of the HCPs) and who share in the judgment awards that may result from such cases. See id.; SHOWALTER, supra note 36, at 235; E-HEALTH BUSINESS, supra note 397, at 126-27.

412 HARRIS, supra note 180, at 169-72. See also supra note 407 (discussing potential criminal liability for violations of anti-kickback statute). Courts deciding whether the anti-kickback law was violated have
anti-kickback and Stark laws as legal obstacles to health IT implementation, noting that even though these laws do not directly address IT, uncertainty over what sorts of shared IT arrangements might run afoul of them could cause HCPs to be reluctant to risk the possible significant penalties associated with their violation. A particular problem noted by some experts was that self-referral prohibitions and anti-kickback laws effectively barred hospitals from helping physicians acquire medical IT in their private practices, despite the necessity of such acquisitions if a comprehensive NHIN is to be achieved.

A precursor to a NHIN may well be the formation of regional health information organizations, which are likely to gain momentum in the near future. Because the adopted an interpretation that does not favor HCPs. In order for HCPs to be in violation, it is necessary for only one of the reasons for giving or receiving payment to have been that of inducing referrals. Federal appellate courts have consistently upheld this interpretation despite defendants’ arguments that this makes almost any relationship between physicians and hospitals potentially illegal. HARRIS, supra note 180, at 169-72. However, merely hoping for or expecting referrals does not constitute a violation, and physicians can receive payments from hospitals to which they refer patients if such payment is entirely for services rendered by the physicians in furnishing healthcare. Id.

413 E-HEALTH BUSINESS, supra note 397, at 64 (Cum. Supp. 2005); GEN. ACCT. OFF., HHS’S EFFORTS TO PROMOTE HEALTH INFORMATION TECHNOLOGY AND LEGAL BARRIERS TO ITS ADOPTION, 2 (2004).


415 Mosquera, supra note 260, at 1. In October 2005, HHS proposed exceptions to federal anti-kickback laws in order to relax this restriction and encourage adoption of EMRs by physicians. Id. For discussion and analysis of the later-adopted exceptions, see infra text accompanying notes 419-59.

416 For an example of the development of healthcare IT interoperability at a regional level, in which pharmacies in six states launched an industry-wide network that links the pharmacies with online information regarding patient medical histories, drugs, dosage, and patient compliance, see Alpert, supra
federal government has recently pushed the concept of EMRs through community-wide networks and because the Stark Law lent itself to an interpretation that physicians could not lawfully receive IT-related services at less than market value from an HCP to which they refer patients, an exception was created to allow physicians access to and sharing of EMRs, provided no violation of anti-kickback statutes occurred.418 This exception has the inherent limitation, however, of applying only to community-wide information

systems, with community being ill-defined. What had been lacking was some authority to deal with regional health information networks.

In response to the medical IT implementation barriers posed by the Stark and anti-kickback laws, the Department of Health and Human Services (HHS) recently promulgated new regulations to create exceptions and safe harbors to these laws for the purpose of facilitating adoption of electronic prescribing and EMRs. These regulatory changes set forth the conditions under which certain designated health services providers can donate IT-related products and services to physicians for purposes of creating interoperable EMRs and electronic prescribing. The new regulations, announced in the


\[420\] Middleton et al., supra note 249, at 17. Such an authority is needed “to guide development and implementation of data sharing policies and procedures among providers and patients, legal frameworks, enabling technologies (e.g., patient matching algorithms), and management of shared expenses and financial benefits in a coherent and sustainable business model.” Id.


\[422\] See sources cited at supra note 419 (discussing the inherent limitation of EMRs).
summer of 2006 and effective in October 2006, create a Stark Law safe harbor for electronic prescribing items and services, and a basically identical anti-kickback statute safe harbor. The promulgation of regulations creating those safe harbors was mandated by Congress in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. In addition, the new regulations establish a broader Stark Law safe harbor for electronic health records items and services and a corresponding anti-kickback statute safe harbor. The Centers for Medicare & Medicaid Services (housed in HHS) and the Office of Inspector General (also housed in HHS) promulgated regulations creating the broader safe harbors pursuant to separate statutory authority authorizing the creation of additional safe harbors when new ones seem necessary.

---


424 42 C.F.R. § 411.357(v) (2006) (Stark Law safe harbor for electronic prescribing items and services); id. § 1001.952(x) (anti-kickback statute safe harbor for electronic prescribing items and services).

425 See CMS Final Rule, supra note 423 at 45140 (discussing statutory directive to develop this new safe harbor regarding Stark Law); id. at 45110 (discussing statutory directive to develop this new safe harbor regarding anti-kickback statute). The statutory directive of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 appears at 42 U.S.C. §1395w-104(e)(6) (2005).


427 See 71 Fed. Reg. 45140-41 (Aug. 8, 2006) [hereinafter OIG Final Rule] (discussing decision by Centers for Medicare and Medicaid Services, an HHS unit that regulates in regard to Stark Law, to promulgate electronic health records items and services exception pursuant to Stark Law provision (42 U.S.C. §1395nn(b)(4)) authorizing HHS to develop appropriate regulatory exceptions); 71 Fed. Reg. 45110 (Aug. 8, 2006) (discussing decision by Office of Inspector General, an HHS unit that regulates in regard to anti-
The new safe harbors for *electronic prescribing items and services* establish that the furnishing of "[n]on-monetary remuneration" taking the form of "hardware, software, or information technology and training services" will not violate the Stark Law or the anti-kickback statute if it is "necessary and used solely to receive and transmit electronic prescription information," and if all further conditions specified in the new safe harbor regulations are satisfied. A key condition dealing with qualifying donors states that the relevant items must have been furnished by a "[h]ospital to a physician who is a member of its medical staff," by a "[g]roup practice . . . to a physician who is a member of the group," or by a Medicare prescription drug plan sponsor or other qualifying Medicare-affiliated organization "to a prescribing physician." Among the further conditions listed in the regulations is the requirement that the donor not take action to "limit or restrict the use or compatibility of the [furnished] items or services with any other electronic prescribing or electronic health records systems."


429 *Id.* § 411.357(v)(1)(i)-(iii) (setting forth Stark Law safe harbor). The same language appears in the regulation setting forth the anti-kickback statute safe harbor, except that the words "healthcare professional" are substituted for "physician" in some instances. *Id.* § 1001.952 (x) (1)(i)-(iii).

430 *Id.* § 411.357(v)(3) (setting forth Stark Law safe harbor); *id.* § 1001.952(x)(3) (setting forth anti-kickback statute safe harbor). The language quoted in the text is identical in each of the regulations just cited. In addition, the conditions specified in the regulations require that the relevant items be provided as part of, or to enable access to, an electronic prescription drug program meeting the standards of Medicare.
The New Safe Harbors: Laudable But Insufficient

Although the electronic prescribing safe harbors rest upon a laudable rationale, the “necessary and used solely to receive and transmit electronic prescription information” language may limit their usefulness, given that much of the software is likely to be bundled with other functions and applications. That language, however, was

Part D; that the receipt of the items not be a condition of the recipient's doing business with the donor; that the recipient be allowed to use the items for any patient regardless of whether he or she is a patient covered by Medicare, Medicaid, or any other health program; and that the arrangement between the donor and the recipient is documented in a detailed written agreement or series of agreements. Id. § 411.357(v)(2), (4), (5), (7) (setting forth Stark Law safe harbor); id. § 1001.952 (x) (2), (4), (5), (7) (setting forth anti-kickback statute safe harbor). Each regulation includes a condition that the donor "not have actual knowledge of, and . . . not act in reckless disregard or deliberate ignorance of, the fact that the [receiving party] possesses or has obtained items or services equivalent to those provided by the donor." Id. § 411.357(v)(8) (setting forth Stark Law safe harbor); id. § 1001.952 (x)(8) (setting forth anti-kickback statute safe harbor). Finally, there is the condition that the eligibility of a physician or other healthcare professional to be a recipient is determined according to a method that does not take into account "the volume or value of referrals or other business generated between the parties." Id. § 411.357(v)(6) (setting forth Stark Law safe harbor); id. § 1001.952 (x) (6) (setting forth anti-kickback statute safe harbor). However, the condition just noted does not prohibit a donor from considering the number of prescriptions written by a physician in deciding whether he or she should be made a recipient of donated items and services, so long as the donor does not take into account the value of those prescriptions. See 71 Fed. Reg. 45147 (Aug. 8, 2006) (discussing observation to this effect by Centers for Medical and Medicaid Services); id. at 45118 (discussing observation to same effect by Office of Inspector General).

See supra text accompanying notes 419-20 (noting that the rationale seeks to promote development of data sharing).
required by the statutory directive to develop electronic prescribing safe harbors. The concern about whether these safe harbors will be very useful appears to have been part of the reason why the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) decided to adopt the broader safe harbors for electronic health records items and services--items and services that, under the relevant regulations, must include an electronic prescribing component. The broader electronic health records safe harbors thus should be more useful for purposes of a NHIN than the narrower ones for electronic prescribing, though, as will be seen, it is not clear that even the broader safe harbors are properly contoured.

According to the regulations setting forth the new safe harbors for electronic health records items and services, a healthcare entity's furnishing of "non-monetary remuneration" consisting of "software or information technology and training services" to a physician or other healthcare provider does not violate the Stark Law or the anti-kickback statute if the furnished items and services are "necessary and used predominantly to create, maintain, transmit, or receive electronic health records,"

---


433 See id. at 45115, 45144 (discussing a new safe harbor for arrangements involving the provisions of electronic prescribing technology and describing ways in which physicians can transmit electronic prescription information, respectively).

434 See infra text accompanying notes 446-59 (discussing the advantages and disadvantages of physician participation in electronic health records).
assuming all other necessary conditions set forth in the regulations are met. One condition requires that the furnished electronic health records software include an electronic prescribing capability. Various ones of the other conditions match conditions associated with the previously discussed electronic prescribing safe harbors.

435 42 C.F.R. § 411.357(w) (setting forth Stark Law safe harbor); id. § 1001.952 (y) (setting forth anti-kickback statute safe harbor). The words quoted in the text appear identically in each of the two regulations just cited.

436 Id. § 411.357(w) (setting forth Stark Law safe harbor); id. § 1001.952 (y) (setting forth anti-kickback statute safe harbor).

437 See supra note 427. The electronic health records items and services safe harbors likewise require that the receipt of the items not be a condition of the recipient's doing business with the donor; that the recipient be allowed to use the items for any patient regardless of whether he or she is a patient covered by Medicare, Medicaid, or any other health program; and that the arrangement between the donor and the recipient is documented in a detailed written agreement or series of agreements. 42 C.F.R. § 411.357(w)(5), (7), (9) (2006) (regulation setting forth Stark Law safe harbor); id. § 1001.952 (y) (4), (6), (8) (setting forth anti-kickback statute safe harbor). Each regulation includes a condition that the donor "not have actual knowledge of, and . . . not act in reckless disregard or deliberate ignorance of, the fact that the [receiving party] possesses or has obtained items or services equivalent to those provided by the donor." Id. § 411.357(w)(8) (setting forth Stark Law safe harbor); id. § 1001.952 (y) (7) (setting forth anti-kickback statute safe harbor). Finally, there is the condition that the eligibility of a physician or other healthcare professional to be a recipient is determined according to a method that does not "directly take into account the volume or value of referrals or other business generated between the parties." Id. § 411.357(w)(6) (setting forth Stark Law safe harbor); id. § 1001.952 (y) (5) (setting forth anti-kickback statute safe harbor).

However, the regulations go on to say that a method of determining eligibility for receipt of items or services is deemed not to "directly take into account the volume or value of referrals or other business generated" if the method is based on any of the following: the number of prescriptions written by the recipient; the size of the recipient's medical practice; the number of hours that the recipient practices
Important conditions unique to the electronic health records safe harbors include the requirement that furnished software be *interoperable* in regard to other electronic prescribing or health records systems.\(^{438}\)

In a critical difference from the electronic prescribing safe harbors, the regulations establishing the electronic health records safe harbors contain the further requirement that the receiving physician or other recipient pay 15 percent of the donor's costs for the relevant items or services before receiving them.\(^{439}\) No such cost-sharing requirement exists under the electronic prescribing safe harbors.\(^{440}\) The regulations also provide that the donor of electronic health records items and services cannot finance, by grant or loan, medicine; the extent of use of technology in the recipient's medical practice; the level of uncompensated-for care furnished by the recipient; the fact that the recipient is or is not a member of the donor's medical staff (if the donor has a medical staff); or other reasonable standards that do not focus on volume or value of referrals or business generated. *Id.* § 411.357(w)(6)(i)-(vii) (setting forth Stark Law safe harbor); *id.* § 1001.952(y)(5)(i)-(vii) (setting forth anti-kickback statute safe harbor).

\(^{438}\) 42 C.F.R. § 411.357(w)(2) (2006) (setting forth Stark Law safe harbor); *id.* § 1001.952(y)(2) (setting forth anti-kickback statute safe harbor). *Interoperable* is defined as being "able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings; and exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered." *Id.* § 411.351. Software is deemed to be interoperable if it is certified as such by a certification body recognized by the Secretary of HHS. *Id.* §§ 411.357(w)(2); 1001.952(y)(2). As a further condition of these safe harbors, donors cannot take actions that limit the software's use, compatibility, or interoperability with other systems. *Id.* §§ 411.357(w)(3), 1001.952(y)(3).

\(^{439}\) *Id.* §411.357(w)(4) (Stark Law safe harbor); *id.* § 1001.952(y)(11) (anti-kickback statute safe harbor).

\(^{440}\) See *id.* §§ 411.357(v); 1001.952(x) (discussing electronic prescribing of items and services).
the receiving physician's (or other recipient's) payment of the necessary 15 percent share of the donor's costs.  

The electronic health records safe harbors differ from those for electronic prescribing in another important respect: the existence of a sunset provision regarding the former but not the latter. To qualify for the electronic health records safe harbors, the transfer of the relevant items and services must take place—and all other necessary conditions must be satisfied—no later than December 31, 2013. HHS envisioned the sunset provision as a partial check against the potential danger that the safe harbor might be abused, given the considerable economic value of the items and services involved.

In choosing the "necessary and used predominantly" language of the electronic health records safe harbors, HHS sensibly recognized that protection against liability under the Stark Law and the anti-kickback statute should still be available if the relevant

---

441 Id. § 411.357(w)(4) (Stark Law safe harbor); id. § 1001.952(y)(11) (anti-kickback statute safe harbor). The regulations setting forth the electronic health records safe harbor to the anti-kickback statute further state that the donor can "not shift the costs of the [furnished] items or services to any Federal healthcare program." Id. § 1001.952(y)(12).

442 Id. § 411.357(w)(13) (Stark law safe harbor); id. § 1001.952(y)(13) (anti-kickback statute safe harbor).

443 Id. § 411.357(w)(13) (Stark Law safe harbor); id. § 1001.952(y)(13) (anti-kickback statute safe harbor). The Dec. 31, 2013 sunset date was chosen because it coincides with the Bush Administration's stated goal of achieving nationwide adoption of electronic health records technology by 2014. CMS Final rule, supra note 423, at 45162 (Aug. 8, 2006); OIG Final Rule, supra note 423 at 45133.

444 See 71 Fed. Reg. 45162 (comments by CMS); id. at 45133 (comments by OIG).

445 As previously noted, the relevant regulations state that the furnished items or services must be "necessary and used predominantly to create, maintain, transmit, or receive electronic health records." 42 C.F.R. § 411.357(w) (Stark Law safe harbor); id. § 1001.952 (y) (anti-kickback statute safe harbor).
software, though primarily used for electronic health records functions, also performs secondary functions such as facilitating billing and office administration.\textsuperscript{446} Accordingly, the electronic health records safe harbors appear to hold more promise for facilitating a NHIN than the more narrowly phrased electronic prescribing safe harbors,\textsuperscript{447} which require that the furnished items or services be "necessary and used solely" for electronic prescribing purposes.\textsuperscript{448}

The new safe harbors are laudable steps in the right direction, but they do not remove all concerns about potential self-referral and anti-kickback liability in the context of furnished and received items and services dealing with electronic prescribing and electronic health records.\textsuperscript{449} Various questions suggested by the conditions associated with the new safe harbors may limit their effectiveness and make them less-than-adequate relaxations of constraints that impede adoption of a NHIN. We now identify those questions to the extent we have not already done so, with a view toward outlining possible subjects of future study as experience with the 2006 safe harbors enables

\textsuperscript{446} CMS Final Rule, \textit{supra} note 423 at 45141, 45144, 45151; OIG Final Rule \textit{supra} note 423, at 45112, 45115-46, 45121, 45124-25.

\textsuperscript{447} CMS Final Rule, \textit{supra} note 423, at 45144, 45151; OIG Final Rule, \textit{supra} note 423, at 45115-16, 45121, 45124-25.

\textsuperscript{448} 42 C.F.R. § 411.357(v) (Stark Law safe harbor for electronic prescribing items and services); \textit{id.} § 1001.952 (x) (corresponding anti-kickback statute safe harbor). The electronic prescribing safe harbor would not be available if, for instance, the furnished software was primarily devoted to electronic prescribing but also performed ancillary functions such as facilitating billing and office administration. CMS Final Rule, \textit{supra} note 423, at 45144-46; OIG Final Rule, \textit{supra} note 423, at 45115-16.

\textsuperscript{449} Middleton, \textit{supra} note 254, at 17.
affected parties, regulators, and commentators to assess the safe harbors' effectiveness in facilitating movement toward a NHIN.

One key question concerns the selection of recipients of electronic prescribing and/or electronic health records items and services. Because the number of prescriptions written by a physician (though not the value of those prescriptions) and the size of the physician's medical practice may be taken into account by a donor in deciding whether to furnish electronic prescribing items and services to a physician, is there a danger that

450 As noted earlier one of the electronic prescribing safe harbor's conditions is that the eligibility of a physician or other healthcare professional to be a recipient must be determined according to a method that does not take into account "the volume or value of referrals or other business generated between the parties." 42 C.F.R. § 411.357(v)(6) (regulation setting forth Stark Law safe harbor); id. § 1001.952 (x) (6) (regulation setting forth anti-kickback statute safe harbor). However, this condition does not prohibit a donor from considering the number of prescriptions written by a physician in deciding whether he or she should be made a recipient of donated items and services, so long as the donor does not take into account the value of those prescriptions. CMS Final Rule, supra note 423, at 45147; OIG Final Rule, supra note 423, at 45118 (observation to same effect by Office of Inspector General). As noted earlier, the electronic health records safe harbor includes a condition that the eligibility of a physician or other healthcare professional to be a recipient must be determined according to a method that does not "directly take into account the volume or value of referrals or other business generated between the parties." 42 C.F.R. § 411.357(w)(6) (regulation setting forth Stark Law safe harbor); id. § 1001.952 (y) (5) (regulation setting forth anti-kickback statute safe harbor). However, the regulations go on to say that a method of determining eligibility for receipt of items or services is deemed not to "directly take into account the volume or value of referrals or other business generated" if the method is based on any of the following: the number of prescriptions written by the recipient; the size of the recipient's medical practice; the number of hours that the recipient practices medicine; the extent of use of technology in the recipient's medical practice; the fact that the recipient is or is not a member of the donor's medical staff (if the donor has a
rural physicians, other physicians who practice in non-metropolitan areas, and physicians who work in small group practices will be less likely to be chosen to receive these important items and services?\(^{451}\) This seems problematic in that these physicians may be the ones most likely to need either gifts of relevant software or financial assistance in order to implement EMR. Are special incentives needed to encourage hospitals and other appropriate donors to furnish electronic prescribing items and services to such physicians?\(^{452}\)

Other important questions center around the cost-sharing requirement that HHS placed into the electronic health records safe harbor, though not into the electronic prescribing safe harbor.\(^{453}\) The requirement that the physician or other recipient bear medical staff; the level of uncompensated-for care furnished by the recipient); or other reasonable standards that do not focus on volume or value of referrals or business generated. Id. §§ 411.357(w)(6)(i)-(vii) (regulation setting forth Stark Law safe harbor); id. §§ 1001.952 (y) (5) (i)-vii) (regulation setting forth anti-kickback statute safe harbor).

\(^{451}\) See CMS Final rule, supra note 423, at 45158-160; OIG Final Rule, supra note 423 at 45129-131 (noting that parties commenting on proposed regulations had voiced such concerns).

\(^{452}\) This observation leads to questions that extend beyond what can be accomplished by way of safe harbors and exceptions to Stark and anti-kickback laws, and that go toward the greater role of the federal government in encouraging a NHIN. Should the federal government provide financial help to physicians and their group practices in order to lessen the financial burden of adopting EMR? If so, what form or forms should that help take (e.g., grants, low-interest loans, partially forgivable loans, or tax breaks), and how should qualification for such financial assistance be determined? As will be seen shortly, these same questions arise in regard to the fifteen percent cost-sharing obligation required of physicians if they want to participate in an electronic health records items and services arrangement that would be protected by the appropriate safe harbors. See infra text accompanying notes 453-56.

\(^{453}\) See supra text accompanying notes 439-40.
fifteen percent of the cost of the furnished electronic health records items and services\textsuperscript{454} presumably reflects a desire on the part of HHS to avoid adopting an exception so broad that it severely undercuts the policies underlying the Stark and anti-kickback statutes.\textsuperscript{455} Nevertheless, the cost-sharing obligation may present a substantial disincentive to physician participation in an agreement under which a hospital or other donor would furnish electronic health records items and services. Even though the donor would bear the bulk of the costs, the 15 percent threshold may make such an arrangement financially infeasible, or at least unattractive, to physicians for whom the costs of EMR systems already seem to furnish a reason not to adopt them. If the cost-sharing requirement makes the electronic health records safe harbors unattractive, those safe harbors objectives—facilitating the move toward nationwide EMR use\textsuperscript{456}—will go largely unfulfilled.

After the electronic health records safe harbor has been in effect for a reasonable time and the extent of its use (or lack of use) can be tracked, it should become more clear whether there should be a cost-sharing requirement and, if so, whether the fifteen percent figure\textsuperscript{457} is the appropriate measure. HHS and Congress must be prepared to revisit the cost-sharing requirement if it appears the financial disincentive to physician participation is substantial enough to make the safe harbor little-used and thus of only token help in

\begin{footnotesize}
\begin{enumerate}
\item 42 C.F.R. §§ 416.357(v); 411.357(w)(4); 1001.952(x); 1001.952(y)(11).
\item CMS Final Rule, supra note 423 at 45160-161 (identifying CMS’ justifications for its cost-sharing regulations); OIG Final rule, supra note 413, at 45132-133 (same with respect to OIG’s cost-sharing regulations).
\item CMS Final Rule, supra note 423, at 45140.
\item 42 C.F.R. §§ 411.357(w)(4); 1001.952(y)(11).
\end{enumerate}
\end{footnotesize}
advancing the goal of widespread EMR use. In a similar vein, Congress and the executive branch will likely have to give careful attention to questions HHS cannot answer by way of safe harbor regulations: whether the federal government should provide financial assistance to physicians and their group practices in order to lessen the financial burden of adopting EMR, and, if so, what form or forms that assistance should take (e.g., grants, low-interest loans, partially forgivable loans, or tax breaks). These questions will not be easy to resolve, and the political disagreements may be considerable along the way, but a determination of the extent to which the federal government will or will not be a major financial player in effectuating nationwide EMR use cannot be postponed indefinitely.

A further potential limitation on the helpfulness of the new safe harbors comes in the form of the position of CMS and OIG that the regulations creating those safe harbors do not preempt state laws prohibiting physician self-referral and furnishing of kickbacks in healthcare contexts. This means that parties complying with safe harbors under federal law could still be at risk of liability under state laws. Federal preemption of state law through compliance with federal law would protect against government actions under both federal and state self-referral laws, and thus seems necessary to facilitate nationwide EMR adoption. Because CMS and OIG, however, believe they lack the authority to give federal safe harbors preemptive effect with respect to state anti-referral and anti-kickback laws, congressional action will be necessary to effect the necessary preemption.

---

458 In addition, there would be the question of how qualification for any such financial assistance should be determined.

459 CMS Final Rule, supra note 423, at 45143; OIG Final Rule, supra note 423, at 45114.

460 Id.
As the foregoing discussion reveals, we believe that despite the commendable actions taken to date by CMS and OIG, additional efforts are needed in the federal regulatory and legislative arenas to smooth the way toward successful NHIN implementation. In addition to the concerns already noted, other questions remain concerning the new safe harbors and whether they satisfactorily remove the barrier to EMR adoption posed by anti-kickback and anti-self-referral laws. For example, is the regulatory safe harbors' definition of electronic health record\footnote{The regulation defines electronic health record as meaning "a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions." 42 C.F.R. § 411.351.} satisfactory for purposes of a NHIN, or is a modified definition desirable? Is the December 31, 2013 sunset provision on the electronic health records safe harbors\footnote{See supra note 440 and accompanying text.} desirable? Should there be no sunset, a later sunset, or perhaps an earlier one to encourage faster adoption of healthcare? The various questions and concerns noted here cast serious doubt on whether HHS has accomplished its stated goal of having "rules that cleanly define what a facility can and cannot do to supply or subsidize healthcare,"\footnote{Joseph Conn, IT Safe Harbors Are Close, MODERN HEALTHCARE, May 1, 2006, at 32.} and serve to underscore the need for more holistic federal action in the area of anti-kickback and anti-self-referral laws.

Patient Privacy Versus Availability of Patient Data

Of the categories of legal barriers to the realization of a NHIN, privacy is perhaps the greatest.\footnote{E.g., Rubenstein, supra note 23, at B1.} The public’s growing fears of identity theft and of who might see their health records are barriers to the establishment of inter-operative health information

\footnote{The regulation defines electronic health record as meaning "a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions." 42 C.F.R. § 411.351.}
networks.\textsuperscript{465} A principal concern is the tradeoff between patients’ rights to privacy regarding their healthcare information and interoperability within a NHIN.\textsuperscript{466} On the one hand, many argue that the sharing of complete information is critical to making meaningful reductions in the incidence of medical errors.\textsuperscript{467} Full disclosure to both the patient and the institution where the error took place is necessary to better understand patterns of error.\textsuperscript{468} On the other hand, patients represent the largest and most important stakeholder groups with respect to a NHIN, the success of which will likely depend upon their trust and participation.\textsuperscript{469} At least one skeptic of a NHIN has argued that security of data has been protected in the main by tight compartmentalization at the local level (and presumably by somewhat idiosyncratic terminology that varies across HCPs as well).\textsuperscript{470} For example, despite the restrictions placed by HIPAA on the dissemination of patient information to unauthorized persons,\textsuperscript{471} leading opponents of a NHIN believe that EMRs


\textsuperscript{466} See Greg Piper, \textit{Interoperability Clashes with Privacy in Health IT System Development}, \textsc{Wash. Internet Daily}, Jul. 28, 2005 (on file with authors) (explaining that varying privacy protection standards create a “direct barrier” to interoperability).

\textsuperscript{467} Kate Ackley, \textit{Privacy Groups Wary of Health IT Bill}, \textsc{Roll Call}, June 19, 2006, at 115.

\textsuperscript{468} Rosenthal, \textit{supra} note 13, at 324.

\textsuperscript{469} \textit{Doctors Slowly Going Digital With Records}, \textit{supra} note 24.

\textsuperscript{470} See Nina Youngstrom et al., \textit{NCVHS Privacy Chair Sees NHIN as ‘a Chance to Rethink Everything’ in Privacy Regulation}, \textsc{Report on Patient Privacy}, Jul. 2006, at 1, 8-9, (\textit{noting} that a national system will increase exposure of patient data to insecure entities).

represent a monstrous risk to patient privacy. As one group of authors has noted, “Choices about the structure and ownership of these [patient] records will have profound impact on the accessibility and privacy of patient information.”

Experts often refer to three fundamental aspects of any effective health IT system: (1) **confidentiality**—the prevention of unauthorized and/or improper disclosure of patient data, (2) **integrity**—the prevention of unauthorized modification of data, and (3) **availability**—the accessibility of information and data when and where they are needed. These three aspects, however, embody natural tradeoffs that often set the first two at odds with the third. The need for information security must be balanced against

---


473 Mandl et al., *supra* note 31, at 283. Consequently, if EMRs are shared by multiple providers, privacy restrictions by virtue of ownership logically become an example of the type of problems that can arise because of current privacy laws. Is ownership joint or several? If records on the same patient differ among HCPs as one might expect, is the shared information jointly owned and the individual information severally owned? At what point does the patient information become jointly owned? If private information is released without authorization, does the network bear responsibility in addition to the HCP that released the information? Without tremendous difficulty, one can envision a host of such questions arising when laws created with a simple information network in mind are applied in a vastly different, far more complicated network.


475 Ackley, *supra* note 467, at 114-15 (discussing examples of the types of debates these tradeoffs have spawned).
the need for access in a consistent manner to ensure adequate care, and this is not always an easy task given the variety and numbers of personnel and entities involved in the care of a single patient.\footnote{Grogan, supra note 239, at 16-17.}

A study conducted by the British Columbia Medical Association summarized Canada’s analogous patient information privacy-versus-availability challenge succinctly: \footnote{The issue of the balance between privacy of patient information and legitimate demands for information appears to be international in scope, given the concerns of Canadians and the existence of data protection legislation in Europe. David Markwell, \textit{Commentary: Open Approaches to Electronic Patient Records}, \textit{322 Brit. Med. J.} 286, 286 (2001); Vere-Jones, supra note 383, at 9 (discussing examples of dialogue among physicians regarding the tradeoffs between privacy and availability of EMRs).}


There is no question that privacy is a major concern among consumers of healthcare services, their elected officials, and HCPs,\footnote{\textit{CR Investigates the New Threat to Your Medical Privacy}, supra note 25, at 39.} apparently with good reason.\footnote{See Spence Wilcox & Bob Brown, \textit{Developing Policies and Procedures for Electronic Information Access}, \textit{J. Healthcare Compliance}, Jan.-Feb. 2005, at 47-48 (noting that poor controls over user access to patients’ health information exist, and that users may have access to systems they should not have as well as higher levels of access than their positions warrant). See also Robeznieks, supra note 465, at 6 (to same general effect).}

Although the greatest concern at the patient level seems to be centered on unauthorized
local access that might permit medical personnel who know the patient to view embarrassing health information, health IT advocates argue that this potential exists today with paper records, and might actually be better controlled in an electronic environment. Privacy concerns on the part of healthcare consumers go far beyond simple disclosure to local acquaintances, however, and extend to concerns that data might be shared with data warehouses that process prescriptions for pharmacies, insurance companies, employers, and lenders, thereby potentially affecting insurance, employment, and credit relationships. Concerns of elected officials have manifested themselves in

---

481 Robeznieks, supra note 465, at 6.

482 Shailagh Murray, On Medical-Privacy Issue, the Doctor Finally May Be In, WALL ST. J., Aug. 20, 1999, at A12. (“Patients generally assume that their most embarrassing or devastating health problems are safe in a color-coded file. But the reality is, every note that doctors scribble or prescription they write may pass through dozens of hands and be typed into multiple computer databases.”) Id.


484 Hanscom, supra note 483. (Noting that access to patient data could come through seemingly strange venues such as the performance of due diligence by a corporation in the acquisition of a pharmacy or insurance company.); see Youngstrom, supra note 470 (noting that "one of the greatest threats to patient privacy comes not from CEs [covered entities, i.e., entities covered under HIPAA], but from business associates and others that are not covered by the rule," and that "[b]ecause the possibility for information to be inappropriately released will be magnified under a national system, the issue must be addressed before a NHIN is implemented"); see also Murray, supra note 482, at A12 ("[O]ne of six people are so worried about leaks that they lie or ask their doctors to lie, or go to different doctors, or don’t seek treatment at all,
numerous ways, as evidenced by the rancor in various government deliberations\(^{485}\) and the federal government’s apparent willingness to place Medicare data into patients’ records on the condition that the record would be visible to only the patients and their HCPs in order to help overcome privacy concerns.\(^{486}\) Reservations on the part of HCPs relate not only to the largely flawed perception that IT networks represent a threat to data confidentiality,\(^{487}\) but also to the liability risks currently posed by violations of federal and state privacy laws.\(^{488}\) One legal expert has stated that it seems likely courts will consider privacy a part of a contract between HCPs and patients.\(^{489}\) Such concerns are exacerbated by a few high-profile cases that have received considerable publicity and by

\(^{485}\) See, e.g., *Interoperability Clashes with Privacy in Health IT System Development, supra* note 466; Murray, *supra* note 482, at A12 (discussing Congress’ many attempts to pass a national law on medical record privacy); *President To Push Medical Record Computerization, supra* note 19, at 1 (discussing President Bush’s planned push for digitizing medical records).

\(^{486}\) See Alpert, *supra* note 18, at 44 (discussing Medicare’s proposal to send patient data electronically).

\(^{487}\) Shortliffe, *supra* note 30, at 1226.

\(^{488}\) Karash, *supra* note 382, at 1. The genesis of such concerns rests, in part, in unanswered questions such as the following: Should EMRs be encrypted? If so, who is allowed access and under what circumstances? How are healthcare personnel authenticated for access? Who has the authority to override security barriers in emergency situations? How does one balance the legal risk from not overriding in emergencies with the legal risk associated with allegations of unnecessary overrides? *Id.*

the frequent silence of liability insurance policies on the issue of violations of cyber security.\footnote{Id.  The author cites examples of the records of approximately 5,000 patients at the University of Washington Medical Center being hacked, a 17-year old secretary posing electronically as a physician, and email traffic regarding patients being routed to unauthorized recipients at Kaiser Permanente. \textit{Id.} Examples of other situations posing risk include outsourcing transcription of physician notes and permitting vendors into sensitive HCP areas for purposes such as equipment maintenance. \textit{Id.} Also, insurance companies may not insure against cyber-security risk because they are, at this juncture, incapable of assessing this risk well enough to know how to impound it in their premium pricing. \textit{Id.} Finally, the greatest risk could be damage to the HCP’s reputation, which a commentator has termed the “Mike Wallace factor.” \textit{Id.} That is, little good can come from an event wherein the media appears at the HCP’s offices (or other premises) with cameras and a horrific story of patient privacy being violated. \textit{Id.}}

There appears to be a substantial amount of conflict and confusion concerning the extent and type of protections that will provide sufficiency in both patient protection and interoperability, with even leading government officials at times making contradictory assertions. For example, at a House Ways and Means Committee hearing conducted in July, 2005, Rep. Rahm Emanuel (D-Ill.) argued against too much private sector input on the privacy-versus-interoperability issue.\footnote{\textit{Interoperability Clashes with Privacy in Health IT System Development, supra} note 466.} In the same hearing, David Brailer, then the HHS National Coordinator for Health IT, rather counter-intuitively maintained on the one hand that too much variability in privacy rules constituted a “direct barrier” to interoperability, while on the other hand asserting that HIPAA represented only a floor on which states could build their own privacy rules.\footnote{\textit{Id.} During the hearing, Joy Pritts, assistant professor at Georgetown University’s Health Policy Institute, worried that HIPAA does not cover some organizations that may gain access to patient healthcare} A major problem, however, is that...
HIPAA does not address some of the more fundamental issues associated with data ownership.\textsuperscript{493} Some experts argue that allowing patients to control who has access to their records is the key to ensuring a balance between privacy and interoperability,\textsuperscript{494} others favor excluding material related to mental health, sexually transmitted diseases, and other stigmatizing information,\textsuperscript{495} and some privacy advocates have gone so far as to say that any NHIN must provide patients the prerogative of opting out of the network, in data under a NHIN and predicted dire consequences from federal preemption of state laws. In contrast, Healthcare Leadership Council President Mary Grealy argued that HIPAA already permits significant variations among states, and that it is “virtually impossible” to allow states too much latitude to maintain their own privacy laws and achieve real interoperability. \textit{Id.}  

\textsuperscript{493} Middleton et al., \textit{supra} note 254, at 17.  

\textsuperscript{494} Mandl et al., \textit{supra} note 31, at 283-86. The authors note that patient confidence is essential to the success of interoperable EMRs, and assurance of privacy of personal medical information is essential to such confidence. \textit{Id.} at 283. They argue that any interoperable healthcare information system containing EMRs must include the right by patients to determine who sees their EMRS and under what conditions. \textit{Id.} “Consumers are managing bank accounts, investments, and purchases on line, and many turn to the web for gathering information about medical conditions; they will expect this level of control to be extended to online medical portfolios.” \textit{Id.} Some patients are not so confident, however, as indicated by this comment from a patient: “I am not a technophobe, but I am wary of giving out personal financial information over the Internet, and the thought of my entire medical history floating somewhere in cyberspace doesn’t fill me with confidence.” Rhona MacDonald, \textit{Commentary: A Patient’s Perspective}, 322 BRIT. MED. J. 287, 287 (2001).  

\textsuperscript{495} Vere-Jones, \textit{supra} note 385.
whole or in part.\textsuperscript{496} NHIN advocates, however, argue that allowing patients to opt out would result in incomplete patient records that would increase medical errors.\textsuperscript{497} They also argue that even though assurance of the privacy of EMRs is essential, patients’ medical information must be universally accessible and systems must be built according to public standards.\textsuperscript{498}

\textit{EMRs and the HIPAA Framework: Questions and Concerns}

Even if HIPAA represents a “floor” on which to build, it appears to be a shaky floor given the many questions that remain regarding how EMRs will fit within the HIPAA security framework. The American Health Management Association reports that despite an average of 150 healthcare personnel having access to a patient’s health record during the typical hospital stay, there are no clearly defined laws and federal regulations that govern who may have access, under what circumstances, precisely what information a particular individual is allowed to see, and with whom this information can be shared.\textsuperscript{499} Examples of specific unanswered questions include: (1) Precisely what information in an EMR qualifies as protected health information (PHI)?\textsuperscript{500} (2) If a patient


\textsuperscript{497} Ackley, \textit{supra} note 467, at 115.

\textsuperscript{498} Mandl et al., \textit{supra} note 31, at 284.

\textsuperscript{499} Goldberg, \textit{supra} note 472, at 8-9 (“\[M\]uch of the sharing of medical information [about a patient] actually occurs without the affected patient’s knowledge.”).

\textsuperscript{500} See Slack, \textit{supra} note 230, for an example of such a question: whether a person’s genome belongs to herself. If a gene is discovered that gives rise to some disease or psychological disorder, what are a patient’s rights to prevent HCPs from having that information?
requests information, in what form must this PHI be provided?\textsuperscript{501} (3) Can patients update their EMRs with patient-supplied PHI, and what rights do HCPs have regarding denial of inclusion of patient-supplied information in their EMRs? (4) Is all information contained in an EMR subject to disclosure to a patient?\textsuperscript{502} Furthermore, despite the fact that private lawsuits cannot be pursued under HIPAA, the extent to which HIPAA might factor into other private civil actions asserting PHI-related violations of patient privacy involving PHI is unclear.\textsuperscript{503}

\textsuperscript{501} See, e.g., Liz Meszaros, Meeting Secure E-Mail Requirements Just got Easier, OPHTHALMOLOGY TIMES, May 1, 2004, at 69. If a patient logs onto a physician’s web site and completes a contact form, the communication meets privacy standards. \textit{Id.} If the physician replies via email to the patient, however, the communication is no longer secure and may violate HIPAA. \textit{Id.}; James J. Moynihan, Providers Need Email Security Management, HEALTHCARE FINANCIAL MGMT., at 64 (Jan. 2000).

\textsuperscript{502} Vogt, \textit{supra} note 466, at 43-47. These major questions embed a host of subordinate questions, including the following: Does an electronic audit trail of an EMR constitute PHI? Given that most patients will not understand the medical terminology contained in their EMRs, should patients be given login and passwords for direct access to their EMRs? What documents are essential and therefore must always be replicated in all systems? Must written correspondence related to a denial of patients’ requests to amend their EMRs be included in all systems containing the EMRs? How will HCPs be required to respond to requests for an “entire” EMR that includes physicians’ private notes? \textit{Id.} at 44.

\textsuperscript{503} James Swann, HIPAA Privacy Compliance: What Does it Mean?, COMMUNITY BANKER, Jun. 2003, at 66 (noting that even though “[o]nly covered entities qualify for direct penalties under HIPAA, and no private lawsuits can be initiated under the act. . . . the specter remains that HIPAA could indirectly become referenced in lawsuits,” and that plaintiffs in private lawsuits “might bolster their arguments by using HIPAA as a best practice measure, which could conceivably open the floodgates of litigation”). Field study revealed physician concerns about the murkiness of entitlement to online access to a patient’s EMR in familial situations. Can parents make entries into a child’s EMR? Can both parents make entries in the
As if the questions and complexities associated with PHI security mandated by HIPAA were not enough, \textsuperscript{504} conflicts between one national standard and the existing “patchwork” of state patient-data privacy laws\textsuperscript{505} loom as a giant impediment to implementation of a NHIN.\textsuperscript{506} For example, Georgia and Florida have laws that preclude an HCP from viewing laboratory test results unless the HCP is the physician responsible for ordering the tests.\textsuperscript{507} A study performed by the Texas attorney general of child’s EMR, and what should a physician do with respect to conflicting entries? In divorce situations where one parent has total custody of a child, should both parents have access to the child’s EMR? Similar concerns exist regarding senile members of a family. Some physicians voice concerns about teenagers being unwilling to communicate openly with their physicians about such matters as alcohol and drug use, sexual activity, pregnancy, and sexually transmitted diseases if parents have access to the teenagers’ EMRs. Floor comments, Harvard Seminar, supra note 30 (notes on file with authors).


\textsuperscript{505} See Murray, supra note 482, at A12.

Medical privacy is difficult terrain for federal lawmakers. They must navigate around a patchwork of popular state laws, many of them targeted to specific conditions such as HIV and genetic disorders. They are also bumping against two perennial controversies: abortion and liability (as in access to juvenile abortion records, and a patient’s right to sue).

\textit{Id.}


\textsuperscript{507} Dart, supra note 364.
approximately fifteen hundred state statutes covering patient privacy indicated that all but ten of these statutes were more stringent than the privacy criteria imposed by HIPAA.\textsuperscript{508} Despite this serious conflict between the need for a single national set of IT healthcare standards and the extant profusion of disparate state laws, legislation proposed to date does not effectively address critical aspects of this tension. For instance, “[the] current bills establishing a national health records infrastructure all shy away from the issue of whether patients must be notified before personal data are shared with another party.”\textsuperscript{509}

Some opponents of preemption of state privacy laws argue that there should be no such preemption prior to enactment of national standards with regard to patient privacy.\textsuperscript{510} Others demand to know exactly what laws are impeding the progress of health IT,\textsuperscript{511} a position that implies a reactive rather than proactive approach to dealing with conflicting statutes in the case of a yet-to-be-attempted NHIN. It is true that, despite some reluctance on the part of federal administrators who prefer a gradual, market-sensitive implementation to having government decide how healthcare IT will operate,\textsuperscript{512} the government is moving in some ways to facilitate the usage of medical IT by means of a standards-setting process to promote interoperability through common procedures and language. For example, in November 2005, HHS proposed new messaging standards and

\textsuperscript{508} Id. See Cheng & Hung, supra note 470, at 22 (observing that even within HIPAA, privacy rules have yet to be standardized for internet services, and that “so far no comprehensive solutions to the various privacy issues have been defined in this area.”).

\textsuperscript{509} Gilchrist, supra note 502.

\textsuperscript{510} Dart, supra note 364.

\textsuperscript{511} Robeznieks, supra note 461, at 6.

\textsuperscript{512} Lueck, supra note 357, at 1.
code for electronic requests for information used in processing government claims affecting six categories of health information: laboratory results, emergency services, ambulance services, medications, clinical reports and various rehabilitation specialties.\textsuperscript{513} However, such initiatives appear to fall considerably short of the standards that will be required for a NHIN to be maximally effective.\textsuperscript{514}

Mark Rothstein, privacy subcommittee chairman of the National Committee on Vital and Health Statistics (NCVHS), which provides guidance to HHS, views a NHIN as furnishing an opportunity to rethink patient privacy rules.\textsuperscript{515} We agree with Rothstein. What is needed is a zero-based approach that contemplates replacing all state and federal law with one comprehensive set of privacy rules to balance patient privacy with the interoperability necessary for a NHIN to be fully effective. To be sure, patient privacy will suffer in some—hopefully modest—respects compared to security under current and excessively restrictive laws in some states such as Georgia,\textsuperscript{516} but, given the evidence supporting the development of a NHIN, it seems highly likely that gains in overall patient benefit will far exceed this cost. Granted, developing any consensus on how to achieve such a balance will no doubt be difficult, but reconciling the various existing state and federal laws with a comprehensive set of privacy rules can achieve this balance.

\begin{footnotes}
\textsuperscript{513} Proposed Standards Seek to Reconcile Demands of HIPAA Privacy Rules, Electronic Data Transfer, \emph{Health Care Strategic Mgmt}, Nov. 1, 2005, at 6.


\textsuperscript{515} Youngstrom, \textit{supra} note 466.

\textsuperscript{516} Dart, \textit{supra} note 364.
\end{footnotes}
federal laws and regulations seems almost a “mission impossible” from both operational and political perspectives.\textsuperscript{517}

If and when such an effort is undertaken, the scope of one set of state-law-trumping federal privacy standards should sensibly include several other related matters, some of which are more obvious than others. For example, privacy rules should apply not just to HCPs but rather to all persons and entities involved in the creation, compilation, storage, transmission, and other use of patient health information and data, “including employers, insurers, financial institutions, commercial data providers, application service providers, and schools.”\textsuperscript{518} There is also the major issue of whether patients should be able to opt out of a fully operational NHIN.\textsuperscript{519} Further, patients who join a NHIN, whether voluntarily or involuntarily, should neither be permitted to dictate the form and content of their healthcare records nor be allowed to opt out of certain

\begin{flushright}
\textsuperscript{517} See, e.g., Youngstrom, supra note 466 (discussing the difficulty, even within the NCVHS privacy subcommittee (which functions as a “watchdog” for patient privacy), in formulating a framework for what a new federal privacy law might include. The notion of reconciling the utility functions of 50 state legislatures, which are likely to be far more disparate than those of the privacy subcommittee, would seem to be exceedingly impractical.).

\textsuperscript{518} Id.

\end{flushright}
aspects of the system. To allow such choices would not only create gray areas wherein HCPs may be forced to treat emergencies with incomplete information but could also disrupt the normal flow of medical operations that would depend upon the presence of basic medical information, thereby affecting the speed at which other emergency patients are treated.

Other Necessary Subjects of National Standards

Other matters that should be contemplated in a set of national standards include the inevitability that HCPs will be concerned about how existing and prospective patients will judge their performances. Greater information availability in a NHIN regarding HCP performance will give almost certainly rise to greater incentives for HCPs to

520 Youngstrom, supra note 466. The NCVHS has not taken a position on this except to state that any rights to limit information placed in healthcare records stored in a NHIN should be limited. Id. See 45 C.F.R. §§ 164.520, 164, 524, 164.526 (2005) (permitting patients to ask to have their medical records amended, but giving HCPs the option to refuse).

521 An interesting question is whether patients who would opt out of a NHIN should be responsible for the higher costs associated with treatment. This raises a rather complex set of social concerns, including whether indigent patients who cannot afford healthcare might be forced to join a “voluntary” NHIN system. One might argue that a NHIN could be considered a national asset even if many, if not most, of its components are privately owned. An analogy might be the banking system which is both regulated and private. See Grogan, supra note 239, at 17 (analogizing security of banking records to EMRs). Consumers using bank services subject themselves to having sensitive financial data—data that are more or less common to all users of bank services, stored in databases without any right to select what data are stored. Further, these data are often accessible by third parties, usually with, but sometimes without, the consent of the consumer. The issue of voluntary versus involuntary patient membership in a NHIN is too complex to be explored in depth here and is better left to future research.

522 See Shortliffe supra note 30, at 1223 (questioning IT’s effect on the patient doctor relationship).
conceal and distort data on medical errors in order to make themselves appear to be rendering higher quality healthcare than is the case (with the effects of not only deceiving consumers of healthcare services but also potentially skewing national healthcare databases on illnesses).\(^{523}\) Moreover, patient wellbeing could be directly affected if HCPs misreport diagnoses and treatment outcomes, either out of self-interest or an arguably misplaced desire to protect patients from having their records contain certain types of potentially embarrassing or deleterious information. Any new examination of legal rules should address the possibility of such deliberate misreporting, in order for a NHIN to realize its full potential in reducing medical errors.

Another privacy-related subject for national standards treatment is the use of medical information for marketing purposes.\(^{524}\) For example, should an HCP be allowed to make patient data from EMRs contained in a NHIN available to an advertising agency retained to develop a marketing campaign regarding quality of care rendered by the HCP? On the one hand, fair representation of the quality of care provided by HCPs would likely only be of use in some aggregated form--with patient identities thereby

---

\(^{523}\) See Edmund F. Haislmaier, Health Care Information Technology: Getting the Policy Right (2006), http://www.heritage.org/Research/HealthCare/wm1131.cfm. (noting that one advantage of a properly run system is the ability to track and respond to communicable diseases). For example, one could imagine that a patient and/or an HCP might wish to exclude information pertaining to illness with epidemic potential in order to avoid any stigma associated with fear of contagion. Such exclusion, however, would reduce the information available about the spread of the illness and would therefore understate what might be a potential national crisis. Also, private financial interests can result in incentives to underreport illnesses as was apparently the case with the Bird Flu in the People’s Republic of China.

\(^{524}\) Youngstrom, supra note 466.
concealed--and would have the social benefit of informing the public of which HCPs provide the best care. Such use could thereby facilitate some market governance over quality of care and provide incentives for HCPs to improve care.\footnote{See Jane Metzger, Using Computerized Registries in Chronic Disease Care 10 (2004) (discussing the advantages of registries in treating chronic diseases).} On the other hand, it could be argued plausibly that the use of patient records for this purpose does not meet a minimum standard as a necessary disclosure in the interests of the individual patients involved.\footnote{Youngstrom, supra note 466. The chairman of the NCVHS privacy subcommittee has taken the position that patient data used in health marketing communications should require authorization by the patient. Id.}

Taken together, the issues surrounding the trio of categories of legal barriers discussed in this section suggest that realization of a NHIN will require a federal legislative and regulatory agenda that has yet to be framed, much less articulated. Federal legislative and regulatory guidelines regarding the boundaries of legal liability under a NHIN are preferable to the possibility of a morass of civil litigation from which it would take years for clarity to emerge.\footnote{One of the steps necessary to the creation of a NHIN is the creation of a legal framework. Dollens Interview, supra note 349.} It also appears that despite recent HHS efforts to further the proliferation of healthcare IT by providing safe harbors and exceptions to the Stark and anti-kickback laws, there remain legal issues to be resolved at the federal level. Finally, many questions persist regarding the balance between patient privacy in EMRs and the need for HCP interoperability, especially with respect to conflicts among federal and state laws. A national-level legislative agenda is therefore needed if a national-level health information system is to become a reality without a great deal of
legal angst that will retard the development of a NHIN and vex the courts with burdensome litigation for years to come. Accordingly, this national-level agenda should include the measures noted above: clarification of issues related to professional responsibilities under a NHIN, measures to address malpractice liability concerns, further attention to the Stark and anti-kickback laws, and preemption of state patient privacy laws by federal statute.

VIII. CONCLUSION

An unacceptably high rate of medical errors continues to plague the nation. At the same time, medical malpractice liability remains an emotional subject among HCPs, and one for which simplistic solutions—with little hope of being efficacious—continue to be proffered by concerned industry advocates and political figures engaged mostly in a posturing exercise. Many barriers have impeded the adoption of new science into healthcare, and inefficient public policy is one of these barriers. When one examines the medical malpractice liability issue with the same degree of care that one would hope a

528 Dart, supra note 364.

529 For example, in addition to relaxation of the Stark and anti-kickback laws, one health IT luminary recommends the establishment of a federal policy on data ownership, a national policy for regional healthcare information authorities, and national licensure for the health professions. Middleton, supra note 320; Middleton et al., supra note 254, at 17.

530 See supra text accompanying notes 11, 173-76 (discussing the risk of malpractice).

531 See supra text accompanying notes 109-19, 133-57, 168-69 (analyzing liability issues related to medical malpractice).

532 Sanford A. Garfield et al., Considerations for Diabetes Translational Research in Real-World Settings, 26 DIABETES CARE 2670, 2671 (2003).
physician examines a patient, it becomes apparent that naive and self-serving solutions such as malpractice damages caps fail to meet logical and empirical litmus tests in light of the high incidence of medical errors, most of which are spawned by process and not individual care-provider negligence. If, in fact, it is true that a principal reason for imposing tort liability is to provide a “strong incentive to prevent the occurrence of the harm” and that “[h]istorically the courts have almost always found health care providers nonculpable if they complied with ‘customary standards of medical practice,’” then shifting a greater portion of the economic burden of medical error from physicians to patients through medical malpractice liability caps is not the answer. That said, tort liability as currently functioning has failed—along with industry self-regulation, government regulation, and market forces—to reduce medical errors to acceptable levels, and HCPs worry that cybermedicine will make them more vulnerable to

533 See supra text accompanying notes 133-57, 168-75 (discussing high incidences of medical errors and damage caps).


536 See supra text accompanying notes 300-305 (discussing regulatory efforts and litigation in the field of torts). See also RICHMOND & FEIN, supra note 335, at 212-13 (noting that small but legitimate claims are not litigated because patients are unaware of their options and plaintiff’s attorneys may consider the cases uneconomical, that most claims and litigation do not result in payment, and that there is little evidence of a strong deterrent effect when it comes to medical errors). Lamenting the present state of affairs, these commentators add:

It may be overly optimistic to believe that such [tort] reform will be embraced in the near future (especially in a politically polarized environment) and that out of it would come a system that will
We argue that it is time for an industry accounting for sixteen percent of the nation’s gross domestic product to engage in a piercing self-examination aimed at cleaning up its inefficient, too-often-harm-producing processes rather than grasping at overly simplistic tort reform initiatives that do not do justice to the root problems underlying the costs of medical malpractice. One great hope as part of this process cleanup rests in embracing state-of-the-art information systems to help guide what has become a very technologically sophisticated array of treatment processes, the complexity of which is increasing exponentially with the inexorable march of medical innovation.

Id.

Id. Slack, supra note 230, at 2259.

Stires, supra note 319, at 131.

Kevin Freking, Bill for Reporting Medical Errors Cleared, THE HERALS SUN, Jul. 27, 2005, http://www.light1998.com/Futurenews-2010/Bill_Medical_Errors.htm (“It is estimated that more than 250 Americans die every day as a result of preventable medical errors.”) (last visited Nov. 14, 2007).

See Rosenthal, supra note 13, at 324 (citing Banja’s failure "to note that any authentic replacement of the tort system has to include rigorous efforts on the part of the medical profession itself to reduce medical errors and improve patient safety"). See also Kilo Emerging trends, supra note 334 (contending that “[c]urrent legislation will fail to deliver on its promises,” and that “the answer is in system design that includes technology, not in technology by itself”); AM. COLL. OF PHYSICIANS, THE ADVANCED MEDICAL HOME: A PATIENT-CENTERED, PHYSICIAN-GUIDED MODEL OF HEALTH CARE (2006) (asserting that “[t]he U.S. health care system is poorly prepared to meet the current, let alone the future, health care needs of an aging population.”); Evans, supra note 31 (commenting on current state of healthcare system).

See supra text accompanying notes 220-360 (discussing the need for more IT in healthcare).
That medical IT is fast becoming critical to the delivery of healthcare is evidenced by the use of IT in multiple facets of patient care ranging from diagnosis to CPOE to drug interaction alerts.\textsuperscript{542} One renowned physician has summed up the healthcare-IT dilemma succinctly: “The most pressing question now is not whether computers have a place in medicine (they unquestionably do), but whether this still-emerging field of cybermedicine will fulfill its potential for enhancing the clinical transaction, reducing [medical] errors of omission and commission, and improving the quality of medical care.”\textsuperscript{543} The complete measure of IT’s success in reducing medical errors will only be realized when the nation has a fully functional NHIN in place.\textsuperscript{544} There are many barriers, however, that must be surmounted before such a network can become a reality.\textsuperscript{545} Not the least of these obstacles are legal barriers, but we have yet to observe a holistic, thorough examination of these barriers, much less a national initiative leading to

\textsuperscript{542} Grogan, \textit{supra} note 241, at 19.

\textsuperscript{543} Slack Health e-bytes, \textit{supra} note 400.

\textsuperscript{544} \textsc{American College of Physicians}, \textsc{Response of the American College of Physicians to the Request for Information Published November 15, 2004, by the National Coordinator for Health Information Technology: Development and Adoption of a National Health Information Network} 13 (2005), \textit{available at} http://www.acponline.org/hpp/nhin.pdf.

\textsuperscript{545} Memorandum from Gregory C. Simon, President, FasterCures/The Center for Accelerating Medical Solutions on Request for Information on the Development and Adaptation of a National Health Information Network to the Office of the National Coordinator for Health Information Technology, a division of the Department of Health and Human Services (Jan. 18, 2005).
their removal.\textsuperscript{546} Even if a NHIN evolves bottom up, overcoming these barriers cannot be accomplished in a timely manner on a bottom-up basis, for reasons previously articulated. Instead, necessity calls for a top-down, federal legislative agenda to (a) establish sound parameters for HCP malpractice liability consistent with technological capabilities, (b) complete the process of dealing with still-too-restrictive physician referral and anti-kickback laws, and (c) create one set of privacy standards to override conflicting and unduly restrictive state patient privacy laws.\textsuperscript{547}

In the end, a \textit{national} health information network requires a \textit{national} legal framework to be fully efficacious. If healthcare IT is to fulfill its potential in reducing medical errors, a far grander, more holistic vision than today's status quo is needed for shaping healthcare's legal environment. We do not wish to imply that development of such a legal framework will be simple or easy, for we most certainly expect that it will be neither. With medicine being a critically important industry, not to mention the nation's largest\textsuperscript{548} and arguably most deadly,\textsuperscript{549} serious federal attention to the legal aspects of the healthcare crisis is necessary to avoid floundering in a legal morass that will take decades

\textsuperscript{546}See supra text accompanying notes 363-529. (discussing legal barriers to implementation of a NHIN). The articulation of one possible approach to this framework first requires development of the architecture of a NHIN and is the subject of a different study.

\textsuperscript{547}See supra text accompanying notes 363-407, 431-63, 489-527.


\textsuperscript{549}With medical errors resulting in more deaths in a decade than in all wars in which the U.S. has been involved — combined — ever, this claim seems hardly exaggerated. Gary Null et al., \textit{Death by Medicine}, \textsc{Life Extension Magazine}, August 2006, at 1, available at http://www.lef.org/magazine/mag2006/aug2006_report_death_01.htm.
to resolve through case law while a potentially heavy attendant cost of lives continues. The nation needs a legal vision for healthcare IT that matches the vision of the commentators and policymakers who advocate a national health information network.\footnote{See, e.g., \textit{Electronic Health Records Will Save Money, Improve Care, Sen. Frist Writes, MED. NEWS TODAY}, Aug. 4, 2006 (reporting on the argument of former Sen. Bill Frist (R-Tenn.) for federal legislation to establish a structure for health IT). Sen. Frist is quoted as saying:}

“\textit{[S]ystems for managing medical information remain far behind the times….It has become clear the government should set standards and set the ball rolling….Bringing medicine into the information age will take serious work….But, when we provide secure, privacy protected, interoperable electronic medical records for all Americans who want them, we'll save money, improve health, and, most importantly, save lives.}”