

Evaluation of Options for Medical Malpractice System Reform

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EXECUTIVE SUMMARY

The report synthesizes the evidence and theoretical predictions regarding the potential of several leading medical malpractice reform ideas to positively affect the performance of the medical liability system and its impact on health care delivery. For most reforms, the report analyzes evidence from well-designed, controlled studies. Where such studies are unavailable, the analysis encompasses anecdotal reports, case studies, and descriptive findings regarding the operation of proposed systems or close analogues in the U.S. and foreign countries. For reforms that have not yet been tested, the report describes theoretical predictions about the likely effects of the reforms based on relevant scholarship in law and economics.

The analysis covers 8 reforms that have been widely implemented by states: caps on noneconomic damages, pretrial screening panels, certificate of merit requirements, attorney fee limits, joint-and-several liability rule reform, collateral source rule reform, periodic payment, and statutes of limitation/repose. It also examines 6 more innovative, less tested reforms: schedules of noneconomic damages, health courts, disclosure-and-offer programs, safe harbors for adherence to evidence-based clinical practice guidelines, subsidized reinsurance that is made conditional upon meeting particular patient safety goals, and enterprise medical liability.

The reforms are evaluated for their effects on the following outcome variables: malpractice claims frequency and costs, medical liability system overhead costs, health care providers' liability costs, defensive medicine (including health care utilization and spending), supply of health care services (including physician supply and patient health insurance coverage), and quality of care.

We find that although the evidence base for evaluating most traditional state tort reforms is substantial and mature, for most reforms, the evidence does not identify significant effects on the key outcome variables. The exception is caps on noneconomic damages, which have well-documented effects on several of the outcomes. The evidence base for evaluating the innovative tort reforms is extremely small, as most have not been tested in the U.S., analogous systems are not clearly predictive of how they would function, and much depends on the choices made about system design. However, based on theoretical predictions and the limited evidence available, most of these reforms are promising enough to merit controlled experimentation in the U.S., such as through demonstration projects.

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1. Objectives

The objective of this report is to evaluate the prospects for several leading medical malpractice reform proposals to positively affect the performance of the medical liability system and the system's impact on health care. During the 2009 federal health reform debate, and particularly since President Obama's September 2009 announcement that federal funds would be made available for pilot projects of medical liability reforms, discussion has centered on several reform possibilities, a number of which are considered innovative (Table 1). This report describes the essential features of each proposed reform and synthesizes the best available evidence about the likely effects of each of 6 outcome variables:

1. **Claims:** malpractice claim outcomes, including the number of claims filed, including the ease and equity with which patients receive compensation, and claims costs
2. **Overhead costs:** malpractice system administrative costs, including litigation costs and insurers' overhead expenses
3. **Liability costs:** malpractice liability costs for health care providers (i.e., malpractice insurance premiums)
4. **Defensive medicine:** defensive medical practices and overall health care spending and utilization
5. **Supply:** health care provider supply and patient access to care, including health insurance coverage and cost
6. **Quality of care:** potential to foster evidence-based care and improve patient safety

Table 1. Reform Options Evaluated

Reform	Basic Description
<i>Traditional State Reforms</i>	<i>Reforms that have been widely implemented at the state level</i>
Caps on noneconomic damages	Limit the amount of money that a plaintiff can take as an award for noneconomic losses, or "pain and suffering", in a malpractice suit. The cap may apply to the plaintiff, limiting the amount she may receive, or to each defendant, limiting the total amount for which each may be liable.
Pretrial screening panels	Panel reviews a malpractice case at an early stage and provide an opinion about whether a claim has sufficient merit to proceed to trial. Typically, a negative opinion does not bar a case from going forward, but can be introduced by the defendant as evidence at the trial.
Certificate of merit	Requires a plaintiff to present, at the time of filing the claim or soon thereafter, an affidavit certifying that a qualified medical expert believes that there is a reasonable and meritorious cause for the suit.
Attorney fee limits	Limits the amount of a malpractice award that a plaintiff's attorney may take in a contingent-fee arrangement. The limitation is typically expressed as a percentage of the award; it may also incorporate a maximum dollar value.
Joint-and-several liability reform	In cases involving more than one defendant, such as a physician and a hospital, this reform limits the financial liability of each defendant

	to the percentage fault that the jury allocates to that defendant. Without this reform, the plaintiff may collect the entire amount of the judgment from one defendant if the other(s) default on their obligation to pay, even if the paying defendant bore only a small share of the responsibility for what happened to the plaintiff.
Collateral-source rule reform	Eliminates a traditional rule that if an injured plaintiff receives compensation for her injury from other sources, such as health insurance, that payment should not be deducted from the amount that a defendant who is found liable for that injury must pay.
Periodic payment	Allows or requires insurers to pay out malpractice awards over a long period of time, rather than in a lump sum. This enables insurers to purchase annuities (sometimes called “structured settlements”) from other insurance companies which cost less than paying the whole award up front. Insurers are also able to retain any amounts that the plaintiff does not actually collect during her lifespan.
Statutes of limitations/repose	Limits the amount of time a patient has to file a malpractice claim. Statutes of limitations bar suits unless they are filed within a specified time after the injury occurs or is discovered. Statutes of repose bar suits unless they are filed within a specified time after the medical encounter occurred, regardless of whether an injury has yet been discovered.
<i>Innovative Reforms</i>	<i>Reforms that have had limited or no implementation in the U.S.</i>
Schedule of noneconomic damages	A hierarchy or tiering system is created for purposes of categorizing medical injuries and creating a relative ranking of severity. A dollar value range for noneconomic damages is then assigned to each severity tier. The schedule is used by juries and judges either as an advisory document or as a binding guideline. ¹
Administrative compensation systems or “health courts”	Routes medical injury claims into an alternative adjudication process involving specialized judges, decision and damages guidelines, neutral experts, and (under most proposals) a compensation standard that is broader than the negligence standard.
Disclosure-and-offer programs	Institutional programs that support clinicians in disclosing unanticipated care outcomes to patients and that make rapid offers of modest compensation in appropriate cases.
Safe harbors for adherence to evidence-based practice guidelines	Provides a legal defense to medical malpractice claims if a defendant health care provider can show that an applicable, credible clinical practice guideline was followed in caring for the plaintiff.
Subsidized, conditional reinsurance	State or federal government provides reinsurance to health care providers at discounted or no cost if they achieve patient safety goals.
Enterprise medical liability	Broadens the prospects for holding health care organizations, such as hospitals and managed care organizations, directly liable for medical injuries, in addition to or instead of holding individual clinicians liable.

Our evaluation is based on existing empirical studies of state tort reforms, including a comprehensive synthesis published in 2006²; case studies and anecdotal reports of particular federal,

state and institutional programs; legal scholarship on the structure and theoretical basis of reforms; and, where no evidence is available, our own judgments. In synthesizing extant empirical research, we do not include the large “grey literature” of reports issued by advocacy organizations, relying instead on academic, government, and foundation reports that meet accepted standards of scientific rigor. For studies evaluating the effects of tort reforms implemented in the states, this meant exclusion of study findings based solely on univariate or bivariate analysis, rather than a well-controlled multivariate regression analysis. A summary of data sources consulted is presented in Table 2.

Table 2. Scope of Literature Search

Source	Sources and Scope of Search
Legal literature	Westlaw’s “Journals & Law Reviews” combined library, 1990-2009; Social Science Research Network (unrestricted date search); older articles cited in more recent works
Health and medical literature	PubMed, 1990-2009
Economics literature	EconLit, 1990-2009; Social Science Research Network (unrestricted date search); older articles cited in more recent works
Government reports	Reports collected on websites of the Congressional Budget Office, General Accountability Office, Office of the Assistant Secretary for Planning and Evaluation, Office of Technology Assessment (archive), and Agency for Healthcare Research and Quality, 1990-2009; website of the Washington State Task Force on Noneconomic Damages
Foundation reports	Reports collected on websites of the Institute of Medicine, Robert Wood Johnson Foundation, Kaiser Family Foundation, Commonwealth Fund, and Pew Charitable Trusts (unrestricted date search)
Other	RAND Compare Dashboard ³ ; 2006 literature synthesis by Mello ²

2. Traditional State Reforms

2.1. Caps on Noneconomic Damages

Caps on noneconomic damages limit the amount of money that a plaintiff can take as an award for noneconomic losses, or “pain and suffering”, in a malpractice suit. The rationale for this reform is to reduce the number of multi-million dollar awards, which are difficult for liability insurers to plan for and pay and which may pose special difficulties for health care facilities that are self-insured. It is also motivated by a desire to reduce the high degree of variation⁴ and perceived arbitrariness in jury awards for “pain and suffering”. Twenty-six states currently impose a cap on noneconomic damages and 6 cap total damages. Medical professional societies strongly desire to see noneconomic damages caps adopted in the remaining states, through state legislation or imposition of a federal cap.

2.1.1. Key Design Features and Decisions

Key design choices for noneconomic damages caps include the following:

- Amount: Although the oldest and most widely publicized example of a noneconomic damages cap, California's, is \$250,000, most states have found it politically difficult to implement such a stringent cap in more recent rounds of reform. It is more common for states to set the cap at \$500,000 or more, and to opt for a tiered cap in which different amounts apply to different kinds of injuries. The appeal of a flat cap is its simplicity and, when set at a low amount, greater potential for cost control. The appeal of a tiered cap is its greater vertical equity—that is, more severe injuries are eligible for a higher award.
- Indexing: Some states adjust their caps for inflation, while others do not. If California's cap had been adjusted for inflation, it would be over \$1 million today. Indexing maintains the intent of the legislature adopting the cap as to the appropriate valuation of noneconomic damages in real dollars, while declining to index provides greater long-term ability to constrain costs.
- Applicability to claims: Most states apply their cap to all medical malpractice injuries, but some limit it to particular kinds of claims—for example, wrongful death claims or claims relating to emergency department care. A decision to carve out particular types of claims may reflect legislative concern about liability stress within a certain clinical specialty or the potential for unpredictable, large damages awards for certain kinds of injuries.
- Applicability to litigants: A cap may be applied to the plaintiff, limiting the amount he may receive, or to each defendant, limiting the total amount for which each may be liable. The latter choice reflects a particular notion of equity, though it may result in inequitable awards in cases where multiple defendants have different shares of fault for causing the plaintiff's injury.
- Judicial waiver: Caps rules may allow a judge the discretion to waive the damages cap in cases where its application would seem especially unjust. The price of avoiding injustice in this fashion is lesser predictability around damages awards.

2.1.2. Effects on Key Outcome Variables

The evidence base concerning the effects of noneconomic damages caps is now quite mature. Although some studies have had conflicting findings, a fairly robust set of conclusions can be drawn based on the strongest studies.

- Claims Frequency and Costs.

The evidence concerning the effects of damages caps on claim frequency is mixed. Two recent studies found that caps were associated with lower claim frequency,⁵⁻⁶ while two have found no association.⁷⁻⁸ The theoretical link is that caps discourage plaintiff's attorneys from filing claims by lowering the expected value of the case, which in a contingent-fee system affects the attorney's expected return on investment. Overall, the evidence is too equivocal at this time to support a conclusion about the effect of caps on claim frequency.

Most studies of the effects of caps on claims payouts have found a significant effect, typically on the order of a 20 to 30 percent reduction in average award size.^{5-6,9-14} One recent simulation analysis of the \$250,000 cap adopted by Texas in 2003 differentiated its effects on payouts from jury verdicts and

settlements, finding that the proportional reduction was larger for the former (27 percent average reduction) than the latter (18 percent average reduction).¹⁴ One study found that caps significantly reduced total insurer losses in some, but not all, econometric models.¹⁵ Finally, 3 studies did not find an effect of caps on payouts,^{6, 8, 16} and one found an effect on claims payments in a regression model that used individual claims as the unit of analysis, but not in a model using states as the observational units.¹⁶

A null finding is difficult to explain, since the literal effect of caps is to reduce awards. It is typically explained by theorizing that caps change the mix of cases that are brought, such that the reduction in average awards due to the cap is offset by an increase in the average award due to an increase in the average severity of the injuries represented. Overall, the weight of evidence favors the conclusion that caps affect payouts.

Caps also have implications for the vertical and horizontal equity of payouts. Vertical equity refers to the extent to which awards increase with the severity of injury, while horizontal equity concerns the degree of homogeneity in awards for injuries of similar severity. Depending on the level at which they are set, and how this level compares to public judgments about appropriate compensation for very severe injuries, caps may undermine vertical equity. They may make awards for the highest-severity injuries the same as awards for less severe injuries. With respect to horizontal equity, caps are likely to make awards for the highest-severity injuries more uniform—they should fall at or near the cap.

- Overhead Costs.

One study has examined the effects of caps on defense costs in malpractice litigation, finding that caps were associated with a significant cost increase.¹⁷ This is counterintuitive to the dominant theory about the effect of caps, which is that they encourage more rapid settlement by increasing certainty about the value of the case. However, the authors offered an alternative explanation: their result could reflect a greater propensity among insurers to allow cases to go all the way to trial, since the downside risk of trial is lower in jurisdictions that cap awards.

- Liability Costs.

The effect of damages caps on malpractice insurance premiums has been the subject of intense controversy. The issue has been exhaustively studied, with mixed findings among well-designed studies. Four studies have identified significant effects of caps,^{13, 18-20} while four older studies found no effect.^{8, 12, 16, 21} A reasonable conclusion based on strong, recent studies is that caps moderately constrain the growth of premiums over time, with an effect on the order of 6 to 13 percent.² One recent study²⁰ found larger effects—17 to 25 percent, depending on the specialty—but did not make an important market-share adjustment to its premium data.

The Congressional Budget Office (CBO) recently estimated the cost of a package of 5 reforms implemented together in all states: a \$250,000 noneconomic damages cap, a punitive damages cap of \$500,000 or twice the economic damages award, collateral-source offsets, a 1-year statute of limitations for adults and 3-year limit for children, and joint-and-several liability reform. Recognizing that many states already have some or all of these reforms in place, CBO estimated the marginal impact of the package as a 10 percent reduction in total national premiums for malpractice insurance.²²

- Defensive Medicine.

There is good, but not uniform, evidence that damages caps are associated with lower rates of utilization of services that are considered to be indicators of defensive medicine. The best-known study of defensive medicine, by Daniel Kessler and Mark McClellan, found that states with one or more “direct reforms” (including damages caps, abolition of punitive damages, no mandatory prejudgment interests, and collateral-source rule reform) had significantly lower Medicare hospital payments for ischemic heart disease and myocardial infarction.²³ A more recent analysis of overall Medicare expenditures, however, found that these reforms had no significant effect on spending on patients with myocardial infarction, breast cancer, diabetes, or stroke.²⁴ Study findings regarding cesarean section are mixed,² but two strong, recent studies find caps to be predictive of lower rates of cesarean section.²⁵⁻²⁶

CBO’s current judgment about the association between tort reforms (including but not limited to damages caps) and the use of health care services is that “the weight of the empirical evidence now demonstrates a link.”²² This finding supersedes its earlier conclusion that the evidence of a link between tort reforms and health care spending was quite limited and was confined largely to spending in the Medicare program.²⁷ Its current cost model estimates that nationwide implementation of the package of 5 reforms listed above would result in a 0.5 percent decrease in total national health care expenditures.²² Another recent analysis (albeit one with methodological weaknesses) also found a significant relationship between caps and health care expenditures per capita, estimating that caps resulted in a 3 to 4 percent savings.²⁸

- Supply.

There is moderate evidence that damages caps modestly increase the supply of physicians in a state, although studies have returned mixed findings.² One study with a very strong methodology found that states with caps and other “direct reforms” experienced 3 percent higher growth than states without caps.²⁹ Other studies, some of which are unpublished, have found effect sizes in the 2 to 12 percent range.³⁰⁻³² A recent study differentiated the effect on physicians in urban and rural areas, finding it to be significant only for rural physicians, with an effect size of approximately 5 percent.³⁰ Another examined only obstetrician-gynecologists and found no effect.³¹ Finally, one unpublished analysis examined the number of hours physicians worked per year and concluded that damages caps had a significant, positive effect.³²

It is difficult to draw conclusions about the effects of damages caps on health insurance coverage.³ The theory underlying a relationship between caps (and all other liability-limiting tort reforms) and health insurance coverage is that the reforms will decrease defensive medicine, thereby lowering health care costs, thereby lowering health insurance premiums, thereby increasing the number of people who can afford insurance. This connection is quite remote.

Two studies have examined the relationship between damages caps and employer-sponsored health insurance premiums. One found no significant association,³³ while the other found that caps were associated with significantly (1.3 percent) lower premiums for self-insured plans, but no significant differences for fully insured plans, most of which were HMOs.³⁴ One unpublished study found a significant, negative association between the presence of a cap and the percentage of state residents under the age of 65 without health insurance, but the study did not control for the presence of other tort reforms.³⁵ Overall, the evidence concerning the effects of damages caps on physician supply suggests a modest, positive effect, while the evidence concerning health insurance coverage and cost is too limited and equivocal to draw a conclusion.

- Quality of Care.

The effect of damages caps and other tort reforms on quality of care has not been directly studied. As a proxy, several groups of researchers have examined the relationship between tort reforms and patient outcomes, but this is unsatisfactory for a number of reasons. Mortality, the outcome variable of choice in most studies, is a crude indicator of patient outcomes. More importantly, outcomes may bear only a weak relationship to quality of care.

One study of birth outcomes has found that noneconomic damages caps are associated with a statistically significant reduction in preventable complications of labor, but not in infants' Apgar scores.²⁶ Others have found no association between damages caps and patients' health or mortality.^{23, 2436-37} Overall, the evidence base is not sufficient to draw inferences about the relationship between caps and quality of care.

2.1.3. Summary

There is a good evidence base regarding the effects of damages caps, though studies have returned mixed findings. The weight of the evidence suggests that caps achieve substantial savings in average claims payments, modestly constrain the growth of malpractice insurance premiums, modestly improve physician supply, and reduce at least some defensive medical practices. They may increase litigation expenses. Evidence concerning their effects on claim frequency, health insurance, and quality of care is too limited or equivocal to support firm conclusions.

2.2 Pretrial Screening Panels

The function of pretrial screening panels is to review a malpractice case at an early stage and provide an opinion about whether or not the claim has sufficient merit to proceed to trial. Typically, a negative opinion does not bar a case from going forward, but can be introduced by the defendant as evidence at the trial. The rationale for this reform is to reduce the number of nonmeritorious malpractice claims, and the litigation expenses incurred in defending them, by bringing expert judgment to bear before a large amount of legal expenses are incurred. Additionally, panel decisions can provide juries with a neutral source of expertise in cases that go to trial.⁴ About 20 states currently have pretrial screening panels of some kind. Screening panels have been repealed in at least 7 states and overturned by courts on constitutional grounds in at least another 5.⁴

2.2.1. Key Design Features and Decisions

Key design choices for pretrial screening panels include the following:

- Timing of review: There is some variation across states in the length of time between the filing of a claim and review by the panel. Longer time periods permit the plaintiff a longer period in which to obtain information in support of the claim, but result in higher litigation expenses as the discovery period progresses.

- Composition of the panel: All states have included physician representation on the screening panel, but states vary as to whether nonphysicians (for example, judges, lawyers, and laypersons) are represented.
- Matters evaluated: Most screening panels evaluate only the merit of the case, but a handful of states have panels that also suggest a recommended amount of damages for meritorious cases.
- Effect of the decision: Among the alternative consequences of the panel's decision that a claim is nonmeritorious are (1) the claim is precluded from advancing; (2) the claim can proceed, but evidence of the panel's decision may be introduced by the defendant at trial; and (3) the claim can proceed, but the plaintiff must post a bond or in some other way provide an up-front payment that is forfeited to the defendant if the plaintiff does not prevail in the litigation.
- Mandatory vs. voluntary: Some states have opted for voluntary rather than mandatory pretrial screening. The rationale for voluntary screening is to create a venue for the parties to get an early, expert opinion about the case, which may encourage settlement or abandonment of the claim.
- Financing: The costs of running the screening panel could be borne by the state or federal government, or could be borne by the parties to litigation through user fees. Some states have adopted a "loser pays" system.
- Discovery powers: In order to ensure that plaintiffs have access to sufficient information to present their case before the panel, some states allow the plaintiff to conduct discovery prior to the panel hearing; some also require that the defendant(s) comply in a timely fashion with discovery requests.

2.2.2. Effects on Key Outcome Variables

- Claims Frequency and Costs.

Theoretically, screening panels should decrease the number of claims that progress to a mature stage and the number and cost of payouts in nonmeritorious cases. However, there is no evidence that they accomplish these objectives. No controlled studies have identified statistically significant effects on claim frequency or payouts, while 7 have found no association.^{6, 8-1138-39} Some single-state, descriptive studies have actually identified a higher rate of claiming in the years following implementation of screening panels than in the years prior.⁴ The reasons that claiming is not reduced are unclear. It may be that screening panels simply do not issue an adverse decision in many cases, or it is possible that plaintiff's attorneys pursue claims notwithstanding adverse panel decisions because they view panels as biased and unreliable.

- Overhead Costs.

Screening panels involve costs. Even if panel members serve on a volunteer basis, there are overhead expenses for convening panel meetings. In states where full hearings are held, both the panels and the litigants incur additional expenses for preparation, which may include substantial discovery activities. It is unknown whether these extra costs are offset by cost savings associated with (1) the termination of

some cases following the panel's decision, or (2) earlier settlements reached after a panel decision indicating the claim likely has merit.

Most expert commentary expresses the view that panels likely increase litigation costs overall.⁴ Single-state, descriptive studies of screening panels have also reached this conclusion. They have found that although panels decrease the number of claims that go to trial, they cause significant increases in average time to claim resolution.⁴⁰ Two multivariate studies of the issue have been conducted. One found that mandatory pretrial screening was associated with a significant reduction in defense costs.¹⁷ The other, which had methodological limitations, found that defense costs and the time from incident to resolution of a malpractice claim did not differ in states that had no screening panels, optional panels, or mandatory panels.³⁸ Overall, the evidence concerning insurers' defense costs is inconclusive, though it is fairly clear that screening panels involve administrative costs to run.

- Liability Costs.

Three studies have examined the relationship between screening panels and malpractice insurance premiums. One study found a significant effect,²¹ while the others (one of which was methodologically stronger⁸ and one of which was weaker³⁸) did not. Overall, there is not a strong basis for concluding that premiums are affected. Theoretically, one would not expect a strong effect, since the effects on claiming and litigation expenses appear to be weak or adverse.

- Defensive Medicine.

The effect of screening panels on defensive medicine or health care spending has not been extensively investigated. Theoretically, the relationship would seem to be very remote. Only if physicians believed screening panels were an effective bulwark against nonmeritorious claims would an effect on defensive medicine be plausible. One study found that states with pretrial screening panels had significantly lower rates of cesarean section and higher rates of vaginal birth after cesarean section, suggesting that physicians may indeed perceive the panels as protective.²⁵

- Supply.

No information is available regarding the effect of screening panels on physician supply. The relationship would seem to be very remote. An effect would only be seen if physicians believed strongly enough in screening panels to migrate to states that had them, which seems implausible in light of the prevalence of screening panels and continued high levels of malpractice fear among physicians in most states.

- Quality of Care.

No information is available regarding the effect of screening panels on quality of care, although one unpublished study found no effect on any of six birth outcomes.³⁷ There is no theoretical reason to believe a relationship exists.

2.2.3. Summary

A handful of well-designed studies have examined the effects of pretrial screening panels, and the weight of the evidence suggests that they are not effective in reducing claims costs, claim frequency, or malpractice insurance premiums. They may help reduce defensive medicine. The evidence concerning their effects on defense costs, physician supply, health insurance premiums, and quality of care is too limited or equivocal to support conclusions about those relationships. Panels involve their own administrative costs.

2.3. Certificate of Merit

Certificate of merit (COM) reforms require the plaintiff in a malpractice suit to present, at the time of filing the claim or soon thereafter, an affidavit certifying that a qualified medical expert believes that there is a reasonable and meritorious cause for the suit. Like pretrial screening panels, the rationale for COM requirements is to reduce the number of nonmeritorious malpractice claims and associated expenses by bringing expert judgment to bear early in the litigation.⁴ At least 11 states have adopted COM requirements, but Washington State's COM law was recently struck down on constitutional grounds.⁴¹

2.3.1. Key Design Features and Decisions

Key design decisions for COM reforms include the following:

- Time to filing of certificate: State laws vary in the time allowed to file the COM, with some requiring simultaneous filing with the initial complaint and others allowing a few weeks or months.
- Definition of qualified expert: Some state statutes specify requirements concerning who may serve as an expert witness for purposes of a COM—for example, a requirement that the individual must spend most of his or her professional time practicing or teaching medicine, a maximum amount of time that may be spent on expert witness work, a requirement that the expert be certified in the same specialty as the defendant, or a requirement that the expert be licensed in the state in which the claim is filed.
- Nature of the affidavit: An affidavit sworn by the expert could be required, or it could be acceptable for the plaintiff's attorney to sign an affidavit attesting that he or she has obtained an expert's opinion that there is reasonable cause for filing the complaint. For expert affidavits, varying levels of substantive detail could be required, from a simple statement that the expert has reviewed the medical record and found there to be evidence of substandard care to a detailed opinion concerning the deviation from the standard of care and how it led to the plaintiff's injury.
- Nature of the attestation: At the outset of litigation, many facts concerning the plaintiff's care may be unclear. For this reason, some states have required experts to attest only that the plaintiff has a reasonable cause to file the claim, or that a reasonable investigation gave the plaintiff a good faith belief that grounds exist to file the claim. Others, however, require the expert to state that after conducting a review, they conclude that the standard of care was not met.⁴² This may be difficult to do early in the litigation when discovery has not yet been completed and some facts are unclear.⁴

- Exceptions: Statutes may be drafted to carve out an exception for *res ipsa loquitur* claims—claims relating to injuries that ordinarily would not have occurred in the absence of a deviation from the standard of care (for example, wrong-site surgery). Arguably, an expert witness affidavit is not necessary to establish that such claims have sufficient merit to proceed. However, whether a particular injury constitutes a *res ipsa* claim may be unclear. Another issue is whether to create an exception or extension for plaintiffs in cases where the defendant has failed to produce the relevant medical records in a timely fashion, since this would hinder the plaintiff from obtaining expert review of the case.⁴² An alternative mechanism for addressing this problem is to include in the statute a requirement that defendants promptly comply with plaintiff's requests for document production during the period between the filing of the complaint and the filing of the affidavit. This approach may help address conflicts between COM requirements and state constitutional provisions guaranteeing access to courts.⁴¹
- Consequences of failure to comply: In some states, where a plaintiff has not met all of the requirements of the COM statute, the case is dismissed with prejudice (meaning that the plaintiff cannot re-file the complaint). Other states allow a plaintiff to correct technical deficiencies in the affidavit of merit as long as the plaintiff is substantially in compliance with the COM requirement. Still others impose sanctions on the plaintiff's attorney for noncompliance.

2.3.2. Effects on Key Outcome Variables

Somewhat curiously, studies of state tort reforms have generally omitted COM statutes from their analyses.⁴ Evidence concerning the effects of COM is extremely limited.

- Claims Frequency and Costs.

No information is available regarding the effect of COM requirements on claim frequency or payouts. Because COM requirements are often implemented as part of a package of several tort reforms, single-state studies that have found large reductions in the number of claims filed after implementation of reforms⁴³⁻⁴⁴ do not permit inference about the specific effect of the COM law. Anecdotally, plaintiff's attorneys complain that COM statutes with heavy sanctions for noncompliance are used to defeat meritorious complaints: defendants allege some technical noncompliance with the requirement that results in the plaintiff's claim being dismissed.⁴⁵ Some experts have made the observation that experienced plaintiff's attorneys routinely obtain an expert opinion before agreeing to invest in bringing a case, calling into question the marginal value of a COM requirement.⁴ If this is true, as seems likely, there is no strong reason to suspect that COM requirements will significantly reduce claims volume or costs.

- Overhead Costs.

COM requirements increase litigation costs for plaintiffs. Obtaining the affidavits entails direct costs for plaintiff's attorneys that are estimated at \$1,000-\$5,000.⁴⁶ In some states, COM requirements have led to additional legal expenses when the defendant has challenged whether the plaintiff's expert meets the statutory requirements.⁴⁶ Such wrangling is more likely to occur when the statutory language concerning expert witness qualifications is vague or subject to interpretation.

- Liability Costs.

No information is available regarding the effect of COM requirements on malpractice insurance premiums. The effect would be determined by the effect on claims frequency and cost. The theoretical prospects for reductions in premiums are not strong.

- Defensive Medicine.

No information is available regarding the effect of COM requirements on defensive medicine or health care spending. There is no theoretical reason to believe there would be a significant effect, since COM requirements do not appear to impose a substantial barrier to bringing malpractice claims. Reforms can affect defensive medicine if physicians perceive them as protective, even if they are in fact ineffective. However, there is no literature to suggest that physicians believe COM requirements provide strong protection. Physicians tend to believe that expert witnesses are widely available to provide whatever testimony plaintiff's attorneys seek.

- Supply.

No information is available regarding the effect of COM requirements on physician supply. The connection would seem to be quite remote.

- Quality of Care.

No information is available regarding the effect of COM requirements on quality of care. There is no theoretical reason to believe there would be a significant effect. One study of birth outcomes found no significant association between COM requirements and infant mortality.³⁶

2.3.3. Summary

No methodologically strong studies have examined the effects of COM requirements. On their face, COM requirements add a modest amount to the cost of litigation. Theoretically, the prospects for affecting the key outcome variables appear quite weak.

2.4. Attorney Fee Limits

Attorney fee limits cap the amount of a malpractice award that a plaintiff's attorney may take as a contingency fee. Nearly all medical malpractice cases are handled by plaintiff's attorneys on a contingent-fee basis, meaning that the attorney takes a percentage of any award the plaintiff receives (legal expenses may be rolled into this percentage, or taken in addition to it), but the attorney receives nothing if no award is recovered. The rationale for attorney fee limits is to discourage plaintiff's attorneys from accepting cases of marginal or no merit by altering the attorney's expected return on investment in the case. Sixteen states currently have limits on attorney fees in medical malpractice cases.

2.4.1. Key Design Features and Decisions

Key design choices for attorney fee limits include the following:

- Nature of the limitation: Fee limits are typically expressed as a percentage of the award, but may also incorporate a maximum dollar value.
- Flat or sliding structure: A single limit may be applied, or some states have opted for a sliding structure that permits attorneys to take a larger share of smaller awards and a smaller share of bigger awards.
- Treatment of legal expenses: The fee limit may be specified to include all fees and expenses that a lawyer would charge, or may apply only to the attorney's fees. In the latter case, expenses such as expert witness payments, deposition expenses, and document filing fees could still be charged against a client's award.

2.4.2. Effects on Key Outcome Variables

- Claims Frequency and Costs.

Theoretically, attorney fee limits should reduce the number of malpractice claims by dissuading plaintiff attorneys from accepting cases that have a low expected return on investment. This effect is not targeted to nonmeritorious cases, as the expected value of a case to an attorney is a function of not only the probability of prevailing, but also the expected damages and the attorney's share of the damages. Contrary to theory, there is strong evidence that attorney fee limits do not affect claiming. Several multivariate studies have shown that attorney fee limits are not associated with either lower frequency of claims^{6,8} or lower average payouts.^{6,8-12} No studies have found a significant association with either of these outcome variables.

- Overhead Costs.

Theoretically, one may expect plaintiff attorneys to invest less time and resources in cases if their share of the proceeds is reduced. However, since lower investment also increases the risk of losing the case and recovering nothing, the theoretical relationship is unclear. Only one study has investigated this issue; it found that attorney fee limits were associated with a significant increase in average defense costs, possibly because attorneys were less inclined to bring small cases.¹⁷

- Liability Costs.

There is strong evidence that attorney fee limits do not affect malpractice insurance premiums. Two well-designed studies^{8,19} and two methodologically weaker studies^{12,21} have reached this conclusion, while no studies have found a significant association. The theoretical relationship to malpractice premiums is quite remote, and is mediated by the effect on claim frequency and payouts.

- Defensive Medicine.

The theoretical relationship between fee limits and defensive medicine or health care spending is tenuous at best, but has not been extensively investigated. CBO's 2006 model found no significant effect on either general or Medicare health care spending.²⁷ One recent study found no relationship

with rates of cesarean section or vaginal birth after cesarean section.²⁵ On the other hand, one study found limited evidence that implementation of one or more “indirect” reforms (attorney fee limits, periodic payment, joint-and-several liability reform, or patient compensation fund) reduced Medicare payments for patients hospitalized for myocardial infarction, breast cancer, diabetes, or stroke. However, the study’s authors expressed concern that the result might be spurious.²⁴ Overall, the existing evidence does not support a relationship between fee limits and defensive medicine or health care spending.

- Supply.

Three multivariate studies directly examined the relationship between attorney fee limits and physician supply and found no relationship.^{31, 36, 47} Another examined whether states that adopted one or more of 5 “indirect” reforms (attorney fee limits, periodic payment, joint-and-several liability reform, statute of limitations reform, or patient compensation funds) experienced different levels of growth in physician supply over time and found that they did not.²⁹ There is no strong theoretical relationship between the two.

- Quality of Care.

No studies have directly examined the effects of attorney fee limits on quality of care. There is no strong theoretical relationship between the two. One study found no relationship between “indirect” reforms, including fee limits, and 1-year mortality among Medicare patients,²⁴ and two others found no association between attorney fee limits and birth outcomes.³⁶⁻³⁷ Overall, the limited evidence available does not support an inference that attorney fee limits affect quality of care or patient outcomes.

2.4.3. Summary

Several well-designed studies have evaluated the effects of attorney fee limits and have uniformly found no effect on claim frequency, claims payouts, malpractice insurance premiums, or physician supply. The limited available evidence concerning defensive medicine and quality of care suggest that fee limits have no effect on these variables.

2.5. Joint-and-Several Liability Reform

At common law, when an award was made against more than one defendant, each defendant would individually be fully liable (“jointly and severally liable”) for paying the amount of the award in the event that the others did not pay, even if he bore only a small share of the causal responsibility for the plaintiff’s injury. For example, if two physicians were both found liable for malpractice in the amount of \$5 million, but one was insured for only \$1 million and had no personal assets that could be used to satisfy the judgment against him, the other physician would be liable for the remaining \$4 million. Thirty-nine states have adopted statutes modifying this common law rule to limit the financial liability of each defendant to the percentage fault that the jury allocates to that defendant. The rationale for this reform is to eliminate the unfairness involved in joint-and-several liability for “deep pockets” defendants.

2.5.1. Key Design Features and Decisions

The key design decisions for joint-and-several liability reform include the following:

- Applicability to types of damages: Joint-and-several liability can be abolished for all components of a plaintiff's award, or only for the noneconomic damages portion of the award.
- Relationship to comparative negligence: Joint-and-several liability can be abolished in all instances, or it can be maintained when a defendant's percentage share of the responsibility for an injury exceeds a certain threshold (typically 50 percent).⁴⁸
- Relationship to private contractual arrangements: Two or more parties who reasonably anticipate that they may be named as joint defendants in malpractice litigation—for example, a hospital and a physician who has staff privileges at the hospital—may choose to specify in a contract how liability will be allocated between or among them. Joint-and-several liability reforms can be designed to respect these contracts or to supersede them.

2.5.2. Effects on Key Outcome Variables

- Claims Frequency and Costs.

The theoretical link between joint-and-several liability reform and claim frequency is highly tenuous. If many defendants were expected to default on their judgments, then the expected value of malpractice claims would be lower and plaintiff's attorneys would be discouraged from bringing them.²⁷ There would need to be a widespread belief that defendants commonly had insufficient resources to cover judgments in order for this to occur, however. Two studies have examined whether joint-and-several liability reform results in fewer claims. One found a significant reduction in per-capita claims frequency,⁵ while the other found no significant association.⁶ Overall, the evidence on this point is limited and inconclusive.

Four multivariate studies have examined the association between joint-and-several liability reform and claims payouts; none found an association.^{5-6, 12, 16} However, one study found the presence of joint-and-several liability reforms to be associated with lower long-run medical malpractice losses for some, but not all, liability insurers.¹⁵ (Insurer losses reflect both the number of paid claims and the average payment, and the study could not determine which component drove the lower losses.) Joint-and-several liability reform theoretically should result in lower claims payments for some defendants and higher payments for others, in cases in which one of the defendants could not pay his entire share. Overall, the evidence is weighted towards the conclusion that joint-and-several liability reform does not significantly affect claims costs in the aggregate.

- Overhead Costs.

There is no clear theoretical link between joint-and-several liability reform and litigation expenses. One study has examined this relationship and found no significant association between the reform and defense costs.¹⁷

- Liability Costs.

The effect of joint-and-several liability reform on malpractice insurance premiums has been studied by several research teams, with mixed results. Two strong studies^{15, 19} and one weaker study²⁰ found no relationship to insurance premiums, while 3 studies with somewhat weaker methodologies found a

significant association with lower premiums.^{12, 16, 18} Theoretically, the link between the reform and premiums is largely mediated by the reform's effect on claims costs, so the positive findings regarding premiums are difficult to explain. It has also been postulated that the reform could cause some physicians' insurance premiums to increase, if the effect of the reform was to decrease hospitals' share of liability in multi-defendant cases. However, there is no evidence to support or refute this thesis.²⁷ Overall, the weight of the evidence (particularly the evidence from more recent studies) slightly favors the conclusion that joint-and-several liability reform does not significantly affect insurance premiums.

- Defensive Medicine.

The effects of joint-and-several liability reform on defensive medicine have been extensively investigated in a handful of studies. The strongest theoretical possibility is that elimination of joint-and-several liability would increase defensive practices by physicians, because the effect of the reform is to increase physicians' liability relative to that of hospitals. Hospitals typically serve as the "deep pockets" defendants in cases involving both physician and hospital defendants, and eliminating joint-and-several liability removes the possibility that physicians' share of the award could be picked up by hospitals.²⁶ A recent CBO analysis lends support to this thesis, finding that joint-and-several liability reform was associated with an increase in general and Medicare health care spending per capita, as well as hospital spending per capita.²⁷ Another study of obstetrical practice found that joint-and-several liability reform led to decreased use of cesarean section and induction or stimulation of labor.²⁶ The authors interpreted this finding as suggesting that the reform leads to *more* defensive medicine because these obstetrical procedures are currently overused and carry a risk of injury to the patient, but others would interpret lower use of these procedures as representing *less* defensive medicine.

Other study findings muddy the waters further. One study (with somewhat weaker methods than CBO's) found no relationship to health care expenditures per capita;²⁸ another found the reform to be associated with lower spending for 4 diagnoses in Medicare patients,²⁴ and still another found no relationship.²⁵ In summary, the evidence on the relationship to health care spending and defensive medicine is equivocal.

- Supply.

Four multivariate studies have examined the effects of joint-and-several liability reform on physician supply. One found that states that adopted one or more of 5 "indirect" reforms, including joint-and-several liability reform, experienced levels of growth in physician supply over time no different from states that did not.²⁹ Two more recent studies that modeled joint-and-several liability separately from other reforms (one of which was limited to obstetrician-gynecologists) found no significant effect on physician supply.^{31, 36} A third found the reform not to be significant in some models, and to have the effect of *reducing* physician supply in others.⁴⁷ Theoretically, there is no clear link between joint-and-several liability reform and physician supply. Overall, the evidence weighs in favor of a conclusion that there is no empirical relationship.

One unpublished study with strong methods examined the relationship between joint-and-several liability reform and employer-sponsored health insurance premiums and found that the reform was associated with significantly (1.4 percent) lower premiums for self-insured plans, but no significant differences for fully insured plans.³⁴

- Quality of Care.

No studies have directly examined the effects of joint-and-several liability reform on quality of care, but 4 have examined patient outcomes. One study investigated the relationship between “indirect” reforms such as joint-and-several liability and 1-year mortality among hospitalized Medicare patients; in nearly all models, the association was not significant.²⁴ The other 3 examined birth outcomes, one finding evidence of a lower rate of preventable complications of labor, but none finding an effect on infants’ Apgar score, likelihood of low birthweight, likelihood of preterm birth, likelihood of birth injury, or mortality or on maternal mortality.^{26, 36-37} There is no plausible theoretical link between joint-and-several liability reform and quality of care, and the weight of the evidence finds no association.

2.5.3. Summary

There is a good evidence base regarding the effects of joint-and several liability reform. Although research findings are somewhat mixed, on balance, the evidence suggests that it has no significant effect on claims payouts, defense costs, liability insurance premiums, physician supply, or quality of care. It may be associated with lower health insurance premiums. The evidence concerning the effect on claim frequency and defensive medicine is equivocal.

2.6. Collateral-Source Rule Reform

At common law, a jury is not permitted to consider evidence that a plaintiff received compensation for his injury from other sources, such as health or disability insurance, when making a decision about how much to award in damages. Thirty-four states have modified this “collateral-source rule” so that any amounts received from other sources are deducted from the amount that a defendant who is found liable for that injury must pay. The rationale for this reform is to eliminate the unfairness and expense of this perceived double recovery to the plaintiff.

Collateral-source rule reforms interact with provisions in insurance contracts (and rules of the Medicare program), known as subrogation clauses, that permit insurers to recoup money they pay in connection with an injury to an insured person if the insured collects damages from a liable third party.⁴⁹ In effect, such provisions already prevent double recoveries. However, subrogation rights are not always exercised (indeed, they may rarely be exercised) because of the associated administrative costs.

2.6.1. Key Design Features and Decisions

The key design decisions for collateral-source rule reforms include the following:

- Types of collateral sources covered: Modifications to collateral-source rules could apply to all collateral sources, or only to a specified set of sources. For example, the reform could apply offsets to health insurance but not life insurance.
- Relationship to subrogation rights: Some states have made their collateral-source rule reforms inapplicable to sources that are entitled to a subrogation right. Some courts have interpreted

the subrogation rights in the federal statutes governing Medicare and Medicaid to override conflicting state law.⁴⁸

- Mandatory or discretionary: The reform can be implemented by automatically reducing a plaintiff's award or by allowing defendants to introduce evidence of collateral sources at trial, allowing the trier of fact discretion to decide whether and how to adjust the award.⁴⁸

2.6.2. Effects on Key Outcome Variables

- Claims Frequency and Costs.

Four multivariate studies have modeled the relationship between collateral-source offset rule reform and claim frequency. The oldest study found a significant, negative association;¹⁰ the other studies did not find a significant association.^{5-6, 8} There is no plausible theoretical link between the reform and claim frequency.

Seven multivariate studies have examined the association between collateral-source offset rule reform and claims payments or insurer losses. Two studies found a significant, negative effect,⁹⁻¹⁰ while the other 5 found no association.^{5-6, 11, 15} Theoretically, collateral-source offsets should substantially reduce average award size because the literal effect is to deduct money from the plaintiff's damages. However, somewhat curiously, most studies do not support this notion.

- Overhead Costs.

One study has examined the effects of collateral-source rule reform on defense costs and concluded that there is no significant association between the two.¹⁷ The only theoretical link is that defendants may incur extra expenses investigating collateral sources.

- Liability Costs.

Seven multivariate studies have examined the association between collateral-source rule reform and malpractice insurance premiums. Five did not identify a statistical association on average.^{8, 12, 18-19, 21} One more recent study found a significant effect on premiums for insurance companies but not others.¹⁵ Another recent study with a notable methodological limitation found a significant effect for mandatory collateral-source offsets but not for laws that merely allow the jury to consider evidence of collateral sources.²⁰ Theoretically, to the extent that collateral-source offsets decrease claims payments, insurers should pass along their savings to their insureds in the form of lower premiums. Overall, the evidence suggests that this effect is weak or nonexistent.

- Defensive Medicine.

There is no plausible theoretical link between collateral-source offsets and defensive medicine or health care spending. Three studies found no significant effect on health care spending,^{24, 27, 28} and other work found no relationship to rates of cesarean section, induction or stimulation of labor, or vaginal birth after cesarean section.^{25, 26}

- Supply.

Three studies have directly measured whether collateral-source rule reform is associated with higher physician supply, and each found no association.^{31, 33, 34} Another study found that states that had adopted collateral-source offsets and/or 3 other “direct” reforms had 3 percent higher growth in physician supply over time,²⁹ but the individual effects of the various reforms cannot be ascertained on the basis of this analysis. The theoretical association is tenuous, as physicians are unlikely to perceive the protection of the offsets as substantial enough to justify a decision to practice in a particular state. Overall, the evidence suggests there is no relationship between collateral-source rule reform and physician supply.

One unpublished study with important methodological limitations examined the relationship between collateral-source rule reforms and the prevalence of health insurance coverage among under-65-year-olds and found no significant association.³⁵ Another unpublished study with stronger methods found that collateral-source rule reforms were significantly associated with lower health insurance premiums for self-insured plans, but not for fully insured plans.³⁴ The theoretical relationship between these variables is tenuous. Subrogation rights allow health insurers to recoup from health care providers the amounts they paid in medical expenses for patients injured by malpractice, which could result in lower premiums. However, these rights may be exercisable whether or not the plaintiff’s award was offset for the collateral source, and the rights may not be exercised much in practice.

- Quality of Care.

No studies have directly examined the effects of collateral-source rule reform on quality of care, but 4 have examined patient outcomes. One study found no association between adoption of one or more “direct” reforms, including collateral-source offsets, and 1-year outcomes for Medicare patients hospitalized for myocardial infarction, breast cancer, diabetes, or stroke.²⁴ Of the 3 studies that examined birth outcomes, 2 found no relationship to rates of preventable complications of labor or infant health or mortality^{26, 37} and the third found a reduction in infant mortality.³⁶ There is no plausible theoretical link between collateral-source rule reform and quality of care. Overall, the evidence weighs against the conclusion that patient outcomes are affected.

2.6.3. Summary

The evidence base concerning collateral-source rule reform is fairly strong. On balance, the evidence suggests that the reform does not significantly affect claim frequency, claims payouts, overhead costs, liability insurance premiums, defensive medicine, physician supply, or patient outcomes. It may reduce health insurance premiums.

2.7. Periodic Payment

Periodic payment allows or requires insurers to pay out malpractice awards over an extended period of time, rather than in a lump sum. This enables insurers to purchase annuities (sometimes called “structured settlements”) from other insurance companies which cost less than paying the entire award up front. Insurers are also able to retain any amounts that the plaintiff does not actually collect during

his or her lifespan. The rationale for this reform is to smooth out an insurer's expenses over time and to permit the purchase of annuities. Thirty states currently permit or require periodic payment.

2.7.1. Key Design Features and Decisions

The key design decision for periodic payment is whether to make it mandatory in all cases, mandatory in cases involving damages over a certain amount, or simply available at the request of either of the parties.

2.7.2. Effects on Key Outcome Variables

- Claims Frequency and Costs.

There is no theoretical reason to believe that periodic payment would affect either the number of claims filed or the average amounts awarded. They do not affect the valuation of a case, only the means through which the award is paid out. Three studies have examined the effect on claim frequency; one found a significant reduction,⁶ while the others found no effect.^{5,9} Five studies have examined the effects of periodic payment on claims payments; 4 found no significant effect.^{6,9,11,12} while one found a significant reduction).⁵ Overall, the evidence concerning claim frequency is too limited and equivocal to support a firm conclusion, while the evidence concerning claims payouts suggests that periodic payment does not result in a significant reduction.

- Overhead Costs.

No information is available regarding the effects of periodic payment on overhead costs. In theory, periodic payment could increase insurers' administrative expenses (e.g., search and transaction costs for annuities; tracking periodic payments over time) or decrease these expenses (e.g., by smoothing out shocks due to large awards that may make reinsurance more expensive or difficult to find).

- Liability Costs.

Theoretically, periodic payment should result in modest savings to insurers due to the availability of annuities. Whether they pass along these savings in the form of lower liability insurance premiums is, however, another matter. Only 2 studies have examined this issue; one found no significant association between periodic payment and premiums¹² and in the other, the results varied across medical specialties.²⁰ Overall, the evidence concerning this effect is limited and equivocal.

- Defensive Medicine.

Very limited information is available regarding the effects of periodic payment on defensive medicine. There is no plausible theoretical nexus between the two. One recent study found no significant relationship between periodic payment and rates of cesarean section or vaginal birth after cesarean section.²⁵ Another found that implementation of one or more "indirect" reforms, including periodic payment, was associated with lower spending for 4 diagnoses for Medicare patients, but the authors were skeptical of the finding.²⁴ Overall, the evidence is too limited and equivocal to support a firm conclusion about the effect on defensive medicine.

- Supply.

The theoretical relationship between periodic payment and physician supply is tenuous at best. There is no reason to think physician location decisions would be influenced by a reform that affects only insurers directly and has no demonstrated effects on physician insurance premiums. Three studies have examined periodic payment in isolation from other reforms, and all found no significant association with physician supply.^{31, 36, 47} Another study that lumped 5 indirect reforms, including periodic payment, together also found no significant effect on physician supply.²⁹

- Quality of Care.

No studies have directly measured the effects of periodic payment on quality of care. There is no plausible theoretical nexus between the two. One study examined the relationship to 1-year mortality among Medicare patients; in most models, the association was not significant.²⁴ The only other pertinent study, an unpublished work, examined 6 birth outcomes and found no significant relationship to periodic payment reforms.³⁷

2.7.3. Summary

The effects of periodic payment have not been extensively studied. The limited evidence available suggests that it has no beneficial effects on claims payments or physician supply. The evidence is too limited to draw conclusions about the effect on overhead costs, defensive medicine, or quality of care. The evidence concerning claim frequency and liability insurance costs is equivocal.

2.8. Statutes of Limitations/Repose

This reform aims to restrict the amount of time a patient has to file a malpractice claim. Statutes of limitations bar suits unless they are filed within a specified time after the injury occurs or is discovered. Statutes of repose are more stringent, specifying that the time limit runs from the date of injury regardless of when the injury is discovered. All states have adopted statutes of limitation or repose for medical malpractice claims, though they vary in length and triggering event. Statutes of limitations typically are set at 2 or 3 years, and statutes of repose at 3 to 4 years.

The primary rationale for this reform in the context of malpractice claims is to shorten the long “tail” associated with such claims—that is, the long time between the incident date and the date the insurer learns what its liability for the incident will be. The tail problem is believed to be one of the factors driving insurer mistakes in pricing malpractice insurance. Many insurers are thought to have underestimated their liability in the 1990s, not realizing what lay in their tail, which led to price shocks in the early 2000s. A second rationale for statutes of limitation and repose is to avoid the difficulties of litigating claims when the evidence has grown stale (for example, when people’s recollections of an event have faded over time).

2.8.1. Key Design Features and Decisions

Key design decisions for this type of reform include the following:

- Discovery rule: Statutes of repose are quite stringent because the time period for filing the claim begins to run from the date of injury, regardless of when the patient discovered the injury. Some types of malpractice injuries, such as missed diagnoses of cancer, may not become known for several years. An alternative is to set the statute of limitations to run from the date of discovery (or the date that a reasonable person would have recognized the injury).
- Length of period: In setting the length of time to file, the competing considerations are, on the one hand, allowing a reasonable period of time for an injured plaintiff or grieving family to obtain legal representation and assemble the information needed to support a claim, and on the other, providing reasonable protection for health care providers against claims relating to incidents that have faded from the recollection of the involved parties.
- Applicability to minors: States typically apply a special rule to minors, allowing the statute to run only after they have reached the age of majority, but the alternative is to put the onus on the minor's parents to file within a specified period of time from the date of injury or discovery of the injury.

2.8.2. Effects on Key Outcome Variables

- Claims Frequency and Costs.

In theory, shorter statutes of limitation/repose should reduce the number of malpractice claims by barring suit by plaintiffs who wait too long to file. Multivariate studies that have examined the association between statutes of limitation/repose and claim frequency have returned mixed findings. Two well-designed studies found a significant effect,^{8,10} while two strong studies did not.^{6,9} Overall, the evidence concerning claim frequency is too equivocal to ground firm conclusions.

Statutes of limitation/repose should not affect average claim payments, and all studies of this issue but one⁹ confirm this theoretical prediction.^{6, 8, 11, 12}

- Overhead Costs.

Theoretically, shorter statutes of limitation/repose could decrease liability insurers' operating expenses by improving their ability to predict their long-term losses, thereby facilitating accurate decisions about reserving, investment, and reinsurance practices. However, the one study to examine this issue found no significant relationship between the reform and defense costs.¹⁷

- Liability Costs.

Four studies have looked at the relationship between statutes of limitation/repose and malpractice insurance premiums. In theory, shorter statutes should decrease insurers' losses and the degree of unpredictability around their long-term liability, both of which could translate into lower premiums for physicians and hospitals. The study with the strongest methodology found a significant effect on premiums,⁸ but 2 other studies did not.^{12,21} The remaining study found a significant association for some clinical specialties but not others.²⁰ Overall, study findings are mixed, but the evidence weighs slightly in favor of a conclusion that premiums are reduced.

- Defensive Medicine.

Very limited information is available regarding the effects of shorter statutes of limitations/repose on defensive medicine or health care spending. The theoretical connection between the two is tenuous at best. One recent study found no effect on rates of cesarean section or vaginal birth after cesarean section.²⁵

- Supply.

Only one study has examined the effect of statutes of shorter statutes of limitations/repose on physician supply, though it did not isolate that effect from the effects of other reforms. It found that the change in physician supply in a state over time was not significantly affected by the state having adopted one or more of the 5 “indirect” reforms.²⁹ There is no plausible theoretical nexus between statutes of limitations and physician supply.

- Quality of Care.

No information is available regarding the effects of shorter statutes of limitations/repose on quality of care. There is no plausible theoretical nexus between the two. The only relevant study is an unpublished study finding no relationship between this reform and any of 6 birth outcomes.³⁷

2.8.3. Summary

The evidence base concerning statutes of limitation/repose is of fair size and strength. The weight of the evidence suggests that this reform does not significantly affect claims payouts, defensive medicine, or physician supply. A limited amount of evidence suggests a beneficial effect on liability insurance premiums. The evidence concerning the reform’s effect on claim frequency is equivocal. The evidence concerning overhead costs and quality of care is too limited to ground firm conclusions.

3. Innovative Reforms

3.1. Schedule of Noneconomic Damages

A schedule of noneconomic damages is an alternative to a flat cap that adjusts the amount of damages awarded for pain and suffering according to the severity or the injury. A more sophisticated version of a tiered cap, a schedule involves (1) creation of a multi-tier hierarchy categorizing medical injuries, (2) assignments of relative value weights to each tier reflecting variations in severity across tiers; and (3) assignment of dollar values for noneconomic damages awards for each tier. The schedule is used by juries and judges either as an advisory document or as a binding guideline.

The rationale for this reform is to achieve the goals of a flat cap on noneconomic damages while avoiding the inequities that occur in applying a single, relatively low dollar amount to all injuries regardless of severity level. Schedules promote both horizontal equity (similar injuries receive similar compensation) and vertical equity (more severe injuries receive higher compensation).⁵⁰⁻⁵¹ Schedules also serve the goal of absolute fairness in compensation—that is, setting damages to match (and not exceed) societal expectations about what constitutes appropriate compensation for particular injuries.⁵¹

Finally, they avoid the negative ramifications of unpredictability in damages awards, including instability in the cost of liability insurance, weakened deterrence of medical error, and loss of public faith in the legitimacy of the compensation system.^{50, 52}

No states have adopted a noneconomic damages schedule, but some have considered it.⁵³ Many public compensation programs for other kinds of injuries award compensation on the basis of schedules, including the Social Security Disability Insurance program and workers' compensation programs.⁵⁴ Schedules are also used for determination of damages in many foreign compensation systems, including administrative compensation schemes for medical injuries in Denmark and Sweden, workers compensation schemes in Australia, the civil justice systems in Belgium, France, Italy, Netherlands, United Kingdom, and Hong Kong, and the traffic accident compensation system in Finland.^{52, 55-57}

3.1.1. Key Design Features and Decisions

Key design decisions for a noneconomic damages schedule include the following.⁵²

- Creation of severity tiers: What source of information should be used to create the injury severity tiers for the schedule and group injuries within tiers? Several options are available, none of which perfectly capture the construct of hedonic (quality-of-life) loss:^{50, 52}
 - *Standardized valuation scenarios*:^{50, 58} Standardized injury descriptions and tier assignments for each could be developed and provided to juries and judges, which could then choose the tier/description that most closely resembled the case at bar. This approach is used in the United Kingdom. An advantage of this option is that it provides very concrete injury description. A disadvantage is that it requires considerable judgment to place injuries that do not closely resemble the examples into a tier.
 - *National Association of Insurance Commissioners' (NAIC) Severity of Injury Scale*:⁵⁹ The 9-point NAIC scale is widely in use among malpractice insurers and other insurers in valuing claims. It is based on the concept of injury-associated disability, dividing disability into 9 levels from "emotional disability only" to "permanent grave" and "death". For each level, the Scale describes a representative group of injuries (e.g., "permanent grave" injuries include "quadriplegia, severe brain damage, lifelong care, and fatal prognosis"). An advantage of this option is that it may be easier for juries to classify injuries if they are given broad category descriptions. The scale has also been shown to have high interrater reliability for injury classification.⁵² A drawback is that it may lump together injuries of quite different severity—for example, both mild fright and severe emotional trauma would be classified in the lowest tier. Additionally, the focus on degree of disability obscures other important aspects of hedonic loss, such as disfigurement or pain that does not affect physical functioning.
 - *Group consensus*: A less quantitative approach to tiering would involve convening a group of experts and asking them to make ex ante judgments about how to classify a wide range of injuries. Examples of such an approach include the American Medical Association's *Guides to the Evaluation of Permanent Impairment*,⁶⁰ which is widely used by state workers compensation programs, and the panels appointed in Sweden and Denmark to scale noneconomic damages awards for their civil justice and no-fault compensation systems.⁵² An advantage—or, from another perspective, a disadvantage—of this approach is that it is anchored in expert judgments about loss. Medical experts are very familiar with the effects of injuries and illnesses, but may value

quality-of-life impacts differently from the lay public or those afflicted with injuries or disease.

- *Health utilities indexes*: Decision science researchers have developed a variety of schemes for valuing states of ill health and disability based on what members of the public would be willing to trade off in order to avoid the state. The most widely used metric is quality-adjusted life years (QALYs), but there are others. Other research has described in detail how these metrics could be used to devise a scale for a noneconomic damages schedule.^{52, 61} An advantage of this approach is that it is grounded in public judgments about hedonic loss and incorporates a broad array of information about hedonic loss (as opposed to just information about disability). Criticisms include the complexity of the method and the documented errors that healthy individuals make in predicting the disutilities associated with health states they have not experienced.⁶²
- Consideration of plaintiff characteristics in tiering: Although the basic tiering scheme in a schedule of noneconomic damages is based on the severity of the injury, additional cells could be added reflecting the plaintiff's age, at least for permanent injuries.⁵⁷ The rationale would be that younger plaintiffs will endure the quality-of-life decrements associated with permanent injuries for a longer period of time than older plaintiffs. A more complicated tiering structure could also incorporate other plaintiff characteristics, such as whether the plaintiff's pre-injury occupation or personal interests made the injury particularly devastating, but care would need to be taken to avoid highly subjective determinations.
- Determination of weights and dollar values: Relative weights must be assigned to each tier in a damages schedule. Assigning numerical weights or "relative values" permits comparison of injuries in different tiers—indicating, for example, that an injuries in Tier 9 is considered three times as severe, in terms of pain and suffering, as an injury in Tier 5.^{50, 52} These weights are then used to assign dollar values to each tier (i.e., some baseline value is determined for Tier 1, and the weights are used as a multiplier to derive values for other tiers).

How should weights and the initial dollar values be assigned? The principle of absolute fairness in compensation suggests that assignment should be accomplished through a deliberative, representative, public process.⁵² One option is to base values on jury awards or settlements in previous, similar cases.^{51, 58, 61, 63-64} This approach reflects extant public decisions about fairness in compensation (at least to the extent that it reflects jury awards), but results in a schedule that is grounded in the judgments of juries who received no guidance.⁶¹ A second option is to assign the task to a committee with representation from all major stakeholder groups and access to information about existing awards and how injuries are valued in other kinds of compensation systems. Such a process would have to be very carefully designed in order to have public legitimacy. A third option is to appoint a group of experts in medicine, decision science, and law to evaluate research about the quality-of-life impacts of various states of ill health and disability and arrive at values based on the findings. This approach would be quite evidence based, but might be perceived as excluding lay opinion. A fourth option is to simply apply a multiplier of the economic damages award or medical expenses award.⁶² However, because lost income and medical expenses may not be highly correlated with pain and suffering (particularly for injuries that cause suffering but not extensive functional impairment and that have no effective treatments), this option strays quite far from the purpose of noneconomic damages. It could also induce strategic behavior by plaintiffs to try to inflate their medical expenses and income loss.⁶⁵

- Expression of dollar values for each tier: Damages for each severity tier can be expressed with a single dollar figure (adjustable for inflation) or as a dollar value range.
- Updating: A process should be identified for periodically considering whether advances in medical care or other factors suggest a need to reevaluate the classification of particular injuries into particular severity tiers. Dollar values should also be adjusted for inflation and other relevant factors on a regular basis.
- Effect on jury and judicial decisions: A schedule could be made binding on juries and judges, merely advisory, or presumptive.⁵² Binding schedules maximize predictability and equity in compensation, but may pose constitutional difficulties in states whose constitutions have been interpreted to preserve the right of juries to determine damages.⁵⁰ They also may result in seemingly unjust awards if juries have no discretion for departures in exceptional cases. Advisory schedules avoid constitutional difficulties, but clearly have less potential for standardizing awards and preventing very large awards. Presumptive schedules fall in the middle, requiring the jury to find a strong reason justifying an upward or downward departure from the schedule. In the context of binding schedules, an alternative way to permit some measure of discretion for the trier of fact would be to permit “special damages” to be awarded in certain narrowly defined types of cases.⁵⁴
- Inclusion of wrongful death cases: Fatal injuries could be classified into one of the severity tiers, but do not create the same kind of hedonic losses as non-fatal injuries. It may be desirable to treat wrongful death cases specially, either through creation of a special injury tier or by exclusion from the schedule.

3.1.2. Effects on Key Outcome Variables

Although many foreign civil justice systems and some U.S. systems of administrative compensation use damages schedules, none of these settings is sufficiently analogous to the American medical malpractice system to permit strong, evidence-based inferences to be drawn about the likely effect noneconomic damages schedules would have on the key outcomes evaluated in this report. However, it is possible to make some theoretical predictions based on these analogues and on evidence concerning how caps on noneconomic damages have worked in the U.S.

- Claims Frequency and Costs.

Although there is some evidence that noneconomic damages caps affect claims frequency, there is no strong reason to believe that a noneconomic damages schedule would necessarily do so. The extent to which plaintiff and attorney incentives to bring claims are dampened by a schedule would depend on how the dollar values chosen for the schedule compare to what is available in the status quo. Most advocates of schedules envision that awards for the high-severity tiers would be higher than those permitted by the damages caps laws that operate in many states. Overall, no conclusions can be drawn about the likely effect on claim frequency without making assumptions about the level of damages available under a schedule.

Similarly, whether scheduling would increase or reduce claims costs depends on the generosity of the damages available in each tier. Clearly, many possibilities can be envisioned, and foreign countries that

utilize schedules vary tremendously in the amounts awarded for noneconomic damages for similar injuries.⁵⁵

These outcome variables might also be affected by whether the schedule is binding on juries, presumptive, or merely advisory. Interestingly, however, experimental research suggests that even purely advisory guidance to juries on noneconomic damages substantially reduces award variability.⁶⁶ Survey research indicates that jurors tend to express frustration at the lack of guidance they receive about noneconomic damages valuation in current jury instructions,⁶⁷ further suggesting that juries would be receptive to even advisory schedules. Behavioral economics research documenting the effects of “anchoring” on people’s valuation decisions⁶⁸ lends further credence to the likely efficacy of advisory or presumptive damages schedules in influencing award decisions. Thus, regardless of whether or not the schedule is mandatory, it is likely to reduce the variance in awards. It remains an open question, however, whether this convergence will be to a mean that is higher or lower than average awards in the current system.

- Overhead Costs.

The process of creating and updating damages schedules would involve administrative costs, which may be quite significant for some of the more complex methodologies.⁶² On the other hand, improved predictability of the value of a case at trial should promote settlement, reducing litigation costs.^{50, 58} Litigation expenses may also be reduced because litigants would not have to offer expert opinion as to the extent of hedonic loss in a case. Overall, it is not clear how these countervailing cost considerations would net out, but it seems likely that schedules could reduce total system overhead costs.

- Liability Costs.

Schedules would improve the predictability of damages awards, enabling insurers to perform more accurate actuarial assessments and make appropriate reserving decisions.⁵⁸ Arguably, they would improve predictability to an even greater extent than flat caps, since they would provide more granular information about the expected noneconomic damages awards for different types of injuries. Hopefully, insurers’ savings would be passed on in the form of lower premiums.⁵² To the extent that schedules lowered claims costs, this could also redound to the benefit of providers through lower prices.

- Defensive Medicine.

Theoretically, defensive medicine might be reduced if schedules enabled physicians to better predict the consequences of malpractice. Law-and-economics theory posits that one of the important reasons for defensive medicine, or “overdeterrence” of medical error, is that physicians tend to overvalue their potential liability and therefore make non-cost-justified precautions.⁵⁰ Evidence concerning noneconomic damages caps suggests that such an effect occurs. However, if what providers fear is the psychological and reputational costs of being sued, rather than the economic sanction of the ultimate payout on the claim, then the effect of schedules on defensive medicine may be rather slight. Overall, there is a reasonable basis for predicting a modest improvement in defensive medicine.

- Supply.

There is evidence that damages caps are associated with small increases in physician supply. However, whether the same would be true for schedules may depend on the levels at which damages are fixed. If schedules do not (or are not perceived as) significantly limiting physicians' liability, merely making it more predictable, there may not be a supply response. Overall, there is no strong theoretical prediction that emerges on this point.

- Quality of Care.

Some commentators have argued that schedules may undermine optimal deterrence, giving health care providers less incentive to practice safely. The decisions made about valuation of noneconomic loss in a scheduling system may not accord with the valuations necessary to induce socially optimal levels of precaution taking by health care providers.⁶² This disjunct may, however, be equally or more true of the current system of awarding noneconomic damages. Moreover, scholars have argued, deterrence should be reinforced by improving the predictability of the sanction that would result from a breach of the standard of care.⁵⁰ That is, health care providers would be more likely to take optimal precautions if they had a better sense of the likely damages awards that would result from malpractice suits. Overall, no clear prediction about the effect of schedules on quality of care emerges from these considerations.

3.1.3. Summary

Very little evidence is available to support conclusions about the likely effects of damages schedules on the key outcome variables. However, analogous systems and law-and-economics theory suggest that schedules could have beneficial impacts on overhead costs, malpractice insurance premiums, and defensive medicine. It is not possible to draw conclusions about the effects on claims frequency and costs, physician supply, or quality of care without making assumptions about how the amount of money available for an injury of a given severity level under a damages schedule would compare to the amount available under the current system.

3.2. Administrative Compensation Systems or "Health Courts"

The use of administrative compensation systems or "health courts" for medical injury has frequently been proposed over the last 40 years.⁶⁹⁻⁸⁵ Proposals for administrative systems or health courts can contain several differing features, but most fit into one of two general models. In one model, often described as a *medical court*, a jury is replaced with a specially (in most proposals, medically) trained judge to adjudicate the negligence determination. Most of the other features of the present tort process are kept without much change. In the second model, an administrative agency investigates and adjudicates claims for medical injury. In this *administrative model*, claims would first be filed with an administrative body (as opposed to a court) that would process the claim, just as an insurance agency would process a claim. Both models are similar in that they attempt to replace the current jury model with a more efficient process, but variations in their approaches can translate to different effects.

The medical court model is a smaller departure from the present tort system than an administrative model. In the former, the primary departure is the replacement of the lay judge and fact-finder (either a judge or jury) with a judge and fact-finder with both medical and legal training. In some medical court models, the court could seek opinions from its own specialized neutral experts on a case-by-case basis.

Other variations are possible, such as changing the compensation standard, but most medical court proposals keep the remainder of the tort process intact. This model is rooted in the notion that better equipped judges and fact-finders would make quicker and more accurate decisions. The objective is not necessarily to improve patient access to compensation, but rather to handle the claims filed more accurately and efficiently.

In the administrative model, compensation decisions are no longer made in court, but rather by an administrative agency. This agency would act as a neutral fact-finder and adjudicator so that the process would not be slowed down by an adversarial fact-finding process. Decisions could theoretically be rendered more cost-effectively because neither attorneys nor experts to represent each point of view would be required. Because filing a claim should be easier, administrative models can have the additional benefit of increasing the number of patients with access to the compensation system. To further boost access to compensation, most administrative models call for the use of a compensation standard broader than negligence, such as “avoidability”.

Because no comprehensive administrative systems for medical injury have been launched in the United States, little direct evidence exists regarding the effects of administrative compensation system models on the key outcome variables evaluated in this report. However, some analysis regarding key design features and outcomes is possible based on the limited administrative systems operating in the U.S., foreign experience with administrative models, and research on the effects of other tort reforms.^{72-73, 85-89} Administrative systems in the United States include Florida’s Birth-Related Neurological Injury Compensation Plan and Virginia’s Birth-Related Neurological Injury Compensation Program, both of which aim to provide compensation for birth-related injuries.^{86, 88-89} In addition, the U.S. National Vaccine Injury Compensation Program has been operating since 1998 to compensate for vaccine-related injuries.^{72, 87} Scandinavian nations (notably Denmark and Sweden) and New Zealand have also operated administrative compensation models since the 1970s when their nations began to abandon their negligence-based system for medical injury.^{73, 85}

3.2.1. Key Design Features and Decisions

The key design decisions for health courts include the following:

- Exclusivity of remedy: In the design of any administrative compensation system, one of the first questions that must be answered is whether the system will be patients’ only legal remedy for malpractice, or whether claimants can opt to pursue their claims in the administrative system or in the courts. Although the administrative system should be attractive to claimants due to the ease with which a claim can be filed, some claimants may prefer the tort system—for example, because it is more likely to lead to a larger award or because juries are perceived as fairer or more sympathetic than judges.^{76, 78}

Any exclusive system must be designed to pass constitutional muster. The United States Constitution and state constitutions guarantee several rights that bear on the constitutionality of health courts, including due process, the right of access to courts, and the right to a jury trial.^{72, 77, 90-91} A detailed constitutional analysis is beyond the scope of this report, but has been conducted elsewhere.^{77, 90-91} Other exclusive administrative systems, such as workers’ compensation systems, have been successfully designed and implemented while withstanding constitutional challenges.^{77, 92}

A voluntary design avoids these constitutional difficulties for the most part, but has other disadvantages. Due-process rights would still require that a mechanism for informing patients about their choice and eliciting informed consent to participation be developed. Laws in some states may prohibit such pre-injury agreements.^{80, 91} A significant loss of cost-control potential arises from possible selection effects if claimants are permitted to choose the system (administrative vs. tort) that best serves their needs. Such an approach perpetuates the current inefficiencies of the tort system and essentially creates two tracks for compensation, leading to greater complexity.^{76, 78, 84} Claimants with higher-value claims may disproportionately select into the tort system, resulting in lost opportunities to curb very high-cost awards through an administrative process.

- Appeals rights: Whether or not use of the administrative system is mandatory, the administrative system will need to address parties' rights to appeal unfavorable decisions.^{77, 91} Claimants may wish to appeal findings that no compensation is warranted or findings as to the appropriate amount of compensation. Providers may also wish to appeal the adjudicator's findings, particularly if an adverse decision results in an unwelcome consequence for the provider, such as a report to the National Practitioner Data Bank. Appeal rights may be structured to provide direct appeal to judicial courts or judicial appeal only after an intermediate, administrative appeal. The standard of appellate review can be specified at various levels ranging from *de novo* review (a fresh look at the evidence, with no deference given to the initial tribunal's decision) to an "arbitrary and capricious" standard (the initial adjudicator's decision will only be overturned if it appears to be totally arbitrary).
- Types of claims: An administrative system will also need to specify what types of claims it will handle. A system may opt to process all claims for medical injury. It may also just hear a subset of them, for example: injuries representing certain types of harm (e.g., neurological injuries to newborns); injuries resulting from specific causes (e.g. medication-related injuries); or injuries of a certain severity level (e.g., only injuries that have resulted in 5 days or more of lost work time). Examples of medical injury schemes that cover specific injuries include Florida's Birth Related Neurological Injury Compensation Plan and Virginia's Birth-Related Neurological Injury Compensation Program.^{76, 88-89} A scheme that covers harm based on the cause of injury is the National Vaccine Injury Compensation Program.⁸⁷ The Swedish and Danish administrative systems provide an example of schemes that apply severity thresholds; in Sweden, claims must be valued above approximately USD\$275 to be eligible for compensation, and in Denmark, approximately USD\$1700.⁷³

One potential benefit of defining a subset of claims for administrative system jurisdiction is the creation of a more predictable set of claims to adjudicate. However, the potential impact on system-wide costs, access to compensation, and other variables is obviously smaller the narrower the set of included claims is. Additionally, legal wrangling may arise over whether a particular claim meets the defined categories for jurisdiction.

- Filing method: In the current tort system, plaintiffs may file without an attorney, but navigating the process is daunting enough that most claimants need an attorney. Administrative systems can be designed to be navigable without an attorney.⁷³⁻⁷⁴ The complexity of the model—whether administrative or medical court model—and the particular claim will determine the likelihood that an attorney will be needed.

The removal of the need for an attorney carries the potential to make filing easier, particularly for claimants whose claims are too small to interest attorneys working on a contingent-fee basis. On the other hand, it would be expected to result in the filing of more claims, possibly including a greater number of nonmeritorious claims.

- Compensation standard: Administrative models generally propose to replace the negligence standard with broader alternative standards that do not require proof of provider negligence or fault. Among the options are an *avoidability* standard (compensating all injuries that ordinarily should not occur in the hands of the best specialist or an optimal system of care) or a *no-fault* or strict liability standard (compensating all injuries attributable to medical management, except for some known, frequent complications). A *no-fault* standard is broader than an *avoidability* standard because it can provide compensation in cases of unexpected or rare complications that may not meet an *avoidability* standard. For example, a *no-fault* standard would compensate a patient who suffers a severe and unexpected adverse reaction to a properly prescribed and administered medication; under an *avoidability* standard, this injury would not be compensable because it could have happened in the hands of the best specialist.

Relevant considerations in selecting a standard include patient access to compensation, operational feasibility, alignment with principles and practices in patient safety, and administrative and liability costs. A broader standard may not only bring compensation to a greater number of patients, but also improve system efficiency because it is more easily adjudicated than negligence.^{73, 75, 93} In addition, an avoidability standard may also better match the concept of preventable harm that dominates the patient safety movement (i.e., provide compensation for injuries which, although not the result of unreasonable actions, are still avoidable or preventable).^{73, 75, 93} An even broader standard, such as no-fault, would be even easier to administer.⁷³ A no-fault standard would not compensate all injuries caused by medical care, but just those that are not “necessary and ordinary to” medical care (e.g., the loss of hair due to chemotherapy would not be compensable but a post-surgical infection would be).⁷³ A no-fault standard would, however, be more expensive because a greater proportion of claims would be paid. It also would not align as well with patient safety principles that focus on preventability of harm.

To bring further efficiency, accuracy, and consistency around application of a compensation standard, some commentators have recommended that consideration be given to creating “accelerated-compensation events” (ACEs) which are automatically or presumptively eligible for compensation on a “fast track” because a group of experts has judged them to be almost always negligent or avoidable (e.g., retained foreign bodies).⁹⁴⁻⁹⁶

- Adjudicators: For the medical court model, the adjudicator will likely be a physician-judge. In the administrative model, the options include a judge who specializes in malpractice cases, a physician-judge, and (at lower levels of decision making) an administrative claims manager (with or without a background in law or health care) with expert physician support. Administrative models, such as those in New Zealand and Scandinavia, tend to rely heavily on administrative claims managers with only limited review by other adjudicators.⁷³ The design of both models will need to include how adjudicators will be assisted in (1) using the best available evidence to yield accurate decisions and (2) how precedent will be created and followed for consistency of decision-making. Some proposals suggest that adjudicators be assisted by both neutral experts

and decision guidelines developed in advance by a group of experts covering considerations relevant to commonly seen injuries.⁷⁴

- Award types and amounts: Except in states that have adopted statutory limits, the tort system does not set limits on the damages (economic, noneconomic, and punitive) that juries and judges may award. The design of an administrative compensation system will need to include whether or not limits on damages (economic, noneconomic, or punitive) will be applied. One option is to adhere to any existing damages caps legislation but impose no other restrictions. Another is to strike the existing caps and allow the adjudicator full discretion, but this may pose cost-control problems. A third option is to create a schedule of noneconomic damages and award full or close to full economic damages.
- Financing: If a new paradigm for compensation will be used, financing options will need to be considered. Maintaining the status quo (liability or self insurance model) is an option, but may encounter some resistance from the insurance community if a broader compensation standard is used or filing made easier (due to uncertainty of total compensation payouts). Other financing options include a tax on medical care, a tax on providers, or a general financing mechanism. A combination is also possible. Private insurers could continue to provide primary-layer insurance but the government could step in to provide reinsurance or other stop-loss protection.
- Potential links to quality and patient safety improvement: The current tort system is not designed to systematically capture and catalog the adverse events represented in claims.^{74, 93, 97} If such data were collected, a database to promote patient safety could be developed. An administrative compensation system could be designed to do so.^{74, 93, 97-98} The more claims that flow through the system, the more useful the database would become. In this sense, a more liberal compensation process and simple filing procedure would, by encouraging claims filings, provide for greater learning about medical errors and how to prevent them. A linkage to patient safety would directly foster achievement of one of the laudable goals of our current tort system: to help reduce future injury.
- Relationships to provider reporting and discipline: Currently, if a plaintiff files a claim against a physician, the physician must report these claims on state licensing applications and renewals and to credentialing committees and insurance companies. In addition, if a claim is paid on behalf of a physician, the payment must be reported to the National Practitioner Data Bank. Separate Board of Medicine disciplinary investigations may be requested or launched on a claim-by-claim basis. A new administrative system would need to determine how to handle reporting within the current regulatory environment or whether current reporting obligations need to be modified. This can be of particular importance if a compensation standard broader than negligence is selected because many reporting mechanisms are built based on the level of fault required for a negligence determination.
- Level of jurisdiction: The current tort system operates primarily at the state level. Whether or not the administrative system will operate at the state or federal level will need determination. A federal system would likely create greater uniformity and a greater potential pool of claims for patient safety analysis, but may be more challenging to implement.

3.2.2. Effects on Key Outcome Variables

- Claims Frequency and Costs.

Theoretically, total liability costs (compensation paid to claimants) in an administrative system will be a function of the number of claims generated, the claims success rate, and the amount of the average award (economic plus non-economic costs). We consider each of these components in turn for each model.

Medical court model: Based on current evidence, it is difficult to determine what effect a medical court model would have on claims frequency. If the medical court model gives the impression that claims with less merit are less likely to be successful, there may be a reduction in the number of claims seen. However, if it appears that more accurate adjudication of claims will lead to greater claims success rates, more claims may result. As discussed above, screening panels and certificates of merit, which also strive to improve the accuracy of adjudication through application of expertise, have not been demonstrated to significantly affect claim frequency. On balance, though, a medical court model that retains a negligence standard and requires an attorney for filing is unlikely to affect claim frequency.

Based on one recent study of malpractice claims, the claims success rate may not change much, either. This study found that approximately 60 percent of all claims contain medical error. Approximately equal proportions (about 25 percent) of claims containing medical error and claims not containing medical error are resolved discordantly with their merit (i.e., errors are unpaid and non-errors are paid).⁹⁹ A more accurate system of adjudication would theoretically reduce the number of claims incorrectly paid, but this may be more than offset by greater number of claims that would now receive payment.

It is unclear what would happen to the average award in a medical court model, as it would depend on what type of guidance judges or juries were given on damages and the extent to which damages were limited by design. Overall, a medical court model's costs are hard to predict without making assumptions about its rules around damages.

Administrative model: One of the main goals of an administrative model is to make the claim filing and adjudication process easier. It rationally follows that more claims will result from the decreased transaction costs. Altering the compensation standard to be more favorable to claimants should also increase the number of claims filed by affecting the expected value of the claim. International systems that have adopted administrative models (with broader standards than negligence) see higher claiming rates per population.⁷³ Estimates of claims per million persons per year are 200 in the U.S.; 1000 in Sweden and Denmark; and 750 in New Zealand.⁷³

The claims success rate is likely not to change much if the standard is maintained at negligence (similar to medical courts), but will increase if a broader standard (such as avoidability or no-fault) is used.

The average award will depend on whether and how compensation award limits are set. However, because of the lack of a need for an attorney, many smaller claims can be anticipated. Thus, it is very likely that claim frequency will rise and the average award will shrink. One study utilized malpractice claims in Utah and Colorado (for the year 1992) to model costs based on an avoidability standard (and also applied some disability thresholds, caps to pain and suffering, and some reasonable limits on allowable benefits, as the administrative compensation systems in Sweden and Denmark do).^{75, 84} The authors found that the number of compensated events would rise, but that total costs would remain

approximately the same in Utah (approximately \$55 million) and drop in Colorado (from \$100 million to \$82). The savings was due to lower awards and overhead costs. Overall, weighing the changes in all three factors—a larger number of claims, a likely greater number of successful claims, and on average smaller awards—the total liability costs are somewhat uncertain, but could be neutral if design choices similar to those made in the Nordic countries were made.

In summary, total claims are likely to remain the same in a medical court model and to rise in the administrative model. In both models, the claims success rate may climb a small amount if negligence is the standard or a larger amount if an easier standard is chosen. The average award will depend upon what damage limits, if any, are set, but is likely to remain the same (in a medical court model) or decline (in an administrative model).

- Overhead Costs.

Medical court model: Medical court models are also designed to streamline the adjudication process through the use of neutral fact finders with medical expertise. This change can reduce the overhead costs currently used to educate juries and hire experts. However, no firm conclusions can be drawn from available evidence.

Administrative model: Administrative models are designed to help lower overhead costs by reducing the adversarial nature of the adjudication, making use of neutral experts and decision guidelines, and reducing the need for attorney involvement. These alterations result in streamlined compensation determinations. Data from the Florida, Virginia, and foreign systems have shown a lower administrative cost structure than compared to tort.^{73, 76, 78, 85-86, 99-102} Current overhead cost estimates are as follows: U.S. tort system, 40 percent; Florida and Virginia’s birth-related injury systems, about 8-10 percent; Sweden and Denmark, 15-20 percent, New Zealand, 10 percent.^{85, 99, 101-102}

For both models though, the overall effect on overhead costs can depend on how often the courts are utilized for appeal.¹⁰³ With proper system design, it would be anticipated that the contribution of appeals to overhead costs would be minimal. Appeals rates in the foreign administrative systems (Sweden, Denmark, and New Zealand) have been about 18-20 percent.⁷³

- Liability Costs.

The liability costs that a provider will experience will depend on the choice of system financing. If the present financing system is retained (liability insurance), provider insurance costs will be a function of claims costs, but as noted above, these are unclear under both models. However, if a different method of financing, such as a general tax on medical care or on providers or a general public levy, the liability costs providers experience could drop substantially.

- Defensive Medicine.

To the extent that either model creates a perception that claims will be adjudicated correctly and assuages fears that “non-defensive” medicine is legally risky, defensive medicine may decline.^{23-24, 104} Many other model features such as financing of the system and provider reporting requirement can also be adjusted to reduce defensive behavior.

Medical court model: It is unclear how a medical court model (using a negligence standard and not changing the current provider reporting requirements) would change perception unless it was able to disseminate information on the accuracy of its judgments. Physicians may, however, be reassured by the knowledge that claims will be evaluated by a fellow physician.

Administrative model: The greater number of claims and claims success rate (if using a broader standard) could lead to increased defensive medicine. However, the use of an alternative compensation standard that does not carry the stigma of negligence could reduce the reputational and psychological costs of being sued, potentially enervating the propensity to practice defensively. Additionally, the use of decision guidelines could reduce defensive medicine by sending a clearer signal to providers about the legal standard of care.

- Supply.

Medical court model: A medical court model, if it can help reduce liability insurance costs and non-meritorious claims, may decrease physicians' likelihood of leaving practice or restricting their scope of practice. As discussed above, some evidence concerning traditional tort reforms supports a link between reduced liability pressure and increased physician supply. However, with respect to medical courts, it is unclear what will happen to liability costs and how financing of the model would be undertaken. To the extent that a medical court model could be designed to reduce overhead and liability costs, a small increase in physician supply may occur.

Administrative model: As with the medical court model, to the extent that an administrative compensation model decreases physicians' liability insurance premiums or liability risk, it could decrease their propensity to leave practice or restrict their scope of practice. However, if financing of liability costs is kept as is, and liability costs increase, physician supply could be adversely affected. Overall, changes in supply with an administrative model are not possible to predict.

- Quality of Care.

To the extent that either model would decrease defensive medicine or improve access to treatment (physician supply), quality of care may be improved. However, as noted above, the likely effects of administrative systems on defensive medicine and physician supply are opaque. Nevertheless, administrative compensation models hold promise for improving quality of care by providing the infrastructure for patient safety improvement (e.g., a database of medical injuries and their contributing factors). Precedent for the systematic use of claims to improve safety exists, as seen in the Anesthesia Closed Claims Project in the United States and the foreign administrative compensation systems.^{73, 98, 105} For example, the foreign systems have started cataloging claims into electronic databases so that they can analyze them for patient safety related issues. They have also created feedback mechanisms to health care institutions.

3.2.3. Summary

Proposals for administrative compensations systems or "health courts" come in two general models: a medical court model in which the specially trained judges adjudicate claims or an administrative model that replaces the courts with an administrative agency to adjudicate claims. Both seek to reduce the high overhead costs associated with the tort system as well as create more accurate and consistent

decisions. Both can be designed to capture and catalog events to drive patient safety improvements. Both can also be designed to improve access to compensation by using a broader compensation standard, but most recent proposals for broader standards relate to the administrative model. An administrative model also offers the added advantage of easing the claiming process for patients, and the resultant disadvantage (from a cost-control perspective) of increasing claim frequency.

Very little actual experience on administrative systems for medical injury in the United States exists, but it is possible to learn from narrowly crafted administrative compensation systems for vaccine injuries, birth injuries, and workplace injuries, as well as from other nations that have switched from negligence-based tort to administrative systems. Collectively, these systems demonstrate that an administrative model can reduce overhead cost and boost quality and safety improvement efforts. The number of new claims remains unknown, but is likely to remain fairly static under a medical court negligence model and grow substantially under an administrative model. Some modeling has predicted that total costs in an administrative compensation system may remain unchanged or slightly decline as compared to the negligence based tort system. Total costs, nevertheless, will vary based on the compensation standard and award limits (if any). Effects on defensive medicine and quality of care are likely to be positive, while effects on insurance premiums and physician supply are difficult to predict.

3.3. Disclosure-and-Offer Programs

Disclosure and offer (D&O) programs support clinicians in disclosing unanticipated care outcomes to patients and make rapid offers of compensation in appropriate cases. Presently, they are operated by a handful of hospitals and liability insurers (predominantly self-insured hospital systems). The goals of D&O programs are to encourage honest and transparency around unanticipated care outcomes, expedite compensation to injured patients, reduce malpractice claims and average payouts, and reduce overhead costs for claims processing.

D&O programs vary in their structures and processes, but contain some common elements:

1. When an unanticipated outcome occurs, clinicians are asked to promptly report it to institutional risk management. Disclosures of the outcome are made whether or not it is believed that the outcome is due to a medical error.
2. With the institution's support, clinicians disclose the unanticipated outcome to patients and/or their families. A disclosure occurs when a provider reveals and explains an adverse event and apologizes. Depending on the results of the institution's investigation into the cause of the injury, the apology may be a statement of sympathy ("I'm sorry this happened to you") or a statement of responsibility ("I'm sorry that I injured you during the operation").
3. A rapid investigation into the cause of the error is conducted, and further disclosures are made regarding the findings of the investigation. Disclosure is viewed as an ongoing process that unfolds along with the investigation.
4. The institution makes an expedited decision about whether compensation in some form is appropriate, based on the compensation standard it has adopted. If the standard is met, an offer is made to the patient.
5. Incidents not resolved through settlement after this process can go on to become malpractice claims in the tort system.

D&O programs as we define them are different from programs or policies of full disclosure that many health care institutions have adopted. They are both broader and potentially more narrow than full-disclosure policies: broader in that they include both a disclosure process and a compensation

determination, but potentially narrower in that D&O programs may exclude particular kinds of incidents from eligibility for the program. Depending on their design, D&O programs could coexist with extant full-disclosure policies, routing some or all of the disclosed incidents into the expedited compensation process.

D&O programs (and full disclosure policies more generally) appeal to many clinicians because they are consonant with principles of medical ethics (fiduciary duty, patient autonomy, and justice).¹⁰⁶⁻¹⁰⁷ Leading organizations such as The Joint Commission and the National Quality Forum have also called for disclosure as part of greater patient safety agendas.¹⁰⁸⁻¹¹⁰ In addition, several states require that disclosure alone be made to patients and families in certain circumstances in which a harmful error occurs and protect information conveyed in apologies.¹¹¹⁻¹¹²

On the other hand, there are significant barriers to greater transparency around medical errors. Liability risk is widely regarded to among the chief barriers, and the number of institutions with formal D&O programs remains limited.¹¹³⁻¹¹⁵ Other barriers to disclosure include the emotional difficulty of the conversation, shame and guilt, the stress of a possible lawsuit, potential consequences in credentialing processes, and reputational harm.^{113, 116-117}

D&O programs differ from the varying types of statutory “Early Offer” programs that have been proposed.¹¹⁸⁻¹²⁷ In these proposed programs (including one proposed in a federal bill in 1984), providers are given a defined period of time (e.g., 120 or 180 days) to make an offer of compensation for claims asserted against them.^{121-123, 125, 127} The offer need only include a promise to make periodic payments for economic damages. With the offer, the provider would ideally also disclose any error in care. In many Early Offer proposals, claimants do not receive noneconomic damages, but do receive reasonable attorney fees. The patient may refuse the offer and sue for all damages, including noneconomic damages. However, the claimant either must prove a more culpable breach than negligence (e.g., gross misconduct) or face a higher burden of proof (e.g., clear and convincing evidence). Statutory amendments may also allow for modified National Practitioner Data Bank reporting requirements to mitigate reporting effects.

Early Offer programs seek to improve upon the tort system by creating administrative efficiencies (less litigation), quicker compensation for patients (less litigation with an offer deadline for providers), awards that better reflect the “real” losses patients suffer (by eliminating or limiting “pain and suffering” payments), and improved quality of care (by sending clinicians clearer signals). However, there are no real-world examples of Early Offer programs to test the extent to which they achieve their aims. In 2003, the Institute of Medicine called for system demonstrations of Early Offer programs with limits on noneconomic damages coupled with government-provided reinsurance.¹²⁵

Early Offer programs are different than disclosure programs in the sense that their primary driver is remedying the ails of the tort system (it is a means to manage asserted claims and not necessarily cases of harm that are not known to the patient) whereas disclosure programs are primarily driven by ethical and patient safety principles (whether or not a claim is filed). For the remainder of this section, we discuss design features, decision, and outcomes related to D&O programs.

3.3.1. Key Design Features and Decisions

- **Eligibility:** D&O programs could be available for all injuries, or only a subset. Some extant programs exclude very severe injuries, deaths, or cases that already involve an attorney or a

written demand for payment. Although on principled grounds, all harmful events merit disclosure, some institutions have opted for restricted eligibility for early compensation. For example, the Colorado Physician Insurance Company's (COPIC's) 3Rs program is not available to patients who make a written demand for compensation or have obtained an attorney or in cases of death.^{111, 128-129} The COPIC program simply seeks to assist patients who have experienced an unanticipated medical outcome by facilitating candid, early communication between a physician and a patient, thereby preserving the relationship. The program assists a physician in: (1) responding in a timely fashion to an unanticipated medical outcome; (2) communicating with the patient in an empathetic manner; and (3) arranging for additional care or services the patient might need as a result of the outcome

- Compensation standard: D&O programs could award compensation only in cases in which the legal standard of care appears not to have been met, in all cases in which the institution "could have done things better," or in all cases involving an injury due to medical management, regardless of its avoidability. The more stringent the compensation standard, the more extensive the required investigation, but the lower the program's total compensation costs.
- Types of damages: A determination of what types of damages will be provided with offers should be made. Most programs make some offers that include only a waiver of medical charges and courtesy items such as complimentary hotel stays for family members during the patient's hospitalization. The next step up is to provide only reimbursement for out-of-pocket expenses. Alternatively, some or all of the patient's economic losses (including lost income) could be compensated. Finally, programs could also offer some amount representing noneconomic loss, whether characterized as "pain and suffering" or "loss of time." The more generous the offer, the less likely a patient or family may be to file a lawsuit. On the other hand, program costs will obviously be higher with more generous settlements. There are existing models of each of these types of compensation.
- Timing of compensation assessment: Some programs specify target timelines for investigation and compensation decisions, while others do not. Timelines could vary from a few days to a few months. Programs also must determine how they will make offers to patients with injuries that are permanent, uncertain in duration, or uncertain in extent. This issue is most acute for severe neurological injuries to newborns, as the developmental implications for the child may not become apparent until testing can be conducted at 2 years of age. Programs could opt for periodic payments based on regular assessments of the severity of injury or for a lump sum payment. The former improves accuracy in compensation, while the latter achieves a rapid disposition of the case and enables the insurer to better understand its extent of liability.
- Amount of damages: Programs will also need to decide if there is a maximum amount that will be offered for economic and noneconomic damages. Setting maximums may help speed negotiations, but may also result in more patients rejecting the offer. A further issue, particularly for programs with no preset maximums, is the basis for valuation of the case. Offers could be determined based on what the insurer believes the case would be worth if it went to trial, or based on its own assessment of what is required to make the patient whole.
- Assignment of responsibility: For D&O programs that are based at an institution, it will be important to determine on whose behalf the offer and settlement will be made. For self-insured institutions or insurers that are covering all involved parties, the financial consequences of who

accepts responsibility can be minimal for the insurer. However, there can be reporting ramifications for the involved physicians. If the error is a system-level error, a health care institution (such as a hospital) may opt accept responsibility and have individual clinicians dropped from the financial settlement. This may obviate the need for provider reporting to the National Practitioner Data Bank, but may also run afoul of the intent of the Data Bank statute.

- Attorney involvement: Once a disclosure is made to an injured patient or family, some D&O programs may suggest that the patient or family get attorney representation. This may occur only in certain cases—for example, high-severity cases or cases in which the institution feels that the patient or family has inflated expectations of the value of the case. Attorney representation can affect not only the equity of patient compensation, but also the perception of how fairly patients are treated. In some cases, it may result in lower, more rapid settlements, as families' expectations are adjusted by their attorney.
- Waiver of rights: Programs must decide whether acceptance of an early compensation offer will constitute a waiver of further liability claims for the event or whether patients will not be asked to waive their right to sue. The advantages of waiver are clarity and finality for the involved providers and insurer. The advantage of not requesting a waiver is that it may increase the patient's or family's belief in the good faith of the institution at low risk, since few families reportedly go on to sue even in the absence of a waiver.
- Non-institution based/Non-self insured program: Providers or institutions that are not self-insured will need to ensure that the disclosure and offer program is compatible with duty-to-cooperate clauses so that their insurers will not attempt to deny coverage.¹³⁰ These clauses are frequently found in malpractice insurance policies and require insured providers to cooperate with the insurance company in its defense of the claim. Cooperation clauses commonly forbid insureds from admitting liability without the consent of the insurance company.
- Enrollment of physicians: A D&O program could be designed to automatically include all physicians insured by the sponsoring insurer or could require physicians to formally enroll in the program (at or before the time of an incident). The advantage of a universal program is its comprehensiveness and uniformity of approach, while an opt-in program preserves autonomy for clinicians who do not want to participate in disclosures while creating a mechanism for targeting disclosure training and outreach to willing providers and comparing outcomes for participating and nonparticipating physicians.

3.3.2. Effects on Key Outcome Variables

Though the concept of disclosure with offer continues to capture interest, there is little evidence in the public domain concerning its effect on key outcome variables.^{111, 115} To date, only one health system has published the effect of its D&O program on malpractice-related compensation costs.¹³¹ In addition, COPIC has published some information on its 3Rs program.¹²⁹

- Claims Frequency and Costs.

There remains a fair amount of uncertainty about the effects of the D&O approach on claims volume and costs. Several commentators and a simulation analysis of injury and claims data have suggested

that full disclosure policies may increase health care providers' liability by alerting patients to the fact and cause of a medical error.^{111, 113-115, 132} Although survey research suggests that disclosure improves trust in providers, that patients often sue out of a sense of "cover up",¹³³⁻¹³⁶ and that patients are more likely to sue if they learn of an error on their own as opposed to having a provider disclose it,¹³⁷⁻¹³⁸ At least one survey study has found that disclosure is unlikely to dissuade patients from seeking legal advice.¹³⁹ Rather, a substantial number of patients will expect compensation if informed of a harmful error in their care.¹³⁷⁻¹³⁸

However, D&O programs go beyond full disclosure to provide a remedy—early settlement offers—that may avoid the consequences that may otherwise flow from disclosure. This result seems particularly likely if patients perceive the disclosures in these programs to be carried out well and the compensation offers to be part and parcel of the provider's acceptance of responsibility for the error that has been disclosed. There is some anecdotal evidence that D&O programs are successful in reducing the number and cost of claims.

The University of Michigan, which has operated a formal D&O program since 2001, has seen the number of claims drop almost 50 percent in the first five years of the programs operation.¹⁴⁰ The COPIC 3Rs program has been in operation since 2000 and they have reported a decline the number of legal claims closed from 643 in 2003 to 584 in 2005.¹²⁹ During that same time COPIC reported a drop in the average claim payout and number of paid claims from \$303,326 (138 cases) in 2003 to \$258,799 (99 cases) in 2005.

A Veterans Affairs Medical Center (VAMC) in Lexington, Kentucky, after adopting a policy of full disclosure with offer, saw its total liability compensation costs drop from the top to the bottom quartile compared to its peers.¹³¹ Generalizability of the VAMC experience is open to question, as liability in that system is limited by the Federal Tort Claims Act. The other anecdotal reports arise from self-insured academic medical centers and may not be generalizable to other kinds of organizations.

Nonetheless, there are strong theoretical reasons for optimism in the ability of D&O programs to constrain claims costs. Logically, average payouts should be lower in a D&O program because (1) many patients would willingly trade off the possibility of a larger award for a quick resolution; (2) the reduced involvement of attorneys should alter the existing incentives in the contingent-fee system to seek a large award (although attorney involvement could also help manage the expectations of some patients who seek large awards); and (3) a greater number of low-severity incidents should receive a payment under D&O programs than in the tort system. The last effect arises from the fact that disclosures and offers are carried out even for low-severity injuries, whereas in the tort system, claims with low expected value may not be brought due to lack of interest on the part of plaintiff's attorneys. This raises the countervailing possibility that the lower average payouts could be offset by a large increase in the number of low-severity incident compensate, but there is no indication that this has occurred in any of the existing programs. In summary, the evidence concerning the effects of D&O programs on claims volume and costs derives from unverified, anecdotal reports by a small number of institutions. However, the reported results are remarkable, making these programs attractive candidates for further experimentation and study.

- Overhead Costs.

D&O programs may require additional administrative FTEs to run—for example, to administer disclosure training and support services and to enable risk management to more quickly investigate incidents.

However, it is very likely that the D&O approach reduces insurers' overhead costs substantially overall. Early settlement of incidents, in most cases without recourse to litigation, avoids costs relating to protracted investigation and discovery, consultation with external expert witnesses, involvement of outside counsel, and preparation for trial.¹¹⁹ Although no controlled studies are available, anecdotal reports from the University of Michigan indicate a significant decline in legal overhead costs.⁹⁷

- Liability Costs.

Whether providers will see lower liability costs will depend upon what happens to sum of the claims costs and compensation costs. Overhead costs are likely to decline and it is also possible, but not proven, that total compensation costs will also decline. With the adoption of its D&O program, the University of Michigan has seen its reserves (the amount of money set aside in anticipation of having to pay claims) drop by more than two-thirds.¹⁴⁰ If insurers pass along any savings, it is possible providers may see lower premiums.

- Defensive Medicine.

It remains unclear what effect a properly run D&O system will have on defensive medicine. If a climate of disclosure creates greater trust between patients and providers or lessens the liability threat (litigation and costs), it is conceivable that this could diminish defensive medicine, but no evidence exists with which to evaluate this empirically.

- Supply.

It is unclear whether and to what extent widespread use of the D&O approach would affect physician supply. At least two key factors could be affected by a D&O model: liability costs and the quality of physician-patient relationships. Of these, liability costs will likely have the largest influence on supply. Based on available data that indicate that liability-reducing tort reforms can improve physician supply, it seems likely that a jurisdiction where successful D&O programs were widespread might be more attractive as a practice location for physicians than higher-risk jurisdictions. There is no evidence available to indicate whether individual institutions that have implemented D&O programs have seen an effect on physician recruitment or retention.

- Quality of Care.

Efforts to improve the prevalence of disclosure are on the agendas of several organizations that seek to improve quality and safety.^{108-109, 111, 140-141} Greater disclosure itself is a measure of higher quality care because of the (1) greater transparency and honesty delivered to patients, (2) trust that can be built as a result of it, and (3) better informed decision-making that can result. In addition, disclosure may also have a secondary, downstream benefit on quality improvement efforts. If providers disclose their errors to patients, many subsequent and critical steps to improve patient safety will be made easier: promotion of a culture of transparency and safety, facilitation of reporting of errors (because the error is now known to the patient), and the open discussion of errors so that efforts to improve can be initiated. While disclosure's direct and immediate effect on greater quality is fairly clear, the subsequent downstream quality and safety benefits have not yet been proven.

3.3.3. Summary

D&O programs have only been implemented by a handful of institutions, and only 2 have made public any information about the performance of the programs. Consequently, the evidence base for evaluating the effects of such programs on the key outcome variables is extremely small. However, the anecdotal reports from extant programs are highly impressive in terms of reductions in claim frequency, payouts, and overhead costs. Program administrators also report positive effects on the culture of safety and quality of care within institutions, but these are subjective reports with no accompanying empirical measurements.

On theoretical grounds, widespread implementation of D&O programs appears to hold considerable promise for effecting improvements in all of the key outcome measures. However, there is some risk associated with experimentation with this approach. Most extant programs are in self-insured hospital systems with relatively good ability to influence physician practice, and the potential to achieve high rates of reporting, disclosure, and physician behavior change may be lower for other types of insurers. There is also a risk that poorly executed disclosures or inadequate offers of compensation may inflame patients and families, prompting additional claims. Not all states provide legal protection for statements of apology, so disclosures may result in admissible evidence in malpractice litigation. Finally, there is no information available to shed light on which particular design choices for D&O programs produce the greatest gains.

3.4. Safe Harbors for Adherence to Evidence-Based Practice Guidelines

“Safe harbors” proposals would strengthen health care providers’ ability to use evidence that they adhered to an accepted, applicable clinical practice guideline to defend a malpractice claim. There are two primary rationales for this reform. First, it is intended to help prevent or quickly dismiss claims that lack merit. A reasonable plaintiff’s attorney arguably would investigate whether practice guidelines were applicable to the incident and complied with during the incident before agreeing to pursue a malpractice claim. Nonmeritorious claims would be more easily defended because defendants could offer evidence of the applicable guideline to obtain a rapid judgment on the claim and/or to avoid the “battle of the experts” that typically dominates malpractice trials. Second, safe harbors are intended to reduce the prevalence of defensive medicine. If health care providers know that they will not be held liable for failing to provide tests and services that are not indicated according to the accepted medical standard of care, they will have less incentive to provide such services.

Several states experimented with safe harbors in the early 1990s under limited-time demonstration projects:

- **Maine:** In 1990 and 1991, the Maine legislature passed legislation creating a five-year demonstration project known as the Maine Medical Liability Demonstration Project (MLDP).¹⁴² The MDLP created an affirmative defense for physicians in four selected specialties (obstetrics and gynecology, anesthesiology, radiology, and emergency medicine) who adhered to designated clinical practice guidelines.¹⁴³ In total, about 100 physicians practiced in the state of Maine in these specialties. Physicians were permitted to opt in to the system, and rates of participation varied from 58 percent (in anesthesiology) to 90 percent (in obstetrics and gynecology).¹⁴⁴ The applicable guidelines were selected by a committee composed mostly of physicians, and the committee chose guidelines issued by the national medical associations for the relevant specialties, with some modifications to reflect local practice in Maine.¹⁴⁵ The affirmative defense was (through legislation introduced in 1991) permitted to be raised before

Maine’s pretrial screening panel. The MLDP authorizing legislation did not include funds for an evaluation, but did require insurers to report data on malpractice claims in the 5 years prior to the project and during the project period. In addition to an interim evaluation by the Maine Bureau of Insurance,¹⁴⁶ the project attracted external evaluators, including the General Accounting Office¹⁴⁵ and the Agency for Health Care Policy and Research.¹⁴⁷

- **Florida:** For a 4-year period beginning in 1994, Florida operated the Cesarean Demonstration Project (CDP), which allowed physicians to introduce evidence of compliance with practice guidelines for cesarean section as a defense to a malpractice claim.¹⁴⁸ A limited evaluation of the CDP’s effect on cesarean section rates was conducted.¹⁴⁹ Based on the findings, the project was not renewed in 1998, although the evaluator’s report recommended further experimentation with practice guideline safe harbors.¹⁴⁹⁻¹⁵⁰
- **Minnesota:** In 1992, Minnesota passed legislation allowing the state’s Health Care Commissioner to approve practice guidelines for use as an absolute defense to malpractice claims.¹⁴⁵ No information is available concerning any formal program evaluation. The program was not renewed and Minnesota law now expressly forbids the admission of guidelines issued by a “review organization” into evidence in malpractice litigation.¹⁵¹
- **Vermont:** Vermont passed legislation very similar to Minnesota’s in 1992,¹⁴⁵ but no information on the program is available.

In addition to these demonstration projects, current Kentucky law states that health care providers who adhere to practice guidelines approved by the executive director of the state worker’s compensation program will be presumed to have met the standard of care in malpractice litigation.¹⁵² The safe harbor is, however, limited to providers who are rendering services in connection with injuries eligible for worker’s compensation. The executive director is given latitude to develop the guidelines or to adopt any guidelines issued by “qualified bodies, as determined by the executive director.”

Safe harbor proposals were considered in the Clinton health reform initiative, by Medicare’s Physician Payment Review Commission in 1990, and during the current round of health reform.¹⁵³⁻¹⁵⁴ Aside from Kentucky’s limited program, no state currently has a formal safe harbor. However, courts in all states allow experts testifying in malpractice cases to discuss clinical practice guidelines and their relevance to the standard of care and allow litigants to introduce documents containing the guidelines into evidence.¹⁵⁵ Thus, the primary effects of safe harbors reforms are to increase the weight given to clinical practice guidelines, give litigants the ability to introduce them into evidence without the accompanying testimony of a medical expert, and permit their introduction at an early stage in the litigation in support of a motion to dismiss or motion for summary judgment.

3.4.1. Key Design Features and Decisions

Key design decisions for safe harbors reforms include the following:

- **Nature of the safe harbor:** Although safe harbors for practice guideline compliance are sometimes described as creating “immunity” from suit, applying blanket immunity is not feasible because it will often be unclear whether a covered guideline applies to the particular clinical situation before the court.¹⁵⁶ Instead, safe harbors need to be designed to allow consideration by some qualified decision maker of whether the guideline is relevant to the physician, patient, and clinical situation in the case. Thus, a judge could consider whether to dismiss or enter summary judgment in the case on the basis of the defendant’s proffer of the guidelines. The weight given to the guidelines can vary: the strongest protection would come

from establishing an *irrebuttable presumption* that a health care provider's compliance with a specified guideline in an applicable situation constitutes adherence to the legal standard of care. The plaintiff could dispute the applicability of the guideline, but if it was clearly relevant to the plaintiff's clinical situation, the defendant would have a very strong defense. A lesser form of protection would be to create a *rebuttable presumption*; this would open the door for the plaintiff to contest that the guideline, indeed, reflects reasonable and customary medical practice.^{63, 66}

- **Mechanism of invoking the defense:** Safe harbors are typically described in terms of an *affirmative defense* that a defendant can assert in pleadings at an early stage of the litigation (indeed, state law often requires affirmative defenses to be plead in the defendant's initial answer to the complaint). In states with pretrial screening panels, the defendant can present the guidelines as evidence for consideration by the panel. An alternative would be to require defendants to wait until trial to introduce the guidelines into evidence, but this approach has less potential to reduce litigation costs.¹⁴³ The timing issue is critical not merely because it affects litigation expenses, but also because it determines who will decide whether the proffered guidelines are applicable to the plaintiff's situation. Vesting judges of general jurisdiction with the authority to make this decision on the basis of motions and briefs alone, without benefit of input by medical experts, carries some risk of error in decision making. Judges who believe that important factual issues are contested at this stage will be bound to deny a defendant's motion for dismissal or summary judgment and allow the case to proceed. Pretrial screening panels, in contrast, generally are staffed by physicians, though perhaps not in relevant specialties.
- **Selection of covered guidelines:** The selection of which practice guidelines, among the thousands in existence, will constitute the basis for a safe harbor is likely to be contentious.¹⁵⁵ The decision probably should be reposed with an expert committee, but the composition of the committee itself, particularly the balance between medical experts and other stakeholders, is likely to be controversial.¹⁵⁷ Although Maine relied heavily on physicians to select the guidelines, such an approach carries the risk that the public will perceive the process as biased. An alternative would be to allow trial judges the discretion to determine whether a guideline offered by the defendant is authoritative and applicable,¹⁵⁶ although this removes the decision from individuals with relevant medical expertise.
- **Continuing review process:** A process must also be established for continuing review of selected guidelines to ensure that they remain current and appropriate, and for considering how local variations in medical practice can or should be accommodated in a safe harbors system. The obsolescence of the covered guidelines in the Maine demonstration project has been cited as one reason the project was not more successful.¹⁵⁰
- **Universal vs. opt-in program:** A safe harbor could be made available to any health care provider or only to those who choose to enroll in a safe harbor demonstration project. A universal program has greater potential to impact practice patterns and cost, while an opt-in program may facilitate better tracking of program outcomes and may allow the program administrator to condition the safe harbor on the physician's commitment to perform certain actions or meet certain goals.

- Covered providers: The safe harbor program should specify which types of medical providers are eligible to invoke the safe harbor. Options include: all institutional and individual health care providers; all individual providers; physicians only; and physicians or providers in particular specialties only. The inclusion of providers in a particular specialty only makes sense if the safe harbor includes guidelines that are relevant to that specialty.
- Inculpatory use of guidelines: Some states that have experimented with safe harbors have allowed plaintiffs to use the defendant's noncompliance with the specified guidelines for inculpatory purposes—that is, to show that the defendant was negligent. Others have only permitted the use of guidelines by defendants, to show that they were in compliance with the standard of care. The appeal of the first approach is its evenhandedness and the possibility of reinforcing legal incentives for guideline adherence,¹⁵⁸ while the latter is more narrowly tailored to the goal of reducing nonmeritorious litigation.

3.4.2. Effects on Key Outcome Variables

The evidence base for safe harbors is very small, consisting almost solely of the limited evaluations of the Maine and Florida demonstration projects.

- Claims Frequency and Costs.

In theory, safe harbors should discourage plaintiff's attorneys from bringing claims that clearly lack merit because the facts suggest that a practice guideline was followed. A small empirical literature shows that adherence to practice guidelines in obstetrical practice is associated with reduced medicolegal risk.¹⁵⁹⁻¹⁶⁰ However, there is no evidence from the state demonstration projects to support or rebut the notion that safe harbors decrease the frequency or cost of claims.

It was difficult to evaluate the effect of Maine's demonstration project on claims because the project was so limited in scope. The 22 guidelines selected in Maine covered only select areas of practice within 4 specialties, estimated to constitute 3-4 percent of all medical practice in the state. Moreover, because claims are a rare event for any given physician, an experiment involving such a small number of physicians could not support quantitative evaluation of changes in claiming and claim disposition over time.^{144, 161} Five years into the demonstration, only one claim in which a participating physician invoked a covered guideline as a defense had been reported.¹⁴⁶

Florida's project was even more limited in clinical scope than Maine's. Moreover, the CDP evaluators were unable to obtain data on the frequency of malpractice claims.¹⁵⁰ At the time of evaluation (January 1998), there was no known case of a participating physician invoking a CDP-covered guideline as a defense in a malpractice claim.¹⁵⁰

- Overhead Costs.

No information is available regarding the effect of safe harbors on overhead costs. Theoretically, litigation costs should decrease substantially in cases in which guidelines are applicable and were complied with. However, such cases could represent a small proportion of all claims.

- Liability Costs.

No information is available regarding the effect of safe harbors on liability insurance premiums. The Maine superintendent of insurance estimated that the MLDP would result in a 0.5 percent savings in medical malpractice premiums, but the Bureau of Insurance subsequently reported that it was unable to determine the effects of the MLDP on premiums.^{146, 157} The Florida evaluators also were unable to obtain data to permit an evaluation of the CDP's effect on malpractice premiums.¹⁵⁰ The theoretical connection between safe harbors and insurance premiums is remote; it is mediated by the extent to which quality of care improves as a result of better guidelines adherence and the extent to which attorneys are discouraged from bringing claims.

- Defensive Medicine.

Even if safe harbors have no effect on claims frequency and cost, they may nonetheless have a reassuring effect on physicians that leads to reductions in defensive medical practice. The reassurance may spring from a perception that frivolous claims will be less likely to be brought or easier to defend, or simply from greater clarity about what standard of care the law requires. The appeal of safe harbors is that they target defensive medical practices for which there is little or no evidence of a salutary effect on patient care.⁴⁰ Theoretically, the effect of safe harbors on defensive medicine should vary according to the strength of the safe harbor, the clarity and comprehensiveness of the selected guidelines, the level of physician awareness of the safe harbor, and the extent to which physicians are already practicing in compliance with the guidelines.⁴⁰

The most relevant available evidence concerning these effects is the AHCPR evaluation of the Maine demonstration project.¹⁴⁷ Using medical record reviews and physician and hospital surveys, the evaluation compared obstetrical practice in Maine in the four years following implementation of the project to (1) practice in Maine in the five years prior and (2) practice in Vermont and New Hampshire during the project period. Among the key findings of the evaluation were the following:

- The MLDP did not affect rates of diagnosis of failure to progress and prolonged pregnancy (which are associated with cesarean section) or rates of cesarean section. All of these rates declined among MLDP-participating physicians during the intervention, but similar or greater decreases were seen in the comparison groups.
- The MLDP did improve adherence to guidelines for management of fetal distress. Adherence increased among all groups, but the increase was significantly larger among MLDP-participating physicians. The effects of guideline adherence on birth outcomes were not evaluated.
- Documentation of adherence to the guidelines was higher among MLDP-participating physicians than among others.
- Low proportions of Maine physicians perceived the MLDP to have reduced malpractice risk (38 percent), defensive medicine (25 percent), or cesarean section (10 percent). Only 1 in 5 physicians reported that the MLDP had led them to make changes to their practice; many reported in this and an earlier survey¹⁴⁵ that they were already in compliance with the guidelines.

An earlier evaluation of the Maine project by the General Accounting Office was unable to draw conclusions about the effect of the MLDP on defensive medicine because of the unavailability of baseline data on utilization of sentinel procedures and inability to control for confounding effects of regulatory changes, changes in insurance coverage, and changes in insurance reimbursement in Maine during the study period.¹⁶²

The results of the Florida evaluation are not publicly available at this time. However, the Florida CDP had very limited uptake among eligible physicians: only 20 percent of obstetricians chose to participate. This limits the prospects for affecting any of the key outcome variables.

- Supply.

No information is available regarding the effect of safe harbors on physician supply. Theoretically, a safe harbor program with demonstrated success in reducing malpractice risk could serve as a magnet for physicians who experience liability pressure in other states.

- Quality of Care.

Safe harbors programs have considerable theoretical promise for improving the quality of care by providing incentives for adherence to evidence-based practice guidelines (assuming that the guidelines selected for coverage by the safe harbor reflect high-quality, evidence-based care). However, little is known about how this plays out in practice. The effects of the MLDP on outcomes of care were not evaluated, nor were its effects on adherence to practice guidelines in specialties other than obstetrics. The MLDP resulted in higher adherence to guidelines for management of fetal distress among participating physicians than among comparators, but was not associated with higher rates of adherence to other practice guidelines. Survey evidence suggests that obstetrical practice may have been relatively static under the MLDP because most physicians believed they were already following the selected guidelines at the time of project implementation.¹⁴⁷

3.4.3. Summary

Safe harbors have considerable appeal as a mechanism for discouraging frivolous malpractice claims, reducing defensive medicine, and providing incentives to move toward evidence-based care. However, existing experimentation with safe harbors is too limited and too poorly evaluated to provide reliable evidence for or against the concept.

3.5. Subsidized, Conditional Reinsurance

Reinsurance is defined as insurance purchased by primary insurers to limit their loss exposure for very high-severity claims. More broadly, the concept of secondary-layer insurance is that some third party offers insurance coverage that kicks in when a claim exceeds a particular dollar threshold. In this discussion, we use the term “reinsurance” in this broad sense and discuss proposals to offer such reinsurance to health care providers on a subsidized basis if they achieve particular patient safety goals or satisfy other conditions.

A precedent for government-subsidized medical liability reinsurance exists in state-run patient compensation funds (PCFs). At least thirteen states have enacted legislation authorizing PCFs.¹⁶³⁻¹⁶⁴ The funds are currently operated in 10 of these states (IN, KS, LA, NE, NM, NY, PA, SC, WI, WV).¹⁶³⁻¹⁶⁴ Of the remaining 3, PCFs were never implemented in 2 states (OR, WY), and in 1 state (FL) the PCF has been

closed.¹⁶³⁻¹⁶⁴ The goals of PCFs are to make affordable insurance coverage available and affordable to providers and to ensure that patients will have access to larger awards.¹⁶⁴⁻¹⁶⁵ In general, these funds operate by providing liability coverage for judgments or settlements in excess of the primary insurance coverage. Nearly all states have minimum levels of primary coverage that providers must carry, but the amounts vary from state to state. PCFs may assume liability above a specified threshold or between two specified thresholds.

PCFs are typically financed by a surcharge levied on individual and institutional health care providers, and may be partially subsidized by the state government. Physician participation in PCFs can be voluntary or mandatory. PCFs can be subject to issues of adverse selection if voluntary and issues of equity if mandatory (providers in low-cost areas will subsidize those in high-risk areas). Despite their long existence, PCFs have received very little attention in the academic literature.¹⁶⁴

There is no precedent for conditioning subsidized reinsurance on patient safety improvements or other requirements. Participation in PCFs has traditionally been open to all providers on the basis of licensure status and payment of the surcharge. However, a related proposal is found in the Institute of Medicine's 2003 report, *Fostering Rapid Advances in Health Care: Learning from System Demonstrations*.¹²⁵ The report recommended experimentation with state-based demonstration projects of Early Offer or administrative compensation in which participants would be given government reinsurance or other umbrella coverage. The purpose of the reinsurance was to provide incentives for participation by minimizing the downside risk.

In considering the potential for conditional, subsidized reinsurance to impact the key outcome variables discussed in this report, it is useful to consider not only the experience of PCFs, but also that of "pay-for-performance" programs implemented by health insurers. The rationale for conditioning part of a provider's reimbursement on the achievement of certain goals or standards is to provide a financial incentive for quality and outcomes improvement. The past decade has seen considerable growth of pay-for-performance schemes,¹⁶⁶⁻¹⁷¹ with Medicare, Medicaid, and several private payers now offering payment for a broad range of measures.^{166-169, 171-172} The evidence base concerning the effectiveness of pay-for-performance, too, is growing. Some studies show modest improvements in health outcomes and process measures of quality of care, but others do not demonstrate any improvement).^{166, 173-179}

3.5.1. Key Design Features and Decisions

Innovative programs that conditioned reinsurance for providers on the achievement of patient safety or risk management goals would confront several key design choices.

- **Value of subsidy:** The program will need to determine how much of a subsidy will be offered for the reinsurance and how extensive the reinsurance coverage will be (i.e., what the triggering threshold is). The greater the subsidy and coverage, the larger the incentive to the provider to achieve the specified conditions. If the financial benefits of the subsidy are minimal (or eclipsed by the cost of meeting the performance goal), the incentive to motivate the selected patient safety benefits may be trivial.^{173, 177, 180} One recent analysis of the Bridges to Excellence pay-for-performance program found that with larger physician incentives, there was greater physician participation.¹⁸¹ Of note, subsidized reinsurance will have less value in states with lower liability costs.

Subsidy financing: The program will also need to decide how the subsidy will be financed. PCFs have almost universally been funded by assessments on providers, with one state providing public funding.¹⁶⁴ Subsidized reinsurance could be financed through mandatory provider surcharges that are later refunded to providers who meet the specified conditions; through surcharges levied only on non-performing providers; or through general state revenue that is used to purchase policies for performing providers. Analogously, pay for performance can either be arranged as a withhold on physician reimbursement or as an additional bonus pool. Logically, if payment rates are identical in the two choices, physicians would prefer the bonus model. However, behavioral economics research suggests that people are more risk averse in the domain of losses, so withholds and surcharges may induce stronger compliance.

- Mandatory primary coverage and minimums: If reinsurance will be offered at a subsidized rate, providers should carry primary coverage to prevent all risk from being shifted to the reinsurance pool. All PCFs have set minimum primary coverage limits.¹⁶⁴⁻¹⁶⁵
- Mandatory vs. voluntary reinsurance purchase: If reinsurance purchase is mandatory, this will help more evenly spread the reinsurance pool risk. It will also help strengthen the incentive because all providers will have an additional expense that can be reduced through the achievement of patient safety goals. If the reinsurance is voluntary, not only does the risk of adverse selection rise, but the incentive is lost for those not purchasing.
- Selection of patient safety goals: The selection of appropriate patient safety goals can be a broad and daunting task. However, if the goal is that the government to bear some liability risk, it would make sense to select goals in areas of patient harm that are known to increase liability exposure. This strategy would best synchronize patient safety improvement with liability reduction. Targets of opportunity could be centered in the areas that comprise the bulk of malpractice claims costs: medication-related injury, missed and delayed diagnoses, surgery-related injuries, and obstetrical injuries.⁹⁹ By contrast, many current pay-for-performance metrics are focused on quality of care initiatives that do not necessarily impact high-liability-risk areas.¹⁷² There do, however, exist many areas of overlap between the current quality-focused environment and high-liability areas. For example, The Joint Commission maintains accreditation standards on reducing the risks associated with anticoagulants (medication-related); wrong-site surgeries and surgical infections (surgery-related), and critical test results (missed and delayed diagnoses).¹⁸² Care must be taken to select measures that will not lead to unintended consequences.^{175, 177}
- Selection of target level performance: Once the goals or measures are determined, setting the target performance becomes important.¹⁶⁸ Targets can be set for a provider to score relatively high compared to predetermined peers, meet an absolute target, meet an absolute target and improve from the previous year, or improve from the previous year.
- All or nothing vs. incremental returns for performance: Some providers may make progress toward, but not entirely achieve target performance levels on selected patient safety goals. For these providers, a decision will have to be made on whether or not they will be eligible to receive a portion of the subsidy or none of it. The benefit to creating the possibility of a partial return is that it gives a continuing incentive to improve performance even if the ultimate target will not be reached. Research on pay-for-performance also suggests that all-or-nothing,

threshold-based systems tend to reward already high-performing providers, enervating incentives for low baseline performers to improve.¹⁷⁹

3.5.2. Effects on Key Outcome Variables

In the absence of direct evidence pertaining to subsidized reinsurance conditioned on the achievement of patient safety goals, conclusions concerning the likely effects of this reform can only be hazarded based on the findings from the two related initiatives we have identified, PCFs and pay-for-performance schemes, as well as theoretical predictions.

- Claims Frequency and Costs.

Whether or not subsidized, conditional reinsurance will affect claims will depend upon three major factors: (1) the effect of higher coverage limits on claims; (2) how often providers will achieve the selected safety goals; and (3) how effective the goals are at reducing claims.

There is no theoretical reason to believe that reinsurance would alter the number of claims brought. States with PCFs have not been found to experience higher frequency of paid claims.¹⁶⁴ Theoretically, ensuring that providers have access to affordable reinsurance could increase claims payouts by expanding the pool of resources available to claimants. One concern frequently voiced about PCFs is that primary insurers have less incentive to settle high-value cases because they do not bear the risk associated with a large trial verdict.¹⁷ Moreover, to the extent that subsidized reinsurance makes more compensation available for patients (via greater availability of higher coverage limits), total liability payouts may rise. These theoretical predictions have not been tested. No studies have examined whether average claim payouts or insurers' total losses vary systematically across states that do and do not have PCFs.

For a discussion of the prospects for reducing injuries that lead to claims, please see the Quality of Care section below. Overall, there is no basis for concluding that subsidized, conditional reinsurance would lower claim frequency or total claims costs significantly.

- Overhead Costs.

To the extent PCFs may act as passive financial intermediaries, claims may be settled more quickly (because primary insurers will have a reduced incentive to litigate large claims down to upper coverage limits) and lead to a reduction in overhead costs. Limited experience from PCFs has demonstrated that this may indeed be the case.^{17, 164}

The incentive portion of the subsidy for safety goals program need not necessarily affect overhead costs per claim, but the administration of the incentive program (i.e., selecting patient safety goals and target levels and measuring performance) will involve its own overhead costs. These costs will not be allocated to malpractice claims handling, but would be new expenses nevertheless.

If the patient safety goal that providers must achieve is implementation of an Early Offer or D&O program, as opposed to instituting particular clinical process improvements to reduce medical errors, additional savings in overhead costs may result from the accompanying improvements in time to incident resolution.^{119, 123, 126}

- Liability Costs.

Although subsidized, conditional reinsurance may not decrease total claims costs, it would shift the burden of these costs away from physicians' primary insurers. Primary carriers should pass along this benefit to their insured physicians in the form of lower premiums.^{17, 164} Whether physicians' *total* liability insurance costs decrease, however, depends on whether a surcharge is levied on physicians to fund the reinsurance and the amount of the surcharge. Of course, reinsurance that was entirely paid for by the government, with no surcharge levied on providers, would result in lower premium costs for providers relative to what they now pay for full coverage.

Researchers have not been able to conclusively show that PCFs affect the availability or affordability of malpractice insurance.¹⁶⁴ Although it would seem certain that the availability of PCFs would reduce primary insurance premiums, the combined cost of primary- and secondary-layer coverage will not necessarily be lower. It does seem plausible that the widespread availability of reinsurance in a state would make the state attractive to primary insurers, thereby helping to ensure availability of primary-layer coverage. This has been reported anecdotally concerning PCFs.¹⁶⁴ Greater competition among carriers in a market may help constrain the growth of premiums as well. In addition, to the extent that the "carrot" of subsidized reinsurance is effective in stimulating providers to make patient safety improvements, long-term savings in liability costs could be realized through reduction of medical errors, although this is quite speculative.

- Defensive Medicine.

To the extent that PCFs can protect providers from larger awards, they may reduce incentives to practice defensive medicine. However, a larger driver for defensive medicine is likely the psychological stress of a suit (e.g., the fear of reputational harm, the discovery and trial process, and reporting requirements), rather than the amount of the award. Although reinsurance theoretically reduces the risk that a physician will incur a judgment in excess of his policy limits, threatening his personal assets, research suggests that in practice, malpractice cases rarely settle above the defendant's policy limits.¹⁸³ Overall, the impact on defensive medicine is likely to be minimal, but no data exist to inform conclusions.

- Supply.

To the extent that patient compensation funds would make liability coverage more available and affordable, physician supply may increase. However, studies evaluating the effects of PCFs on physician supply have not found any improvement.^{24, 29} If the creation of unconditional insurance subsidies does not improve physician supply, it follows that insurance subsidies that are harder to obtain because they are conditioned on performance goals are even less likely to benefit physician supply.

- Quality of Care.

The linkage between PCFs and quality of care has not been studied, presumably because that is not PCFs' purpose. PCFs are created to address providers' concerns about insurance availability and affordability and patients' access to sufficient resources to pay large damage awards. Theoretically, the presence of PCFs or other forms of reinsurance may dampen incentives for safety improvement by reducing the economic consequences of harmful errors.¹⁶⁴

Pay for performance, in contrast to PCFs, is designed to improve the quality of care. However, as discussed above, it is too early to draw conclusions about whether pay for performance can induce significant improvements in quality.^{166-167, 175} There have been some success stories which suggest it has promise—for example, a recent evaluation of the impact of the Centers for Medicare and Medicaid Services’ pay-for-performance demonstration project for hospital care found an improvement of 2.6 to 4.1 percent in performance measures over a 2-year period. Overall, though, substantial returns to quality or patient safety are not in evidence.^{174, 178}

A key question is whether provision of subsidized reinsurance will be enough of an incentive to motivate safety-enhancing change on the part of physicians and health care organizations. Rational actors will weigh the relative costs of investment in safety improvements against the savings associated with the reinsurance subsidy. They may find that the cost-benefit balance disfavors attempts to meet the conditions established for obtaining the subsidy. On balance, there is a very thin basis for predicting effects of subsidized, conditional reinsurance on quality of care, but the pay-for-performance literature is mildly suggestive of modest benefits.

3.5.3. Summary

Government provision of subsidized reinsurance for providers who achieve patient safety goals can be viewed as a pay-for-performance initiative aimed at easing providers’ liability cost concerns and improving patient safety. The evidence base for evaluating this proposal is very limited, requiring reasoning by analogy from the experience of PCFs and pay-for-performance reimbursement programs. Overall, the evidence does not suggest that subsidized, conditional reinsurance would substantially affect claim frequency or total claims cost, although it would shift the cost burden away from physicians and primary insurance carriers unless a surcharge was levied on them to pay for the scheme. To the extent that subsidized reinsurance can lower or stabilize the premiums that physicians pay, an increase in physician supply is possible, but the available data do not support such an effect. Perhaps the most alluring aspect of subsidized, conditional reinsurance is the direct incentive to improve quality and safety in high-risk clinical areas. Effective incentives will depend on the relative costs of the subsidy compared to the clinical interventions needed to improve safety.

3.6. Enterprise Medical Liability

Enterprise medical liability is a legal doctrine assigning liability to a health care organization for tortious injuries that occur within its facilities or are caused by its clinical staff affiliates, including but not limited to its employees. Under this system, the liability of individual physicians and other clinicians is reduced or eliminated.

Courts historically have been reluctant to impose liability for medical malpractice on hospitals, and state statutes prohibiting the “corporate practice of medicine” have made it difficult for litigants to argue that hospitals should be held liable for malpractice. Although some judicial loosening in this area has been visible over time, it remains difficult to hold health care facilities directly liable for medical malpractice outside of a few narrow circumstances. These circumstances include negligence in the administrative functions that hospitals perform, such as credentialing decisions and general quality oversight; vicarious liability for the acts of hospital employees; and negligent acts by anesthesiologists, radiologists, pathologists, and others who perform services for which patients look to a hospital (as opposed to a

particular physician).¹⁸⁴⁻¹⁸⁶ In other situations, it is individual, non-employee physicians who are held liable.

The two most important rationales for imposing enterprise medical liability are economic efficiency and fairness. In the malpractice context, enterprise medical liability addresses the perceived unfairness of holding individual health care providers liable for “systems failures” within an organization that lead to preventable injuries and that the individuals have little or no ability to control. The efficiency rationale is that placing liability on the organization provides economic incentives for the organization—which *does* have control over the “systems failures” and is in a position to prevent injuries at a lower cost than the clinician—to invest in cost-justified changes to improve patient safety.¹⁸⁷ Future injuries will therefore be prevented at a socially efficient level. Without enterprise medical liability, the tort system sends an economic signal to actors who arguably are not in a good position to effect the kind of changes that are needed to prevent injuries.

A third rationale for enterprise medical liability is to ensure that injured plaintiffs receive the compensation to which they are entitled. Holding health care organizations liable introduces “deep pockets” defendants that can pay judgments that individual physicians may not be well enough insured to pay in full.

A fourth rationale is that enterprise medical liability permits more effective use of experience rating in insurance.¹⁸⁸ Experience rating is the practice of pricing insurance premiums to reflect the insured’s past claims experience. This is actuarially difficult to do for individual physicians because they are sued so infrequently, but it is considerably easier at the level of the health care organization. The advantages of experience rating are that it more fairly apportions insurance costs to those who create losses and that it more accurately targets the “deterrent signal” of the tort system to those who most need to modify their behavior in order to prevent injuries.

Although there is variation across states in the circumstances under which a health care organization can be held liable for malpractice, enterprise medical liability is not currently available in any state. A proposal for demonstration projects of health-plan-based enterprise medical liability was part of the Clinton health reform package. However, the proposal did not advance due to adverse reactions, ranging from disinterest to strong opposition, on the part of key stakeholder groups, including physician organizations, liability insurers, plaintiff’s attorneys, and managed care organizations.^{185, 189}

3.6.1. Key Design Features and Decisions

Key design decisions for enterprise medical liability reform include the following:

- **Liabile enterprise:** Some proposals for enterprise medical liability have focused on health plans as the locus of liability,^{73, 74, 75, 76, 190} while others have suggested that hospitals and other health care provider organizations serve as the responsible enterprise.^{48, 185, 188, 191-192} Today, the latter formulation receives more attention in policy debates, largely due to the ascendancy of network-model managed care organizations in the market, which have less control over their affiliated physicians than closed-panel HMOs.¹⁸⁹ The “accountable care organization” (ACO) is another, more modern concept with potential applicability for this reform.¹⁹³ Economic theory suggests that liability should be placed on an organization that can realistically be expected to have the power to institute systemic patient safety improvements within health care systems and influence individual physician behavior. ACOs may be more likely than health insurers and

some hospitals to have this characteristic.¹⁹¹ Health insurers' leverage may vary considerably depending on their market share and the nature of their affiliation with physicians, and many community hospitals (as opposed to academic medical centers) may not have close relationships with the physicians they credential. On the other hand, placing liability on health plans is argued to serve as a counterweight to health plans' extant incentives to provide less care than might be medically optimal.¹⁸⁹

- **Role of individual liability:** Most proposals for enterprise medical liability specify that there would no longer be any liability for individual clinicians.⁴⁸ An alternative would be to greatly expand the potential for holding health care organizations liable while retaining the possibility of holding individuals liable as well. Different rules could be imposed depending on whether the care was rendered within the walls of a hospital or other health facility as opposed to a non-hospital-affiliated physician office. Individual liability might also remain available in the rare case of extreme negligence or deliberate conduct on the part of the physician. The strongest rationale for allowing individual liability is the fairness argument that health care facilities and payers cannot completely control the actions of individuals, particularly when the individuals are not employees of the organization. If the responsible enterprise is a health care facility or system rather than a health plan, one must also consider the need to make compensation available to patients who are injured in an unaffiliated physician office. The strongest argument against retaining individual liability is that pure enterprise medical liability maximizes the incentive for the organization to institute systems improvements to improve patient safety, including improvements designed to detect and mitigate the consequences of error on the part of individuals working within the organization. Pure enterprise medical liability is also a simpler regime that avoids fights among defendants in a malpractice case about who was responsible for the injury.
- **Scope of liability:** In the context of facility-based enterprise medical liability, the organization's liability could be limited to injuries that occur within its walls or could extend to all injuries caused by physicians whose primary affiliation is with the facility.¹⁸⁵ The former would more tightly tie liability to the hospital's ability to prevent injuries, but administrative costs would be higher because physicians would still need to purchase insurance to cover injuries that occur outside the hospital, and physicians and hospitals could expend resources disputing where the injury occurred. Where the locus of liability is a health plan, the plan's liability could be limited to injuries caused by physicians who receive the greatest share of their reimbursement from that payer, or could extend to any injury incurred by the plan's insured patients. The former would better peg liability to the plan's ability to influence the physician's practice, since the plan's threat not to contract with physicians in the future if they did not improve would have greater financial consequence for the physician. However, it could allow plans that did not have a large market share to evade liability altogether.
- **Contributory or comparative negligence defense:** Most states currently allow evidence of a plaintiff's own negligence to be introduced and allow juries and judges to reduce a plaintiff's award according to her own percentage fault. In some states, if a plaintiff is more than 50 percent contributorily negligent, she will recover no money at all, even if the defendant was also negligent. For example, a plaintiff who failed to disclose an important risk factor in his medical history before a surgical procedure might be held contributorily liable for an adverse surgical outcome relating to that risk factor. A decision should be made about whether these defenses will apply in cases involving enterprise medical liability. The strongest argument in favor of

eliminating them is to maximize the enterprise's economic incentive to improve safety. The strongest arguments against eliminating them are fairness to the defendant and the need to incentivize organizations to invest only in the socially optimal level of precaution-taking.

- Status of damages caps and charitable immunity laws: States with laws providing not-for-profit hospitals with total immunity from malpractice suits or limiting their liability would need to be reconsidered if enterprise medical liability were imposed. Charitable immunity laws would need to be struck. Damages caps could theoretically be retained, but would undermine the intent of enterprise medical liability. In a pure regime where no suit against individual physicians was possible, caps could also severely limit the available compensation for injured patients.
- Financial arrangements: The shift to enterprise medical liability would involve cost shifting from physicians to health care facilities or health plans, as physicians reduced or eliminated their separate malpractice insurance coverage and the liable enterprise increased its own coverage. Presumably, the liable enterprise would choose to transfer some of these costs back through their contractual arrangements with physicians—for example, by applying surcharges on hospital admitting privileges or adjustments to insurance reimbursement rates.¹⁸⁵ Since Medicare's fee schedule already includes a factor for malpractice insurance costs, Medicare reimbursements rates for both physician and hospitals certainly would be adjusted in a health-plan-based enterprise liability scheme.
- Voluntary or mandatory: Enterprise medical liability is generally discussed in the literature as a mandatory scheme imposed by statute. An alternative is that health plans or health care facilities could voluntarily elect to assume liability for some or all of their affiliated physicians, with the physicians agreeing by contract to the necessary financial adjustments to finance the new arrangement. (Patients would also need to be given notice of the arrangement and an opportunity to consent to being subject to it.) An advantage to this approach would be that it permits experimentation with different approaches. One drawback would be that hospitals or health plans who opted in to higher liability costs and failed to fully pass them back to physicians could find themselves at a competitive disadvantage in the marketplace.¹⁸⁹ A second disadvantage would be the fragmentation of incentives that would occur if not all physicians affiliated with the sponsoring hospital or health plan agreed to participate in the new arrangement. Similarly, incentives for safety improvement within hospitals would be fragmented if some, but not all, important payers assumed liability for malpractice.

3.6.2. Effects on Key Outcome Variables

There is a very limited evidence base upon which to base conclusions about the likely effects of enterprise medical liability. Although there are several institutions in the U.S. that reflect principles of enterprise liability, no studies are available comparing their experience and performance on key outcome variables to other types of institutions in a manner that enables isolation of the effect of the enterprise liability. The relevant institutional examples include:

- **Veterans Health Administration (VA) hospitals**. Individual VA physicians cannot be sued; under the Federal Tort Claims Act, the U.S. government consents to be sued for malpractice relating to care in VA hospitals, but a range of special conditions apply. The government also makes available an administrative process for obtaining service-connected disability compensation for

injuries incurred in VA hospitals. The range of special circumstances surrounding the VA system makes it an inapt analogy for how enterprise medical liability would work in non-federal hospitals.

- **Hospitals owned and operated by the University of California.** State law makes the Regents of the University of California liable for the actions of physicians practicing within them.⁴⁰
- **Academic medical centers** that are self-insured and directly employ physicians, along with other clinical staff, providing them with malpractice insurance through the hospital as part of their employment arrangement. Physicians in these centers can, of course, be sued. However, the “channeling” of insurance into a single policy makes the medical center financially responsible, and as a practical matter, many such hospitals encourage malpractice plaintiffs to drop individual clinicians from their claim and proceed only against the medical center.
- **Integrated delivery systems** such as Kaiser Permanente, which serve as both insurer and health care provider, directly employing their clinical staff and furnishing liability insurance as part of the employment contract. Although physicians can be sued in such systems, the institution foots the bill for the liability.

- Claims Frequency and Costs.

No conclusions about the effect of enterprise medical liability on the frequency of malpractice claims can be drawn on the basis of the available evidence. There is no theoretical reason that claims should become more or less frequent in the absence of individual physician liability.

No conclusions about the effect of enterprise medical liability on the cost of malpractice claims can be drawn on the basis of the available evidence. The fact that liability is borne by one entity rather than another does not affect the valuation of any particular plaintiff’s damages, and should not affect indemnity payments in that respect. It is possible that plaintiffs could have an easier time proving a case against a hospital than against individual clinicians, but this is not clear. It is possible, but not proven, that enterprise liability could spur health plans or hospitals to invest in safety improvements that result in lower malpractice costs. However, because most instances of medical error and negligence never result in malpractice claims, but there are many claims that do not actually involve negligence, even significant improvements in patient safety may not translate into a large reduction in malpractice claims.¹⁹⁴

- Overhead costs.

No conclusions about the effect of enterprise medical liability on the frequency of malpractice claims can be drawn on the basis of the available evidence. Theoretically, defense costs should be lower in a system of pure enterprise liability for claims involving injuries in which more than one health care provider is implicated. In such cases, there is no need for individual clinicians to be represented by separate counsel and no battling among litigants as to who is responsible for the plaintiff’s injury. Overhead costs for liability insurance should also be lower in a pure enterprise liability system because individual clinicians should not need to take out separate insurance policies (except to cover claims arising from conduct that is carved out of enterprise liability, such as intentional acts).

- Liability costs.

Under enterprise medical liability, physicians would certainly pay less (perhaps nothing) for malpractice insurance. However, the responsible enterprise likely would find mechanisms for transferring some or all liability costs back to physicians through other means.

- Defensive medicine.

No conclusions about the effect of enterprise medical liability on defensive medicine can be drawn on the basis of the available evidence. In theory, enterprise medical liability should provide considerable relief to physicians who currently feel pressured by liability concerns to practice defensively. However, this relief would be undercut if the responsible enterprise transferred liability costs back to individual clinicians by adjusting their salary or reimbursement or levying a surcharge.

- Supply.

No conclusions about the effect of enterprise medical liability on defensive medicine can be drawn on the basis of the available evidence. To the extent that physicians felt more comfortable practicing in settings in which they did not have individual liability, institutions with enterprise medical liability theoretically should attract physicians. There is some evidence that during the recent malpractice insurance crisis, physicians in one hard-hit state, Pennsylvania, sought closer ties to hospitals that could offer them more affordable insurance coverage.¹⁹⁵ However, there has not been a general influx of physicians into institutions such as the VA or academic medical centers that offer channeled insurance.

- Quality of care.

No conclusions about the effect of enterprise medical liability on the quality of care can be drawn on the basis of the available evidence. There are strong theoretical reasons to believe that hospital- or ACO-based enterprise medical liability would spur greater efforts to improve the safety of medical care. Recent research indicates that medical error causation tends to reflect a complicated web of individual and system factors.^{187, 196} Academic medical centers and other hospitals that have some means of exerting influence over the physicians that practice within them are well placed to implement systemic improvements and communicate necessary improvements in individual physician practice to physicians. Additional tort liability could create the necessary economic incentives to spur hospitals to invest in safety-enhancing practices, although as long as malpractice claiming rates are low relative to the actual incidence of medical error, the incentive will remain enervated.¹⁹⁷

No systematic studies are available to examine the safety-enhancing effects of enterprise medical liability, but anecdotal evidence of initiatives launched by academic medical centers are often cited as “proof of concept.” There is no evidence that care is safer overall in such hospitals than in hospitals that do not bear as large a share of tort liability, but anecdotes abound of proactive hospitals and captive insurers who recognize areas of significant loss among their malpractice claims and institute programs to reduce risk in those areas. The best known example is the Harvard hospitals’ successful anesthesia safety initiative,¹⁹⁸ but there are many others.¹⁸⁸

The prospects for health-plan-based enterprise liability to produce changes in quality of care seem more limited. Most health insurers have a fairly low degree of control over the practices of their affiliated physicians and hospitals, although this varies across health plans. Direct controls such as utilization review have given way to “pay for performance” (P4P) programs that seek to incentivize changes in

practice pattern rather than directly alter them. These programs have met with limited success.¹⁷⁹ It seems likely that P4P programs would be the main mechanism through which health plans would seek to influence physicians and hospitals to adhere to safe practices and avoid malpractice claims, but it is not clear that enterprise liability would produce significant marginal gains relative to what has been achieved through existing P4P programs.

An argument that is sometimes raised against enterprise medical liability is that removing individual liability would dampen physicians' incentives to practice safely. There is no evidence to support or refute the notion that greater insulation from tort liability results in less safe care by physicians, and many theoretical reasons to question the value of tort liability in spurring safer practices among physicians.¹⁹¹ Because hospitals experience malpractice claims more frequently than individual physicians, arguably, the incentive to institute improvements and to monitor and encourage improvement among "problem" physicians is stronger at the hospital level.

3.6.3. Summary

Enterprise medical liability is promising on theoretical grounds, but existing examples of this arrangement in the U.S. are limited and have not been evaluated in a way that supports inferences about its effect on any of the key outcome variables.

4. Conclusions

The findings of this analysis concerning the effects of traditional and innovative tort reforms are summarized in Tables 3 and 4, respectively. Table 3 describes the level of empirical *evidence* underlying the reforms' effect on each of the outcomes variables. In contrast, because the base of evidence for the innovative reforms is so limited, Table 4 describes the certainty with which the effects can be *predicted* based on theory, anecdotal reports, and related programs, rather than the strength of the direct evidence.

We find that the evidence base for evaluating most traditional state tort reforms is large and mature. However, studies have generated limited or no evidence that most reforms have significant effects on the key outcome variables examined in this report. The exception is caps on noneconomic damages, which have well-documented effects on several of the outcomes.

The evidence base for evaluating the innovative tort reforms is extremely small. Most have not been tested in the U.S., and where experimentation has taken place, the programs have not been systematically evaluated, at least in materials released to the public. Analogous systems in the U.S. and abroad are not clearly predictive of how these innovative systems would function in the American medical liability setting, and much depends on the choices made about various aspects of system design. However, based on theoretical predictions and the limited evidence available, most of these reforms show sufficient promise for impacting some of the key outcome variables to merit controlled experimentation, such as through demonstration projects.

Two important limits on the scope of our analysis should be noted. First, constitutional and other legal barriers to implementing these reforms have been noted only selectively and in passing. They merit much more serious consideration in any process of further experimentation, particularly with the more innovative reforms and particularly where patient participation in an alternative system is made

mandatory. Second, this report has not considered how the various reforms could be implemented through the Medicare program. However, other scholarship provides some insights.^{81, 199-201}

In closing, tort reform in the states to date has been characterized by a pattern of imitation of reforms implemented in other jurisdictions—even in the absence of evidence that they are effective in achieving their goals. Reform initiatives have often been driven by health care providers’ and insurers’ urgent demands that policy makers do something to ameliorate the effects of highly volatile liability environments. Today, most states are experiencing at least a moderate easing of the “crisis” conditions of the last decade. This environment presents more favorable conditions for experimentation with more novel reforms.

Table 3. Summary of Evidence Concerning the Effects of Traditional Tort Reforms

	Claims frequency and costs	Overhead costs	Liability costs	Defensive medicine	Supply	Quality of care
Caps on noneconomic damages	0 for frequency (M) ↓↓ for costs (M)	↑ (L)	↓ for premiums (M)	↓ (H)	↑ (M) for physician supply 0 (L) for health insurance premiums	0 (L)
Pretrial screening panels	0 (H) for frequency and costs	↑ (L)	0 (M)	↓ (L)	0 (L)	0 (L)
Certificate of merit	0 (L) for frequency and costs	↑ (L)	0 (L)	0 (L)	0 (L)	0 (L)
Attorney fee limits	0 (H) for frequency and costs	↑ (L)	0 (H)	0 (L)	0 (M)	0 (L)
Joint-and-several liability reform	0 (L) for frequency, 0 (H) for costs	0 (L)	0 (M)	0 (M)	0 (M) for physician supply ↓ (L) for health insurance premiums	0 (L)
Collateral-source rule reform	0 (M) for frequency, 0 (H) for costs	0 (L)	0 (M)	0 (H)	0 (M) for physician supply ↓ (L) for health insurance premiums	0 (M)
Periodic payment	0 (L) for frequency, 0 (M) for costs	0 (L)	0 (L)	0 (L)	0 (M)	0 (L)
Shorter statute of limitations/repose	0 (M) for frequency, 0 (M) for costs	0 (L)	↓ (M)	0 (L)	0 (L)	0 (L)

Notes:

Effects are classified as large increase (↑↑), modest increase (↑), no change (0), modest decrease (↓), or large decrease (↓↓).

Evidence or certainty levels for these effects are classified as low or theoretical only (L), moderate (M), or high (H).

Table 4. Summary of Probable Effects of Innovative Tort Reforms

	Claims frequency and costs	Overhead costs	Liability costs	Defensive medicine	Supply	Quality of care
Schedule of noneconomic damages	0 (L) for frequency 0 (L) for costs (highly dependent on award levels)	↓ (L)	↓ (L)	↓ (L)	0 (L)	0 (L)
Administrative compensation systems or “health courts”	Medical court model: 0 (L) for frequency 0 (L) for costs Administrative model: ↑↑ (M) for frequency, 0 (L) for costs	Medical court model: ↓ (L) Administrative model: ↓↓ (H)	Medical court model: 0 (L) Administrative model: 0 (L)	Medical court model: 0 (L) Administrative model: ↓ (L)	Medical court model: 0 (L) Administrative model: 0 (L)	Medical court model: 0 (L) Administrative model: ↑ (M)
Disclosure-and-offer programs	↓ (L) for frequency, ↓ (L) for costs	↓↓ (M)	↓ (L)	0 (L)	0 (L)	↑ (M)
Safe harbors for adherence to evidence-based practice guidelines	0 (L) for frequency, 0 (L) for costs	↓ (L)	0 (L)	↓↓ (L)	↑ (L)	↑↑ (L)
Subsidized, conditional reinsurance	0 (M) for frequency, 0 (M) for costs	↓ (L) (possibly greater savings with early offer or disclosure programs)	0 (M) (possibly ↓ with early offer or disclosure programs)	0 (L)	0 (M)	↑ (L)
Enterprise liability	0 (L) for frequency, 0 (L) for costs	↓ (L)	↓ (L)	↓ (L)	0 (L)	↑ (L)

Notes:

Effects are classified as large increase (↑↑), modest increase (↑), no change (0), modest decrease (↓), or large decrease (↓↓). Certainty levels for these predicted effects are classified as low (L), moderate (M), or high (H).

References

1. Washington State Task Force on Noneconomic Damages. Report to the Legislature. 2005. (Accessed October 7, 2009, at <http://www.ofm.wa.gov/rmd/publications/nedfinalrpt.pdf>).
2. Mello MM. Medical Malpractice: Impact of the Crisis and Effect of State Tort Reforms. Princeton, NJ: The Robert Wood Johnson Foundation; 2006. Report No.: 10.
3. RAND. COMPARE Dashboard: Analysis of Medical Malpractice. 2009. (Accessed at <http://www.randcompare.org/analysis-of-options/analysis-of-medical-malpractice#spending>).
4. Struve CT. Expertise in Medical Malpractice Litigation: Special Courts, Screening Panels, and Other Options; 2003.
5. Avraham R. An Empirical Study of the Impact of Tort Reforms on Medical Malpractice Settlement Payments. *Journal of Legal Studies* 2007;36:S186-S229.
6. Waters TM, Budetti PP, Claxton G, Lundy JP. Impact of State Tort Reforms on Physician Malpractice Payments. *Health Affairs* 2007;26:500-9.
7. Donohue JJ, Ho DE. The Impact of Damage Caps on Malpractice Claims: Randomization Inference with Difference-in-Differences. *Journal of Empirical Legal Studies* 2007;4:69-102.
8. Zuckerman S, Bovbjerg RR, Sloan F. Effects of Tort Reforms and Other Factors on Medical Malpractice Insurance Premiums. *Inquiry* 1990;27:167-82.
9. Danzon PM. The Frequency and Severity of Malpractice Claims. *Journal of Law and Economics* 1984;27:115-48.
10. Danzon PM. The Frequency and Severity of Medical Malpractice Claims: New Evidence. *Law and Contemporary Problems* 1986;49:57-84.
11. Sloan FA, Mergenhagen PM, Bovbjerg RR. Effects of Tort Reforms on the Value of Closed Medical Malpractice Claims: A Microanalysis. *Journal of Health Politics, Policy and Law* 1989;14:663-89.
12. Blackmon G, Zeckhauser RJ. State Tort Reform Legislation: Assessing Our Control of Risks In: Schuck P, ed. *Tort Law and the Public Interest: Competition, Innovation, and Consumer Welfare*. New York: W.W. Norton and Company and the American Assembly; 1991:272-309.
13. Viscusi WK, Born PH. Damages Caps, Insurability, and the Performance of Medical Malpractice Insurance. *Journal of Risk and Insurance* 2005;72:23-43.
14. Hyman DA, Black B, Silver C, Sage WM. Estimating the Effect of Damages Caps in Medical Malpractice Cases: Evidence from Texas. *Journal of Legal Studies* 2009;1:355-409.
15. Born P, Viscusi WK, Baker T. The Effects of Tort Reform on Medical Malpractice Insurers' Ultimate Losses. *Journal of Risk and Insurance* 2009;76:197-219.
16. Viscusi WK, Zeckhauser RJ, Born P, Blackmon G. The Effect of 1980s Tort Reform Legislation on General Liability and Medical Malpractice Insurance. *Journal of Risk and Uncertainty* 1993;6:165-86.
17. Ambrose JM, Carroll A. Medical Malpractice Reform and Insurer Claims Defense: Unintended Effects? *Journal of Health Politics, Policy and Law* 2007;32:843-65.
18. Danzon PM, Epstein AJ, Johnson SJ. The "Crisis" In Medical Malpractice Insurance. In: Harris R, Litan R, eds. *Brookings-Wharton Papers on Financial Services*: Brookings Institution Press; 2004.
19. Thorpe KE. The Medical Malpractice 'Crisis': Recent Trends and the Impact of State Tort Reforms. *Health Affairs* 2004;Suppl Web Exclusives:W4-20-30.
20. Kilgore ML, Morrissey MA, Nelson LJ. Tort Law and Medical Malpractice Insurance Premiums. *Inquiry* 2006;43:255-70.
21. Sloan FA. State Responses to the Malpractice Insurance "Crisis" of the 1970s: An Empirical Assessment. *Journal of Health Politics, Policy and Law* 1985;9:629-46.
22. Congressional Budget Office. Letter from Douglas W. Elmendorf, Director, to Senator John D. Rockefeller IV. 2009.

23. Kessler D, McClellan M. Do Doctors Practice Defensive Medicine? *Quarterly Journal of Economics* 1996;111:353-90.
24. Sloan FA, Shadle JH. Is There Empirical Evidence For "Defensive Medicine"? A Reassessment. *Journal of Health Economics* 2009;28:481-91.
25. Yang YT, Mello MM, Subramanian SV, Studdert DM. Relationship between Malpractice Litigation Pressure and Rates of Cesarean Section and Vaginal Birth after Cesarean Section. *Medical Care* 2009;47:234-42.
26. Currie J, MacLeod WB. First Do No Harm? Tort Reform and Birth Outcomes. *Quarterly Journal of Economics* 2008;123:795-830.
27. Congressional Budget Office. *Medical Malpractice Tort Limits and Health Care Spending*; 2006.
28. Hellinger FJ, Encinosa WE. The Impact of State Laws Limiting Malpractice Damage Awards on Health Care Expenditures. *American Journal of Public Health* 2006;96:1375-81.
29. Kessler DP, Sage WM, Becker DJ. Impact of Malpractice Reforms on the Supply of Physician Services. *JAMA* 2005;293:2618-25.
30. Matsa DA. Does Malpractice Liability Keep the Doctor Away? Evidence from Tort Reform Damage Caps. *Journal of Legal Studies* 2007;36:S143-S82.
31. Yang YT, Studdert DM, Subramanian SV, Mello MM. A Longitudinal Analysis of the Impact of Liability Pressure on the Supply of Obstetrician-Gynecologists. *Journal of Empirical Legal Studies* 2008;5:21-53.
32. Helland E, Showalter MH. *The Impact of Liability on the Physician Labor Market*. RAND Working Paper RAND Working Paper; 2006.
33. Morrissey MA, Kilgore ML, Nelson LJ. Medical Malpractice Reform and Employer-Sponsored Health Insurance Premiums. *Health Services Research* 2008;43:2124-42.
34. Avraham R, Dafney LS, Schanzenbach MM. The Impact of Tort Reform on Employer-Sponsored Health Insurance Premiums. NBER Working Paper 15371; 2009.
35. Sun J, Schmit JT. *How Do State Medical Malpractice Laws Affect Access to Health Insurance?* Working Paper Working Paper; 2007.
36. Klick J, Stratmann T. Medical Malpractice Reform and Physicians in High-Risk States. *Journal of Legal Studies* 2007;36:S121-S42.
37. Yang YT, Studdert DM, Subramanian SV, Mello MM. Does Tort Law Improve the Health of Newborns, or Miscarry? A Longitudinal Analysis of the Effect of Liability Pressure on Birth Outcomes. Working paper; 2009.
38. White FJ, Pettiette LW, Wiggins RB, Kiss A. Medical Malpractice Review Panels and Medical Liability System Cost, Timeliness, and Efficiency: A Cross-Sectional Study. *Journal of Empirical Legal Studies* 2008;5:375-405.
39. Yoon A. Mandatory Arbitration and Civil Litigation: An Empirical Study of Medical Malpractice Litigation in the West. *American Law and Economic Review* 2004;6:95-134.
40. Office of Technology Assessment USC. *Defensive Medicine and Medical Malpractice*; 1994.
41. *Putnam v. Wenatchee Valley Med. Ctr.* 216 P3d 374 (Wash).
42. Parness JA, Leonetti A. Expert Opinion Pleading: Any Merit to Special Certificates of Merit? *Brigham Young University Law Review* 1997;1997:537-90.
43. Spurr SJ, Simmons WO. *Medical Malpractice in Michigan: An Economic Analysis*. *J Health Polit Policy Law* 1996;21:315-46.
44. Morlock LL, Malitz FE. *Short-Term Effects of Tort and Administrative Reforms on the Claiming Behavior of Privately Insured Medicaid and Uninsured Patients*. Report to the Office of Technology Assessment, U.S. Congress. Washington, DC 1993.
45. Brown AS. The Affidavit of Merit Mess: The Law Has Resulted in a Tidal Wave of Contradictory Decisions by Trial and Appeals Courts. *New Jersey Law Journal* 2001;163:427.

46. Stroub ML. The Unforeseen Creation of a Procedural Minefield—New Jersey’s Affidavit of Merit Statute Spurs Litigation and Expense in Its Interpretation and Application. *Rutgers Law Journal* 2002;34:279-320.
47. Klick J, Strattmann T. Does Medical Malpractice Reform Help States Retain Physicians and Does It Matter? Working Paper; 2005.
48. American Law Institute. Reporter's Study: Enterprise Responsibility for Personal Injury, Vol. II. Philadelphia: American Law Institute; 1991.
49. U.S. General Accounting Office. Medical Malpractice: Effects of Varying Laws in the District of Columbia, Maryland, and Virginia. Washington, DC: General Accounting Office; 1999. Report No.: GAO/HEHS-00-5.
50. Bovbjerg RA, Sloan FA, Blumstein JF. Valuing Life and Limb: Scheduling "Pain and Suffering". *Northwestern University Law Review* 1989;83:908-72.
51. Studdert DM, Yang YT, Mello MM. Are Damages Caps Regressive? A Study of Malpractice Jury Verdicts in California. *Health Affairs* 2004;23:54-67.
52. Studdert DM, Mello MM. Options for Rational Scheduling and Valuation of Noneconomic Damages. Report to the Washington State Noneconomic Damages Task Force; 2005.
53. Washington State Task Force on Noneconomic Damages. Report to the Legislature; 2005.
54. Kinney ED. Administrative Law Approaches to Medical Malpractice Reform. *St Louis University Law Journal* 2004;49:45-72.
55. Sugarman SD. A Comparative Law Look at Pain and Suffering Awards. *DePaul Law Review* 2006;55:299-434.
56. Sebok A. Translating the Immeasurable: Thinking About Pain and Suffering Comparatively. *DePaul Law Review* 2006;55:379-98.
57. Comande G. Towards a Global Model for Adjudicating Personal Injury Damages: Bridging Europe and the United States. *Temple International and Comparative Law Journal* 2005;19:241-349.
58. Blumstein JF. Making the System Work Better: Improving the Process for Determination of Noneconomic Loss. *New Mexico Law Review* 2005;35:401-17.
59. National Association of Insurance Commissioners. Malpractice Claims: Final Compilation: Medical Malpractice Closed Claims, 1975-1978. Washington: National Association of Insurance Commissioners; 1980.
60. Cocchiarella L, Andersson GBJ, eds. Guides to the Evaluation of Permanent Impairment. 5th ed: American Medical Association; 2000.
61. Geistfeld M. Placing a Price on Pain and Suffering: A Method for Helping Juries Determine Tort Damages for Nonmonetary Injuries. *California Law Review* 1995;83:773-852.
62. Avraham R. Putting a Price on Pain and Suffering: A Critique of the Current Approach and a Preliminary Proposal for Change. *Northwestern Law Review* 2006;100:87-119.
63. Chase OG. Helping Jurors Determine Pain and Suffering Awards. In: Kramer L, ed. *Reforming the Civil Justice System* New York: New York University; 1996:339-62.
64. Levin FS. Pain and Suffering Guidelines: A Cure for Damages Measurement "Anomie". *University of Michigan Journal of Law Regorm* 1989;22:303-32.
65. O'Connell J. A Proposal to Abolish Defendants' Payment for Pain and Suffering in Return for Payment of Claimants' Attorneys' Fees. *University of Illinois Law Review* 1981;1981:333.
66. Saks MJ, Hollinger LA, Wissler RL, Evans DL, Hart AJ. Reducing Variability in Civil Jury Awards. *Law and Human Behavior* 1997;21:243-56.
67. Wissler RL, Kuehn PF, Sakes MJ. Instructing Jurors on General Damages in Personal Injury Cases: Problems and Possibilities. *Psychology, Public Policy and Law* 2000;6:712-37.
68. Kahneman D. Reference Points, Anchors, Norms, and Mixed Feelings. *Organizational Behavior and Human Decision Processes* 1992;51:296-312.

69. Havighurst CC, Tancredi LR. Medical Adversity Insurance — a No-Fault Approach to Medical Malpractice and Quality Assurance. *Milbank Memorial Fund Quarterly* 1973;51:125-68.
70. Johnson KB, Phillips CG, Orentlicher D, Hatlie MS. A Fault-Based Administrative Alternative for Resolving Medical Malpractice Claims. *Vanderbilt Law Review* 1989;42.
71. Chow E. Health Courts: An Extreme Makeover of Medical Malpractice with Potentially Fatal Complications. *Yale Journal of Health Policy, Law, and Ethics* 2007;7:387-427.
72. Barringer PJ, Studdert DM, Kachalia AB, Mello MM. Administrative Compensation of Medical Injuries: A Hardy Perennial Blooms Again. *Journal of Health Politics Policy and Law* 2008;33:725-60.
73. Kachalia AB, Mello MM, Brennan TA, Studdert DM. Beyond Negligence: Avoidability and Medical Injury Compensation. *Social Science and Medicine* 2008;66:387-402.
74. Mello MM, Studdert DM, Kachalia AB, Brennan TT. "Health Courts" And Accountability for Patient Safety. *Milbank Quarterly* 2006;84:459-92.
75. Studdert DM, Thomas EJ, Zbar BIW, et al. Can the United States Afford A "No-Fault" System of Compensation for Medical Injury? *Law and Contemporary Problems* 1997;60:1-34.
76. Bovbjerg RR, Sloan FA, Rankin PJ. Administrative Performance Of "No-Fault" Compensation for Medical Injury. *Law and Contemporary Problems* 1997;60:71-115.
77. Elliott ED, Narayan SA, Nasmith MS. Administrative "Health Courts" For Medical Injury Claims: The Federal Constitutional Issues. *Journal of Health Politics Policy and Law* 2008;33:761-98.
78. Studdert DM, Fritz LA, Brennan TA. The Jury Is Still In: Florida's Birth-Related Neurological Injury Compensation Plan after a Decade. *Journal of Health Politics Policy and Law* 2000;25:499-526.
79. O'Connell J. Expanding No-Fault Beyond Auto Insurance: Some Proposals. *Virginia Law Review* 1973;59:749-829.
80. Abraham KS. Medical Liability Reform: A Conceptual Framework. *JAMA* 1988;260:68-72.
81. Sage WM. The Forgotten Third: Liability Insurance and the Medical Malpractice Crisis. *Health Affairs* 2004;23:10-21.
82. Struve CT. Expertise in Medical Malpractice Litigation: Special Courts, Screening Panels, and Other Options: Project on Medical Liability in Pennsylvania (Pew Charitable Trusts); 2003.
83. Struve CT. Improving the Medical Malpractice Litigation Process. *Health Affairs* 2004;23:33-41.
84. Studdert DM, Brennan TA. Toward a Workable Model Of "No-Fault" Compensation for Medical Injury in the United States. *American Journal of Law & Medicine* 2001;27:225-52.
85. Barringer PJ. Windows of Opportunity: State-Based Ideas for Improving Medical Injury Compensation and Enhancing Patient Safety. Washington, D.C.: Common Good; 2006.
86. Siegal G, Mello MM, Studdert DM. Adjudicating Severe Birth Injury Claims in Florida and Virginia: The Experience of a Landmark Experiment in Personal Injury Compensation. *American Journal of Law & Medicine* 2008;34:493-537.
87. National Vaccine Injury Compensation Program. (Accessed January 1, 2010, at <http://www.hrsa.gov/Vaccinecompensation/>).
88. The Florida Birth Related Neurological Injury Compensation Association. (Accessed January 1, 2010, at <http://www.nica.com/>).
89. The Virginia Birth-Related Neurological Injury Compensation Program. (Accessed January 1, 2010, at <http://www.vabirthinjury.com/>).
90. Widman A, Hochberg FA. Federal Administrative Health Courts Are Unconstitutional: A Reply to Elliott, Narayan, and Nasmith. *Journal of Health Politics Policy and Law* 2008;33:799-832.
91. Mello MM, Studdert DM, Moran P, Dauer EA. Policy Experimentation with Administrative Compensation for Medical Injury: Issues under State Constitutional. *Harvard Journal on Legislation* 2008;45:59-106.
92. Paglia AD. Taking the Tort out of Court — Administrative Adjudication of Medical Liability Claims: Is It the Next Step? . *Southwestern University Law Review* 1991;20:41-76.

93. Studdert DM, Brennan TA. No-Fault Compensation for Medical Injuries: The Prospect for Error Prevention. *JAMA* 2001;286:217-23.
94. Bovbjerg RR, Tancredi LR. Liability Reform Should Make Patients Safer: "Avoidable Classes of Events" Are a Key Improvement. *The Journal of Law, Medicine & Ethics* 2005;33:478-500.
95. Bovbjerg RR, Tancredi LR, Gaylin DS. Obstetrics and Malpractice: Evidence on the Performance of a Selective No-Fault System. *JAMA* 1991;265:2836-43.
96. Studdert DM, Mello MM, Brennan TA. Medical Malpractice. *New England Journal of Medicine* 2004;350:283-92.
97. Clinton HR, Obama B. Making Patient Safety the Centerpiece of Medical Liability Reform. *New England Journal of Medicine* 2006;354:2205-8.
98. Bismark M, Paterson R. No-Fault Compensation in New Zealand: Harmonizing Injury Compensation, Provider Accountability, and Patient Safety. *Health Affairs* 2006;25:278-83.
99. Studdert DM, Mello MM, Gawande AA, et al. Claims, Errors, and Compensation Payments in Medical Malpractice Litigation. *New England Journal of Medicine* 2006;354:2024-33.
100. Horwitz J, Brennan TA. No-Fault Compensation for Medical Injury: A Case Study. *Health Affairs* 1995;14:164-79.
101. Joint Legislative Audit And Review Commission Of The Virginia General Assembly. Review of the Virginia Birth-Related Neurological Injury Compensation Program; 2003.
102. Office of Program Policy Analysis and Government Accountability. Report No. 04-04 Special Report: NICA Eligibility Requirements Could Be Expanded, but the Costs Would Increase Significantly; 2004.
103. Shmanske S, Stevens T. The Performance of Medical Malpractice Review Panels. *Journal of Health Politics Policy and Law* 1986;11:525-35.
104. Kessler DP, McClellan MB. How Liability Law Affects Medical Productivity. *Journal of Health Economics* 2002;21:931-55.
105. American Society of Anesthesiologists (Asa) Closed Claims Project. (Accessed January 2, 2010, at <http://depts.washington.edu/asaccp/>).
106. Snyder L, Leffler C, for the Ethics Human Rights Committee-American College of Physicians. Ethics Manual: Fifth Edition. *Annals of Internal Medicine* 2005;142:560-82.
107. Finkelstein D, Wu AW, Holtzman NA, Smith MK. When a Physician Harms a Patient by a Medical Error: Ethical, Legal, and Risk-Management Considerations. *Journal of Clinical Ethics* 1997;8:330-5.
108. National Quality Forum. Safe Practices for Better Healthcare - 2009 Update: A Consensus Report; 2009.
109. The Joint Commission--Hospital Accreditation Standards. Oakbrook Terrace, IL; 2008.
110. Weinstein L. A Multifaceted Approach to Improve Patient Safety, Prevent Medical Errors and Resolve the Professional Liability Crisis. *American Journal of Obstetrics and Gynecology* 2006;194:1160-5.
111. Gallagher TH, Studdert D, Levinson W. Disclosing Harmful Medical Errors to Patients. *New England Journal of Medicine* 2007;356:2713-9.
112. McDonnell WM, Guenther E. Narrative Review: Do State Laws Make It Easier to Say, "I'm Sorry?". *Annals of Internal Medicine* 2008;149:811-5.
113. Gallagher TH, Waterman AD, Ebers AG, Fraser VJ, Levinson W. Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors. *JAMA* 2003;289:1001-7.
114. Lamb RM, Studdert DM, Bohmer RM, Berwick DM, Brennan TA. Hospital Disclosure Practices: Results of a National Survey. *Health Affairs* 2003;22:73-83.
115. Kachalia A, Shojania KG, Hofer TP, Piotrowski M, Saint S. Does Full Disclosure of Medical Errors Affect Malpractice Liability? The Jury Is Still Out. *Joint Commission Journal on Quality and Safety* 2003;29:503-11.

116. Gallagher TH, Waterman AD, Garbutt JM, et al. US and Canadian Physicians' Attitudes and Experiences Regarding Disclosing Errors to Patients. *Archives of Internal Medicine* 2006;166:1605-11.
117. Charles SC, Wilbert JR, Franke KJ. Sued and Nonsued Physicians' Self-Reported Reactions to Malpractice Litigation. *American Journal of Psychiatry* 1985;142:437-40.
118. Moore H, O'Connell J. Foreclosing Medical Malpractice Claims by Prompt Tender of Economic Loss. *Louisiana Law Review* 1984;44:1267-88.
119. Hersch J, O'Connell J, Viscusi WK. Evaluation of Early Offer Reform of Medical Malpractice Claims: Final Report. Washington, D.C.: U.S. Department of Health and Human Services; 2006.
120. Hersch J, O'Connell J, Viscusi WK. An Empirical Assessment of Early Offer Reform for Medical Malpractice. *The Journal of Legal Studies* 2007;36:S231-S59.
121. O'Connell J. Offers That Can't Be Refused: Foreclosure of Personal Injury Claims by Defendants' Prompt Tender of Claimants' Net Economic Losses. *Northwestern University Law Review* 1982;77:589-632.
122. O'Connell J. Commentary: Binding Early Offers Versus Caps for Medical Malpractice Claims? *Milbank Quarterly* 2007;85:287-96.
123. O'Connell J, Bryan PB. More Hippocrates, Less Hypocrisy: "Early Offers" As a Means of Implementing the Institute of Medicine's Recommendations on Malpractice Law. *Journal of Law and Health* 2000;15:23-51.
124. O'Connell JO, Neale JF. HMO's, Cost Containment, and Early Offers: New Malpractice Threats and a Proposed Reform. *Journal of Contemporary Health Law and Policy* 1998;14:287-314.
125. Corrigan JM, Greiner A, S.M. Erickson SM, eds. *Fostering Rapid Advances in Health Care: Learning from System Demonstrations*. Washington, D.C.: National Academies Press; 2002.
126. Black BS, Hyman DA, Silver CM. The Effects of 'Early Offers' in Medical Malpractice Cases: Evidence from Texas. *Journal of Empirical Legal Studies* 2009;6:723-67.
127. Moore WH, Hoff JS. H.R. 3084: A More Rational Compensation System for Medical Malpractice. *Law and Contemporary Problems* 1986;49:117-24.
128. COPIC: 3Rs Program. (Accessed January 2, 2010, at <http://www.callcopic.com/home/what-we-offer/coverages/medical-professional-liability-insurance-co/physicians-medical-practices/special-programs/3rs-program/>).
129. Sorry Works! Coalition: Copic's 3Rs Program. (Accessed January 5, 2010, at <http://www.sorryworks.net/copic.phtml>).
130. Banja J. Does Medical Error Disclosure Violate the Medical Malpractice Insurance Cooperation Clause? In: *Advances in Patient Safety: From Research to Implementation*. Rockville, MD: Agency for Healthcare Research and Quality; 2005.
131. Kraman SS, Hamm G. Risk Management: Extreme Honesty May Be the Best Policy. *Annals of Internal Medicine* 1999;131:963-7.
132. Studdert DM, Mello MM, Gawande AA, Brennan TA, Wang YC. Disclosure of Medical Injury to Patients: An Improbable Risk Management Strategy. *Health Affairs* 2007;26:215-26.
133. Hickson GB, Clayton EW, Githens PB, Sloan FA. Factors That Prompted Families to File Medical Malpractice Claims Following Perinatal Injuries. *JAMA* 1992;267:1359-63.
134. Vincent C, Young M, Phillips A. Why Do People Sue Doctors? A Study of Patients and Relatives Taking Legal Action. *Lancet* 1994;343:1609-13.
135. Levinson W, Roter DL, Mullooly JP, Dull VT, Frankel RM. Physician-Patient Communication: The Relationship with Malpractice Claims among Primary Care Physicians and Surgeons. *JAMA* 1997;277:553-9.
136. Mazor KM, Simon SR, Yood RA, et al. Health Plan Members' Views on Forgiving Medical Errors. *The American Journal of Managed Care* 2005;11:49-52.

137. Mazor KM, Simon SR, Yood RA, et al. Health Plan Members' Views About Disclosure of Medical Errors. *Annals of Internal Medicine* 2004;140:409-18.
138. Witman AB, Park DM, Hardin SB. How Do Patients Want Physicians to Handle Mistakes? A Survey of Internal Medicine Patients in an Academic Setting. *Archives of Internal Medicine* 1996;156:2565-99.
139. Wu AW, Huang IC, Stokes S, Pronovost PJ. Disclosing Medical Errors to Patients: It's Not What You Say, It's What They Hear. *Journal of General Internal Medicine* 2009;24:1012--7.
140. Boothman RC, Blackwell AC, Campbell DA, Commiskey E, Anderson S. A Better Approach to Medical Malpractice Claims? The University of Michigan Experience. *Journal of Health & Life Sciences Law* 2009;2:125-59.
141. Peto RR, Tenerowicz LM, Benjamin EM, Morsi DS, Burger PK. One System's Journey in Creating a Disclosure and Apology Program. *Joint Commission Journal and Quality and Safety* 2009;35:487-96.
142. Me Rev Stat Ann tit 24 §2971-79 (1993).
143. Begel J. Maine Physician Practice Guidelines: Implications for Medical Malpractice Litigation. *Maine Law Review* 1995;47:69-103.
144. Smith GH. A Case Study in Progress: Practice Guidelines and the Affirmative Defense in Maine. *Joint Commission Journal on Quality Improvement* 1993;19:355-62.
145. U. S. General Accounting Office. Medical Malpractice: Maine's Use of Practice Guidelines to Reduce Costs. GAO/HRD-94-8; 1993.
146. Maine Department of Professional and Financial Regulation, Bureau of Insurance. Interim Report on the Medical Liability Demonstration Project. Augusta, ME: Maine Bureau of Insurance; 1997.
147. Public Health Research Institute. Impact of Obstetric Practice Guidelines on Physician Behavior: Final Report to the Agency for Health Care Policy and Research. Portland, ME: Public Health Research Institute; 1997.
148. Fla Stat §408.02.
149. Agency for Health Care Administration. Practice Guidelines as Affirmative Defense: The Cesarean Demonstration Project Report. Tallahassee: State Center for Health Statistics; 1998.
150. Matthews JR. Practice Guidelines and Tort Reform: The Legal System Confronts the Technocratic Wish. *J Health Polit Policy Law* 1999;24:275-304.
151. Minn Stat Ann §145.65 (repealed).
152. Ky Rev Stat Ann §342.035(8).
153. Physician Payment Review Commission. Annual Report to Congress; 1990.
154. Healthy Americans Act. (111st Cong. 2009): S.291
155. Mello MM. Of Swords and Shields: The Use of Clinical Practice Guidelines in Medical Malpractice Litigation. *University of Pennsylvania Law Review* 2001;149:645-710.
156. Hall MA. The Defensive Effect of Medical Practice Policies in Malpractice Litigation. *Law and Contemporary Problems* 1991;54:119-45.
157. Rosoff AJ. Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines. *Journal of Health Politics, Policy and Law* 2001;26:327-68.
158. Shuman DW. The Standard of Care in Medical Malpractice Claims, Clinical Practice Guidelines, and Managed Care: Towards a Therapeutic Harmony? *California Western Law Review* 1997;34:99-113.
159. Ransom SB, Studdert DM, Dombrowski MP, Mello MM, Brennan TA. Reduced Medicolegal Risk by Compliance with Obstetric Clinical Pathways: A Case--Control Study. *Obstetrics & Gynecology* 2003;101:751-5.
160. Clark SL, Belfort MA, Dildy GA, Meyers JA. Reducing Obstetric Litigation through Alterations in Practice Patterns. *Obstetrics & Gynecology* 2008;112:1279-83.
161. Morton JR. The Maine Demonstration Project: Using Practice Parameters as an Affirmative Defense. *Bulletin of the American College of Surgeons* 1995;80:30-3.

162. U. S. General Accounting Office. Maine Practice Guidelines. GAO/HEHS-95-118R; 1995.
163. AMA Advocacy Resource Center: State Patient Compensation Funds. (Accessed January 6, 2010, at www.ama-assn.org/ama1/pub/upload/mm/378/mlrpatcomp.pdf).
164. Sloan FA, Mathews CA, Conover CJ, Sage WM. Public Medical Malpractice Insurance: An Analysis of State-Operated Patient Compensation Funds. *DePaul Law Review* 2005;54:247-76.
165. Schrero ED. Patient Compensation Funds: Legislative Responses to the Medical Malpractice Crisis. *American Journal of Law & Medicine* 1979;5:175-95.
166. Petersen LA, Woodard LD, Urech T, Daw C, Sookanan S. Does Pay-for-Performance Improve the Quality of Health Care? *Annals of Internal Medicine* 2006;145:265-72.
167. Tanenbaum SJ. Pay for Performance in Medicare: Evidentiary Irony and the Politics of Value. *Journal of Health Politics Policy and Law* 2009;34:717-46.
168. Werner RM, Dudley RA. Making the 'Pay' Matter in Pay-for-Performance: Implications for Payment Strategies. *Health Affairs* 2009;28:1498-508.
169. Rosenthal MB, Fernandopulle R, Song HR, Landon B. Paying for Quality: Providers' Incentives for Quality Improvement. *Health Affairs* 2004;23:127-41.
170. Epstein AM, Lee TH, Hamel MB. Paying Physicians for High-Quality Care. *New England Journal of Medicine* 2004;350:406-10.
171. Kuhmerker K, Hartman T. Pay-for-Performance in State Medicaid Programs: A Survey of State Medicaid Directors and Programs: The Commonwealth Fund; 2007.
172. The Leapfrog Group Compendium: A P4P/Consumer Incentive Database. 2009. (Accessed December 30, 2009, at <http://www.leapfroggroup.org/compendium2>).
173. Pearson SD, Schneider EC, Kleinman KP, Coltin KL, Singer JA. The Impact of Pay-for-Performance on Health Care Quality in Massachusetts, 2001-2003. *Health Affairs* 2008;27:1167-76.
174. Lindenauer PK, Remus D, Roman S, et al. Public Reporting and Pay for Performance in Hospital Quality Improvement. *New England Journal of Medicine* 2007;356:486-96.
175. Rosenthal MB, Frank RG. What Is the Empirical Basis for Paying for Quality in Health Care? *Medical Care Research and Review* 2006;63:135-57.
176. Glickman SW, Ou F-S, DeLong ER, et al. Pay for Performance, Quality of Care, and Outcomes in Acute Myocardial Infarction. *JAMA* 2007;297:2373-80.
177. Damberg CL, Raube K, Teleki SS, dela Cruz E. Taking Stock of Pay-for-Performance: A Candid Assessment from the Front Lines. *Health Affairs* 2009;28:517-25.
178. Rodriguez H, von Glahn T, Elliott M, Rogers W, Safran D. The Effect of Performance-Based Financial Incentives on Improving Patient Care Experiences: A Statewide Evaluation. *Journal of General Internal Medicine* 2009;24:1281-8.
179. Rosenthal MB. What Works in Market-Oriented Health Policy? *New England Journal of Medicine* 2009;360:2157-60.
180. Fisher ES. Paying for Performance -- Risks and Recommendations. *New England Journal of Medicine* 2006;355:1845-7.
181. de Brantes FS, D'Andrea BG. Physicians Respond to Pay-for-Performance Incentives: Larger Incentives Yield Greater Participation. *American Journal of Managed Care* 2009;15:305-10.
182. The Joint Commission: 2010 National Patient Safety Goals (NPSGs). (Accessed January 2, 2010, at <http://www.jointcommission.org/patientsafety/nationalpatientsafetygoals/>).
183. Zeiler K, Black BS, Silver C, Hyman DA, Sage WM. Physicians' Insurance Limits and Malpractice Payments: Evidence from Texas Closed Claims, 1990-2003. *Journal of Legal Studies* 2007;36:S9-S45.
184. Havighurst CC. Making Health Plans Accountable for the Quality of Care. *Georgia Law Review* 1997;31:587-647.
185. Abraham KS, Weiler PC. Enterprise Medical Liability and the Evolution of the American Health Care System. *Harvard Law Review* 1994;108:381-436.

186. Furrow BR. Enterprise Liability and Health Care Reform: Managing Care and Managing Risk. *St Louis University Law Journal* 1994;39:77-132.
187. Mello MM, Studdert DM. Deconstructing Negligence: The Role of Individual and System Factors in Causing Medical Injuries. *Georgetown Law Journal* 2008;(in press).
188. Peters PG. Resuscitating Hospital Enterprise Liability. *Missouri Law Review* 2008;73:369-97.
189. Sage WM. Enterprise Liability and the Emerging Managed Health Care System. *Law and Contemporary Problems* 1997;60:159-210.
190. Arlen J, MacLeod WB. Torts, Expertise, and Authority: Liability of Physicians and Managed Care Organizations. *RAND Journal of Economics* 2005;36:494-519.
191. Mello MM, Brennan TA. Deterrence of Medical Errors: Theory and Evidence for Malpractice Reform. *Texas Law Review* 2002;80:1595-637.
192. Abraham KS, Rabin RL, Weiler PC. Enterprise Responsibility for Personal Injury : Further Reflections. *San Diego Law Review* 1993;30:333-64.
193. Medicare Payment Advisory Commission. Report to the Congress: Improving Incentives in the Medicare Program; 2009.
194. Mello MM, Hemenway D. Medical Malpractice as an Epidemiological Problem. *Social Science and Medicine* 2004;59:39-46.
195. Mello MM, Kelly CN, Studdert DM, Brennan TA, Sage WM. Hospitals' Behavior in a Tort Crisis: Observations from Pennsylvania. *Health Affairs* 2003;22:225-33.
196. Kachalia A, Gandhi TK, Puopolo AL, et al. Missed and Delayed Diagnoses in the Emergency Department: A Study of Closed Malpractice Claims from 4 Liability Insurers. *Ann Emerg Med* 2007;49:196-205.
197. Mello MM, Studdert DM, Thomas EJ, Yoon C, Brennan TA. Who Pays for Medical Errors? An Analysis of Adverse Event Costs, the Medical Liability System, and Incentives for Patient Safety Improvement. *Journal of Empirical Legal Studies* 2007;4:835-60.
198. Holzer JF. The Advent of Clinical Standards for Professional Liability. *Quality Review Bulletin* 1990;16:71-9.
199. Kinney ED. Resolving Medical Malpractice Claims in the Medicare Program: Can It Be Done? *Connecticut Insurance Law Journal* 2005-2006;12:77-136.
200. Blumstein JF. Medical Malpractice Standard-Setting: Developing Malpractice "Safe Harbors" As a New Role for QIOs? *Vanderbilt Law Review* 2006;59:1017-49.
201. Sage WM, Kinney ED. Medicare-Led Malpractice Reform. In: Sage WM, Kersh R, eds. *Medical Malpractice and the US Health Care System*. New York: Cambridge University Press; 2006:318-49.