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Medical Malpractice, the Affordable Care Act and State Provider Shield Laws: More Myth than Necessity?

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By Mary Ann Chirba and Alice A. Noble

Given the ambitions and reach of the Affordable Care Act, confusion about its intended and inadvertent impact is inevitable. Since its enactment in 2010, the ACA has raised legitimate and less grounded concerns among various stakeholders ranging from individuals and employers facing coverage mandates to States deciding whether and how to implement the Act's Medicaid expansions. One item has

received far less attention even though it weighs heavily on any provider engaged in the clinical practice of medicine: the ACA's impact on medical malpractice liability. The Act does little to address medical malpractice head on. Nevertheless, physicians and other providers, the states and even some members of Congress have expressed concern that the Act will increase a provider's exposure to medical malpractice liability.

In response, the American Medical Association has drafted model legislation to shield providers from newly created malpractice claims resulting from the ACA. It would prevent malpractice claimants from using federal or state practice guidelines, quality measures, reimbursement criteria and the like to establish or define the standard of care without expert testimony. In Congress, a version of this model, H.R. 1473, was introduced in the House of Representatives in 2012, and again in April of 2013 [link: http://beta.congress.gov/bill/113th-congress/house-bill/1473/cosponsors].

In April, the governor of Georgia signed H.B. 499 [link: http://www.legis.ga.gov/legislation/en-US/display/20132014/HB/499] into law, becoming the first state to pass legislation based on the AMA model act.

This came on the heels of a Medical Association of Georgia Advocacy Brief [link: http://www.mag.org/sites/default/files/downloads/issue-brief-provider-shield2-2013.pdf] stating that the ACA's "guidelines" concerning health care quality measures; payment adjustments; hospital value-based purchasing; and value-based payment modifiers "will raise [the medical malpractice] standard to unreasonable levels by exposing physicians to a number of *new liabilities*…." [Emphasis added]

It is too early to tell whether states will follow Georgia's lead and enact similar measures. What is clear is that such "standard of care protection" or "provider liability shield" legislation raises interesting questions about the ACA's impact on state medical malpractice law.

The intersection of federal standards and state personal injury litigation against a regulated industry is nothing new. It has long played a role, for instance, in product liability claims ranging from medical drugs and devices to motor vehicles. The literature is already quite deep as to whether federal regulations preempt state requirements or have evidentiary value at trial, and we will not add to it today. What is of particular interest with the Georgia law and, therefore, will be the focus of this discussion is: (1) why the ACA has fueled concerns of expanded malpractice liability, and (2) whether the Georgia law achieves any real gains in shielding physicians or other health care providers from malpractice liability beyond what already exists under state law.

Put simply, we consider: why was the Georgia law passed, and does it really accomplish anything?

A. Georgia Malpractice Law

In a medical malpractice case, the standard of care under state law is generally based on actual or "customary" practice. Expert testimony is generally required to determine what the standard of care is and whether it was breached or followed in the case at hand. Quality and practice guidelines have been used by both plaintiffs and defendants as *some evidence* of the standard of care, but do not establish that standard on their own. [1] Rather, they are introduced through the testimony of an expert witness who can authenticate the reliability of the guidelines or standards and can provide the necessary link between the guidelines or standards and medical "custom."

Georgia's new liability protection statute provides, in pertinent part, that in any civil action for medical malpractice or product liability:

> *[T]he development, recognition, or implementation of any guideline by any public or private payor or the establishment of any*

> *payment standard or reimbursement criteria under any federal law or regulations related to health care shall not be construed, without competent expert testimony establishing the appropriate standard of care, to establish a legal basis for negligence or the standard of care or duty of care owed by a health care provider.*

The provision goes on to provide similar protection to the plaintiff by preventing a defendant's compliance with such standards from establishing due care without, again, competent expert testimony. Similarly, H.R. 1473 § 2 (a) states that "the development, recognition, or implementation of any guideline or other standard under any Federal health care provision shall not be construed *to establish* the standard of acre or duty of care owed by a health care provider to a patient in any medical malpractice case." [Emphasis added.]

The Georgia law focuses solely on *administrative* criteria, guidelines, and standards, expressly excluding from the definition of such terms those criteria, guidelines, and standards "relating to medical treatment, quality of care, or best practices." Based on comments by supporters of the Georgia law, such "*administrative* criteria, guidelines, and standards" would include readmission rates, complication rates, payment withholding or adjustments based on performance criteria.[2] (The federal H.R. 1473 version refers to "guideline or other standard under any Federal health car provision" without further definition.)

Thus, Georgia's new law does not preclude the admission of guidelines, standards, criteria, etc., as evidence that the standard of care was met or breached. It simply insists that using them to establish the standard of care be done through accompanying expert testimony. [3] Indeed, without expert testimony that could be subject to cross examination or other challenge at trial, a court would be hard pressed to determine whether its admissibility or relevance to the case at hand.

With this in mind, we turn to an examination of whether the ACA's guidelines, standards, etc., impose the kind of new liability risks that should concern physicians and other health care providers, at least for the reasons proffered by the Georgia shield law's supporters.

B. The ACA and Medicare Payment Provisions: Cause for Concern?

An overarching goal of the ACA and earlier Medicare provisions is to improve the quality of health care and the efficiency with which it is delivered. For example, the ACA expands Medicare's existing uses of quality criteria by developing additional measures; linking quality patient care to provider reimbursement; and increasing transparency through broader public access to information on providers and quality. It further seeks to improve the quality of care, increase administrative efficiency, reform provider reimbursement, and promote patient outcomes research by incentivizing and expanding the use of electronic health records (EHRs) and other health information technology (HIT).

Because these and other initiatives are designed to improve both quality and efficiency, they are by definition, intended to influence the practice of medicine. Their implementation will surely affect what constitutes ordinary or customary practice and, consequently, affect what the standard of care is and the imposition of liability based on that standard.

Beyond the ACA's impact on the content of existing standards of care, however, proponents of the Georgia-type provider shield law fear the Act will create new and distinct bases for liability. According to the Medical Association of Georgia's Advocacy Brief, *"states have the constitutional authority to amend their laws to prevent these kinds of federal provisions from being used in medical liability lawsuits that are filed in the state."* This is misguided at best in at least two respects. First, the ACA does not impose new bases for liability. Second, even if it did, a state would have no authority, constitutional or otherwise, to override federal payment reforms for federally

financed programs. Moreover, despite traditional state oversight of the practice of medicine, states have no power to preclude a federal law from *influencing* the practice of medicine.

According to proponents of the Georgia law, these are just a few of the ways in which the ACA creates new liability risks for health care providers:[4]

- The development of health care quality measures.
- The development of hospital readmission measures, which are used to reduce payments to hospitals with excessive rates of readmission for patients with certain conditions.
- The development of hospital-acquired conditions measures, which will reduce or deny Medicare or Medicaid payments for treating certain hospital-acquired conditions.
- The Medicare shared savings program that encourages, but does not require certain Medicare providers to form Accountable Care Organizations (ACOs) which will assume financial risk for meeting specific performance goals and in return be eligible for additional payments for meeting or exceeding CMS's predetermined objectives.
- The use of value-based payment modifiers to award financial incentive payments to providers that met CMS-determined, quality based performance standards.

The payment adjustments and value-based purchasing initiatives are largely accomplished through the ACA's Medicare payment reforms. Therefore, the federal "guidelines" targeted by the Georgia law were implemented through Congress's Article I tax and spending power. By deciding to participate in the Medicare program and receive Medicare payments, a provider agrees to comply with the federal government's Medicare payment provisions including those added by the ACA.

The ACA's payment, quality and similar measures go to the very heart of its cost and quality reforms – and what keeps that heart beating is data. More data on patient outcomes and provider compliance with quality measures will be collected than ever before. Public reporting of certain measures on both the institutional and individual physician level will be expanded under the ACA, as well. Payment will be increasingly tied to performance–from meeting reporting requirements, to satisfying quality measures, to readmitting patients with certain conditions at unacceptable intervals, to preventing hospital-acquired infections– as fee for service reimbursement shifts to value-based reimbursement. Although these reforms target Medicare and Medicaid programs, their impact may affect health care in general over time as other payors adopt similar reimbursement methods.

Will these changes affect "medical custom" or the standard of care? Hopefully yes and hopefully, in a positive way. By increasing quality and decreasing costs, the ACA should raise the standard of care as practice variability and waste decline. In theory at least, improved quality should lead to fewer medical malpractice suits (although we stop short of that prediction, given other factors at play – e.g., more individuals with more access to more providers and more visits, the use of financial incentives, etc.).

C. Does the State Shield Law Provide Value Added to Physicians and Patients?

Although the ACA's quality initiatives will affect what the standard of care *is*, it does not create new and independent bases of malpractice liability. Therefore, the concerns that spawned the Georgia legislation, the AMA model act, and the Congressional bills seem misplaced.

Collecting and analyzing data on hospital readmission or hospital-based infections will not change a malpractice suit's basic inquiry into whether a specific provider breached the standard of care in treating a specific patient. Even data available at the physician level would have little if any bearing

on a claim of negligence brought by a specific plaintiff-patient against a specific treating physician.

Metrics for institutions that have some oversight of specific physicians and their practice may be somewhat more useful to malpractice litigants. For example, evidence that a hospital has been lax in its oversight of infection prevention protocols might be admissible as evidence of the hospital's negligence given a suitable set of facts. This is nothing new however, except that now more data may be available (assuming it is discoverable, admissible, and useful as evidence.) And again, the Georgia law would not prevent the use of such evidence, as long as it is introduced through an expert witness as has always been the case with general evidentiary requirements of state medical malpractice laws.

D. Time to Focus on the Real Problems

We have considered in past writings how the ACA has been misunderstood and even mythologized, ranging from it constituting a federal takeover of health care (it is not) to being unnecessary for young adults who do not want coverage (they do). We worry that myth-making is at work again here.

The answers to our initial questions of why the Georgia law passed and whether it accomplished anything will surely disappoint the shield law's backers. Georgia's provider shield law was passed to address provider fears that the ACA would impose new liability risks separate and apart from those already existing under state malpractice law. As explained, those concerns are unfounded; the ACA may influence what constitutes the standard of care just as any technological, societal or legal development may influence that standard. The ACA does not, however, create new forms, bases or versions of malpractice liability. As a result, Georgia's and similar state provider shield laws are unnecessary and do nothing to assuage the quite legitimate liability concerns of providers.

For this reason, those who are concerned about *new* liability risks stemming from health reform are off-track with Georgia-

type legislation. We agree that examining the ACA for liability loopholes is an important exercise. It is a complex statute with many moving parts. Compounding its complexity is the fact that the law gives regulators significant discretion to define its scope, meaning, and application. For these reasons and more, stakeholders must be vigilant in their assessment of the ACA as it moves toward full implementation. That assessment, however, should be based on more than mythology.

[Cross-posted from HealthLawProf Blog]

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