

Prognosis

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The Chair's Comments



Jim Wall

As we wrap up this year's work on the Health Law Section Council, I wanted to share with you some of the good work that your colleagues have done.

First and foremost, our end of life committee under the leadership of Melissa Phipps, Sissy Holloman and Ken Burgess has launched a pro bono project entitled "A Gift to Your Family: Advance Directives Planning Clinics." Our committee orchestrated and conducted a clinic in January in Durham, and in April conducted more than a handful of clinics throughout the state. The committee recruits and trains volunteers to provide advice at these clinics, recruits "subject matter experts" to train lawyers and coordinates the logistics and publicity of the clinics. The committee's goal is to conduct clinics throughout the state in the coming months. With this in mind, and with significant input from our colleagues in the Elder Law Section, the Health Law Council voted unanimously in its April meeting to invite the Elder Law Section to populate the committee with volunteers from our respective sections. Kudos to Melissa, Sissy and Ken for their continued leadership. There are plenty of volunteer opportunities with respect to this project. Please let me know if you are interested.

The section continues to reach into law schools to encourage young lawyers to explore careers in health care law. For the past two years, we've had several health council meetings at law schools, have attended law school information sessions, and have provided law schools with a presentation entitled "What Every First Year Health Lawyer Should Know About a Transaction." This year Joe Kahn and Jennifer Hutchens were our presenters at the law schools.

At our recently concluded annual meeting, we appointed five new members to the Health Section Council: John B. Garver III, Amy Kindle, Timothy McNeill, Richard Saver and McLain Wallace. Additionally, at our annual seminar superbly organized by Kimberly Kirk, we honored a very deserving Claire Moritz for her years of service to the Bar and the Section. Finally, we welcome Joe Kahn as next year's chair, Kim Licata as next year's vice chair, new mom Jennifer Hutchens as secretary and Kimberly Kirk as treasurer.

Thank you for the opportunity to serve as your chair.

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Will ACOs Raise (Or Lower) Liability Risks For Physicians?

By Julian D. "Bo" Bobbitt Jr.

There is significant potential for accountable care organizations to improve both the quality and efficiency of health care delivery for patient populations. The clinical and economic incentives are aligned for all stakeholders to promote higher patient satisfaction, population health, individual health, and waste reduction. However, for an ACO to be successful, physicians in ACOs must practice in a new way, be financially and clinically interdependent with other providers across the continuum of care, adhere to practice guidelines, be "patient-centric," and access broad new bodies of electronic health care data. As theories of legal duties associated with these changes emerge, thoughtful opinions differ as to whether the net impact will be for heightened liability exposure for physicians or reduced liability risk. This article explores the emerging theories and suggests strategies which ACOs and their physicians should follow to mitigate these risks. The article focuses primarily on the emerging professional malpractice liability risks facing physicians, and briefly touches on the other more settled and predictable areas of potential liability, but which still require compliance vigilance.

Yes, it is a legal minefield, but while creative theories of liability will surely be raised in our litigious society, at the end of the day, physicians providing better care, better patient engagement, and utilizing available tools and clinical knowledge through ACOs should feel confident that

Continued on page 3

Inside this Issue...

- 2 | NCSHCA President's Report
- 6 | Conducting Medicare Appeals When Facing The Ever Growing Backlog
- 11 | Bill Promoting Greater Access to Advance Directives Ends in N.C. House
- 12 | Case Law Update

ACOs, continued from the front page

they will be able to navigate that minefield successfully. In fact, since mal-occurrences stand to be reduced by following best practices and by better accessing patient information, liability exposure may well be **less** for physicians within ACOs relative to those without. For those mindful of the new areas of potential exposure and who adopt practical mitigation strategies, the outlook should be even brighter.

Potential New Risks

These are new and untested waters. Potential new areas of risk include the following:

Joint, Several and Vicarious Liability – A fundamental goal of an ACO is to remove care from fragmented silos to integrated care across the full continuum. There are new and enhanced roles for allied providers, such as nurse navigators and coordinators, who are encouraged to practice “at the top of their licenses” but pursuant to physician supervision. Primary care physicians will access specialist knowledge and judgment directly and electronically. Practices, health systems, and ACOs are being restructured into new frameworks.

For a patient in an ACO population litigating injury alleged from treatment, it is logical to expect a professional negligence complaint to use the “shotgun” technique. The shotgun approach includes any provider, employer, or related entity even remotely connected with the mal-occurrence. The patient will likely claim that all should be held liable and be jointly and severally liable for the alleged damages.

With multiple providers having contact with the patient, and more providing clinical input, there will be some novel challenges in sorting out who actually was responsible for the patient. If there was a failure of the standard of care, whose was it, and did it proximately cause the injury? Or, was it truly a joint care event and all involved should be held jointly and severally liable?

Since vicarious liability is liability that a supervisory party, such as an employer, bears for the actionable conduct of a subordinate based on the relationship of the parties, this theory may come into play in ACOs. Hospitals are employing more and more ACO-participating physicians. Allied providers of health systems, group practices and ACOs are assuming greater direct patient care responsibility. In most states, regardless of employment status, these increasingly active providers must be under the supervision of a physician, meaning that the physician retains legal responsibility for adequate supervision. ACOs will be tempted to hold themselves out as providing better high-value care, which likely raises the chances of them being held vicariously responsible (or liable for contractually assumed liability) should those claims not be met.

Lawsuits are foreseeable against a physician who never saw the patient, and such suits may arise because of the acts of an employed or supervised provider.

New Duties to Patients? – Will “patient centeredness” create a heightened duty of informed consent? Will new duties (*i.e.*, required individual care plans) lead to new claims for breach of those duties?

The regulations of the Medicare Shared Savings Program (MSSP) (42 C.F.R. § 425.112, **et seq.**) require ACOs to “Promote ... beneficiary engagement ..., adopt a focus on patient centeredness ..., and have defined processes to fulfill these requirements.” 42 C.F.R. § 425.112(a)(1)(iii). Clinical knowledge must be communicated to patients in a way that is understandable to them. 42 C.F.R. § 425.112(b)(2)(iv). Shared decision-making must take into account the patient’s “unique needs preferences, values, and priorities.” 42 C.F.R. § 425.112(b)(2)(v). The ACO must submit a description of its individualized care program 42 C.F.R. § 425.112(b)(4)(ii)(A).

It is foreseeable that a plaintiff might try to convert these requirements into independent legal standards. Will a physician be held liable for failure to have sufficiently involved the patient, failed to have a care plan, or even if so, failed to document same? Will this patient engagement notion heighten the standard for obtaining informed consent? How can you prove that the patient “understood?”

Heightened Standard of Care? – The MSSP requires ACOs to define processes to promote evidence-based medicine. 42 C.F.R. § 425.112(a)(1)(i). This could be viewed as creating a heightened standard of care owed by the treating physician to the patient.

Conflict of Interest Allegations? – Remembering the litigation during the capitation era when complaints against physicians and managed care organizations commonly alleged that appropriate care was withheld because the physician negligently prioritized their financial success over the health of their members, some predict a similar wave of claims because of the ACO’s shared savings incentives. Since ACOs have mandatory and explicit quality standards and processes that are prerequisites to savings distributions, this author believes the capitation litigation is distinguishable and such claims will not be successful. This assumes that the quality benchmarks mirror or exceed the relevant legal standard of care.

Defensive Medicine No Longer an Option? – What happens when that defensive medicine extra test does not comport with the ACO’s best practice guidelines?

E-Health Liability Risks – ACOs are encouraged to use digital technologies to gather, sort, and transmit patient data, including the use of electronic health records. These are intended to be available at the point of care along with best practice decision support to assist the physician in optimum patient treatment. These activities raise interesting malpractice issues:

The Duty to Consult Medical Records – Because the standard of care in medical malpractice cases is based upon medical expert testimony, it is an evolving, normative measure of physician performance. Failure to consult electronic medical records may not be viewed as negligent today, but as the standard of care evolves, failure to consult may constitute negligence in the future. Thus, a claim for malpractice involving failure to review an electronic health record (“EHR”) would have to show that: (1) the standard of care included a duty to consult the medical record, and (2) the electronic technology involved was the medium dictated by the

standard of care to access the medical record in question. However, the case law on the basic question of whether physicians have a duty to consult a medical record is inconclusive. Additionally, how much of a potentially voluminous digital medical record must the physician review?

The Duty to Adopt New Technology – New technology is sought by an ACO to give physicians access to more records and tools to promote better health care. Should that new technology (such as a database allowing access to a patient’s information) change the standard of care and thereby enhance medical liability exposure for laggard adopters of a given technology? However, by their nature, standards of care change rather slowly. Those involving a duty to use a particular technology will, as well.

Negligence in EHR Use – Malpractice risks may stem from improper data entry, with later reliance on that data resulting in patient harm. Even with good data entered, there could be user error or a system-wide EHR failure. There can be negligent documentation gaps caused by the interface between payor and electronic records. These risks can be mitigated by prudent system design, training, and monitoring.

“With EHR systems, clinicians may find it extremely difficult to process the plethora of information that floods their computer screens. Yet, those who miss a critical detail could be held liable for negligence because the fact in question was likely just a few clicks away when the physician was reviewing the patient’s EHR.” **Hoffman, S., et al., *E-Health Hazards: Provider Liability and Electronic Health Record Systems*, 24 Berkley Tech L.J. 1523, 1541 (2009)** Another side of the same coin is when the physician does review the information but overrides the decision support best practice guidelines in protest over “cookbook medicine.”

Other Risks

Though beyond the scope of this article, other more predictable and settled potential liability risks for physicians participating in ACOs include the following:

- Cyber Liability
- Antitrust
- Contractual Liability
- Officer and Director Liability
- Self-Referral and Anti-Kickback Regulatory Compliance
- Civil Monetary Penalties Law
- Tax Exemption and Inurement
- Corporate Practice of Medicine
- Insurance, Business and Intellectual Property Laws

Potential Reduced Risk

Following Evidence-Based Best Practices – Following evidence-based best practices will likely reduce risks in two ways. First, there should be fewer claims since following best practices will result in fewer mal-occurrences. Second, abiding by an aspirational nationally recognized standard of excellent care can serve as a shield in the physician’s defense. An example of this is when anesthesiologists in North Carolina agreed to follow treatment guidelines. This

was somewhat controversial at the time, as debate ensued concerning the fate of the physician who did **not** follow the guidelines. Dale Jenkins, CEO of Medical Mutual Insurance Company of North Carolina, confirmed that “No doubt this specialty impacted their claims experience with guidelines, and their malpractice insurance rates, which went down.” Dr. Grace Terrell, president of Cornerstone ACO, put it another way. She said, “Despite the hoopla that ACOs would increase liability, I have seen no evidence of it. Doing the right thing for patients is never the wrong thing to do.”

The infant ACO movement is now ushering in ubiquitous adherence to clinical guidelines. Liability statistics for physicians in ACOs are almost nonexistent, and the professional liability benchmark of community standard of care evolves slowly. Notwithstanding, there is a solid basis to predict that patient outcomes will improve, mal-occurrences will decline, juries will view the physician following guidelines as not being negligent, and the overall net professional liability exposure for physicians will be reduced.

Access to Clinical Knowledge – A physician in an ACO can call in specialty expertise on a troublesome issue, virtually or actually. The previously overwhelmed physician, working in his or her silo, did not have the same access to real-time clinical judgment. One example is the change in risk exposure for emergency physicians. They often had no ongoing physician/patient relationship for the patient entering the Emergency Department, limited or no medical information, and usually no follow-up appointment arranged before discharge. It is understandable that the urge to practice defensive medicine is great in that setting. Contrast that with the care of an ACO patient. The emergency medicine physician will likely have the relevant medical history and an opportunity for consult, and every ACO patient walking out should have a follow-up appointment to see the ACO’s primary care physician in his or her hand. That patient will be seen in a few days, greatly reducing the chance of a mishap. Some ACOs are posting cardiologists and other specialists in EDs, to provide real-time support. In this scenario, quality goes up, costs go down, and the chances of a mal-occurrence are reduced.

Strategies to Manage Professional Liability Risks

There are several opportunities to reduce professional liability risks for ACO participating physicians.

Best Practices as Shield – Obviously, to obtain the defense shield noted above, it is important for ACO physicians to establish, understand, and follow clinically-valid evidence-based best practices that meet or exceed the relevant standard of care. Mr. Jenkins cautioned that a physician choosing not to follow guidelines should carefully document the clinical rationale for that decision.

Prudent System Design – Prudent policies, data protection plans, systems, and training will go a long way to mitigate risks. The goal of this article is to target those risks to allow system design to avoid them.

System-wide Risk Management – The ACO should consider employing real-time adverse event management utilizing the ACO’s data collection capabilities. Some ACOs may have the critical mass to compliment the risk management system by forming a captive

insurance company and/or becoming a Patient Safety Organization (“PSO”). Pursuant to the Patient Safety and Quality Improvement Act of 2005, PSOs may receive medical information on a privileged and confidential basis, for aggregation and analysis of a patient safety event. See **Patient Safety and Quality Improvement Act of 2005, Pub. L. 109-41, 42 U.S.C. 2996-21-b-26; see also 42 C.F.R. Part 3.**

Informed Consent Process – The notions of patient engagement and patient centeredness imply an ongoing two-way relationship. The same can be said for the process whereby the patient becomes informed. It is not a single-shot discussion, but a process whereby the patient gains understanding over time. The process should be thoroughly documented and an informed consent document should be signed by both parties.

Insurance – Insurance products are being created to address the uniquely different professional liability risks for ACOs and their providers. These probably should be combined in an insurance product that covers the full range of exposure of ACOs and their participants. The package may include: health care professional liability, directors and officers liability, business errors and omissions (E&O), including managed care, cyber liability, privacy, and social media.

Conclusion

Transformative new interaction will be required between physicians and their patients in ACOs. On one hand, it presents a legal minefield that is partially uncharted. On the other, as Dr. Terrell said: “Doing the right thing for patients is never the wrong thing to do.” Physicians in ACOs that have identified the new risks and adopted prudent best practices, systems, and policies stand a fair chance to practice in an environment of better patient experiences and reduced liability exposure.

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