Introduction

The Patient Protection and Affordable Care Act ("PPACA" or the "Act") provides for the formation of "Accountable Care Organizations" ("ACO"), which have been defined as "groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high quality care to their Medicare patients" and the chronically ill. As part of the PPACA's "Medicare Shared Savings Program," ACOs are eligible to receive financial incentives from the federal government in the form of shared savings from an overall reduction in Medicare expenditures that is expected to come about through implementation of the Act. As many providers, along with their risk managers and counsel, move toward implementing accountable care models encouraged by the Act, they face potentially broadened categories of risk and liability from those to which they have grown accustomed in traditional care provision. While many responses to anticipated increases in liability can be predicted, it seems the process of defending against issues borne of these changes must be as fluid and dynamic as the new models for coordinated care they seek to protect. Below, we set forth several areas for potential liability for the accountable care model along with some potential defense solutions which may assist with their mitigation or alleviation.

Changing Care Models, Changing Liability

It is important to note two points from the outset. First, the PPACA does not provide a statutory cause of action as other federal and state legislation, such as the Emergency Medical Treatment and Active Labor Act ("EMTALA") or the New York State Public Health Law, have in the past. Second, there is no known federal or state preemption available for claims that may be brought against ACOs pursuant to key provisions in the PPACA. We believe it is very likely that, at least in the short term, we will see claims for malpractice against ACOs and ACO-affiliated providers that will be enhanced because of key provisions in the Act. More specifically, because the provisions of the Act encourage ACOs to implement patient care standards and in fact to participate directly in increasing the quality and efficiency of patient care, protections from liability that were previously afforded health maintenance organizations ("HMO") due to considerations that they did not directly participate in patient care will not likely be available to ACOs.

Indeed, in New York, protections available to HMOs and other traditional coordinated care models, including preemption under the Employee Retirement Income Security Act ("ERISA") and common law protection from liability for corporate structures, seem inapplicable to ACOs in certain respects. More broadly, from surveying the PPACA, the Department of Health and Human Services ("HHS") regulations that seek to implement it, and cases that deal with the imposition of vicarious and other types of liability, we can predict that prior protections from certain kinds of liability will not apply to ACOs going forward. This is primarily because, as ACOs are formed and adopt rules for their provision of care as directed by the PPACA and regulations governing their existence, they demonstrate that, unlike HMOs, they are more than just administrative entities or benefits coordinators. The language of the Act and the regulations that implement it reinforce the notion that the likely trend will be towards holding these entities vicariously responsible for the actions taken by their affiliated care providers, including for claims of medical malpractice.

New Duties and Heightened Standard of Care

There are many ways in which ACOs and affiliated providers may face increased risk of liability for their actions. The first is an increase in liability for new duties imposed by certain documentary requirements of the Act. For example, the Act requires each ACO to demonstrate "that it meets patient-centeredness criteria specified by the Secretary [of HHS], such as the use of patient and caregiver assessments or the use of individualized care plans." The HHS regulations further require each ACO to "provide documentation in its application describing its plans to: (1) Promote evidence-based medicine; (2) promote beneficiary engagement; (3) report internally on quality and cost metrics; and (4) coordinate care." Care plans and assessments are not new forms of documentation for health care providers. Indeed, physicians, nurses, and other providers routinely use these types of documents to track patient care in discrete care environments, such as hospitals, skilled nursing facilities, and same-day surgery centers. The PPACA, however, envisions that ACOs will share information, thereby improving knowledge among all providers and eliminating duplication of testing and treatment across the continuum of a patient's care. In the ACO context, then, documents such as individualized care plans and assessments will track patient care and interaction with health care providers across several different care environments together. The liability stemming from this type of documentation is therefore likely to increase in the following ways.

Traditionally in New York, as in most jurisdictions, in order to prove medical malpractice in a civil action a plaintiff must provide evidence of duty, breach, causation, and damages. According to the New York Civil Pattern Jury Instructions ("PJI"), negligence for a physician is "the failure to use reasonable care under the circumstances, doing something that a reasonably prudent doctor would not do under the circumstances, or failing to do something that a reasonably prudent doctor would do under the circumstances." The current duty a Hospital must meet is "to use reasonable care in [hiring and supervising] its..."
employees, including members of its medical staff, such as doctors, interns, residents, as well as non-physician personnel, such as nurses, technicians, and aides.\textsuperscript{15} Reasonable care is defined as “that degree of care customarily used by general hospitals in [hiring and supervising] their employees.”\textsuperscript{16}

It is possible to see that the Act’s requirements add the duty for care providers to create and maintain documents including individualized care plans and patient and provider assessments that track patient care through several care environments. The duty to maintain these documents provides more potential for plaintiffs’ attorneys in malpractice actions to claim that provider and ACO actions were not reasonable under a given set of circumstances. We must presume that ACO application and formation documents outlining policies and procedures for maintaining these patient tracking documents, as well as the documents themselves, will all be discoverable in civil lawsuits targeting ACOs.

Providers and ACOs will thus be held responsible for all the same documentation and record keeping issues that arise from traditional health information records, including errors of omission for necessary information that was not recorded properly. But, in the ACO setting, the sheer breadth of the material required to be maintained will likely increase the chances for liability that have traditionally resulted from these records. In addition, the very existence of all this documentation pertaining to any given patient will likely create a duty for providers within the continuum of the patient’s care to be fully familiar with all of the patient’s documentation, no matter its source, before undertaking any treatment.

**Defense Solutions to New Duties and Heightened Standard of Care**

Interestingly, the same aspect of the PPACA that has the potential to create so much liability stemming from increased record-keeping also holds the key to defending against that liability. Because the Act contemplates increasing access to information about patient treatment through electronic health records (“EHR”),\textsuperscript{17} it appears that there will be more opportunity for providers to update and add information to patient records. Providers would be wise to take advantage of this opportunity by frequently adding to patient charts and care plans. These notes, including notes pertaining to interactions with patients, should be considered part of the overall treatment plan.

Additionally, since providers updating care plans will likely be held responsible for the information in those plans that bears on patient treatment, providers should monitor the information before them, such as patient history, current medication regimen, and recommendations of other providers, and, if any inaccuracies are noticed, should correct the information without criticism or editorialization, so as to avoid drawing fire for earlier inaccurate entries. Having such a wealth of information available about each patient’s history of care and treatment should be of great benefit to the patient and his or her providers, but only if it is accurate. For this reason, ACOs and affiliated providers must place a high priority on the accuracy of patient information in the voluminous documentation required by the Act.

**Institutional Liability for Accountable Care Organizations**

ACOs may not only face increased liability stemming from record-keeping requirements in the PPACA, but also from the nature of the services they render. According to the Act, “[t]he ACO shall be willing to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to it.”\textsuperscript{18} This language in the Act suggests that a significant shift may be underway in how vicarious and direct liability will be determined for healthcare organizations with respect to the providers caring for patients under their auspices. Traditionally, liability has stemmed from control over patient care. In the hospital setting, this has generally meant that hospitals themselves were not liable for medical negligence when it was caused by a private physician attending to his or her own patient in the hospital’s bed, or when members of the hospital's professional staff followed the orders of a private attending physician. Under such circumstances, responsibility for patient care rests with the physician, and it is the physician, therefore, who has borne the lion’s share of responsibility for care-related decisions.

Similarly, HMOs and other managed care organizations have been largely shielded from liability for the actions of providers with whom they contract on the theory that the organization itself, while functioning primarily to arrange for and finance healthcare, is not directly providing or controlling patient treatment. On the contrary, it is the independent contractor who exerts control over the patient and who therefore bears responsibility for care-related decisions. Even New York’s Public Health Law has formally recognized that HMOs do not provide care: “The provision of comprehensive health services directly or indirectly, by a health maintenance organization through its comprehensive health services plan shall not be considered the practice of the profession of medicine by such organization or plan.”\textsuperscript{19} In other words, the HMO itself is not engaged in the “practice” of medicine and is therefore not liable for actions related to patient care.

In cases where HMOs have been shown to exert direct control over network physicians’ medical judgment, however, i.e., where HMOs themselves make decisions about medical necessity, these entities have been found vicariously liable for negligence stemming from the decisions.\textsuperscript{20} In lawsuits related to medical negligence, then, the touchstone for liability has traditionally been control over patient care. HMOs and other managed care entities were able to minimize their liability by expressly disclaiming that what they did was the provision of care and by emphasizing in marketing and patient-facing materials that network providers were independent contractors.

The Employee Retirement Income Security Act (“ERISA”)\textsuperscript{21} also provided liability protection for HMOs. According to the United States Supreme Court, Section 502(a) of ERISA preempts any state law claims for malpractice against HMOs for decisions related to eligibility and administration because such activities do not fall under the guise of patient care and treatment.\textsuperscript{22} Again, we see the touchstone that liability for medical negligence attaches where there is direct control over patient care. It is for this reason that protections from liability traditionally afforded HMOs and similar organizations are less likely to shield ACOs from liability.
As stated above, the Patient Protection and Affordable Care Act envisions that ACOs will become “accountable” for the “quality, cost, and overall care” of patients. Because the ACO structure thus explicitly integrates administrative and patient care functions, it is likely to be much, much harder for an ACO to argue that it is not involved in care with respect to a given patient, but is only involved with claims processing, for instance. Similarly, because ACOs are required to actually provide “care” and are furthermore required to become “accountable” for the “overall” trajectory of patients’ care, it should be much more difficult for them to distance themselves from individual providers by arguing that they are independent contractors.

In the past, managed care organizations were able to avoid liability for care-related functions by creating marketing and other patient-facing materials that explicitly disclaimed their role in providing patient care. Given the PPACA’s mandate that the ACO should become accountable for providing care, however, and given the greater integration envisioned between financial, administrative, and patient care functions in the ACO structure, it is likely that the barrier shielding entities such as HMOs and managed care organizations from negligence liability will not protect ACOs, even with respect to functions traditionally considered administrative. Furthermore, because institutional cost-cutting measures which have a consequential effect on patient treatment, is often seen as minimizing patient understanding and consent into a “discrete paper-signing event.” The present process of informed consent is often criticized for placing greater emphasis on protecting physicians from liability than on providing patients with truly meaningful information about their health and choices. The standard consent form, which is central to this process, is often seen as minimizing patient understanding and consent into a “discrete paper-signing event.”

Whereas the present system places the emphasis on “consent,” the Final Rule of the HHS places the emphasis on “informed.” This will arguably make it more difficult for providers participating in ACOs to meet this standard, but certain changes in the way patients are consented may work to alleviate some of the increased risk created by the heightened standard.

**Defense Solutions for Issues Related to Heightened Informed Consent**

One solution may be for ACOs and affiliated providers to think of consent not as a discrete moment, but as a process whereby the patient gradually acquires information, asks questions, and is given the opportunity to discuss the information with friends and family, if time permits. Providers should have a full and frank discussion with patients at their level of understanding, taking care to explain the risks and benefits of all alternative treatments as well as the likely consequences of forgoing treatment altogether. The emphasis should be on each individual patient, and the process of gaining the individual’s consent should be thoroughly documented. A further possibility is for the patient to write the informed consent document in his or her own words, describing what was discussed, what questions were asked and answered, and how and why the treatment decision was reached. This form, along with a standard form prepared by the physician, could be signed by both parties to demonstrate adherence to the heightened standard of patient engagement.

A crucial aspect of the PPACA’s mandate calls for ACOs to promote “patient engagement” in the process of individualized care and treatment. Working to implement this requirement, the HHS Secretary has suggested that “patient engagement” is the active participation of patients and their families in the process of making medical decisions. More specifically, ACOs are responsible for communicating clinical knowledge and evidence-based medicine to patients in a way that is understandable to them, sharing patients’ medical records with them, and engaging patients in “shared decision-making that takes into account [their] unique needs, preferences, values, and priorities.” This language arguably creates a higher threshold for obtaining informed consent.
Integrated Medical Care

In addition to its emphasis on patient engagement, the PPACA also requires ACOs to utilize new technologies in providing patient care. ACOs must “define processes to . . . coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies.”

Overall, the regulations governing the Medicare Shared Savings Program place a heavy emphasis on integrated medical care through technology, including the use of electronic health records and other measures intended to effectively coordinate care among primary care physicians, specialists, and acute and post-acute providers. While such integration is designed to facilitate greater quality of patient care at reduced costs, it also has the potential to expose ACOs and affiliated providers to increased risk of liability for negligence related to these integrated systems and the procedures and processes that they facilitate.

While the Medicare Shared Savings Program supports “value-based” purchasing of healthcare, traditional Medicare expenditures followed a fee-for-service model in which greater volume generated greater income. More admissions, tests, and procedures meant greater revenue for providers. As well, providers typically maintained their own medical records in isolated systems and did not generally share information. Consequently, there was little incentive or opportunity for providers to avoid duplicating the same information about patients in their respective records or to avoid duplicating diagnostic studies at different facilities. In order to reap the benefits of the shared savings available under the PPACA, however, providers will need to share information about patients and minimize the number of admissions, tests, and procedures conducted on a given patient. Although the potential benefits to patients from this move toward efficiency are obvious, so are the risks. For providers accustomed to ordering and interpreting all of their own diagnostic studies, the need to rely on others could result in missed diagnoses and opportunities for treatment. It also could prejudice future treatment based on initial diagnostics and evaluations.

The envisioned ubiquitous use of electronic health records (EHR) also creates significant opportunities for liability. Doctors have always used handwritten notes as a means of communication, but the electronic format facilitates compiling more lengthy and detailed notes. While this may provide better support and justification for billing, it also carries the risk that key pieces of information will get lost in mounting documentary data for each patient. Similarly, the temptation to cut and paste in electronic charts can result in the omission of crucial data or the propagation of a single error to multiple providers engaged in caring for a patient. Also, as text in patients’ hospital records becomes increasingly boilerplate, it may be less defensible to claim reliance upon it when justifying a medical decision. Similarly, the increased use of electronic information regarding provider–patient interaction means an increase in the creation of metadata, such as timestamps and record access logs. The more metadata that becomes available—and potentially discoverable—the greater will be the liability for providers with respect to fine-grained details of day-to-day patient care.

Furthermore, because all patient records will theoretically be available to any treating provider at any given time, failure to respond to or act in accordance with a piece of data buried in a patient’s chart may open the provider to a malpractice claim. It is easy to see how patient care could drastically be improved if all relevant patient information were accessible to all providers at all times, but it could be dangerous from a liability perspective. Providers may be expected to have full familiarity with all information in a patient’s chart, accumulated perhaps for years across multiple sites of care, before rendering any medical treatment. There is an even greater danger should patients have access to update their own medical records. As only one example, misspellings or mistakes in the names and dosages of prescription drugs taken could abound. Providers would not only have to contend with the volume of information in patient charts, but also with patient-generated content, the veracity of which could not necessarily be ensured. Under such circumstances, it would be dangerous for providers to rely on such information and equally dangerous for them to ignore it.

Defense Solutions for Integrated Medical Care

One solution to the potential for liability imposed by integrated medical care is for providers to be vigilant and active about editing patient charts. Any inaccuracies should be immediately corrected without editorialization or other comments that could draw attention to the error that persisted before the correction. Providers should also resist the temptation to copy and paste and should ensure that the volume of notes they create does not obscure key pieces of necessary information. With respect to efficiency, physicians should ensure that the reason for decisions not to run a test, perform a procedure, or admit a patient to the hospital are well documented and supported so that mere financial considerations cannot be claimed as the sole basis for these important decisions. Physicians must also have the autonomy and flexibility in their practice to duplicate tests or recommend admissions or expensive procedures where necessary and appropriate.

Conclusion

Assuming all goes to plan, Accountable Care Organizations appear to be destined to be a greater part of the healthcare landscape, and individuals as well as populations will see improvement in the care and services available to them, while the government will see lower growth in Medicare expenditures. Through the ACO model, physicians, hospitals, and other care providers and the patients they serve will all stand to benefit from the savings expected to flow from greater efficiency in providing services. While many of the scenarios for care and corresponding liability in this new environment will be familiar to providers, they appear likely to lead to potential new pitfalls as well. It is worth emphasizing again that while the PPACA does not create a statutory cause of action, there is no known preemption for claims that may be brought under the Act.

Given the Act’s infancy and the fact that provisions are being implemented on a rolling basis, it may be years before claims based on language in the Act make it to the
courts. Nonetheless, a close reading of the Act appears to indicate that liability for healthcare organizations and professionals may be enhanced in the coming years. For this reason, it is important for those who have begun providing services in the context of an ACO as well as those who will likely do so in the years to come, to be mindful of areas where liability for organizations and individual providers may increase. We have attempted to demonstrate that even though the liability landscape for providers may look drastically different, with planning, foresight, and attention to detail, all of the potential new and expanded risks may be mitigated or averted.

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5 N.Y. PUB. HEALTH LAW § 2801-D (McKinney 2012).
6 Cf., e.g., N.Y. PUB. HEALTH LAW § 4410 (exempting Health Maintenance Organizations from lawsuits related to the practice of medicine).
10 Cf., e.g., N.Y. PUB. HEALTH LAW § 4410. (emphasis added).
14 CENTER FOR MEDICARE & MEDICAID SERVICES, ACCOUNTABLE CARE ORGANIZATIONS, supra note 4.
16 Id. § 2:151.
17 Id.
20 Cf., e.g., Petrovich v. Share Health Plan of Ill., Inc., 719 N.E.2d 756 (Ill. 1999); also see Burg v. Health Care Plan, 281 A.D.2d 976 (4th Dep’t 2001) (holding that HMOs are not precluded from vicarious liability for malpractice of employee physicians).
21 Patient Protection and Affordable Care Act § 3022, 42 U.S.C. § 1899(b)(2)(G) (requiring ACOs to “define processes to promote evidence-based medicine).}
22 Id.
25 See, e.g., N.Y. PUB. HEALTH LAW § 2805-d.
30 See 76 Fed. Reg. at 67,829 (“Processes to Promote Coordination of Care”).
31 See id. at 67,803.
32 See id.