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HEALTH CARE REFORM: RECOGNIZING THE RISKS

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INTRODUCTION

The Patient Protection and Affordable Care Act (PPACA) is settled law, having been approved by Congress and upheld by the U.S. Supreme Court.[1] On October 1, 2013, the insurance marketplace opened for business despite huge technical issues for those seeking enrollment. As of February 2014, four million Americans had enrolled for care under PPACA.[2] Despite controversy, ongoing political opposition and the increasingly remote possibility of a weakening or a repeal of PPACA,[3] health care reform will permanently alter the landscape of perhaps the most important industry, one that affects virtually every American citizen's life from cradle to grave.

Too many variables exist to give us a clear picture of a health care delivery system in five or 10 years. PPACA will likely be tweaked over time; this is already occurring, as many predicted. Even if this landmark law had been overturned, there still would have been a strong movement towards reform and clinical integration. The health care industry's payers, chiefly the Centers for Medicare and Medicaid Services (CMS) and other commercial health insurers and HMOs, along with hospital systems, are the primary drivers of reform. The rapid acceleration of health care costs is a societal concern, since health care consumes more than 17% of GDP and is projected to grow to almost 20% of GDP by 2021.[4] Payers will primarily focus on payment methodologies that will require hospitals to manage populations through quality and financial metrics that will seek to improve outcomes and directly affect reimbursement.

Clinical integration has a number of possible definitions, but the American Hospital Association says that these definitions "generally focus on efforts that involve collaboration among different health care providers and sites to ensure higher quality, better coordinated and more efficient service for patients."[5] Clinical integration seeks to create a more aligned and efficient health care delivery system at both macro and micro levels.

Change presents challenges and opportunities for risk managers, in-house and outside counsel, and health care professional liability insurers. New liabilities can arise and risk management strategies should be refined. These challenges include:

- Increased health care (hospital and medical) professional liability exposures
- Increased non-professional liability exposures: cyber, fraud and abuse, directors and officers, errors and omissions, regulatory risk, and financial risk
- More complex claim defense
- No existing data on the impact of reform: the risks are prospective

Many in the medical professional liability (MPL) insurance industry are concerned that reform will reverse the positive trends and profitability of the last decade. Some have predicted that health care reform will lead to another malpractice crisis. But will it? Underwriting by commercial carriers and self-insured entities, such as captives and risk retention groups, must also evolve to meet the challenges posed by reform.

Health care reform may also reduce clinical risk in numerous ways. Regardless, risk management strategies of health care providers must keep pace with the challenges posed by reform.

REFORM: KEY MACRO-TRENDS

While there is not sufficient space in this article to discuss these key macro-trends in any detail, risk managers and insurance professionals must keep them in mind when formulating strategies to manage and finance health care risks. They impact potential liability, particularly in times of transition in health care organizations.

- Payment transformation: volume-based to value-based
- Focus on wellness: keeping patients out of the hospital with Population Health Management (PHM)
- Patient care delivered in non-traditional settings
- Patient care will be more coordinated than ever
- Physicians are critical to organizational success
- The EMR is crucial for system coordination/collaboration/communication
- Hospitals will be at financial risk through new reimbursement methodologies
- Data is king: quality metrics, evidence-based medicine protocols[6]

REFORM AND CLINICAL LIABILITY EXPOSURES

Health care systems have become increasingly larger through mergers and acquisitions. They may also extend their market share through other alignment strategies, such as affiliations, joint ventures, joint operating agreements and management contracts.[7] They are highly capitalized and, as potential defendants, are viewed as having "deep pockets." Health care systems' increased size could adversely affect public and patient perceptions, leading to more litigation if they are also perceived to deliver impersonal and expensive care and as patients are left to pay higher deductibles pursued through aggressive collection strategies.

The potential also exists for an increased volume of previously uninsured patients entering the system seeking primary care. One projection estimated the increase of primary care visits to be from about 15 million to 24 million by 2019.[8] A real concern (not undisputed) exists that there are inadequate numbers of primary care physicians, specialists,[9] and physician extenders, such as physician assistants and nurse practitioners, to serve these new patients.[10] Patient visits could be unduly delayed and patient encounters could be shorter. Health care professionals may be spending less time with patients, thereby contributing to errors resulting in harm.

There will be more use of allied medical professionals, especially nurse practitioners and physician's assistants. These physician extenders will likely be asked to assume more responsibility and see a higher volume of patients due to the influx of newly insured patients, especially to primary care practices.[11] Issues will arise in litigation about their scope of practice, what duties are delegable or not, and the requisite standard of care. Plaintiffs will argue that the applicable standard of care is that of a physician, depending on the circumstances.

Novel care delivery will spring up in new outpatient settings, especially in private businesses (under contract with local providers) and in retail-based health clinics in stores and pharmacies. This is already occurring and should mushroom over the next decade. Physician extenders, as well as pharmacists, may be delivering care in these new settings. Issues of adequate supervision, use of proper patient care protocols or the absence of patient care protocols, failure to refer to a physician or hospital, are just some of the issues indigenous to this new landscape.[12]

The use of telemedicine, connecting outlying hospitals with urban hospitals and allowing specialists to help evaluate patients, will proliferate.[13] This can occur across state lines and complicate litigation. While telemedicine applications have burgeoned over the last five years, there has been very little litigation to date and almost no case law as very few cases have gone to trial. The number of cases to date is "tiny."[14] Telemedicine is rarely the primary focus of the very few cases that have gone to litigation, according to the author's discussions with medical professional liability insurance carriers.

Reform's financial incentives could distort medical necessity decisions. Whereas a fee-for-service payment methodology can lead to over-utilization through increased testing and therapies, global payments, bundled payments, and other financial risk reimbursement models to provide care for small segments or large populations may lead to under-utilization. Plaintiffs' attorneys can argue that care was denied or withheld to save money. Providers and risk managers will need to help physician and administrative leadership evaluate when utilization can be safely decreased at the macro and micro levels.

Meeting quality metrics, maximizing efficiencies and reimbursement will require more coordinated care than ever before, making patient hand-offs more crucial than ever. We can expect to see more "you dropped the ball" claims from the plaintiff's bar if patients get lost in a care delivery system and are harmed. Risk management and quality initiatives will need to concentrate more on care delivery processes and systems. Some hospitals are using management tools to help, such as Kaizen and Six Sigma.

The electronic medical record (EMR) is potentially a great tool for coordinating and improving patient care, but initial implementation bugs can cause patient injury.[15] A major issue that must be addressed is how a provider makes corrections in the EMR so as not to weaken the defense of any malpractice case.[16]

REFORM AND LEGAL LIABILITY EXPOSURES

Although the national environment for hospital and medical professional liability is almost surely the best it has been since the mid-1970s (thanks to widely enacted malpractice reform laws and a focus on patient safety), the potential for hospital and medical professional liability claims continues to exist. Medical professional liability coverage continues to be one of the most profitable lines of property/casualty insurance.

MEDICAL MALPRACTICE INSURANCE TRENDS

Medical Professional Liability Combined Ratio 2008 – 2012

Year	Combined Ratio
2008	77.4
2009	83.4
2010	80.6
2011	87.9
2012	93.8

Source: A.M. Best 2013

Consolidation of hospitals into larger systems makes them easier targets for very large verdicts.

One trend that must be closely observed is the increased number of "jumbo" malpractice verdicts over the last few years.

JUMBO VERDICTS

Month	Venue	Amount	Loss
Mar 2010	New York	$60.9M	Negligence at birth
Jul 2010	California	$670M	Inadequate staff at assisted living facilities
Jul 2010	Florida	$114M	Wrongful death suit against nursing home
May 2011	Connecticut	$58.6M	Negligence at birth
Aug 2011	West Virginia	$91.5M	Nursing home negligence
Oct 2011	Michigan	$144M	Negligence at birth
Jan 2012	Florida	$168M	Brain damage following surgery
Oct 2012	New York	$144.7M	Failure to diagnose MI

Source: Western Litigation 2012

The acquisition of physician practices and other entities (e.g., as ambulatory surgery centers and imaging facilities), creates the potential for increased vicarious liability. The physician exposures are often new and may be unfamiliar to hospital administrators, attorneys and risk managers; exposures such as claims for physician misdiagnosis or improper performance of a surgical procedure. Employing pediatricians and obstetricians creates the potential for high-damage claims, as damage caps do not help with economic damages when a child is severely injured.

The movement of physicians to hospital employment may impact liability in that the higher limits of liability coverage carried by the hospital will now be exposed in litigation where employed physicians are the primary actors in claim scenarios.

These types of claims, such as misdiagnoses, seldom exposed hospitals to verdicts and settlements in the past, but they now become more volatile on theories of vicarious liability. Hospitals have aways been more reluctant to take cases to trial than physicians and their insurers out of concern for exposure to high verdict amounts and adverse publicity.

The myriad formations and creations of care networks by contract or new corporate structures, such as joint ventures, affiliations and partnerships under the guise of accountable care organizations (ACOs), clinically integrated organizations (CIOs), and other non-ownership arrangements creates potential legal liability on a theory of ostensible agency. These arrangements may also fuel claims for negligent credentialing of the organization or individual providers. Due diligence in risk management should be a part of these arrangements at inception as well as clarifying the arrangements to patients using printed materials and other media.

With new reimbursement methodologies driving new approaches to patient care delivery, the legal standard of care will evolve accordingly. But the standard of care will remain fluid for the indefinite future. Claims, risk management, and underwriting strategies of health care providers and insurers must take this into account.

The increasingly widespread use of quality metrics and evidence-based medicine protocols can potentially help achieve better patient outcomes, create efficiencies and reduce costs. But they can and almost surely will be used by the plaintiff's bar as evidence of the standard of care that was not met during the patient's treatment. However, this should not deter their use to improve care and patient outcomes.

REFORM AND NON-PROFESSIONAL LIABILITY EXPOSURES

CYBER/NETWORK PRIVACY LIABILITY

Reform and clinical integration will require vast volumes of financial and protected health information (PHI under the HIPAA laws) to be transmitted among health care providers, creating the potential for cyber/network privacy liability. Internal policies and practices must be adopted to address these exposures, but human errors will still occur. The classic health care scenario is the lost laptop computer with PHI on perhaps hundreds or even thousands of patients. Commercial insurance policies are available to insure this risk.

DIRECTORS AND OFFICERS LIABILITY

Another exposure raised by reform is antitrust. Exclusion of providers from networks and highly concentrated market penetration may create litigation and regulatory enforcement scrutiny. There has been – and likely will be more – vigorous federal enforcement of antitrust laws as consolidation occurs through mergers and acquisitions. Directors and Officers policies can help address this exposure.

REGULATORY LIABILITY

HIPAA violations, fraud and abuse violations, and other governmental fines and penalties come into play in the even more highly regulated health care industry due to reform. Commercial insurance policies are now available that can assist with defense and legal costs and payment of fines and penalties for regulatory actions if permitted by statute.

ERRORS AND OMISSIONS COVERAGE

If providers accept bundled, capitated, or global payments, they will be making decisions about utilization and appropriate methods of treatment. This is primarily a management decision but can cross over into clinical decision making, creating a professional liability exposure. There are commercial errors and omissions (E&O) policies available that can also include coverage for clinical liability if that is not found elsewhere in a provider's insurance program.

FINANCIAL RISK

Evolving reimbursement methodologies, such as bundled payments, global payments and other reimbursement models (such as capitation, where a provider is paid a set amount of money per member per month), will increasingly place providers at financial risk. Commercial insurance and reinsurance products can help mitigate financial risk. Insurance for capitation contracts has been called either *provider excess* or *provider stop loss* and works much like an employer stop loss policy or a HMO reinsurance policy.

For all of these non-professional exposures, commercial insurance coverages are usually available. Many large health care systems are assuming or considering assuming some or all of the risks for these exposures through their self-insurance vehicles, chiefly captive insurance companies.

Many health care organizations are also devising enterprise risk management (ERM) strategies. ERM goes beyond addressing the traditional property/casualty risks and takes into account organization-wide risks created by operations, finance, and external environmental factors.

CLAIMS CROSSING INTO MULTIPLE LINES OF COVERAGE

Multiple lines of coverage may apply in some claim scenarios, e.g., a hospital accepting financial risk and making utilization decisions. A claim arising in such a scenario could potentially touch on health care professional liability coverage, E&O coverage and even D&O coverage.

REFORM AND CLAIM DEFENSE STRATEGIES

The defense of health care professional liability claims will become more complex with reform and clinical integration. There could be more co-defendants due to more participants in delivering patient care to large populations, such as within an ACO, a CIO, networks, and a myriad of other corporate structures where not all participants are owned by a single entity.

Contracted entities may create ostensible agency exposure, but this can be partially addressed with contractual indemnification language. Minimum limits of liability coverage should be determined prior to participation and should reflect the advice of defense counsel as to local experience.

Hospitals will be defending physician claims, and their claim staff may lack the experience of defending individual physician claims. The hospital's full excess insurance limits may now be exposed in a physician claim. Many hospital systems have set up claim committees in order to fairly apportion liability among co-defendants. Some hospitals use claim TPA firms to defend all claims or physician claims, and some contract with local physician carriers for claim services.

More telemedicine risk may result if health care systems cross state lines. This means managing claims in unfamiliar venues using defense firms that are new to the claim staff of the health care system. Most hospital carriers are comfortable defending telemedicine claims, as they do business in almost all states. Physician carriers may sometimes lack the insurance department filings in multiple states to be able to accommodate insuring telemedicine risk.

These claim defense issues raised by reform are all manageable so long as there is a conscious effort made to address them before litigation results. Joint defense and collaborative defense agreements can be attempted, particularly with local physician carriers. Disclosure policies in the event of a patient injury should be discussed with local physician carriers and agreement reached on protocols. Health care systems that are self-insured for the first layer of coverage may have more flexibility in this regard.

REFORM: RISK MANAGEMENT STRATEGIES MUST EVOLVE

Evolving risk management strategies must include both patient populations and individual patient encounters. If a major increase in patient volume due to PPACA's impact on those currently uninsured does in fact occur, then managing patient expectations regarding wait times, comparative brevity of patient encounters, and the use of physician extenders must be factored into risk management programs. Managing patient expectations can be done verbally, through written materials, and through other media.

As continuity of care becomes the standard of care, risk managers should focus more on the patient care processes that affect how patients flow through their facilities and provider systems for care. Looking for gaps and weaknesses before they cause patient injury is more important than ever.

There must be more attention on risk management initiatives for physician extenders. Historically, these professionals have not generated a high volume of claims and have low claim severity experience, but the increase in patient encounters may challenge their diagnostic skills. Protocols must address physician supervision and the limits of physician extender practice subject to varying state laws and the requisite standard of care.

Implementation of the EMR presents huge operational challenges and increased risk of liability. Defense counsel should be consulted as to medical record preservation, discovery, and other defense implications of the EMR, such as making corrections.

With more employment of physicians, management of critical test results becomes important in risk management strategy. Technological solutions are currently available to reduce this risk.

REFORM MAY REDUCE RISK

Reform and clinical integration will certainly generate new risks but may reduce risk as well. Patients may be less likely to sue if health insurance covers the cost of poor outcomes.

One goal of reform, for example, is to reduce over-utilization. Less treatment means less patient exposure to harm. More and better preventive care should reduce the need for more acute care therapies that can generate side effects or errors.

Patient care will be more coordinated versus today's highly fragmented and sometimes inefficient delivery system. In time, patient care will improve resulting in fewer patient injuries. Telemedicine is an example of a new delivery model that is improving access to care and clinical outcomes, making specialty care available where it would not have been in the past.

The electronic medical record will improve communication among professionals and reduce errors over the long term, although implementation glitches may cause errors in the short term. Bedside clinical informatics through the EMR or other technologies can reduce errors and help professionals make better diagnoses and provide more timely treatment.

CONCLUSION

The pace of health care reform is accelerating. New risks pose new challenges for health care risk managers, counsel and insurers. Many of the risks of reform will be offset by improvements in the delivery of care that will significantly reduce clinical risk.

Organizational risk management must address the emerging clinical and non-clinical risks of reform and clinical integration. Claim defense strategies must evolve accordingly. In devising these new risk management strategies, risk managers can call on the expertise of their business partners (e.g., defense lawyers, insurance brokers, and insurance carriers) and their risk management consulting staff.

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