

Executive Summary

As part of the 2010 healthcare reform legislation, the Affordable Care Act contains several provisions that support the expansion of Accountable Care Organizations (ACOs) to manage and coordinate care for Medicare beneficiaries. The law provides ACOs with financial incentives in return for providing quality, cost-effective healthcare to Medicare beneficiaries. While the legislation has laudable objectives, there are risk implications for ACOs and the healthcare providers who decide to become associated with them. Among the potential areas of risk are:

- · Anti-competitive behavior,
- Violation of laws pertaining to the corporate practice of medicine,
- · Medical malpractice and other liability risks, and
- · Violation of privacy laws.

Because of the significant risks, risk management should be a high priority activity within ACOs.

Introduction

Today, the majority of Medicare beneficiaries has five or more chronic conditions and receives care from multiple physicians¹. The theory behind ACO's is to bring together all the different components of healthcare to encourage comprehensive and coordinated patient care for Medicare beneficiaries. The expectation is that this will lead to improved quality of care while reducing overall health care costs. The Department of Health and Human Services estimates that ACOs could save Medicare approximately \$1.1 billion in the first five years of the program².

The joining of doctors, hospitals, and other healthcare providers may allow for better care and cost-savings across the board, but healthcare providers should be aware of the risks before deciding to join an ACO. Factors to consider include how the entity will be structured, who is responsible for the medical errors and/or omission of other ACO members, and how patient privacy matters (e.g. sharing of patient information) will be managed.

Potential Areas of Risk

ACOs are exposed to many of the same risks faced by other healthcare entities such as hospitals and managed care organizations. For example, ACOs may have Managed Care Organization E&O exposures such as care management, peer review, credentialing, and network management functions.³ Additionally, ACOs are subject to heightened risks in certain areas including anti-competitive activities, corporate practice of medicine laws, medical professional liability, and data security and privacy laws.

Formation of ACO's may lead to anti-competitive concerns

While the federal law encourages the formation of ACO's, their very formation may raise anti-competitive concerns. For example, the formation of ACO's could run afoul of anti-trust laws because the ACO may have significant influence in the area in which it operates. This may limit competition and could cause prices to rise. The Federal Trade Commission and the Department of Justice have announced that they will closely scrutinize ACOs, and have jointly developed a "Statement of Antitrust

The joining of doctors, hospitals, and other healthcare providers may allow for better care and cost-savings across the board, but healthcare providers should be aware of the risks before deciding to join an ACO.

Heathcare.gov, "Accountable Care Organizations: Improving Care Coordination for People with Medicare", (March 2011) http:// www.healthcare.gov/news/factsheets/2011/03/ accountablecare03312011a.html

² Centers for Medicare & Medicaid Services

Mary S. Botkin, "Accountable Care Broadens Risk Management Responsibilities," HEALTHTREK, Willis, http://www.willis.com/ documents/publications/Industries/Healthcare/ HealthTrek_Accountable_Care_1210_v4.pdf

Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program."⁴

ACOs may violate the Stark Law

Another concern when forming an ACO is the Stark Law. The Stark Law prohibits a physician that has a financial relationship with an organization from referring a patient to that organization for health services paid for by Medicare. This seems to be contrary to the new legislation and the issue of legality of ACOs may need to be decided by the courts.

Corporate practice of medicine prohibited in many states

Another issue for ACO's is the prohibition of the corporate practice of medicine. This is a principle steeped in tradition, initially sponsored by the American Medical Association (AMA) to prevent the practice of medicine from becoming too commercialized. This doctrine essentially prohibits corporations, entities or non-physicians from practicing medicine⁵. The original intent of the doctrine was to safeguard the public by ensuring that medical care was dispensed only by those who hold an active medical license in addition to stemming any potential conflict of interest by corporations pursing profits over the practice of medicine in the patients' best interest⁶.

Over the years, many states have enacted laws restricting the corporate practice of medicine. While only licensed physicians can practice medicine, the states that prohibit the corporate practice of medicine generally have exceptions which allow for the existence of physician-owned practices in the form of a medical professional corporation (P.C.), or a limited partnership (LP), if all shareholders hold a medical license. Additionally, some states allow corporations to work with healthcare professionals who are employed as independent contractors.

This prohibition can create concern for ACOs because they may be managed by individuals who do not hold a medical license. For this reason, care should be used when creating the ACO corporate entity so as not to violate state laws prohibiting the corporate practice of medicine.

Medical Professional Liability

One of the main reasons for healthcare providers to join an ACO is the financial incentives that it will reap if the ACO reaches its goals. However, financial gains could be offset by medical malpractice or other professional liability claims. Some industry experts think medical malpractice exposures will increase for ACOs due to factors such as:

- Difficult new standards of care. "Evidence-based medicine," a theme of the
 regulations concerning ACOs, requires considerable documentation and advanced
 procedures and processes, which may create a heightened standard of care.
- More causes of action. The ACO payment model, which rewards primary care
 providers for curbing "unnecessary expenditures," may expose physicians to
 charges of failing to order necessary tests, premature discharges, or even some
 variation of patient dumping.

http://www.justice.gov/atr/public/ guidelines/269155.pdf

⁵ Physician's News Digest, Inc.

⁶ Physician's News Digest, Inc.

More stringent informed consent. A key feature of the final rule that implements
the ACO provisions of the Affordable Care Act is that ACOs "must define,
establish, implement, and periodically update processes to promote patient
engagement," including "shared decision-making." This creates standards that
arguably are stricter than existing informed-consent standards.

Discoverability of individualized care plans by plaintiffs attorneys. Regulations require individualized care plans for some categories of patients. As a result, healthcare providers named in a lawsuit may need to defend their actions in accordance with the prevailing standards as well as to affirm that their duties within the care plan were met. Legal experts note that, unless expressly stated otherwise, these individualized care plans may be discoverable by plaintiff attorneys.⁷

Privacy concerns

Because one of the main goals for ACOs is coordinated care, the sharing of information within an ACO is vital. Since the sharing of information takes place among an expanded network of providers, the risk of a data breach is increased, if only because of the increased number of times the data is shared.

Additionally, as with other healthcare providers, ACOs are responsible for complying with the requirements of Health Insurance Portability and Accountability Act (HIPAA).

HIPAA is the principal federal regulation concerning the privacy of medical information, and sets forth requirements for the safeguarding of this information. ACOs can share personal health information among its members when necessary for patient care and other limited circumstances. However, if information is improperly disclosed, ACOs can be subject to significant civil and even criminal penalties.

While it is almost second nature for medical facilities and doctors to provide their patients with the notifications required by HIPAA in the office setting, and to be rigorous about maintaining privacy safeguards, responsibility for this notice requirement may fall through the cracks. It is important for ACOs to set up procedures to prevent what could be costly violations of HIPAA. ACOs must implement clear guidelines to employees to prevent the unintentional and unauthorized disclosure of patient information.

The new legislation will allow Medicare patients to opt out of having their personal health information shared with ACOs. According to the Center for Medicare Services, the new laws require that Medicare patients receive written notification from the ACO regarding their right to opt-out, as well as information on how to do so.

Risk Management and Insurance

The Joint Commission mandates risk managers for hospitals, but no similar requirement exists for ACOs. Nonetheless, risk management should have high priority within ACOs. Many of the risks faced by ACOs are similar to those faced by other types of healthcare entities, but risk managers must be especially attuned to those areas where ACOs face heightened risks. Many of the liability issues confronting ACOs are an outcome of untested regulations that create new organizational structures for the delivery of medical care, new payment (and

The Joint Commission mandates risk managers for hospitals, but no similar requirement exists for ACOs.

Nonetheless, risk management should have high priority within ACOs.

Brian S. Kern,, 8 Ways That ACOs Can Increase Your Malpractice Risk, Medscape Today, http://www.medscape.com/viewarticle/749258

incentive) models, and new criteria for patient involvement in healthcare decision-making. Risk managers will be challenged to identify all the new and emerging areas of risk and to develop innovative strategies to address them. Hospital and manage care organization risk management practices may provide useful frameworks, but they do not contemplate many exposures that are specific to the ACO model.

One important risk management consideration is the legal structure of the ACO, which can help to minimize risk to the individuals and organizations participating in the ACO. For example, if the ACO is structured as a partnership, the partners may be joint and severally liable for the errors and omissions of another partner. Forming the ACO as a medical professional corporations (P.C.), or a limited liability company (LLC) may provide a shield for the ACO members from having to share in the liability arising out of the acts of another member.

ACO risk managers should work closely with their insurance brokers to map their organization's risk profile and to assure that all appropriate insurance protections are in place. According to one broker, liability insurance policies to be considered for ACO operations include health care professional/general liability, environmental liability, managed care E&O, D&O, fiduciary liability, network privacy/cyber risk, clinical trials and auto liability.⁸ Since owner entities are likely to have their own insurance programs in place, close cooperation among the ACO risk manager and owner-entity risk managers is essential to coordinate risk transfer in order to prevent gaps and overlaps in coverage.

Conclusion

According to Scott Weingarten, president and CEO of Zynx Health, "At the end of the day, there remains promise that ACOs will provide the structure to improve quality of care, reduce undesirable clinical variations, stabilize costs, and improve clinical decision making." However, the transformations in the delivery of healthcare envisioned by the ACO model undoubtedly will result in new and heightened exposures to loss to ACOs and their members. Some of these exposures are comparatively novel – the product of regulations that may result in new standards of care and new causes of legal actions – and many exposures are probably not yet fully understood. Risk management should be a high priority in every ACO, and ACO risk managers will be called upon to exercise insight and creativity in identifying emerging exposures and crafting effective strategies for addressing them.

The information in this publication was compiled from sources believed to be reliable for informational purposes only. Any and all information contained herein is not intended to constitute legal advice and accordingly, you should consult with your own attorneys when developing programs and policies. We do not guarantee the accuracy of this information or any results and further assume no liability in connection with this publication, including any information, methods or safety suggestions contained herein. Moreover, Zurich reminds you that this cannot be assumed to contain every acceptable safety and compliance procedure or that additional procedures might not be appropriate under the circumstances. The subject matter of this publication is not tied to any specific insurance product nor will adopting these policies and procedures ensure coverage under any insurance policy.

⁸ Botkin

⁹ Scott Weingarten, "Accountable Care Organizations Transforming Patient Care," Advance http://community.advanceweb. com/blogs/al_4/archive/2011/05/12/guestcommentary-accountable-care-organizationstransforming-patient-care.aspx

The information in this publication was compiled from sources believed to be reliable for informational purposes only. All sample policies and procedures herein should serve as a guideline, which you can use to create your own policies and procedures. We trust that you will customize these samples to reflect your own operations and believe that these samples may serve as a helpful platform for this endeavor. Any and all information contained herein is not intended to constitute legal advice and accordingly, you should consult with your own attorneys when developing programs and policies. We do not guarantee the accuracy of this information or any results and further assume no liability in connection with this publication and sample policies and procedures, including any information, methods or safety suggestions contained herein. Moreover, Zurich reminds you that this cannot be assumed to contain every acceptable safety and compliance procedure or that additional procedures might not be appropriate under the circumstances. The subject matter of this publication is not tied to any specific insurance product nor will adopting these policies and procedures ensure coverage under any insurance policy.

Zurich

1400 American Lane, Schaumburg, Illinois 60196-1056 800 982 5964 www.zurichna.com

The information in this publication was compiled from sources believed to be reliable for informational purposes only. All sample policies and procedures herein should serve as a guideline, which you can use to create your own policies and procedures. We trust that you will customize these samples to reflect your own operations and believe that these samples may serve as a helpful platform for this endeavor. Any and all information contained herein is not intended to constitute legal advice and accordingly, you should consult with your own attorneys when developing programs and policies. We do not guarantee the accuracy of this information or any results and further assume no liability in connection with this publication and sample policies and procedures, including any information, methods or safety suggestions contained herein. Moreover, Zurich reminds you that this cannot be assumed to contain every acceptable safety and compliance procedure or that additional procedures might not be appropriate under the circumstances. The subject matter of this publication is not tied to any specific insurance product nor will adopting these policies and procedures ensure coverage under any insurance policy.

