



TROUBLESHOOTING THE AFFORDABLE CARE ACT

A WHITE PAPER COMPILATION OF VIEWS AND LESSONS AFTER FIVE YEARS

**STATE BAR OF MICHIGAN HEALTH CARE LAW SECTION
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**TROUBLESHOOTING THE AFFORDABLE CARE ACT
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FOREWORD

There are many things that can be said and many opinions that can be had on the Affordable Care Act (“ACA”), all leading in opposite directions. But one thing is unassailable: The ACA is the most important piece of health care legislation of our time. In five years since its inception, it has expanded access to health care to millions of uninsured Americans, has turned on its head volume-driven health care, and has been the subject of two United States Supreme Court opinions which both unified and divided the nation on matters as far and wide as the taxing powers of Congress, State rights, and human rights to health care, just to name a few. On this five-year anniversary of the ACA, therefore, the State Bar of Michigan Health Care Law Section (the “Section”) thought a retrospective look at five years of the ACA was in order. And that is exactly what this compilation brings the reader.

This white paper compilation combines a little bit (and sometimes a lot) of law, a little bit of anecdote, and a little bit of “what worked and what did not” in some of the most important areas of the law. Our learned authors have gone so far as to offer their best theories (and sometimes unavoidable guesses) as to where the health care sector needs to go next to succeed under the ACA. For the hard work and the insight our authors brought to this project, the Publications Committee thanks you. Many thanks also go to the tireless Publications Committee members for all their work soliciting and editing articles for this compilation. Without the dozens of hours of mostly invisible work they bring to the table, this and other valuable resources brought to you by the Section would not have been possible.

Happy reading,

Monica P. Navarro

Editor in Chief/Chair of the Publications Committee

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topics. Louis is a graduate of Cornell University Law School, where he concentrated in business law and regulation, and of the University of Michigan.

INTRODUCTION TO THE ACA

By Julie Janeway

In March 2010, the 111th Congress passed health reform legislation called the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010 and other laws, commonly known as the Affordable Care Act (“ACA”).¹ This comprehensive legislation was aimed at remedying major parts of a broken and disjointed health care structure that does not conform to any other known or recognized form of health care system in the world. It was not designed to bring the American health care structure into conformity with other countries or their existing systems, but instead to integrate the best parts of other systems into the American structure. It was designed to support the public/private model at work in this country and fit within the framework of American values and norms regarding payment for and provision of health care services.

The ACA was intended primarily to expand access to health care coverage and increase the number of insured individuals in the country, to control health care costs, and to improve the health care structure.² The law itself has ten Titles or sections and what follows is a brief summary of each Title.

Title I: Quality, Affordable Care for All Americans

The ACA was not intended to convert the country’s health care structure to a fully government-operated system, but rather to augment the current structure of public and private sector shared responsibility.³ The first Title of the ACA contains three main factors in the provision of quality, affordable health care for all Americans. The first factor is systemic insurance market reform that seeks to eliminate potentially predatory and discriminatory practices such as life-time dollar limits, excessive premiums, and coverage refusal for pre-existing conditions.⁴ The second factor is to increase the national risk pool(s) by requiring that all Americans have coverage because, they will participate in and benefit from the health care structure.⁵ This aspect is also intended to keep premiums from rising because the risk pool is increased, not only by additional persons who will use the health care services for which they pay, but also by those who are young and healthy and use less services each year. The third factor is the provision of tax credits and subsidies to help ensure that coverage is affordable for everyone.⁶

These three tenets are designed to provide improvements such as: (a) the elimination of lifetime and annual limits on benefits; (b) assistance for those who are uninsured because of pre-existing conditions; (c) the prohibition against refusal to insure children with pre-existing conditions; (d) required coverage of preventative services and immunizations (to help meet national health policy public health goals); (e) capping insurance company non-medical administrative expenditures; (f) extending unmarried dependent coverage up to the age of 26; and (g) ensuring customers have access to an

effective appeals process and assistance in navigating that process.⁷ Finally, this Title provides for operating the health insurance exchanges so consumers can compare policies and coverage for themselves.⁸

Title II: The Role of Public Programs

This portion of the law made substantial changes to Medicaid.⁹ Title II, as written, appeared to permit all lower-income persons (subject to revised eligibility requirements) to enroll in their state's Medicaid programs.¹⁰ However, a challenge to the state Medicaid expansion provisions of the law were addressed in the 2012 Supreme Court case (*National Federation of Independent Business v Sebelius*, *Florida v DHHS*, and *DHHS v Florida*, 132 S. Ct. 2566 (2012) hereinafter *NFIB v Sebelius*), which held that states were not required to expand their Medicaid programs, nor was the federal government permitted to withhold Medicaid funding from any state that chose not to participate in the expansion.¹¹ Therefore, many states have chosen not to expand their Medicaid systems as provided in this Title.¹²

This Title also provides enhanced support for the Children's Health Insurance Program ("CHIP"), simplified Medicaid and CHIP enrollment, requires improvements for Medicaid services and quality, and provides new options for long-term, community-based attendant services and support to those with disabilities who would otherwise require hospitalization or services of a nursing or intermediate care facility.¹³ Finally, it provides for payment and coverage coordination for those who are eligible under both Medicare and Medicaid.¹⁴

Title III: Improving the Quality and Efficiency of Health Care

Title III deals with improving the quality, effectiveness, efficiency, and patient-focus of medical care. It adds preventive care benefits for Medicare enrollees,¹⁵ closes the "donut hole" coverage gap under the Medicare Part D drug benefit,¹⁶ makes prescription coverage under the benefit more affordable,¹⁷ and links payment for services to better quality outcomes.¹⁸ It creates new patient care models such as "medical homes" providing community-based coordinated care, Accountable Care Organizations ("ACOs") that receive a share of Medicare savings they achieve by taking more responsibility for cost and quality of care, and a voluntary pilot program featuring bundled payments for participating hospitals, doctors, and post-acute providers.¹⁹ Several other Medicaid and Medicare improvements and improved models for sustainability are also featured portions of this Title of the ACA.

Title IV: Prevention of Chronic Disease and Improving Public Health

One of the most ambitious pieces of the ACA, this Title is aimed at prevention of disease and disability by moving the populace and health care structure from its current

biomedical/reactive care model to a more proactive/preventative care model.²⁰ Under this Title, the National Prevention, Health Promotion, and Public Health Council will devise a national prevention strategy, and evidence-based, clinical preventive care services will be provided through most health insurance policies without cost-sharing.²¹ It also aims to improve the public consciousness regarding nutrition by requiring chain-based restaurants to post the calorie content of their foods.²² These initiatives are backed by a 13 billion dollar trust fund to provide a sustained investment in meeting public health and policy goals.²³ This portion of the law also provides for the operation of school-based health clinics, awards grants to states with Medicaid beneficiary participation in programs that provide incentives for healthy lifestyle changes, requires Medicaid coverage for counseling and pharmacotherapy to pregnant women to stop smoking, and for an oral health care prevention education campaign, among other things.²⁴

Title V: Health Care Workforce

Under this Title, primary care doctors should become more of a priority to the nation's health care structure. Title V provides numerous programs to assist current health care workers, and to expand the employment market to include additional trained personnel. As a result of this Title, the federal government established a National Health Care Workforce Commission that will review the current state of the health care workforce, and will project future needs in particular disciplines, occupations, and professions.²⁵

This portion of the ACA also provides for expansion and modification of the federal student loan program to encourage individuals to work in primary care positions, as well as those with clinical pediatric and mental or behavioral health specialties for children and adolescents to work in health profession shortage areas, medically underserved areas, or with medically underserved populations.²⁶ It provides loan repayment incentives for public health students and workers in exchange for working at least three years at a federal, state, local, or tribal public health agency.²⁷ With this Title, new financial support exists for health care workforce training in a variety of general and public health care respects.²⁸

After 2011, the Health and Human Services ("HHS") Secretary may redistribute unfilled residency positions and refocus them as primary care residencies, and those residencies may be allotted to medically underserved areas. Additional programs have been created pursuant to this Title, many of which are aimed at specific types of training including pediatric, community and public health, and public health epidemiology, laboratory science, and informatics.²⁹

Title VI: Transparency and Program Integrity

This portion of the law provides authority and additional funding to state and federal agencies who are combatting public and private sector health care fraud, waste, and abuse, as well as possible reductions in civil money penalties ("CMPs") for self-disclosure and self-correcting billing errors. To support the anti-fraud provisions of the ACA and other federal laws, **all** health care providers and facilities who accept Medicare, Medicaid, and other federal insurance forms are required to establish written compliance plans that meet, at the bare minimum, the eight core elements established by the Office of the Inspector General ("OIG") of the HHS.³⁰ Having such written compliance plans in place is now a condition of enrollment ("CoE") in federal health care insurance programs.³¹

This Title requires nursing homes and skilled nursing facilities (SNFs) to comply with many new regulations to protect patients and their families. It establishes the Elder Justice Act to prevent abuse, neglect, financial exploitation, and violence against senior citizens in the health care environment.³² Health care employees have to undergo dementia management and patient abuse training sessions before beginning new employment.³³ Drug companies must publicly disclose any payments, gifts, and gratuities to physicians³⁴ (as do physicians), and a public-private research institute will study comparative clinical effectiveness in an ongoing attempt to move medical services to an evidence-based system.³⁵ Through this portion of the ACA there are some additions to the Stark law and anti-kickback statute ("AKS"),³⁶ as well as numerous changes to the tax code and other federal statutes and regulations.

Title VII: Improving Access to Innovative Medical Therapies

The ACA provides the Food and Drug Administration ("FDA") with a route to producing generic/biosimilar biological products.³⁷ It also ends anticompetitive actions that aim to keep generics off the market thus lowering prescription costs for millions of Americans.³⁸ Hospitals and communities that serve low-income patients are eligible for drug-discounts, as are certain children's hospitals, cancer hospitals, critical access and sole community hospitals, and rural referral centers.³⁹

Title VIII: CLASS—Community Living Assistance Supports and Services

The CLASS Act in this Title was designed to institute a voluntary long-term disability insurance program to working individuals with cash payments and support if they become permanently or temporarily disabled. On October 15, 2012, The Obama administration announced that it was abandoning the program because of non-sustainability projections, creating a hole in the ACA to finance long-term care. This Title was repealed on January 2, 2013.⁴⁰ To date, no replacement for the CLASS Act has been proposed.

Title IX: Revenue Provisions

This part of the ACA made provisions for funding approximately half of the costs of the ACA. It established numerous new taxes and fees, and changes to health savings and other individual health accounts.⁴¹

Title X: Strengthening Quality Affordable Care

Title X of the ACA made many changes and improvements to the preceding nine titles, and descriptions of those changes are included in the above sections. However, Title X created new, important provisions for the ACA. This Title created financial incentives for states to move Medicaid beneficiaries from nursing homes and into home and community based health services. It established a Pregnancy Assistance Fund to award competitive grants (with a matching component) to states to assist pregnant and parenting teens and women. It also reauthorized the Indian Health Care Improvement Act, which provides health care to American Indians and Alaskan natives, made numerous additional tweaks and modifications to Medicare administration, authorized additional research programs, created new administrative entities, and authorized many public and private health improvement programs. With regard to transparency and fraud prevention, Title X enhanced the fraud sentencing guidelines, changed the intent requirement for fraud under the AKS, extended the protections of the Federal Tort Claims Act to free clinics, and modified the labeling requirements for generic drugs.⁴²

Although this is not an exhaustive list of the components of the ACA, it does provide a general overview of the important points in the legislation, and will provide the reader some reference for the articles that follow. In light of the 2012 Supreme Court decision in *NFIB v Sebelius* and other challenges to the ACA, some of the provisions of the Act may have changed from their intended paths, while others have evolved through implementation and evaluation. The bulk of the legislation, however, remains intact, and the majority of the provisions have been implemented.

Endnotes:

1. *Patient Protection and Affordable Care Act*, codified in various sections of 42 U.S.C. and 21 USC (2010).
2. *Id.*
3. *Id.*
4. *Patient Protection and Affordable Care Act*, 42 U.S.C. § 300gg, et seq (2010); *United States Senate, The Patient Protection and Affordable Care Act Detailed Summary*, (last visited June 1, 2015), www.dpc.senate.gov/healthreformbill/healthbill04.pdf; Congressional Research Service, *ACA: A Brief Overview of the Law, Implementation, and Legal Challenges* (March 23, 2012), www.law.umaryland.edu/marshall/crsreports/crsdocuments/R41664_07032012.pdf.

5. *Patient Protection and Affordable Care Act*, 26 U.S.C. § 36B, 42 U.S.C. § 18071, et seq, 26 U.S.C. § 6103, 26 U.S.C. § 45R (2010); *United States Senate, The Patient Protection and Affordable Care Act Detailed Summary*, (last visited June 1, 2015), www.dpc.senate.gov/healthreformbill/healthbill04.pdf; Congressional Research Service, *ACA: A Brief Overview of the Law, Implementation, and Legal Challenges* (March 23, 2012), www.law.umaryland.edu/marshall/crsreports/crsdocuments/R41664_07032012.pdf.
6. Congressional Research Service, *ACA: A Brief Overview of the Law, Implementation, and Legal Challenges* (March 23, 2012), www.law.umaryland.edu/marshall/crsreports/crsdocuments/R41664_07032012.pdf.
7. *Patient Protection and Affordable Care Act*, 42 U.S.C. § 18001 and 300gg, et seq (2010); *United States Senate, The Patient Protection and Affordable Care Act Detailed Summary*, (last visited June 1, 2015), www.dpc.senate.gov/healthreformbill/healthbill04.pdf; Congressional Research Service, *ACA: A Brief Overview of the Law, Implementation, and Legal Challenges* (March 23, 2012), www.law.umaryland.edu/marshall/crsreports/crsdocuments/R41664_07032012.pdf; Kaiser Family Foundation, *Summary of the Affordable Care Act* (April 25, 2013), <http://kff.org/health-reform/fact-sheet/summary-of-the-affordable-care-act/>.
8. *Patient Protection and Affordable Care Act*, 42 U.S.C. §§ 18031, 18032 (2010).
9. *Patient Protection and Affordable Care Act*, 42 U.S.C. § 1396a, et seq. (2010).
10. *Id.*
11. *National Federation of Independent Business v Sebelius, Florida v DHHS, and DHHS v Florida*, 132 S. Ct. 2566 at 55-58 (2012).
12. Kaiser Family Foundation, *Status of State Action on the Medicaid Expansion Decision* (last updated May 25, 2015), <http://kff.org/health-reform/state-indicator/state-activity-around-expanding-medicaid-under-the-affordable-care-act/>
13. *United States Senate, The Patient Protection and Affordable Care Act Detailed Summary*, (last visited June 1, 2015), www.dpc.senate.gov/healthreformbill/healthbill04.pdf; Congressional Research Service, *ACA: A Brief Overview of the Law, Implementation, and Legal Challenges* (March 23, 2012), www.law.umaryland.edu/marshall/crsreports/crsdocuments/R41664_07032012.pdf; Kaiser Family Foundation, *Summary of the Affordable Care Act* (April 25, 2013), <http://kff.org/health-reform/fact-sheet/summary-of-the-affordable-care-act/>.
14. *Patient Protection and Affordable Care Act*, 42 U.S.C. § 1396 (2010).
15. *Patient Protection and Affordable Care Act*, 42 U.S.C. § 1395x (2010).

16. *Patient Protection and Affordable Care Act*, 42 U.S.C. § 1395w (2010).
17. *Patient Protection and Affordable Care Act*, 42 U.S.C. § 1395w (2010).
18. *Patient Protection and Affordable Care Act*, 42 U.S.C. § 1395w-22 (2010).
19. *Patient Protection and Affordable Care Act*, 42 U.S.C. § 1395, et seq. (2010).
20. *United States Senate, The Patient Protection and Affordable Care Act Detailed Summary*, (last visited June 1, 2015),
www.dpc.senate.gov/healthreformbill/healthbill04.pdf.
21. *Patient Protection and Affordable Care Act*, 42 U.S.C. § 300u-10, et seq. (2010).
22. *Patient Protection and Affordable Care Act*, 21 U.S.C. § 343(q) (2010).
23. *Patient Protection and Affordable Care Act*, 42 U.S.C. § 300u-10, et seq. (2010).
24. *United States Senate, The Patient Protection and Affordable Care Act Detailed Summary*, (last visited June 1, 2015),
www.dpc.senate.gov/healthreformbill/healthbill04.pdf.
25. *Patient Protection and Affordable Care Act*, 42 U.S.C. § 294q-r, et seq. (2010).
26. *Patient Protection and Affordable Care Act*, 42 U.S.C. § 292q-y, et seq. (2010).
27. *Id.*
28. *Patient Protection and Affordable Care Act*, 42 U.S.C. § 294q-r, et seq. (2010).
29. *United States Senate, The Patient Protection and Affordable Care Act Detailed Summary*, (last visited June 1, 2015),
www.dpc.senate.gov/healthreformbill/healthbill04.pdf.
30. *Patient Protection and Affordable Care Act*, 42 U.S.C. § 1395cc(j)(8) (2010).
31. *Id.*
32. *Patient Protection and Affordable Care Act*, 42 U.S.C. § 1397k (2010).
33. *Patient Protection and Affordable Care Act*, 42 U.S.C. § 1396r (2010).
34. 47 CFR 402-403 (2014).
35. *Patient Protection and Affordable Care Act*, 42 U.S.C. § 1320e (2010).
36. *Patient Protection and Affordable Care Act*, 42 U.S.C. § 1320(a)-7(b)(h) and 42 U.S.C. § 1395nn (2010).
37. *Patient Protection and Affordable Care Act*, 42 U.S.C. § 262 (2010).
38. *Id.*

39. *United States Senate, The Patient Protection and Affordable Care Act Detailed Summary*, (last visited June 1, 2015), www.dpc.senate.gov/healthreformbill/healthbill04.pdf.

40. *Id.*

41. *The American Taxpayer Relief Act of 2012* (Pub.L. 112–240, H.R. 8, 126 Stat. 2313, enacted January 2, 2013).

42. *United States Senate, The Patient Protection and Affordable Care Act Detailed Summary*, (last visited June 1, 2015), www.dpc.senate.gov

**ACA Physician Practice Compliance Programs
For Small and Medium Sized Providers**

**By
Julie Janeway
Edited By
Louis C. Szura**

ACA Physician Practice Compliance Programs For Small and Medium Sized Providers

Table of Contents

1. Introduction
2. Compliance programs are mandatory pursuant to the ACA
3. What is a compliance program?
4. What health care entities must have a compliance program?
5. Enforcement/penalties for failing to have a compliance program
6. What constitutes a proper compliance program?
7. The 9 minimum components of a compliance program
 - Commitment to compliance
 - Designation of a Compliance Officer and Committee
 - Regular compliance training programs
 - Open channels to receive questions and complaints
 - HIPAA and HITECH compliance
 - Ongoing audits and monitoring
 - Disciplinary actions for violations and noncompliance
 - Investigative and corrective action for violations and noncompliance
 - Response to special agents' visit for investigation purposes
8. Expanding the basic compliance program to become a comprehensive compliance program
9. Other benefits of having a compliance program
10. Conclusion

Mandatory ACA Physician Practice Compliance Programs For Small and Medium Sized Providers

By Julie Janeway

Introduction

The passage of the Patient Protection and Affordable Care Act ("ACA") in 2010, provided a plethora of new requirements, regulations, and mandates, as well as amendments to a variety of federal statutes, including The Social Security Act. One of the least noticed changes, (other than by hospitals and large health care organizations), is the requirement that ***all*** medical providers and suppliers of medical equipment participating in Medicare and Medicaid, have a written compliance program, and have that program implemented and operational in their organizations.

Almost all hospitals and larger health care institutions have had some form of compliance program in place for years, although they are not necessarily up-to-date or written properly. This article has not been created for those provider institutions, although lawyers representing these organizations may benefit from some of the information contained herein. This article seeks to explain the requirements, purpose, and proper method of creating a useful compliance program for small, individual provider practices participating in Medicare, Medicaid, other health insurance programs affiliated with the Centers for Medicare & Medicaid Services ("CMS"), and other state and federal health insurance programs. The vast majority of individual provider practices in Michigan and nationwide do not appear to have a compliance program in place, and, know that they must have one, or the consequences of failing to comply with the requirement to do so under the ACA.

Compliance Programs are Mandatory Pursuant to the ACA

Pursuant to Title 6401 of the ACA, Title XVIII of The Social Security Act (42 U.S.C. §1395cc(j)(8)) was amended to include as a condition of (provider) enrollment ("CoE") in the Medicare program:

(8) Compliance programs

(A) In general

On or after the date of implementation determined by the Secretary under subparagraph (C), a provider of medical or other items or services or supplier within a particular industry sector or category shall, as a condition of enrollment in the program under this subchapter, subchapter XIX, or subchapter XXI, establish a compliance program that contains the core elements established under subparagraph (B) with respect to that provider or supplier and industry or category.

(B) Establishment of core elements

The Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall establish core elements for a compliance program under subparagraph (A) for providers or suppliers within a particular industry or category.

(C) Timeline for implementation

The Secretary shall determine the timeline for the establishment of the core elements under subparagraph (B) and the date of the implementation of subparagraph (A) for providers or suppliers within a particular industry or category. The Secretary shall, in determining such date of implementation, consider the extent to which the adoption of compliance programs by a provider of medical or other items or services or supplier is widespread in a particular industry sector or with respect to a particular provider or supplier category.¹

...

The Social Security Act contains a similar provision for participation in Medicaid and Program of All-Inclusive Care for the Elderly ("PACE")² and State Children's Health Insurance Programs ("CHIP").³ In addition, providers who accept TRICARE as network providers are required to be approved providers of Medicare services, which makes the Medicare CoEs applicable to TRICARE participation as well.⁴ TRICARE requires that network providers "have a signed Medicare CMS-460 Agreement or participate with Medicare on a claim-by-claim basis for Medicare-eligible beneficiaries. (Note: Does not apply to pediatrics, obstetrics or speech/language pathology.)"⁵ As a network provider for TRICARE, the provider must agree to accept requests from the Veterans' Administration ("VA") to treat veterans, and must agree to be reported to, and listed as an approved provider for the Civilian Health and Medical Program of the Department of Veteran's Administration ("CHAMPVA").⁶ If a provider accepts CHAMPVA patients, then the provider is required to serve as a participating provider and accept assignments from the VA.⁷ As one can see, participation in other federal health care programs turns on compliance with Medicare CoEs, including the new requirement to have a compliance program in place.

What is a Compliance Program?

University of Michigan Law School graduate and Harvard School of Public Health Professor, George B. Moseley III, defined compliance programs this way: "A compliance program is a multi-faceted infrastructure of rules, training, penalties, and response protocols that will reduce the incidence of noncompliance, detect it faster when it happens, and prevent its recurrence."⁸ Although succinctly stated, this definition covers a bare bones compliance program addressing only fraud and abuse. However, a few more very important words could, and should, be added to this definition to address the nature of a comprehensive compliance program. Stated more specifically: A compliance

program is an *organization specific document that declares compliance or intent to comply with legal and accreditation requirements, and is a multi-faceted infrastructure of rules, policies, training, penalties, internal controls, and prevention and response protocols that will reduce the incidence of noncompliance, detect it faster when it happens, and attempt to prevent its recurrence.*

The purpose of a compliance program (may also be referred to as a compliance plan) is to bring the organization into compliance with the law by deterring, preventing, and correcting fraud, waste, and abuse, to set forth the framework and internal controls as stated above, and serve as a defense document if the organization is found to be in a position involving alleged violation of the law, or violation of other requirements to which the organization is subject or has agreed.⁹ Compliance programs were originally intended to help organizations detect and prevent fraud, waste, and abuse, especially with regard to practices and claims for Medicare and Medicaid.¹⁰ They originally grew out of documents from other industries intended to show the government and the public that the organization respected and complied with the law, and was a good corporate citizen.¹¹

Concerning health care organizations, compliance programs are also an outgrowth of Corporate Integrity Agreements ("CIA"), or for physician practices, Integrity Agreements.¹² CIAs are imposed on larger health care organizations by CMS when that organization is found to have potentially violated one or more of the federal fraud and abuse laws.¹³ A CIA is negotiated between the Department of Health and Human Services ("HHS") Office of the Inspector General ("OIG") and the organization that may have violated the False Claims Act or other relevant federal fraud law, or violated Medicare/Medicaid regulations regarding fraudulent claims.¹⁴ It is incorporated into a civil settlement agreement between the OIG and the organization, and agreement by the organization results in the OIG agreeing not to exclude the organization from participation in Medicare/Medicaid and other federal health care programs.¹⁵ This is a tool used in situations in which the OIG feels that the organization can be rehabilitated with the strong guidance of a CIA.¹⁶ If the organization violates a provision of the CIA, the OIG may impose predetermined penalties and imposed federal program exclusion.¹⁷ CIAs are both reactive and proactive in their scope and nature.¹⁸ A typical CIA can be viewed at: <https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp>.

Compliance programs are proactive version of CIAs, initiated by the health care organization itself. There is no OIG involvement (other than providing the core elements and guidance) and the organization is not creating the program in response to allegations of fraud or abuse. The threat of OIG imposed penalty or sanction is reduced because the establishment of the compliance program is intended to move the organization closer to compliance with the law, and to establish internal protocols to prevent violations¹⁹. If the organization has a compliance program in place and maintains internal monitoring and auditing procedures, the chances of government

claims of fraud or abuse is decreased significantly because the OIG will acknowledge the organization's good faith effort to comply with the law and prevent false claims. It should be mentioned that some fraud violations require the government to prove intent, therefore the existence of a good compliance program and document may make that burden of proof more difficult. The existence of a compliance program is *not* a guarantee, however, that the OIG will not impose sanctions or penalties in the event fraud or abuse is discovered within a health care organization.

What Health Care Entities Must Have a Compliance Program?

The language of the ACA states that a *“provider of medical or other items or services or supplier within a particular industry sector or category shall, as a condition of enrollment in the program under this title, title XIX, or title XXI establish a compliance program that contains the core elements established under subparagraph (B) with respect to that provider or supplier and industry or category.”*²⁰ A provider must have a compliance program in place if they participate in Medicare, Medicaid, PACE, or CHIP, and it must contain the core elements established by the OIG (which will be discussed below). Obviously this includes hospitals and health systems, but also includes other entities as well. Various care facilities must have in place a compliance program as required by the ACA, including:

- physician practices
- skilled nursing facilities
- rehabilitation facilities
- long-term care facilities
- home health care companies
- hospice facilities
- clinical laboratories
- third party medical billing companies
- autism care entities
- accountable care organizations
- children's special health care services entities
- adult day primary care facilities
- chiropractic practices
- pharmacy and pharmaceutical manufacturers
- dental care practices
- ambulance providers and suppliers
- optometry practices
- physical and occupational therapy entities
- mental health entities
- research facilities
- urgent care facilities
- nutrition counseling entities

- managed care organizations
- Medicare Advantage organizations
- prescription Part D plan entities
- prosthetics and orthotics entities
- durable medical equipment companies²¹

As of 2015, the great majority of hospitals, health systems, and larger care facilities already have compliance programs in place, but they should still be reviewing those programs to determine if they are up-to-date and clearly written

Health care entities should also keep any ancillary service providers, business associates, vendors, and contractors or medical equipment providers that fall into these categories of service apprised of their own compliance programs, and the expectation of compliance (the existence and implementation of a compliance program) by these ancillary providers in their own right.

The purpose of requiring compliance programs from these other providers, who may bill or receive funds from Medicare, Medicaid, PACE, and/or CHIP, is to prevent fraud and abuse, but also to curtail assertions by larger, related, or referring organizations that pursuant to established agency law they are not responsible for the fraudulent actions of these often partially-owned subsidiaries and other independent contractors. It is also an attempt to prevent abdication of responsibility and vicarious liability of the ancillary entities by using agency law to shift some of the responsibility burden from the larger organization to the ancillary provider, and force the provider to take its own proactive stance against fraud and abuse of these and other federal programs. Many of these ancillary businesses may not have as much interaction with Medicare, Medicaid, PACE, or CHIP as hospitals, health systems, and physicians' practices, but the government is aware that some of the most organized fraud schemes have come out of these types of businesses precisely because they are not as "front and center" as hospitals and physicians' practices.²²

This leaves physicians' practices in the spotlight because hospitals and health systems have or are attending to their compliance duties, and have compliance programs of some sort in place. Physicians' practices, other than those owned by hospitals and health systems, are generally unaware of the concept of compliance programs, and have no idea that they are required to have one, or the consequences of not having one. It is for this reason that this article is written.*

Enforcement/Penalties for Failing to Have a Compliance Program

Title XVIII of The Social Security Act (42 USC §1395cc(j)(8)) makes the existence and implementation of a compliance program a mandatory condition of enrollment for providers in the Medicare program. Chapter 15 of the Medicare Integrity Manual defines enrollment as the process that Medicare uses to grant Medicare billing privileges.²³ Medicare regulations (42 CFR 424.516(a)(1)) state that to maintain

Medicare enrollment a provider must certify that it meets, and continues to meet, and CMS verifies that it meets, and continues to meet ... compliance with Title XVIII of the Act and applicable Medicare regulations... . Pursuant to 42 CFR 455.410 providers enrolled in Medicaid programs must first meet Medicare screening and eligibility standards, which include compliance with Title XVIII of the Social Security Act requiring the existence and implementation of compliance programs.

Under authority of 42 CFR 434.535(a) CMS may revoke a currently enrolled provider's Medicare billing privileges and any corresponding provider agreement for the following reasons:

(1) *Noncompliance*. The provider ... is determined to not be in compliance with the enrollment requirements described in this subpart P or in the enrollment application applicable for its provider ...type, and has not submitted a plan of corrective action as outlined in part 488 of this chapter. The provider ... may also be determined not to be in compliance if it has failed to pay any user fees as assessed under part 488 of this chapter.

(i) CMS may request additional documentation from the provider ... to determine compliance if adverse information is received or otherwise found concerning the provider...

...

(4) *False or misleading information*. The provider or supplier certified as "true" misleading or false information on the enrollment application to be enrolled or maintain enrollment in the Medicare program. (Offenders may be subject to either fines or imprisonment, or both, in accordance with current law and regulations.)

(5) *On-site review*. Upon on-site review or other reliable evidence, CMS determines that the provider or supplier is either of the following:

...

(ii) Otherwise fails to satisfy **any** Medicare enrollment requirement (emphasis added).

...

In addition, section 6402 of the ACA regarding making false statements or misrepresentation of material facts states that such falsity can lead to permissive exclusion from all federal programs. Exclusion can be imposed on both individuals and entities such as vendors, consulting, or management firms. The broadening of the list of offenses for which permissive exclusion may be imposed makes it possible for a provider to be excluded for "knowingly making or causing to be made any false statement, omission, or misrepresentation of a material fact in a Medicare or Medicaid enrollment application, agreement, bid, or contract, or obstructing an investigation or

audit.”²⁴ Falsifying the attestation of compliance with all laws and regulations on the enrollment application by not having a compliance program in place may lead to permissive exclusion.²⁵

Enforcement for failure to comply with the CMS legal and regulatory requirements, especially concerning fraud, waste, abuse, and employment of excluded individuals has been delegated by the Secretary of Health and Human Services and is the responsibility of the HHS OIG. The OIG is authorized to order Civil Monetary Penalties ("CMPs") against violators, and exclusions from Medicare, Medicaid, and all federal health care programs pursuant to sections 1128 and 1156 of the Social Security Act.²⁶ Section 6402 of the ACA also adds new instances in which CMPs can be imposed.²⁷ The relevant provision states that CMPs may be imposed for “knowingly making or causing to be made any false statement, omission, or misrepresentation of a material fact in any application, agreement, bid, or contract to participate or enroll as a provider of services or supplier under a federal health care program.”²⁸ Pursuant to 42 CFR 1003.103, the OIG is authorized to impose differing amounts of CMPs and assessments based on the various types of violations. Section 6402 of the ACA now provides for a CMP of “\$50,000 for each false statement or misrepresentation of a material fact,” or “an assessment of not more than 3 times the total amount claimed for each item or service for which payment was made based upon the application containing the false statement or misrepresentation of a material fact.”²⁹

From a practical perspective, CMS will most likely refrain from hunting down errant physician practices solely because they failed to implement compliance programs. What may happen, however, is that when a physician’s practice either self-discloses billing issues, a Recovery Audit Contractor investigates suspected billing issues, CMS requests investigation, CMS finds fraud or the employment of an excluded individual, or CMS investigates a disclosure of confidential information from the National Practitioner Data Bank or other non-fraud issue, failing to have the required compliance program in place will raise additional concerns. This can lead to much bigger problems than just enrollment revocation.

So, if a provider fails to implement a compliance program per Title XVIII of the Act and falsifies on the enrollment application that it is in compliance with all the required laws and regulations, then the OIG is authorized to revoke the provider’s enrollment in the program. The OIG is also authorized to order exclusion and to impose CMPs solely for failing to comply with the compliance program requirement.

A situation in which the provider is found to have other violations come to light, beyond the falsification issue, is the fulcrum on which exclusion may turn. It is these types of additional breaches of Medicare regulations, CoEs, and other laws that can persuade the OIG to exclude an individual in a permissive exclusion situation. Medicare enrollment revocation and exclusion has a cascade effect, as noted previously, on the eligible enrollment and participation in other federal health care programs as they rely on the Medicare screening procedures and enrollment as a pre-condition for

participation in those other programs. Exclusion, however, is a much bigger problem than simply not being able to participate in federal programs.

The effect of an OIG exclusion is that no federal health care program payment may be made for any items or services furnished by an excluded person or at the medical direction or on the prescription of an excluded person.³⁰ This is not as simple a sanction as it seems. It has broad-reaching effect as detailed by the HHS OIG, in Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs (2013):

. . . The exclusion and the payment prohibition continue to apply to an individual even if he or she changes from one health care profession to another while excluded. For example, the prohibition against federal health care program payment for items and services would continue to apply to a person who was excluded while a pharmacist even after the person earns his or her medical degree and becomes a licensed physician. This payment prohibition applies to all methods of federal health care program payment, whether from itemized claims, cost reports, fee schedules, capitated payments, a prospective payment system or other bundled payment, or other payment system and applies even if the payment is made to a state agency or a person that is not excluded. For example, no payment may be made to a hospital for the items or services furnished by an excluded nurse to federal health care program beneficiaries, even if the nurse's services are not separately billed and are paid for as part of a Medicare diagnosis-related group payment received by the hospital. Also, the excluded nurse would be in violation of her exclusion for causing a claim to be submitted by the hospital for items or services the nurse furnished while excluded.

The prohibition on federal health care program payment for items or services furnished by an excluded individual includes items and services beyond direct patient care. For instance, the prohibition applies to services performed by excluded individuals who work for or under an arrangement with a hospital, nursing home, home health agency, or managed care entity when such services are related to, for example, preparation of surgical trays or review of treatment plans, regardless of whether such services are separately billable or are included in a bundled payment. Another example is services performed by excluded pharmacists or other excluded individuals who input prescription information for pharmacy billing or who are involved in any way in filling prescriptions for drugs that are billed to a federal health care program. Also, excluded individuals are prohibited from providing transportation services that are paid for by a federal health care program, such as those provided by ambulance drivers or ambulance company dispatchers.

In addition, exclusion includes administrative, management, and leadership health care related positions:

Excluded persons are prohibited from furnishing administrative and management services that are payable by the federal health care programs. This prohibition applies even if the administrative and management services are not separately billable. For example, an excluded individual may not serve in an executive or leadership role (e.g., chief executive officer, chief financial officer, general counsel, director of health information management, director of human resources, physician practice office manager, etc.) at a provider that furnishes items or services payable by federal health care programs. Also, an excluded individual may not provide other types of administrative and management services, such as health information technology services and support, strategic planning, billing and accounting, staff training, and human resources, unless wholly unrelated to federal health care programs.

Further, any individual or entity that knows of, or should know of an individual's exclusion cannot receive payment for items or services furnished or prescribed by the excluded individual:

In addition, any items and services furnished at the medical direction or on the prescription of an excluded person are not payable when the person furnishing the items or services either knows or should know of the exclusion. This prohibition applies even when the federal payment itself is made to a state agency or a provider that is not excluded. Many providers that furnish items and services on the basis of orders or prescriptions, such as laboratories, imaging centers, durable medical equipment suppliers, and pharmacies, have asked whether they could be subject to liability if they furnish items or services to a federal program beneficiary on the basis of an order or a prescription that was written by an excluded physician. Payment for such items or services is prohibited. To avoid liability, providers should ensure, at the point of service, that the ordering or prescribing physician is not excluded.

In essence, once an individual is excluded from participation in federal health care programs by the HHS OIG, it leaves very little room to work in or around the health care industry, let alone practice medicine. The effect of exclusion is significantly increased if the individual decides to violate the exclusion. Again, the Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs states with regard to Civil Monetary Penalties:

An excluded person violates the exclusion if the person furnishes to federal health care program beneficiaries items or services for which federal health care program payment is sought. An excluded person that submits a claim for payment to a federal health care program, or causes such a claim to be submitted, may be subject to a Civil Monetary Penalty of \$50,000 for each claimed item or service furnished during the period that the person was excluded. The person may also be subject to an assessment of up to three times the

amount claimed for each item or service. In addition, violation of an exclusion is grounds for OIG to deny reinstatement to federal health care programs.

With regard to criminal penalties and civil actions:

Such exclusion violations may lead to criminal prosecutions or civil actions in addition to the CMPs for violation of OIG exclusion. An excluded person that knowingly conceals or fails to disclose any action affecting the ability to receive any benefit or payment with the intent to fraudulently receive such benefit or payment may be subject to criminal liability. Other criminal statutes may also apply to such violations. An excluded person may be civilly liable under the False Claims Act for knowingly presenting or causing to be presented a false or fraudulent claim for payment. Moreover, persons that order or prescribe items or services while excluded are subject to CMP liability when the excluded person knows or should know that a claim for the item or service may be made to a federal health care program.

The Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs also notes that health care entities are subject to severe penalties if they employ any excluded person:

If a health care provider arranges or contracts (by employment or otherwise) with a person that the provider knows or should know is excluded by OIG, the provider may be subject to CMP liability if the excluded person provides services payable, directly or indirectly, by a federal health care program. OIG may impose CMPs of up to \$10,000 for each item or service furnished by the excluded person for which federal program payment is sought, as well as an assessment of up to three times the amount claimed, and program exclusion.

Health Care organizations should routinely check the exclusion databases and refuse to hire or contract with any excluded individual.

The effects of exclusion, however, do not end there. Once a provider is listed on the OIG's List of Excluded Individuals/Entities ("LEIE") (<http://exclusions.oig.hhs.gov>) many private insurers will also drop the provider from participation because inclusion on the list means a serious violation of the CMS regulations, the law, or both, and it is often inferred by private insurers that the individual or entity committed intentional fraud, rather than being excluded for other reasons like employing an excluded individual. Participation in many private health care insurance programs hinges on remaining compliant with federal and state law and regulations. If the individual did in fact commit fraud, the OIG will notify the General Services Administration ("GSA") Excluded Parties List System ("EPLS") (www.epls.gov), and System for Award Management ("SAM") (www.sam.gov) websites and the excluded individual or entity will be placed on those lists of excluded individuals/entities as well. Additionally, appropriate state agencies will be notified of the exclusion (42 CFR 1001.2004).

The licensing authority of the state in which the provider is licensed will be notified by CMS (42 CFR 1001.2005) and a license hearing may also be undertaken seeking license sanctions against the individual, up to and including license revocation (MCL 333.16221, and MCL 333.16226). State agencies and law enforcement units may then be notified regarding possible investigations for violations of state law as well.

Sanctions such as these may also trigger termination and indemnification clauses in employment contracts. If the lack of a compliance program provides a patient with a cause of action to sue the practitioner or practice for other than medical malpractice, general liability insurance may be inapplicable to the situation. Finally, failing to have a comprehensive compliance program document and proof of implementation means the entity employing the excluded individual will not be able to use such programs as a mitigation defense.

What Does and Does Not Constitute a Proper Compliance Program?

A review of numerous compliance program documents shows that there is no defined format. CMS and the HHS OIG have not issued a required format, nor laid out any formal, mandatory core components. The current guidance available from the OIG are based on voluntary compliance concepts. The Secretary of Health and Human Services has proposed the adoption of the existing guidelines set forth in the Federal Sentencing Guidelines.³¹ This was done because health care fraud can lead to criminal convictions in many circumstances, resulting in fines, penalties, and jail sentences. The Federal Sentencing Guidelines detail precisely how an implemented compliance program will reduce an organization's "culpability score" as factored into the sentencing matrix.³²

Federal Sentencing Guidelines commentary explains the relevance of a compliance program to the federal sentencing guidelines:³³

These guidelines offer incentives to organizations to reduce and ultimately eliminate criminal conduct by providing a structural foundation from which an organization may self-police its own conduct through an effective compliance and ethics program. The prevention and detection of criminal conduct, as facilitated by an effective compliance and ethics program, will assist an organization in encouraging ethical conduct and in complying fully with all applicable laws.

The Guidelines present the seven minimum requirements of an "effective compliance and ethics program."³⁴ These requirements will be detailed later in this article.

Currently, many hospital and health system compliance program documents run the gamut from meeting to missing the seven minimum requirements; formal to informal; directed solely to employees or directed solely to patients; long, short, on point, off point, and everything in between. So, what constitutes a good compliance program document? Perhaps, it is easier to first describe what a good compliance program is *not*.

A compliance program is a framework for compliance with the law, *it is not a summary of the law*. Many compliance plans contain lengthy summaries of the federal fraud laws, and state equivalents as well, or reiterate entire chapters of administrative regulations. It is not necessary to include this information in the actual compliance program document. It can, and should, be *incorporated by reference* to another document or manual that contains such information, like an employee manual or procedures manual.

A compliance program document is *not an employee manual*. It should not be written in a conversational tone solely to the employees. Although much of the purpose of the compliance program is to educate and train employees to act in ways that are compliant with the law, and to work as a team in doing so, the document is not intended solely for the benefit of employees. It is not a detailed set of protocols addressing every imaginable situation that could occur, along with corresponding procedures, contact information, and the like. All of that information can and should be *incorporated by reference* to the employee manual or other similar documents containing that type of information. Of course, this necessitates an organization having such employee and policy manuals.

A compliance program document is *not a patient information or education document*. It is not a summary of services or benefits the organization provides for patients. It is not a customer service document. It is not a marketing document. It is not a pledge of allegiance or loyalty to patients. Once again, all of these things should exist elsewhere and can be *incorporated by reference*. Incorporating them by reference makes them part of the program.

A compliance program document is a clear, declarative statement to the world at large of the intent to comply with the law, or a statement of actual compliance with the law—whatever that relevant law might be. It is a corporate citizenship document acknowledging responsibilities not only to the patients and employees, but to the community and government as well. It is a potential defense or mitigation document that can be used to show the character and intent of the organization to be a legally compliant entity, assuming the attendant program, procedures, policies, and protocols that are established in the program document are implemented. Finally, it is a living document that serves as a pivot and integration point for all the major policies and procedures of the organization designed to keep the organization in compliance with the law.

A good compliance program document should be tailored to the organization. There are several templates available from a variety of major private health care insurance plans that cover the absolute basics as required by the Federal Sentencing Guidelines. With careful editing and tailoring they can serve as step one in obtaining compliance with the ACA and CMS mandate, and step one in implementing a fraud, waste, and abuse prevention program at the organization. However, caution should be taken not to simply employ a generic template, as one size does not fit all. A review of

the specific and unique features of the organization, along with a risk management review, will provide numerous opportunities to tailor the document to the organization's needs and features.

When creating the compliance program document it should be written or edited to be in a declarative, third person, active voice, in present tense with future tense where applicable. A good example, would be that it should read like an administrative regulation—declarative, third person. It should not be written in first or second person, should not use “we,” “us,” “our,” “you,” “your,” or “yours,” nor be written in passive voice. It should be written for any individual, organization, employee, patient, or government official. It is not meant to be an internal document. It should be clear, and concise, as well as being truthful and accurate. It should include, at a bare minimum, the nine core elements explained below. Addressing the nine core elements at least will bring the practice into compliance with the ACA. Including additional statements of legal compliance with other areas of the law strengthens the program and the document, and forces the organization to review systems, procedures, and personnel related to those areas upon implementation of the program.

Finally, various provisions or sections of the compliance program document should *briefly* explain the relevant and significant laws, and then make reference to more detailed documents by *incorporating them by reference*. Those related documents may then be written in second or third person language in order to specifically address the conduct, responsibilities, policies, procedures, and protocols for employees in particular situations.

The Nine Minimum Components of a Compliance Program

In order for physicians and their practices to be in compliance with the law and avoid exclusion, a written compliance program containing the minimum core components must be in operation. To be clear, the *program itself* must be in operation, not merely having the written document in existence. The HHS OIG Guidance documents list seven core components which appear below.³⁵ Numbers 5 and 9 are additions, but necessary ones because they are so closely linked to various types of fraud and abuse, as well as HHS audits and investigations:

1. Commitment to compliance
2. Designation of Compliance Officer and Committee
3. Regular compliance training programs
4. Open channels to receive questions and complaints
5. HIPAA and HITECH compliance
6. Ongoing audits and monitoring
7. Disciplinary action for violations and noncompliance

8. Investigation and corrective action for noncompliance

9. Response to special agents' visit for investigation purposes

It is recommended that the physician practice compliance program start with these components and build from there. These nine core components are not exhaustive explanations. Additional topics for possible inclusion in each area, or for additional areas will be discussed near the end of the article.

Commitment to Compliance

The language of this section of the compliance program document should carry a strong declaratory statement that the organization and its employees and agents are committed to compliance with the federal and state laws regarding fraud and abuse prevention, with other laws applicable to all businesses (such as the Americans with Disabilities Act, OSHA, FMLA, and the like), all requirements for participation in federal, state, and private health care insurance programs, as well as any applicable accreditation and certification standards and requirements. It should not be written solely for patients, or employees, or the government. *It should be a strong, general statement of compliance, or intent to comply that is a public notice to the world.* If it should ever be read as evidence to a jury, they should understand that the organization sincerely intends compliance with the law, does comply, and actively attempts to prevent violations and noncompliance.

Furthermore, this section should specifically address written standards of conduct, and specific important policies and procedures concerning fraud, waste, and abuse. Generally this section leads off with a statement of compliance with requirements of a Code of Conduct, and makes reference by incorporation to other existing policies and procedures. This section should contain a general guide to workplace behavior and other expectations for all employees and agents of the practice. The referenced Standards or Code of Conduct should be short, quickly understood, memorable, and should apply to all employees, whether or not they hold a license to practice medicine.

Accompanying policies and procedures in the employment manual or Human Resources office will detail for employees what is expected and how to apply and implement those expectations. Sanctions for violation of the compliance program should be listed in separate employment policies. Employees should acknowledge, in writing, their receipt of the compliance program document, related implementation information, and an understanding of their responsibilities. The acknowledgement should be kept on file by the organization.

There are additional areas to be addressed in this section. These include statements of compliance with the requirements of medical necessity underlying all claims made to health care insurance programs. In this section it is beneficial to state an understanding of the term "medical necessity," that all physicians and ordering

personnel will be cognizant of their duties in this regard and will ensure proper supporting documentation exists, and advanced beneficiary notices will be used in appropriate situations.

Also, compliant billing practices can be succinctly addressed in this section. It is prudent to include a clear statement that the organization will make all reasonable attempts to ensure that billing practices comply with all applicable laws and regulations. To accompany that statement, it is good form to include a clear statement that the organization will not engage in prohibited and illegal practices such as upcoding, unbundling, billing for unnecessary services, and other forms of fraud. Following that subsection, one should include declarations of compliance with the False Claims Act, the Ethics in Patient Referrals Act ("Stark Law"), and the Medicare/Medicaid Patient Protection Act, also known as Anti-Kickback Statute ("AKS"), as well as any applicable state versions of those statutes. It should also include a statement of compliance with all HHS and other governmental agency fraud alerts. Other recommended portions for this section include:

- basic statements of understanding, awareness, and compliance regarding particular state fraud laws;
- fraud prevention with regard to private health care insurance claims;
- a commitment to not hiring excluded individuals;
- an understanding of the limited and proper use of standing orders;
- marketing practices that comply with the FTC, FCC, and other federal and state regulations;
- compliant contract management;
- a commitment to ensuring patient rights;
- maintenance of all licensing and board certification requirements; and
- numerous other additions relevant to the needs and features of the organization.

Designation of a Compliance Officer and Committee

The OIG requires every health care provider, providing organization, and supply provider participating in Medicare, Medicaid, PACE, and CHIP, to name a Compliance Officer ("CO") in the compliance program document.³⁶ The Federal Sentencing Guidelines for organizations state that effective compliance and ethics programs provide: "[s]pecific individuals within high-level personnel shall be assigned overall responsibility for the compliance and ethics program."³⁷ Further, it states:

Specific individual(s) within the organization shall be delegated day-to-day operational responsibility for the compliance and ethics program. Individual(s) with operational responsibility shall report periodically to high-level personnel, and as appropriate, to the governing authority, or an appropriate subgroup of the governing authority, on the effectiveness of the compliance and ethics program. To carry out such operational responsibility, such individual(s) shall be given

adequate resources, appropriate authority, and direct access to the governing authority, or an appropriate subgroup of the governing authority.³⁸

The CO is a single person with overall responsibility for implementation of, and compliance with the program, and for fostering a culture of ethics. Generally, this person is employed full-time at the organization (although the CO duties do not have to be full-time), and has access to the organization's leadership levels and individuals. The CO should not simultaneously serve as the financial or legal officer for the organization.³⁹

The CO should be the "face" of the compliance program, and employees and agents should feel comfortable consulting this person about compliance issues. The CO should be accessible and approachable. This individual is responsible for operation of the program and prevention of violations, but is also responsible for investigations of alleged violations of the compliance program or violation of the law, as well as for implementing corrective action plans. The CO interacts with legal counsel and the government representatives on all matters related to the compliance program.

The OIG and the Federal Sentencing Guidelines not only require designation of a CO, but offer lower fines for organizations with COs as well. In addition, the presence and interaction of a CO may reduce the potential for charges being brought, and may mitigate penalties imposed in criminal matters. It is clear that the CO should participate in all major organization decisions that may impact the compliance program and organizational ethics.

To support the work of the CO, the organization may appoint a Compliance Committee if the organization is big enough to sustain such an entity. The Compliance Committee serves in a support role for the CO, as well as hearing appeals of the CO's disciplinary or corrective action decisions. Generally, individuals from various departments comprise the members of the committee. It is especially important to include persons from billing and claims, records management, and personnel on the committee, as well as persons from other areas of the organization that may be at higher risk for compliance violations.

Regular Compliance Training Programs

The purpose of this element of the compliance program is to communicate to all employees of the organization the policies, procedures, and standards of conduct that are expected in order to remain in compliance with the law while still providing excellent health care services to patients. All new employees should be trained in this regard within 30 days of hiring,⁴⁰ but COs should aim for a much shorter time period (ideally before the employee actually starts work) in order to prevent potentially costly and serious mistakes made by inexperienced and new employees.

Pursuant to OIG Compliance Guidance documents, **all** employees and agents of the organization should be trained on compliance policies, procedures, and protocols at least once a year, and each new training should contain legal, regulatory, and

accreditation updates to ensure all employees are aware of their compliance responsibilities.⁴¹ All employees, affected physicians, vendors, suppliers, consultants, independent contractors, and other relevant agents should be required to attend the annual training and update, whether or not they appear to perform compliance-related work.⁴²

In addition to the general training for all employees and agents, specialized employees working in areas at high risk for noncompliance (for example, billing, coding, records, HIPAA compliance, governing authority members, marketing, IT, and other heavily regulated areas) should receive training specific to their work responsibilities. At each training session attendees should provide written certification of their familiarity with and understanding of the Code of Conduct and other relevant organizational documents. Full records of training sessions, including type of training, dates, length of training, content, attendee lists, and materials distributed should be kept by the organization. Training materials must be available to **all** employees, and that means they may need to be translated into other languages.⁴³

The OIG has made recommendations regarding the content of compliance training. Standard compliance training should cover, at a minimum:⁴⁴

- Overview of the organization's compliance program;
- Overview of the organization's Code of Conduct and culture of ethical practice;
- Relevant federal and state laws, regulations, and guidelines with emphasis on fraud and abuse prevention;
- Federal, state, and private payor program requirements;
- Overview of relevant accreditation/certification requirements;
- Emphasis on the organization's commitment to comply with all legal, regulatory, and accreditation/certification requirements;
- Requirements of proper billing and coding practice;
- Explanation of the claims development and submission process;
- Requirements of proper record keeping and safety practice;
- Acceptable marketing practices in light of current legal, regulatory, and program standards;
- Methods and protocols for reporting suspected or actual violations, issues, and noncompliance;
- Patient rights with regard to matters with compliance implications; and
- A discussion of other compliance issues particular to the organization such as HIPAA, OSHA, ADA, medical malpractice, and other requirements.

The OIG has also created a number of other resources available on its website to assist physicians' practices with training and other compliance program implementation issues. The specifics for billing and coding training are available there as well <https://oig.hhs.gov/compliance/101/index.asp> <https://oig.hhs.gov/compliance/compliance-guidance/index.asp>. If the practice does not

have adequate resources for in-house training there are numerous consulting agencies, associations, and other organizations (online and face-to-face) that can provide the necessary training for employees and provide the necessary documentation of such. If possible, employees and others should be offered a variety of formats in which to complete the required training, including online, face-to-face, written, blended, workshop, and others.⁴⁵

The various Corporate Integrity Agreements available on the OIG website provide another good source of direction for compliance training. These CIAs detail what organizations should have been doing if they implemented and followed a proper compliance program. Guidance from CIAs includes, but is not limited to:⁴⁶

- At least two hours of general training each year for every employee and agent;
- At least four additional hours of specific training for all relevant compliance-related individuals, and then 2 hours per year after;
- Members of any governing organization (board, committee, directors, officers) should receive 2 hours of board specific training regarding organizational governance and personal responsibility for noncompliance issues;
- The organization's leaders shall use their best efforts to ensure that all employees and members of the medical staff complete the required training given their particular positions and responsibilities within the organization; and
- Each person required to attend the training sessions must certify in writing that he or she received the required training.

Compliance must become a part of the organization's culture. One of the ways to accomplish this is to consider employee attendance at compliance training sessions when drafting job descriptions, completing performance reviews, considering promotions or transfers to new positions, and creating disciplinary structures.⁴⁷ Management bears a greater responsibility for compliance than employees. The strength of the message, and methods of fostering that message in subordinates should be considered with regard to advancement in the organization. Required attendance at compliance training should also be a provision in the written agreement with contractors, vendors, and third parties.⁴⁸

Open Channels to Receive Questions and Complaints

This element deals with whistleblowing issues and communication in and throughout the organization. This section should declare compliance with the requirements of non-retaliation in whistleblower situations. It should make a general declaration that any suspected violations of law, regulation, rules, standards, directives, or internal policies *must* be reported to the CO. It should succinctly lay out the methods of communicating with the CO and/or Compliance Committee with regard to reporting suspected or actual violations, and that they may be made anonymously.⁴⁹ It should provide general information regarding how the CO and/or Compliance Committee

disseminate information and materials to employees and notify those employees of training sessions or events. It should contain a general declaration of intent to investigate properly, and fully, all reported matters, and that the CO will work closely with organization leaders and legal counsel to insure proper handling of reported matters.⁵⁰ Finally, it should state that the organization will take the necessary disciplinary steps to enforce compliance as outlined in the employee manual, *incorporated by reference*.

HIPAA and HITECH Compliance

Health Insurance Portability and Accountability Act ("HIPAA") breaches can be disastrous and cost significant amounts in fines and penalties. It can lead to lawsuits under state law against the organization, and civil and criminal penalties.⁵¹ HIPAA audits are one of the HHS Office of Civil Rights' big projects at present. This is an important topic to address in a compliance program. In addition, poor records security is an open invitation for internally and externally generated false claims and fraudulent action, not to mention hacking, theft, and sale of patient information. In this section of the compliance program document the organization should be making a clear declaration of compliance with all requirements of HIPAA and the Health Information Technology for Economic and Clinical Health Act ("HITECH").

This part of the compliance program is not the place to reiterate the content of the Privacy Rule, the Security Rule, or the Omnibus Rule. It is a place to declare an understanding of, and ongoing compliance with those rules, and they can be incorporated by reference to another document if necessary. It is a place to declare publicly that business associates have been apprised of privacy and security requirements, and that Business Associate Agreements are up-to-date and saved on file (and of course, ensure that is in fact true). It is also a place to state that patient records will be maintained safely and securely for the longer of the minimum number of years required by statute or regulation. Michigan requires seven years,⁵² HIPAA requires six years (state law controls),⁵³ but Medicare requires ten years.⁵⁴ State that compliance with the requirement to train all employees is maintained at all times. The main compliance points should be stressed in this section, and then *incorporated by reference* to a more detailed HIPAA/HITECH compliance document. Ensure that the referenced HIPAA/HITECH compliance plan is in place and continually monitored.

Ongoing Audits and Monitoring

This section should bear statements that the organization operates as an ethical and compliant organization and, as such, intends to monitor compliance on a daily basis, and perform periodic audits to assess the effectiveness of the monitoring and other compliance strategies. It should also clearly state that the organization performs periodic risk assessments to determine areas of higher risk for violation, and then performs more frequent audits of those areas to prevent violations.⁵⁵ These duties like

all statements on compliance or intent must of course actually be implemented into the operational program.

The document should state that if noncompliance is confirmed in any area of the practice, corrective action will be taken swiftly, and any required reporting procedures will be followed within applicable time periods.⁵⁶ If audits are to be performed under the attorney-client privilege, this section may or may not declare that information may become public depending on the advice of the organization's legal counsel.⁵⁷ This section may reiterate that employees will receive ongoing training with regard to areas of high risk for noncompliance.

Disciplinary Actions for Violations and Noncompliance

The document should state that the organization and employees are held accountable for violations and noncompliance. The document should state that supervisors and managers will be held accountable for the noncompliance of their subordinates, and organizational leadership will bear its share of responsibility as well. This section will lay out in broad detail the nature of a disciplinary system, making reference to more detailed disciplinary protocols by *reference and incorporation*. It should also stress consistency in the application of those disciplinary procedures. General employment disciplinary protocols do not typically involve a CO, similarly, the CO should not be involved in imposing discipline for compliance related violations either. That job should be left to the manager or designated human resource professional.⁵⁸

Investigation and Corrective Action for Violations and Noncompliance

Although investigation of compliance matters was briefly mentioned above, this should be a broad snapshot of the investigation *procedure*. That snapshot may include the basic steps in the investigation procedure, and the potential corrective action for each broad type of violation, including when matters may be reported to legal authorities.⁵⁹ It may declare or reiterate the broad procedure for how employees under investigation will be dealt with, including temporary suspension and/or suspension of clinical privileges, leave with or without pay, and the like.⁶⁰

This should include a statement that all documentary or other possible evidence related to any investigation shall be maintained and securely stored. It should include clear statements of intent to comply with reporting and self-disclosure protocols, and remittance of overpayments relating to various federal and state statute and regulation violations. It may also be beneficial to include a declaration of intent to comply fully with all requests for information, documentation, or other evidence in outside federal or state investigations.

Response to Special Agents' Visit for Investigation Purposes

This section informs employees what to do, and not to do in response to special agent's investigation, but it (and many other provisions of the document) may be used

to show that the organization considered such possibilities ahead of time and planned for the events in order to ensure maximum compliance and cooperation. This is a declarative statement of how employees should act, what they should and shouldn't do in that situation, who will be contacted, and how patients and others will be handled. It will be key to maintaining an orderly investigation and search by law enforcement authorities while maintaining confidentiality and decorum. It should include statements similar to what follows:⁶¹

- Do not deny admission to the premises
- Do not deny agents permission to talk with employees or agents
- A management level individual will:
 - politely request a copy of the search warrant and the affidavit supporting it;
 - Request an opportunity to contact legal counsel immediately;
 - request to postpone the search until patients can be cleared from the building;
 - permit the premises to be secured if necessary;
 - politely request that no one be questioned until legal counsel is present;
 - politely ask for the names and agencies of each individual requesting access;
 - accompany the agents during the search;
 - record beginning and ending times of the search;
 - record a map of areas and items searched;
 - record items taken if possible;
 - record questions asked or comments made;
 - if employees are interviewed, record in as much detail as possible what was asked and what was said; and
 - cooperate with all reasonable requests, answer questions honestly and succinctly.
- An employee or other individual shall not:
 - Remove, alter, modify or destroy documents, records, items, recording, films, or anything else on the premises;
 - leave without permission to do so;
 - refuse reasonable requests from agents or officers; or
 - lie, omit, or falsify information.

Expanding the Basic Compliance Program to Become a Comprehensive Compliance Program

With a compliance program document and implemented, operational program, the physician practice should be compliant with the ACA mandate. Hopefully, the document will serve its initial purpose, and cause the practice management to investigate and assess areas of risk in the practice, and implement a program to prevent and detect violations of law and regulation. Once that has been established, however, the practice should take the next step and institute a more comprehensive

compliance program and document. This involves adding additional sections/subsections to the document that deal with legal, regulatory, and accreditation compliance in areas that are not fraud, waste, and abuse related, but that are specifically tailored to the features and needs of the practice.

When addressing these new areas, the language should be brief, and remain focused on statements of understanding, awareness, and compliance. The author should remember that the foremost audience for the compliance program document is the government and enforcement agencies, and thus it must contain some legal terms of art or language specific to certain statutes or regulations. Those who are implementing and operating the program should already be familiar with these terms and language. (Documents incorporated by reference, however, are best written in plain English and should be easily understood by the average employee or agent. Legal terms should be used sparingly, and definitions of statutory or regulatory terms provided.) Corrective action wording may be included in expanded compliance program document, but any extensive details, policies, procedures, and protocols should be in documents *incorporated by reference*, not in the body of the compliance program document. Examples of the types of additional provisions the compliance program document might include are an intent to or actual compliance with the requirements of:

- Disclosures and Repayments
- Reverse false claims regulations
- The Americans with Disabilities Act
- Medicare/Medicaid anti-discrimination requirements
- The Civil Rights Act and other laws and regulations regarding anti-discrimination policies and requirements
- OSHA and the state version thereof
- The Fair Labor Standards Act
- Wage and Hour laws
- The Family Medical Leave Act
- The Fair Collection Reporting Act
- The Fair Debt Collection Practices Act
- The Federal Health Care Fraud Act
- Civil Monetary Penalties Act
- No employment of individuals with criminal backgrounds
- EEOC
- Sexual harassment and violence in the workplace
- Drugs and alcohol in the workplace
- Collective bargaining agreement compliance
- Informed consent requirements and compliance
- Mandatory reporting requirements
- Fiduciary responsibilities
- Professional standards of care for specialties

- Accreditation and/or certification standards
- FDA regulations
- The Safe Medical Devices Act
- Hospital privileging and credentialing requirements
- CLIA and laboratory services
- Controlled Substances Act
- Medical device adverse event reporting requirements
- Medication adverse event reporting
- Medical grant and research protocols and requirements
- Protection of trade secrets
- Prevention of Scientific Misconduct
- Whistleblower Protection Act
- Sherman Antitrust Act
- Physician recruitment practices
- Vendor and pharmaceutical company relationships
- Patient Self-Determination Act and Advance Directives
- UNOS requirements
- Women's Health and Cancer Rights Act
- National Practitioner Data Bank reporting
- Controlled substances and prescriber statutes
- Do-Not-Resuscitate laws
- Culturally competent medical practice guidelines
- Telemedicine compliance
- Patient safety
- Employee safety
- Commitment to use of evidence based medicine
- Vendor and supplier compliance
- Keeping accurate corporate records
- General accounting standards
- Conflict of interest
- Any state law version of any of the above

The potential inclusions are endless. The main point with these additional areas is that they are only included in a particular practice's compliance program and document if the practice might truly benefit from their inclusion. The areas with the most risk potential are the ones that should make the top of the list for inclusion. Having those topics addressed in the compliance program document means that the document can be used for defense and mitigation in a variety of law suits, administrative hearings, and criminal matters, so it is more useful than being used in that manner only for fraud, waste, abuse issues. Again, inclusion of particular topics should be cause for the practice to evaluate attendant policies, procedures, behaviors, staffing, and workflows

such that better compliance versions of each of those aspects emerges as part of the overall comprehensive compliance program.

Other Benefits of Having a Compliance Program

Although complying with the mandate to obtain and implement a compliance program is an added business expense, it is a necessary one and not without other significant benefits. It can be viewed much the way purchasing insurance is viewed—the investment is worth it when the need for it arises. If a client is unsure what benefits come with the expense (beyond remaining in compliance with the law by having the compliance program itself), the following may be helpful in educating the client:⁶²

- Compliance programs are mandatory, and implementation permits the provider to participate in Medicare, Medicaid, CHIP, PACE, TRICARE, CHAMPVA, and VA programs, as well eligibility for some research grants;
- Increased compliance in the organization reduces the potential for administrative investigations, hearings, and sanctions, civil damages and monetary penalty imposition, criminal sanctions and punishments, program enrollment termination, program exclusion, private payor exclusion, lawsuits, and the imposition of CIAs;
- In the event violations are detected, the existence of a compliance program may mitigate consequences and penalties pursuant to the Federal Sentencing Guidelines and the Civil Monetary Penalties statute;
- The compliance program and document demonstrates a culture of ethical conduct and good corporate citizenship which is important to regulators, prosecutors, employees, patients, and the public;
- Implementation of a compliance program, training of the leadership body, and updates from the CO shows responsible and involved organizational governance;
- The compliance program document may be used as a defense and mitigation evidentiary document in administrative hearings, civil lawsuits, and criminal trials, especially with respect to allegations of intent to violate the law;
- It provides an opportunity for risk assessment of all operational systems to detect, analyze, correct, and prevent misconduct, violations, and noncompliance with the law, regulations, rules, standards, and directives;
- The program's framework encourages and empowers all employees to actively participate in noncompliance and violation prevention by becoming actively involved and reporting suspected deviations and violations;
- The program creates a framework for appropriate audit and internal investigation and correction of detected violations or noncompliance, including attorney-client work product and possible self-evaluation privilege⁶³ protections;
- The framework provides protocols and procedures for involvement of legal counsel at the commencement of internal or government investigations triggering attorney-client privilege;

- The implementation of a compliance program and the appointment of a CO creates a central point for monitoring and implementing and compliance with legal and payor requirements, as well as receipt of bulletins and information regarding fraud and abuse prevention that are distributed by the government and private payors;
- It creates a more educated, trained, and cohesive workforce that understands there are consequences for violations and noncompliance;
- A comprehensive compliance program improves communication and compliance channels between and among health care entities that may share responsibility for noncompliant acts;
- Compliance programs, or components thereof may be a requirement for accreditation or certification;
- Consistency in investigative procedures, corrective actions, and imposition of disciplinary measures;
- Preparation of claims is faster and more accurate resulting in increased and faster reimbursement, and decreased return of claims for correction;
- Reduction in provision of unnecessary services; and
- Record-keeping is greatly improved which is beneficial in many types of situations both from an operational perspective and a defense perspective.

Conclusion

Additional guidance on drafting compliance program documents for Medicare providers and suppliers can be found at the OIG website under the compliance tab <https://oig.hhs.gov>. Mandatory compliance programs are not going away because governmental attempts to curb the tide of fraud, waste, and abuse are not going away. This is a topic attorneys need to take up with all their health care clients as soon as possible. Having a compliance program document and implementing that compliance program are necessary business expenditures, that will result down the road in both time and money saved.

** Note: this is an overview article intended to provide guidance to health care lawyers with physician practice clients. This is not a comprehensive overview of all laws related to compliance programs, Medicare, or federal or state fraud laws.*

The views in this article are the personal views and experiences of the author and do not necessarily reflect the views of the State Bar of Michigan, or of the State Bar of Michigan Health Care Law Section.

Endnotes:

1. The OIG has yet to determine the timeline for the establishment of the core elements under subparagraph (B) and the date of the implementation of subparagraph (A) for providers or suppliers within a particular industry or category.
2. 42 U.S.C. §1396u-4.
3. 42 U.S.C. §1397aa, §1397bb
4. 32 CFR 199.6.
5. *Health Net Federal Services, Credentialing for Tricare Network Providers*, (last visited June 7, 2015) www.hnfs.com/content/hnfs/home/tn/prov/highlight_sites/credentialing.html
6. Health Net Federal Services, *Tricare Handbook* 13 (2015-2016 ed.)
7. *Id.*
8. George B. Moseley III, *Managing Legal Compliance in the Health Care Industry* 520, (1st ed. 2013).
9. *Id.* at 22, 140.
10. *Id.* at 22.
11. *Id.* at 22.
12. *Id.* at 119.
13. *Id.* at 118.
14. *Id.* at 119.
15. *Id.* at 119.
16. *Id.* at 119.
17. *Id.* at 119.
18. *Id.* at 119.
19. *Id.* at 141.
20. 42 U.S.C. §1395cc(j)(8)
21. 42 U.S.C. §1395cc(j)(8), various CMS guidelines
22. Internal Revenue Service, *Examples of Health Care Fraud Investigations Fiscal Year 2013* (last visited on June 7, 2015) www.irs.gov/uac/Examples-of-Healthcare-Fraud-Investigations-Fiscal-Year-2013, Internal Revenue Service, *Examples of Health*

Care Fraud Investigations Fiscal Year 2014 (last visited on June 7, 2015)
www.irs.gov/uac/Examples-of-Healthcare-Fraud-Investigations-Fiscal-Year-2014

23. CMS, *Medicare Program and Integrity Manual* 15.1.1 (2014).
24. 42 U.S.C. §1320a-7(9), (10), (11), and (16)
25. *Id.*
26. 42 U.S.C. §1320a-7(9), (10), (11) and (16), 42 U.S.C. § 1320a-7a
27. 42 U.S.C. §1320a-7a
28. 42 U.S.C. §1320a-7a(9)
29. 42 U.S.C. §1320a-7a(10)
30. 42 CFR 1001.2
31. George B. Moseley III, *Managing Legal Compliance in the Health Care Industry* 140, (1st ed. 2013).
32. United States Sentencing Commission, *Federal Sentencing Guidelines Manual* §8c2.5 (2014).
33. United States Sentencing Commission, *Federal Sentencing Guidelines Manual* §8b2.1 (2014).
34. *Id.*
35. *Id.*, U.S. Dept. Health and Human Services, Office of the Inspector General, *Compliance Guidance* (last visited June 7, 2015)
<https://oig.hhs.gov/compliance/compliance-guidance/index.asp>
36. U.S. Dept. Health and Human Services, Office of the Inspector General, *Compliance Guidance* (last visited June 7, 2015)
<https://oig.hhs.gov/compliance/compliance-guidance/index.asp>
37. United States Sentencing Commission, *Federal Sentencing Guidelines Manual* §8b2.1 (2014).
38. United States Sentencing Commission, *Federal Sentencing Guidelines Manual* §8b2.1(b)(2)(C) (2014).
39. George B. Moseley III, *Managing Legal Compliance in the Health Care Industry* 169, (1st ed. 2013).
40. George B. Moseley III, *Managing Legal Compliance in the Health Care Industry* 232, (1st ed. 2013).

41. U.S. Dept. Health and Human Services, Office of the Inspector General, *Compliance Program Guidance for Third Party Billing Companies* (last visited June 7, 2015) <https://oig.hhs.gov/compliance/compliance-guidance/index.asp>
42. George B. Moseley III, *Managing Legal Compliance in the Health Care Industry* 232, (1st ed. 2013).
43. U.S. Dept. Health and Human Services, Office of the Inspector General, *Compliance Program Guidance for Third Party Billing Companies* (last visited June 7, 2015) <https://oig.hhs.gov/compliance/compliance-guidance/index.asp>
44. George B. Moseley III, *Managing Legal Compliance in the Health Care Industry* 235, (1st ed. 2013).
45. U.S. Dept. Health and Human Services, Office of the Inspector General, *Compliance Program Guidance for Third Party Billing Companies* (last visited June 7, 2015) <https://oig.hhs.gov/compliance/compliance-guidance/index.asp>
46. U.S. Dept. Health and Human Services, Office of the Inspector General, *Corporate Integrity Agreements* (last visited June 7, 2015) <https://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp>
47. George B. Moseley III, *Managing Legal Compliance in the Health Care Industry* 234, (1st ed. 2013).
48. *Id.* at 235.
49. U.S. Dept. Health and Human Services, Office of the Inspector General, *Compliance Program Guidance for Third Party Billing Companies* (last visited June 7, 2015) <https://oig.hhs.gov/compliance/compliance-guidance/index.asp>
50. *Id.*
51. 42 USC § 1320d-5
52. MCL 333.16213
53. 45 CFR 164.316(b)(2)
54. 42 CFR 422.504 [d][2][iii]
55. U.S. Dept. Health and Human Services, Office of the Inspector General, *Compliance Program Guidance for Third Party Billing Companies* (last visited June 7, 2015) <https://oig.hhs.gov/compliance/compliance-guidance/index.asp>
56. *Id.*
57. George B. Moseley III, *Managing Legal Compliance in the Health Care Industry* 213, (1st ed. 2013).

58. George B. Moseley III, *Managing Legal Compliance in the Health Care Industry* 309, (1st ed. 2013).

59. George B. Moseley III, *Managing Legal Compliance in the Health Care Industry* 157-158, (1st ed. 2013).

60. *Id.* at 477.

61. *Id.* at 202-204.

62. George B. Moseley III, *Managing Legal Compliance in the Health Care Industry* 141, 343, 395 (1st ed. 2013).

63. *Id.* at 213.

The Intersection of the Affordable Care Act and the Michigan No-Fault Automobile Insurance Act

By

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The Intersection of the Affordable Care Act and the Michigan No-Fault Automobile Insurance Act

Table of Contents

Introduction

- I. The Basic Principles of the Affordable Care Act
 - A. The Choice to Obtain Health Insurance Under the ACA or Pay the Applicable Tax Penalty
 - B. The Scope of Health Insurance Coverage Under the ACA
 - C. The Levels of Coverage Available Under the ACA
 - D. Consumer Rights under the ACA
- II. The Basic Principles of the Michigan No-Fault Automobile Insurance Act
 - A. The Goals and Objectives of the MNFA
 - B. Understanding No-Fault PIP Coverage and the Related Limitations on Recovering Damages from the At-Fault Driver
 - C. Uncoordinated vs. Coordinated No-Fault PIP Coverage
 - D. The Ways In Which Medical Providers are Paid Discounted Rates of Reimbursement for Auto Accident-Related Medical Treatment
 - E. Governmental Benefit Setoffs Under MCL 500.3109(1)
 - 1. Government Benefit Setoffs Under the Two-Part Test Established in *Jarosz v DAIIIE*
 - 2. Avoiding the Governmental Benefit Setoff under MCL 500.3019(1) for Uncoordinated No-Fault Coverage, Pursuant to the *Leblanc* Hybrid Benefit Doctrine
 - F. Consumer Rights and Remedies under the MNFA
- III. The Intersection of the ACA and the MNFA
 - A. Michigan No-Fault PIP Coverage is far Broader than ACA Coverage

B. ACA Coverage Should Only be Subject to Setoff Under Coordinated No-Fault Policies

1. ACA Coverage is not Subject to Setoff under MCL 500.3109(1), Because ACA Coverage is not “Provided or Required to be Provided” by the Laws of Any State or the Federal Government
2. ACA Coverage is not Subject to Setoff under MCL 500.3109(1) Because it Fails the *Jarosz* Test
3. ACA Coverage is not Subject to Setoff Under MCL 500.3109(1) for Uncoordinated No-Fault Coverage, Pursuant to the *LeBlanc* Hybrid Benefit Doctrine

C. The ACA may Result in More People Purchasing Coordinated No-Fault Coverage

D. The ACA may Help Lessen the Financial Burdens and Costs of Michigan’s No-Fault System

Conclusion

The Intersection of the Affordable Care Act and the Michigan No-Fault Automobile Insurance Act

By Stephen H. Sinas¹

Introduction

The Patient Protection and Affordable Care Act² ("ACA") provides Americans with a broad range of rights and benefits regarding health insurance that they have never had under federal law. The people of Michigan, as do all Americans, need to be knowledgeable of these rights and benefits so they can make the best decisions regarding their health care and their purchase of health insurance going forward. However, it is also important to understand how the ACA intersects with Michigan state laws relating to health care. One such law is the Michigan No-Fault Automobile Insurance Act ("MNFA").³ For over 40 years, the MNFA has created a unique system of automobile insurance in Michigan that ultimately provides comprehensive health insurance coverage for the care, recovery and rehabilitation of people injured in motor vehicle accidents. The essential purpose of this article is to examine how the ACA and the MNFA intersect and what that means for the people of Michigan.

Although the ACA is over 2,000 pages long, there is not a single reference within those pages indicating how ACA coverage should operate in relation to auto no-fault insurance. Furthermore, the Michigan Legislature has not amended the MNFA or passed any other law providing guidance about the relationship between the MNFA and the ACA. Moreover, there is no case law addressing how these two laws relate to one another. Therefore, in order to properly and thoroughly examine the intersection between these two unique laws, it is necessary to first explain the basic principles and important concepts of each law. Accordingly, Section I of this article explains the basic principles of the ACA and the rights and benefits the ACA provides with respect to health insurance. Section II explains the basic principles of the MNFA and the rights and benefits it provides to people who are injured in motor vehicle accidents. Section III then examines the intersection of the ACA and the MNFA and reaches the following conclusions:

¹Note from author: I thank my firm and my family for tolerating the time it took me to write this article. I also greatly thank my father, George T. Sinas, my partner and mentor, Timothy J. Donovan, my brother, Thomas G. Sinas, and my former no-fault law professor and friend, Wayne J. Miller, for their great insight regarding various issues addressed in this article. Moreover, I greatly thank my fellow Wayne State University Law School alumni and State Bar of Michigan Health Care Law Section member, Mercedes Varatesh Dordeski, for serving as the official editor of this article. I also thank juris doctorate candidate, Jonathan Homa, who helped with the research, citations and editing of this article.

² 42 U.S.C. 18001, *et seq.*

³ MCL 500.3101, *et seq.*

- The coverage under the MNFA for the care, recovery and rehabilitation of motor vehicle accident victims is far broader than the coverage available to those victims under the ACA.
- No-fault insurance companies should not be entitled to set off the payment of no-fault benefits by the amounts available under ACA health insurance coverage, pursuant to the MNFA's mandatory governmental benefits set off provision that applies to uncoordinated and coordinated no-fault policies. Rather, no-fault insurance companies should only be able to set off the payment of no-fault benefits by the amounts actually paid under an injured person's ACA coverage when the person is insured under a coordinated no-fault insurance policy.
- The ACA affects the analysis of whether a person should buy uncoordinated or coordinated no-fault coverage. Ultimately, because of the ACA, more people may eventually purchase coordinated no-fault coverage instead of uncoordinated no-fault coverage.
- For various reasons, the ACA may help lessen the financial burdens and costs of the Michigan no-fault system. Therefore, because the cost of no-fault insurance is the major issue underlying the ongoing no-fault reform debate in Michigan, the ways in which the ACA may help lessen the financial burdens and costs of the no-fault system must be factored into that debate.

I. The Basic Principles of the Affordable Care Act

A. The Choice to Obtain Health Insurance Under the ACA or Pay the Applicable Tax Penalty

While it is maligned by some as a massive government entitlement program, the ACA is largely a rejection of the concept of people obtaining health insurance through the government. With that being said, the ACA contains certain significant aspects of government funding of health insurance for some people. The most notable of these aspects is the funding of the expansion of Medicaid to allow those with income up to 133% of the federal poverty level to be eligible for the program. Also, while the ACA does not expand the eligibility requirements of Medicare, it expands some forms of care available under Medicare and decreases the out-of-pocket expenses for some types of medical services. Furthermore, the ACA also provides subsidies to those who purchase ACA policies with income between 133-400% of the federal poverty level. However, beyond those aspects of government funding, the ACA seeks to increase health care coverage in America by having Americans obtain their own health insurance through private health insurance companies.

With regard to the obligation of employers to provide health insurance, the ACA requires employers with 50 or more full-time employees to provide health insurance to

their employees. Employers of less than 50 full-time employees are not obligated to purchase health insurance for their employees. The definition of full-time employee under the ACA means any employee who, with respect to any given month, works more than 30 hours on average per week.⁴ Notably, the issue of whether a person constitutes a full-time employee can be disputed, depending upon the circumstances of the person's work schedule and actual time spent at work.

If a person does not have health insurance through his or her employer, assuming the person does not fall within the categories of exceptions explained further below, he or she will need to decide whether to purchase a qualified ACA "minimum essential" health insurance policy that covers the person and his or her children. If the person fails to purchase ACA health insurance, he or she will be required to pay a penalty tax to the federal government. Notably, the tax penalty is the only consequence the ACA imposes on these people. There is no threat of criminal liability, imprisonment, or denial of any other liberties and freedoms to any person who fails to obtain health insurance.

The tax penalty for not purchasing health insurance is set forth in 26 U.S.C. 5000(A)(b) and specifically states in pertinent part:

"If a taxpayer who is an applicable individual, or an applicable individual or whom the taxpayer is liable under paragraph (3), fails to meet the requirement of subsection (a) for 1 or more months, then, except as provided in subsection (e), there is hereby imposed on the taxpayer a penalty with respect to such failures in the amount determined under subsection(c)"

The tax penalty in 2015 is the higher of the following: 2% of the person's household income, or \$325 per family member for the year (\$162.50 per child under 18). Notably, in 2015, the maximum penalty per family under the per-person method totals \$975. In 2016, the tax penalty totals 2.5% of income or \$695 per person, whichever calculation method is higher.

In *National Federation of Independent Business v Sebelius*, the United States Supreme Court upheld the constitutionality of the ACA's tax penalty levied against those who fail to purchase health insurance under the ACA.⁵ The Court reasoned that the tax penalty imposed under the ACA was within Congress' taxing power under Article 1, Sec. 8 of the United States Constitution. In reaching this holding, the Court made it clear that the tax penalty did not actually require or mandate the American people to purchase insurance. Rather, the tax penalty essentially presents people with this

⁴ 26 U.S.C. 4980H.

⁵ 132 S. Ct. 2566 (2012).

choice: either purchase health insurance or pay the tax penalty. In this regard, the United States Supreme Court specifically stated in pertinent part:

“By contrast, Congress’s authority under the taxing power is limited to requiring an individual to pay money into the Federal Treasury, no more. If a tax is properly paid, the Government has no power to compel or punish individuals subject to it. We do not make light of the severe burden that taxation—especially taxation motivated by a regulatory purpose—can impose. But imposition of a tax nonetheless leaves an individual with a lawful choice to do or not do a certain act, so long as he is willing to pay a tax levied on that choice.”⁶

Therefore, despite the claim that the ACA contains a “government mandate” to purchase health insurance, the United States Supreme Court has specifically recognized that the ACA does not actually require or mandate that the American people purchase health insurance. Rather, the ACA is simply presenting Americans with the choice of either purchasing health insurance or paying the tax penalty for not doing so. This will be an important point to remember for purposes of the discussion in Section III regarding whether ACA coverage is subject set off from the payment of no-fault benefits under the governmental benefit set off provision of the MNFA.

It is also very important to understand that the ACA explicitly exempts various people from having to pay the tax penalty if they do not purchase health insurance. Specifically, these people include the following:

1. Any person insured under an employer plan (including COBRA), with or without "grandfathered" status.⁷
2. People with uninsured periods of less than 3 months.⁸
3. Members of religious groups opposed to having health insurance coverage.⁹
4. Undocumented immigrants.¹⁰
5. Incarcerated persons.¹¹
6. Members of Indian tribes.¹²
7. Members of health care sharing ministries.¹³

⁶ *Id* at 2600.

⁷ 26 U.S.C. 5000A(f)(1)(D).

⁸ 26 U.S.C. 5000A(e)(4)(A).

⁹ 26 U.S.C. 5000A(d)(2).

¹⁰ 26 U.S.C. 5000A(d)(3).

¹¹ 26 U.S.C. 5000A(d)(4).

¹² 26 U.S.C. 5000A(e)(3).

8. People with family incomes below the tax filing threshold (i.e., \$10,150 for an individual; \$20,600 for a family in 2014).¹⁴
9. People without access to affordable insurance (i.e., in 2014, their premiums for available plans cost more than 8% of income, after accounting for employer contributions or premium tax credits.¹⁵ Notably, the income threshold will be adjusted to reflect the rate of premium growth each year going forward).¹⁶
10. Family members of those with affordable employee-only employer-sponsored insurance (i.e., in 2014, their premium costs less than 8% of income) but unaffordable family coverage (premiums cost more than 8% of income).¹⁷
11. People who live in a state that is not expanding Medicaid and are uninsured because of the non-expansion of Medicaid.
12. People whose insurance policy was not renewed (canceled) and their replacement coverage is unaffordable.¹⁸
13. People who experience financial or domestic circumstances that prevent them from obtaining coverage, including, but not limited to, the following circumstances: homelessness; eviction in the last six months or a shutoff notice from a utility company, or bankruptcy filing in the past six months; domestic violence; unexpected increases in essential expenses because of caring for an ill, disabled or aging relative; substantial recent medical debt from expenses in the last 24 months; disasters that substantially damaged personal property; awaiting a marketplace eligibility appeals decision (if appeal is successful), and certain children, ineligible for Medicaid, who receive medical support through a court order.¹⁹

Therefore, there is a wide variety of individuals in America who can fail or refuse to buy health insurance without being required to pay the tax penalty or face any other consequence or punishment.

¹³ 26 U.S.C. 5000A(d)(2)(B).

¹⁴ 26 U.S.C. 5000A(e)(2).

¹⁵ 26 U.S.C. 5000A(e)(1)(A).

¹⁶ 26 U.S.C. 5000A(e)(1)(D).

¹⁷ 26 U.S.C. 5000A(e)(1)(C).

¹⁸ 26 U.S.C. 5000A(e)(1).

¹⁹ 26 U.S.C. 5000A(e)(5).

B. The Scope of Health Insurance Coverage Under the ACA

A qualified ACA “minimum essential” health insurance policy must provide “Essential Health Benefits”²⁰ (“EHBs”). EHBs include the following benefits and services:

1. **Ambulatory patient services**—These services include visits to a doctor’s office, certain home-health care services and hospice care. However, these services are not required to be covered for more than 45 days per year.²¹
2. **Emergency services**—Emergency room visits and related emergency transportation costs are covered as EHBs. Furthermore, health insurers cannot penalize individuals for going out of network or for failing to obtain prior authorization for emergency services.²²
3. **Hospitalization**—Health insurers must pay costs related to inpatient hospitalizations. However, an individual may have to pay 20% or more if he or she has not paid up to the applicable out-of-pocket cost sharing limit under his or her insurance policy. Surgeries, transplants and care in a skilled nursing facility also are included within this benefit category. However, health insurers are not required to pay any more than 45 days at a skilled nursing facility.²³
4. **Maternity and newborn care**—Policies must cover costs for prenatal care, delivery and care for the mother as well as postnatal care.²⁴
5. **Mental health and substance abuse services**—All policies must provide coverage for both inpatient and outpatient services for mental health issues and substance abuse problems. However, these services may be limited to 20 days per year.²⁵
6. **Prescription drugs**—At least one drug in every category and classification of federally approved drugs must be covered by ACA policies. This can be accomplished by the plan providing generic drug coverage.²⁶

²⁰ 42 U.S.C. 18022.

²¹ 42 U.S.C. 18022(b)(1)(A).

²² 42 U.S.C. 18022(b)(1)(B).

²³ 42 U.S.C. 18022(b)(1)(C).

²⁴ 42 U.S.C. 18022(b)(1)(D).

²⁵ 42 U.S.C. 18022(b)(1)(E).

²⁶ 42 U.S.C. 18022(b)(1)(F).

7. **Rehabilitative and habilitative services and devices**—Policies must provide 30 visits per year for either physical therapy, occupational therapy or chiropractor services, 30 visits for speech therapy and 30 visits for cardiac or pulmonary rehab.²⁷
8. **Laboratory/Preventive services**—Certain preventive screening tests, including those for prostate exams and breast cancer screenings, must be provided free with no out-of-pocket cost to the person. A person may have to share the cost of other laboratory or preventive tests, depending on the terms of his or her policy.²⁸
9. **Preventive and wellness services**—Policies must cover dozens of screenings to help prevent chronic disease. Among these services is testing for diabetes, colorectal cancer, high blood pressure, depression and HIV for those at risk. Furthermore, those who are overweight must have access to dietary counseling, and smokers must have access to programs to help them stop smoking.²⁹
10. **Pediatric dental and eye services**—Dental and vision care, previously not covered by many health policies, must be offered to children younger than 19. This benefit allows children to have their teeth cleaned twice a year and undergo X-rays and fillings. Children also must be able to get an eye exam and one pair of glasses or set of contact lenses a year.

EHBs are not further defined in the ACA. Rather, the ACA requires each state to select a “*benchmark plan*” to serve as a reference plan for the definition and scope of coverage for that state’s EHBs. In a letter dated September 28, 2012, Governor Snyder informed the Department of Health and Human Services (“HHS”) that Priority Health’s HMO plan has been selected as Michigan’s benchmark plan for coverage years 2014 and 2015.³⁰ Accordingly, Priority Health’s HMO plan forms Michigan’s benchmark ACA plan for the years 2014 and 2015. The ACA requires Michigan to take its chosen benchmark plan “*as is.*” In other words, the benchmark plan’s covered services, quantitative limitations, and exclusions become the benchmark for all individual and small group health plans offered both inside and outside of the Insurance Marketplace in Michigan. However, it should be noted that the benchmark plan is a “*floor.*” Therefore,

²⁷ 42 U.S.C. 18022(b)(1)(G).

²⁸ 42 U.S.C. 18022(b)(1)(H).

²⁹ 42 U.S.C. 18022(b)(1)(I).

³⁰ Letter from Rick Snyder, Governor of Michigan, to Kathleen Sebelius, Secretary of Health and Human Services (Sept. 28, 2012) (on file with Michigan.gov) (Discussing Michigan’s benchmark essential health benefits plan), available at www.michigan.gov/documents/lara/EHB_Gov_Benchmark_400142_7.pdf.

it is possible for people to purchase more expensive health plans with more coverage and less limitations than those contained within the benchmark plan.

C. The Levels of Coverage Available Under the ACA

There are four different levels of qualified “*minimum essential*” health insurance policies that people can buy under the ACA. These four plan levels consist of the following:

1. **Bronze Level Plans**—These plans must cover 60% of a person’s health care costs.³¹ The remaining 40% of health care costs must be paid by the person, subject to the personal/family cost sharing limit for EHBs explained further below. Bronze plans have the lowest premiums. The bronze plan may be a good choice for a person who does not expect to require a significant amount of health care throughout a given year.
2. **Silver Level Plans**- These plans must cover 70% of a person’s health care costs, subject to the personal/family cost sharing limit for EHBs explained further below.³² Silver plans offer additional help for those under 250% of the federal poverty limit. For these people, the silver plans offer reduced co-pays and other out-of-pocket expenses. The idea here is to help lower-income people pay for the silver level plan as opposed to have these people buy the bronze level plan simply because it is cheaper.
3. **Gold Level Plans**—These plans must cover 80% of a person’s health care costs, subject to the personal/family cost sharing limit for EHBs explained further below.³³
4. **Platinum Level Plans**—These plans must cover 90% of a person’s health care costs, subject to the personal/family cost sharing limit for EHBs explained further below.³⁴ Despite that platinum plans have the highest premiums, these plans may be the wisest choice for a person who expects to receive a significant amount of health care throughout a given year.

It is very important to understand that the ACA provides limitations on the amount of out-of-pocket costs a person or family must pay in a given year for EHBs. This is known as the “cost sharing limit.” In 2015, the current cost sharing limits are \$6,600 per person and \$13,200 per family. The cost sharing limit is adjusted each year by the “Premium Adjustment Percentage,” which is a standard amount determined and published each year.³⁵ Once a person/family has reached their yearly cost sharing limit

³¹ 42 U.S.C. 18022(d)(1)(A).

³² 42 U.S.C. 18022(d)(1)(B).

³³ 42 U.S.C. 18022(d)(1)(C).

³⁴ 42 U.S.C. 18022(d)(1)(D).

³⁵ 42 U.S.C. 18022(c)(1); 45 C.F.R. 156.130.

for EHBs, their health insurance company must pick up 100% of covered benefits for the remaining portion of that given year. For example, if a family is insured under a bronze level plan, the family will need to pay 40% of their medical charges. However, once the family pays up to the cost sharing limit for a given year for EHBs, their health insurance company will become responsible to pay 100% of the family medical expenses for EHBs for the rest of that year.

Notably, money spent on health insurance premiums does not count toward the cost sharing limit.³⁶ Moreover, for those insured under an HMO, the services a person receives outside of his or her geographic area/network may cost more. In these situations, a person's cost-sharing for out-of-network services is not subject to the out-of-pocket maximum amount.³⁷ Additionally, some policies may have out-of-pocket limits that are lower than the maximum amount prescribed under the ACA. Therefore, when buying insurance, it is important for people to look at all associated costs, i.e., premiums, co-pays, deductibles and coinsurance, etc.

It should be further noted that the ACA allows people under the age of 30, as well as some people who face certain hardship exemptions, to purchase a special health insurance policy called "a catastrophic plan."³⁸ Catastrophic plans generally have lower premiums and higher deductibles. Marketplace catastrophic plans cover the full cost of three annual primary care visits and preventive services. However, these plans do not cover all EHBs available under a typical qualified "minimum essential" health insurance policy under the ACA. Additionally, people with catastrophic plans are not eligible for federal tax credits to lower their monthly premiums, regardless of their income level.³⁹ Catastrophic plans are offered based on the concept that people under the age of 30 are generally healthier and require less health care than people over the age of 30. Notably, people under 30 avoid the tax penalty for not having insurance if they buy a catastrophic plan.

D. Consumer Rights Under the ACA

Prior to the ACA, there was no body of federal law governing private health insurance in America. The ACA now provides Americans with certain important rights that they have never had under federal law with respect to health insurance. These rights include, but are not limited to, the following:

- 1. Ends discrimination for pre-existing conditions**—For all health insurance provided after January 1, 2014, the ACA prohibits health insurers from

³⁶ 42 U.S.C. 18022(c)(3)(B).

³⁷ 45 C.F.R. 147.138(b)(3).

³⁸ 42 U.S.C. 18022(e).

³⁹ 26 U.S.C. 36B.

denying insurance coverage based on a pre-existing condition. Moreover, the ACA also prohibits charging a person a higher premium because of a preexisting condition. This is true even if the person has been turned down or refused coverage due to a pre-existing condition in the past. A person receiving care for a pre-existing condition will still need to pay any deductibles, copayments, and coinsurance his or her insurance plan requires.⁴⁰

- 2. Health insurance premiums can only be based on age and whether a person smokes tobacco**—Prior to the ACA, health insurance premiums could be based on a wide-variety of factors that varied in different states. However, under the ACA, premiums can only be based on the person's age and whether the person smokes tobacco.⁴¹
- 3. Removes annual and lifetime limits on Essential Health Benefits (EHBs)**—Insurance companies cannot impose annual or lifetime spending on EHBs. However, insurance companies can still enforce these limits on spending for health care services that are not considered to constitute EHBs.⁴²
- 4. Insurance plans must allow children to stay insured under their parents' policy until the age of 26**—Under the ACA, if a health insurance plan covers children of the insured persons, the plan must allow the children to be covered under the plan until they turn 26 years old. A person can join, remain, or return to a parent's plan even if the person is married, not living with his or her parents, attending school, financially independent, or, in most cases, eligible to enroll in an employer's plan.⁴³
- 5. Plain language benefits information**—Health insurance companies and group health plans are required to provide an easy-to-understand summary about a health plan's benefits and coverage.⁴⁴ This regulation is designed to help people better understand and evaluate their health insurance choices. The new forms include a short, plain language Summary of Benefits and Coverage, or SBC, and a uniform glossary of terms commonly used in health insurance coverage. All insurance companies and group health plans must use the same standard SBC form to help compare health plans.⁴⁵ The SBC form also includes details, called "coverage examples," which are comparison tools that allow people to see what the plan would generally cover in two

⁴⁰ 42 U.S.C. 300gg-3(a).

⁴¹ 42 U.S.C. 300gg.

⁴² 42 U.S.C. 300gg-11(a)(1)(A) and 42 U.S.C. 300gg-11(b).

⁴³ 42 U.S.C. 300gg-14(a).

⁴⁴ 42 U.S.C. 300gg-15(a).

⁴⁵ 42 U.S.C. 300gg15(b).

common medical situations. A person also has the right to receive the SBC when shopping for or enrolling in coverage.⁴⁶

- 6. Providing better health insurance value for premium dollars through the 80/20 Rule**—The ACA requires health insurance companies to spend at least 80 cents of every premium dollar on expenses related to providing health care or improvements to health care. The other 20% of every premium dollar is supposed to cover a health insurance company's operating costs, overhead, claims handling expenses, etc. If a health insurance company fails to satisfy the 80/20 rule, it can be required to issue its members a refund up to the amounts it failed to allocate to providing or improving health care under the rule.⁴⁷
- 7. Increased scrutiny of unreasonable premium increases**—The ACA prohibits health insurers from unreasonably increasing the cost of premiums.⁴⁸ A premium rate hike is unreasonable if, for example, it is based on faulty assumptions or unsubstantiated trends.⁴⁹ A rate hike can also be deemed unreasonable if it charges different prices to people who pose similar risks to the insurer.⁵⁰ The designated state regulator can approve or reject an unreasonable or excessive rate increase, if state laws give the regulator this authority.⁵¹ The ACA provides grant money to each state to operate a rate review program. The operator of the rate review program in Michigan is the Insurance Commissioner and the Department of Financial and Insurance Services ("DIFS").
- 8. Prohibits arbitrary withdrawals of insurance coverage**—The ACA prohibits health insurance companies from rescinding coverage simply because a member made an honest mistake or left out information on the health insurance application.⁵² However, a health insurance company can cancel a person's coverage if the person knowingly made a false statement or intentionally provided incomplete information on his or her insurance application.⁵³ A health insurance company can also cancel a person's coverage if the person fails to issue timely payment of insurance premiums.⁵⁴

⁴⁶ 42 U.S.C. 300gg15(b).

⁴⁷ 45 C.F.R. 158.251(a)(1).

⁴⁸ 42 U.S.C. 300gg-94.

⁴⁹ 45 C.F.R. 154.205.

⁵⁰ 45 C.F.R. 154.205.

⁵¹ 45 C.F.R. 154.210.

⁵² 42 U.S.C. 300gg-42(a).

⁵³ 42 U.S.C. 300gg-42(b).

⁵⁴ 42 U.S.C. 300gg-42(b).

A health insurance company must give a notice of termination of coverage that includes the termination effective date and reason for termination.⁵⁵

- 9. No prior authorization required for emergency services in or out of network**—In cases of medical emergencies, an ACA plan must cover emergency medical care without regard to whether the provider is within a person's network. Moreover, the insurer generally cannot impose any co-payment or coinsurance greater than what the person would have to pay if the person treated within network.⁵⁶ However, a health insurer under the ACA must cover out-of-network emergency care only at the same level it would if the person were in-network. If the out-of-network provider charges more, the patient may have to pick up the balance.
- 10. No co-pay or deductibles for certain preventative services**—As a way of encouraging people to receive preventative services, the ACA requires health insurance companies to pay the full costs of these services, which includes preventative services and tests such as: blood pressure tests, cholesterol tests, mammograms, colonoscopies, etc.
- 11. Right to appeal decisions made by ACA health insurer**—The right to bring a private cause of action against the health insurer is not well established under the ACA. The ACA allows states to implement procedures by which people can appeal the decisions made by health insurers. In Michigan, people must appeal decisions made by health insurers through the appeal procedures set forth in the health insurance policy and/or through the external review procedures established under the Michigan Patient's Right to Independent Review Act ("PRIRA").⁵⁷ Therefore, people are typically limited in their ability to have their health insurance grievances decided through the ordinary judicial process, i.e., discovery, trial by jury, etc.

Ultimately, the ACA empowers Americans with rights regarding health insurance that they have never had before under federal law. These substantive rights increase the scope of health insurance coverage available to Americans and will presumably improve the quality of that coverage. It may be the case that these rights will result in more people having a better overall consumer experience with health insurance. This would be a welcomed change, especially for those who have had miserable experiences dealing with health insurance.

⁵⁵ 45 C.F.R. 156.270.

⁵⁶ 42 U.S.C. 300gg-19a.

⁵⁷ MCL 550.1901, *et seq.*

II. The Basic Principles of the Michigan No-Fault Automobile Insurance Act

A. The Goals and Objectives of the MNFA

In Michigan, before the MNFA was enacted over 41 years ago, the damages caused by motor vehicle accidents were all subject to traditional tort law principles. Under these principles, people injured in motor vehicle accidents had to sue the at-fault driver in order to recover payment of their damages, including their medical expenses. If there was a dispute about fault, the injured person's medical bills would not be paid until the litigation was over. If the injured person was ultimately found to be at-fault, the person would not be entitled to recover medical expenses from his or her own automobile insurance, and there would often not be another source of insurance from which the injured person could recover adequate payment for his or her accident related medical expenses. This system was fraught with delays and led to many unfair and inadequate results, especially for those most catastrophically injured in motor vehicle accidents. The MNFA was enacted to provide a better way for Michigan to deal with the high costs and damages caused by motor vehicle accidents.

The MNFA compels owners or registrants of a motor vehicle intended to be operated on Michigan roads for more than 30 day to buy what is known as no-fault personal injury protection ("PIP") coverage (hereinafter "no-fault coverage").⁵⁸ In fact, the MNFA imposes criminal liability in the form of a misdemeanor punishable up to a year in jail against a vehicle owner or registrant who fails or refuses to insure his or her vehicle with no-fault coverage.⁵⁹ As explained further herein, no-fault coverage provides payment for reasonably necessary medical and rehabilitation expenses incurred to treat motor vehicle accident victims, as well as payment of certain other economic losses sustained by those victims.

No-fault benefits are payable regardless of fault and are payable for "accidental bodily injury arising out of the ownership, operation, maintenance or use of a motor vehicle as a motor vehicle."⁶⁰ A person injured in a motor vehicle accident in Michigan can be denied no-fault coverage only in these six limited situations: (1) the person intentionally suffered his or her own injury⁶¹; (2) the person was injured in a motor vehicle accident involving an uninsured motor vehicle with respect to which the person was an owner or registrant⁶²; (3) the person was injured while using a motor vehicle he or she knew or should have known was unlawfully taken⁶³; (4) the person was not a

⁵⁸ MCL 500.3102(1).

⁵⁹ MCL 500.3102(2).

⁶⁰ MCL 500.3105(1).

⁶¹ MCL 500.3105(4).

⁶² MCL 500.3113(b).

⁶³ MCL 500.3113(a).

resident of Michigan and did not have automobile insurance through an insurance company authorized to sell insurance in Michigan⁶⁴; (5) the person was operating a motor vehicle that was insured under an insurance policy under which he or she was listed as an excluded driver⁶⁵; (6) the injured person committed or was complicit in committing an act of fraud or misrepresentation in the procurement of the auto no-fault policy covering the person at the time of the accident. As long as those six limited situations do not apply, a victim of a motor vehicle accident occurring in Michigan will be entitled to recover payment of his or her medical expenses arising out of the ownership, operation, maintenance or use of a motor vehicle as a motor vehicle.

It should be further noted that motorcyclists are entitled to no-fault coverage only when injured in an accident that also involves a “motor vehicle” (e.g., a car hitting a motorcyclist). Under the MNFA, a motorcycle is not a motor vehicle. Rather, a motor vehicle is any vehicle “operated or designed for operation upon a public highway by power other than muscular power which has more than 2 wheels.” ⁶⁶ If there is no involvement with a motor vehicle (e.g., a motorcyclist runs off the road because of his or her own doing), the motorcyclist will not be entitled to no-fault coverage.

Ultimately, Michigan’s auto no-fault insurance system is based on the concept that driving a motor vehicle is inherently dangerous, and that just like how people buy their own health insurance to insure themselves against the risks of becoming sick or ill, people who operate motor vehicles should insure themselves against the risks of being injured while doing so. Furthermore, as explained by the Michigan Supreme Court in the landmark no-fault decision of *Shavers v Kelley*, in replacing traditional tort law as the legal regime applicable to auto accidents in Michigan, “the goal of the no-fault insurance system was to provide victims of motor vehicle accidents assured, adequate, and prompt reparation for certain economic losses.”⁶⁷

B. Understanding No-Fault PIP Coverage and the Related Limitations on Recovering Damages from the At-Fault Driver

The MNFA provides broad and comprehensive coverage for the care, recovery and rehabilitation of all motor vehicle accident victims, regardless of whether those victims were at-fault for the accident. Specifically, under MCL 500.3107(1)(a), motor vehicle accident victims are entitled to pursue no-fault benefits called “allowable expense benefits,” which are defined as “all reasonable charges incurred for reasonably necessary products, services or accommodations for the injured person’s care, recovery, or rehabilitation.” ⁶⁸ Michigan courts have interpreted this language to provide

⁶⁴ MCL 500.3113(c).

⁶⁵ MCL 500.3113(d).

⁶⁶ MCL 500.3101(2)(h).

⁶⁷ 402 Mich 554, 578-579 (1978).

⁶⁸ MCL 500.3107(1)(a).

coverage for much more than the victim's expenses for medical and rehabilitation services arising from his or her injuries. Rather, Michigan courts have made it clear that allowable expense benefits can include, but are not limited to, payment for the following: in-home patient care service rendered either by family members or by commercial nursing companies⁶⁹; handicap-accessible home accommodations⁷⁰; handicap-accessible transportation accommodations⁷¹; medical mileage⁷²; vocational rehabilitation services⁷³; guardian/conservatorship services⁷⁴.

Under MCL 500.3107(1)(a), a no-fault insurer is obligated to pay a "reasonable charge" for an allowable expense benefit. Moreover, under MCL 500.3157, a medical provider's charge must not exceed the amount the provider customarily charges in cases not involving any form of insurance. Importantly, the MNFA does not contain any further definitions of a reasonable charge and does not contain any other limitations such as fee schedules, benefit formulas, etc. As a general proposition, the determination of whether a charge is "reasonable" is a question of fact to be decided through a trial.⁷⁵ Furthermore, Michigan courts have made it clear that the amounts customarily paid to hospitals by third-party payers, such as Workers Compensation, Medicare, Medicaid, Blue Cross Blue Shield, HMO's and PPO's, etc., are irrelevant to determining whether a medical providers charge is "reasonable" under the MNFA.⁷⁶ There is often not a perfectly clear answer as to whether a provider's charge satisfies the reasonable charge standard. Accordingly, this issue is frequently disputed between providers and no-fault insurance companies. It is true that the reasonable charge standard allows providers to seek payment for their auto-related medical services at a rate that is typically higher than the rates paid by many other forms of insurance. However, as will be explained further below in Section II. D, there are several ways in which providers receive payment for auto accident-related medical expenses in an amount that is less than the amount that would normally constitute a "reasonable charge" under the MNFA.

⁶⁹ *Douglas v Allstate*, 492 Mich 241 (2012).

⁷⁰ *Sharp v Preferred Risk Mutual Ins. Co.*, 142 Mich App 499 (1985).

⁷¹ *Admire v Auto-Owners*, 494 Mich 10 (2013).

⁷² *Id.*

⁷³ *Kondratek v Auto Club Ins. Ass'n*, 163 Mich App 634 (1987); *Tennant v State Farm*, 143 Mich App 419 (1985).

⁷⁴ *In Re Estate of Carroll*, 300 Mich App 152 (2013).

⁷⁵ *Nasser v ACIA*, 435 Mich 33 (1990) .

⁷⁶ *Johnson v Michigan Mutual Ins. Co.*, 180 Mich App 314 (1989) (amounts paid by Medicaid irrelevant); *Hofmann v Auto Club Ins. Ass'n*, 211 Mich App 55 (1995) (amounts charged by private health insurance irrelevant); *Munson Medical Center v Auto Club Ins. Ass'n*, 218 Mich App 375 (1996) (workers compensation fee schedules irrelevant); *Mercy Mt Clemens Corp v Auto Club Ins. Ass'n*, 219 Mich App 46 (1996) (reimbursement rates from other forms of insurance irrelevant and inadmissible).

Importantly, there are no annual or lifetime monetary caps on the amount an injured person can recover for allowable expense benefits. As long as the injured person can demonstrate the ongoing need for the benefits, the person can claim allowable expense benefits for life. In this regard, the comprehensive medical coverage available under the MNFA is especially beneficial for the most catastrophically injured auto accident victims who require lifelong medical and rehabilitative services, such as those suffering severe brain injury or spinal cord injury.

Notably, other states that have auto no-fault insurance systems have low monetary caps for accident-related medical expenses which are easily exceeded in accidents resulting in serious injuries. When these caps are exceeded, accident victims become dependent upon Medicaid, Medicare or other tax-payer funded government insurance systems. Michigan's auto no-fault insurance system protects Medicaid and other tax-payer funded government insurance programs from being responsible for the enormous costs of treating and caring for those injured in motor vehicle accidents. Therefore, while auto insurance rates in Michigan are comparably higher than other states, it is a fact that Michigan's no-fault insurance systems provides the country's most complete coverage for the care, recovery and rehabilitation of those seriously injured motor vehicle accidents.

In addition to allowable expenses benefits, no-fault coverage also includes three other benefits: (1) work loss benefits; (2) replacement service benefits; and (3) survivor's loss benefits. Work loss benefits are available for up to three years after the accident and are payable for "loss of income from work an injured person would have performed . . . if he or she had not been injured."⁷⁷ Work loss benefits are payable at the rate of 85% of gross pay, including overtime. However, the work loss benefit cannot exceed the legal monthly maximum, which is currently \$5,392 per month.⁷⁸

Replacement service benefits consist of reimbursement to the injured person for expenses incurred to obtain "ordinary and necessary" services that the injured person would have performed had the injury not occurred. This benefit is limited to \$20 per day and is available for up to three years after the date of the accident. Replacement services are primarily meant to cover household services, such as typical housekeeping chores, yard work, snow removal, etc.⁷⁹

Survivor's loss benefits are payable to the dependents of a person who dies in a motor vehicle accident. These benefits cover the decedent's "contributions of tangible things of economic value, not including services, that the dependents would have received" if the decedent had not died in the subject motor vehicle accident.⁸⁰ Survivor's loss benefits also include payment of replacement service benefits discussed above.

⁷⁷ MCL 500.3107(1)(b).

⁷⁸ *Id.*; Mich Admin Code R 500.811.

⁷⁹ MCL 500.3107(1)(c).

⁸⁰ MCL 500.3108.

Survivor's loss benefits are subject to the same monthly maximum that applies to work loss benefits.⁸¹ These benefits primarily consist of the after-tax income of the person who died, the value of any fringe benefits lost as a result of the person's death, and the value of the household chores and services the decedent provided to the family.⁸² Additionally, insurance companies are also required to pay, at minimum, \$1,750 for funeral and burial expenses.⁸³

In exchange for the right to recover no-fault benefits regardless of fault, the MNFA imposes significant limitation on a motor vehicle victim's right to recover damages from an at-fault driver, as long as the at-fault driver is either insured under a Michigan no-fault policy or is an out-of-state resident who is involved in an accident occurring in Michigan and insured by an insurance company certified to sell automobile insurance in Michigan.⁸⁴ Most significantly, the MNFA grants the at-fault driver immunity from liability for any medical expenses the injured person recovers through his or her no-fault coverage.⁸⁵ In this regard, the MNFA essentially abolishes the rights of the injured person to recover his or her medical expenses from the at-fault driver. However, the at-fault driver does not have immunity for medical expense liability if the at-fault driver was uninsured or intentionally inflicted the injury.⁸⁶ Ultimately, the tort immunity for medical expenses is an essential feature of the MNFA that eliminates the threat of a properly insured Michigan motorist becoming financially liable for the medical expenses of people he or she may mistakenly injure while operating a motor vehicle.

Furthermore, under the MNFA, an at-fault driver can only be sued for economic damages that are commonly referred to as "excess economic loss damages." These damages most frequently consist of the injured person's income loss that is not otherwise covered by no-fault work loss benefits. In this regard, if a motor vehicle accident victim loses income in excess of the applicable monthly maximum amount, or loses income beyond the three year work loss benefits that are payable under the MNFA, the victim can pursue that excess income loss from the at-fault driver.⁸⁷ Additionally, if an accident victim dies, the at-fault driver can be held liable for the loss of the household services the victim provided to his or her dependents in excess of those services that are covered as survivor's loss benefits.⁸⁸ However, under current case law, if the accident victim does not die, the at-fault driver cannot be held liable for the loss of the household services the victim provided to his or her dependents in excess of

⁸¹ *Id.*

⁸² *Id.*

⁸³ MCL 500.3107(1)(a)(ii).

⁸⁴ MCL 500.3135(3).

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ *Id.*

those services covered as replacement service benefits.⁸⁹ Ultimately, beyond these damages, an at-fault driver faces virtually no other financial liability for the injured person's economic damages sustained as a result of the accident.

The MNFA also expressly limits an injured person's right to recover noneconomic damages from the at-fault driver. Noneconomic damages cover losses that affect a person's quality of life, such as pain and suffering, disability, incapacity, mental anguish, shock, humiliation, embarrassment, loss of society and social pleasures, etc. Under the MNFA, an injured person can only recover noneconomic loss damages from the at-fault driver if that person sustains an injury that constitutes one or more of the following: (1) serious impairment of body function; (2) permanent serious disfigurement; or (3) death.⁹⁰ Essentially, by imposing these limits, the MNFA prevents the at-fault driver from being sued for noneconomic loss damages in situations involving relatively minor injuries. Under traditional tort law principles, even if a person sustained minor injuries in a motor vehicle accident, the person would have a right to sue the at-fault driver for noneconomic damages. In this regard, the threshold injury requirement under the MNFA ultimately eliminates the ability to sue the at-fault driver for noneconomic loss damages in cases involving minor injuries.

The MNFA further limits the liability of the at-fault driver for noneconomic damages by prohibiting the injured person from suing the at-fault driver for noneconomic damages, if the injured person's comparative fault is greater than 50%.⁹¹ In other words, this rule prohibits an injured person from suing another driver when the injured person is determined to be more at-fault for the accident than the other driver.

These significant limitations on an injured person's rights to recover damages from the at-fault driver are a fundamental part of the MNFA. In this regard, these limitations form the basis of the "quid pro quo" that is necessary to balance the costs of providing comprehensive medical and rehabilitation coverage for motor vehicle accident victims regardless of fault.

C. Uncoordinated vs. Coordinated No-Fault PIP Coverage

Under the MNFA, a person can buy either uncoordinated no-fault coverage or coordinated no-fault coverage. There are significant substantive and practical differences between these two coverages. If a person purchases uncoordinated no-fault coverage, the person's no-fault insurance company is obligated to pay no-fault benefits even though similar benefits may be payable to the person under another health insurance policy. On the other hand, if a person purchases coordinated coverage, the person's no-fault insurer is only obligated to pay those expenses and benefits that are not paid by other applicable health or accident insurance coverage. In other words, a

⁸⁹ See *Johnson v Recca*, 492 Mich 169 (2012).

⁹⁰ MCL 500.3135(1).

⁹¹ MCL 500.3135(2)(b).

coordinated no-fault PIP policy is secondary to other sources of private health insurance plans. In light of the fact that the premium charged for a coordinated benefits policy is less than the premium for an uncoordinated policy, the majority of Michigan motorists have purchased (either knowingly or unknowingly) coordinated no-fault coverage.

The statute permitting coordinated no-fault policies is MCL 500.3109a, which specifically states:

“An insurer providing personal protection insurance benefits under this chapter may offer, at appropriately reduced premium rates, deductibles and exclusions reasonably related to other health and accident coverage on the insured. Any deductibles and exclusions offered under this section are subject to prior approval by the Commissioner and shall apply only to benefits payable to the person named in the policy, the spouse of the insured, and any relative of either domiciled in the same household.”

Notably, pursuant to the language of MCL 500.3109a, no-fault benefits payable to an injured person under a coordinated policy are coordinated with other health coverages only when the injured person is the person named in the policy, the spouse of the insured or any relative of either domiciled in the same household.

It should be further noted that the current language of MCL 500.3109a was the result of a recent amendment to the MNFA passed by the Michigan Legislature in December 2012. The original version of MCL 500.3109a provided that insurance companies “shall offer at appropriately reduced premium rates, deductibles and exclusions reasonably related to other health and accident coverage.” In other words, under the original version of MCL 500.3109a, insurance companies were required to offer coordinated no-fault policies. However, under the amended version, insurance companies are no longer technically required to offer coordinated no-fault policies. It should be noted that, at the time of this article, there is no indication that any major no-fault insurance company has stopped offering coordinated no-fault coverage. In fact, because it is cheaper than uncoordinated coverage, most Michigan motorists who have health insurance continue to buy coordinated coverage.

People who are insured under a coordinated no-fault policy and who are also members of HMOs are confronted with special rules if they seek treatment outside of the HMO network. In *Tousignant v Allstate Ins. Co.*, the Michigan Supreme Court held that if the service or treatment is available within the HMO and the patient seeks the service or treatment outside of the HMO without following proper procedures to obtain HMO approval, the no-fault insurer is not obligated to pay for any of the cost of the service or treatment obtained outside of the HMO.⁹² Notably, this rule only applies

⁹² 444 Mich 301 (1993).

where the specific medical service is available within the HMO policy. If the service is not available under the HMO policy, the no-fault insurer is not released from its obligation to pay for treatment, so long as the treatment is otherwise payable as an allowable expense benefit. In this regard, following the *Tousignant* decision, in *Sprague v Framers Ins. Exchange*, the Michigan Court of Appeals held that the patient's no-fault insurance company was obligated to pay the full cost of chiropractic treatment that was deemed "reasonably necessary" under MCL 500.3107(1)(a) and was not otherwise available through the patient's HMO.⁹³

No-fault insurers have attempted to extend the concepts established in *Tousignant* and *Sprague* to patients who have health insurance coverage with preferred provider plans ("PPOs"). In other words, if a patient has health insurance that will pay the full cost of a particular service if rendered by a participating provider, a coordinated no-fault insurer may attempt to deny payment of all or some of the medical expenses that the patient incurs by treating with a non-participating provider. As of the present date, there is no specific appellate court that has specifically approved of this approach. Nevertheless, one should assume that the same reasoning that applies to HMOs under *Tousignant* and *Sprague* may also apply to PPOs.

D. The Ways in Which Medical Providers are Paid Discounted Reimbursement Rates for Auto Accident-Related Medical Treatment

As explained above, the MNFA requires no-fault insurers to pay a "reasonable charge" for allowable expense benefits. The reasonable charge standard under the MNFA allows providers to seek payment for their auto-related medical services at a rate that is typically higher than the rates paid by many other forms of insurance. However, the reality is that there are many situations in which medical providers are paid discounted rates of reimbursement payment for auto accident-related treatment.

In particular, a medical provider who has agreed to accept discounted reimbursement rates under a participating provider contract with a particular health insurance company is typically limited to recovering those discounted rates for auto-accident related medical treatment the provider renders to people insured with the health insurance company. One example of this occurring is in situations involving coordinated no-fault coverage. Under the Court of Appeals' decision in *Dean v Auto Club Ins. Ass'n*, a medical provider who provides treatment to a person insured under coordinated no-fault policy will be paid based on the discounted reimbursement rates established in the injured person's health insurance plan, and the provider is typically prohibited from balance billing the no-fault insurer for the additional amount that would be payable based on the reasonable charge standard under the MNFA.⁹⁴ Therefore, considering that most people in Michigan have coordinated no-fault coverage, the *Dean* doctrine leads to a significant number of instances when providers receive payment for

⁹³ 251 Mich App 260 (2002).

⁹⁴ 139 Mich App 266 (1984).

accident-related medical treatment in an amount that is less than would be payable as a “reasonable charge” under the MNFA.

Another example of medical providers being paid for auto accident-related medical treatment based on discounted participating provider health insurance reimbursement rates arises when the injured person is insured under an uncoordinated no-fault policy but is also insured with a health insurance company through which the person’s medical provider has contracted to accept discounted reimbursement rates. The Michigan Court of Appeals decision in *Bombalski v Auto Club Ins. Ass’n* stands for the proposition that in these situations, the person’s no-fault insurer only has to pay for the medical provider’s services based on the discounted reimbursement rates applicable under the injured person’s health insurance coverage, even though the person is covered under an uncoordinated no-fault policy.⁹⁵ As of the date of this article, *Bombalski* has not been overturned or distinguished by any subsequent published case. Ultimately, the *Bombalski* doctrine is another significant example of how medical providers often receive payment for accident-related medical treatment in an amount that is less than would be payable as a “reasonable charge” under the MNFA.

It should also be noted that no-fault insurance companies frequently utilize medical bill auditing to limit the payments of auto accident-related medical treatment. The no-fault insurers defend this practice as a way of gathering medical billing data to help determine the reasonable charge for a particular service in a given geographic location. Furthermore, in *AOPP v ACIA*, the Michigan Court of Appeals held that it is not necessarily illegal under the MNFA for a no-fault insurer to utilize a medical bill auditing methodology that limits the payment of medical expenses to the amount paid to 80% of the other medical providers in a given area.⁹⁶ Moreover, the holding in *AOPP* was not overturned by a majority vote when it was appealed to the Michigan Supreme Court.⁹⁷ Therefore, no-fault insurers continue to frequently use medical bill auditing to limit the rates of payment to medical providers. Medical bill auditing is often criticized because the audit companies do not provide a clear explanation about how their audits are calculated or clearly define the sets of data upon which their audits are based. Many providers believe that audits cause them to receive significantly discounted rates of reimbursement from no-fault insurers.

Another example of providers receiving payment for accident-related medical treatment based on discounted reimbursement rates arises in situations commonly known as “Silent PPOs.” In these situations, a medical provider signs a contract with a health insurance PPO under which the provider agrees to accept discounted rates of reimbursements in exchange for provider to be included as a preferred provider within the PPO. However, the contract goes further to state that the medical provider will also

⁹⁵ 247 Mich App 536 (2001).

⁹⁶ 257 Mich App 365 (2003).

⁹⁷ 472 Mich 91 (2005).

accept discounted rates of reimbursements from any other payor that contracts with the PPO. Without the knowledge of the medical provider, the PPO then contracts with a no-fault insurance company to be included as a payor under the PPO network. The no-fault insurance company then argues that with respect to accident-related medical treatment the provider renders to people insured through the no-fault insurance company, the no-fault insurer only has to pay the discounted rates of reimbursement established under the PPO. At this time, there is no appellate case law addressing the legal propriety of a no-fault insurance company using a Silent PPO arrangement to discount the payment of accident-related medical treatment. Therefore, there is currently significant controversy and legal uncertainty about this issue.

In sum, the “reasonable charge” standard does not guarantee that medical providers will be paid for accident-related medical treatment at a higher rate of reimbursement compared to other forms of private health insurance coverage. Rather, there are several ways in which providers rendering auto accident-related medical treatment end up being paid much less than the amount that would constitute a “reasonable charge” amount under the MNFA.

E. Governmental Benefit Set offs Under MCL 500.3109(1)

Under MCL 500.3109(1), a no-fault insurer is entitled to set off its payment of no-fault benefits by the amounts the injured person receives for governmental “benefits provided or required to be provided” under federal and state laws in relation to his or her injuries. Specifically, MCL 500.3109(1) states:

“Benefits provided or required to be provided under the laws of any state or the federal government shall be subtracted from the personal protection insurance benefits otherwise payable for the injury.”⁹⁸

The objective of the governmental benefit set off is to eliminate duplicative recovery of benefits provide by state or federal governments to help keep down the cost of no-fault insurance. It should be further noted that if a benefit is deemed to be subject to set off under MCL 500.3109(1), the set off applies to both coordinated and uncoordinated policies. Therefore, no-fault insurers have a strong incentive to argue that any particular benefit provided by or under the laws of a state or the federal government is subject to set off under MCL 500.3109(1). In this regard, the issue of whether ACA coverage is subject to mandatory set off treatment under MCL 500.3109(1) is a very significant issue that cannot be properly analyzed without a proper understanding of the case law related to this relatively complicated issue.

Within the first decade of the MNFA, the Michigan Supreme Court decided a number of relatively straightforward cases regarding whether certain government

⁹⁸ MCL 500.3109(1).

provided or mandated benefits were subject to set off under MCL 500.3109(1). In *Workman v DAIE*, the Michigan Supreme Court held that Medicaid benefits could not properly be considered a governmental benefit for purposes of MCL 500.3109(1).⁹⁹ The Court held that under the Medicaid statute, Medicaid benefits are only payable to individuals who are “medically indigent.” The Court reasoned that an auto accident victim who is entitled to no-fault PIP benefits is not “medically indigent” and, therefore, has no legal right to receive Medicaid benefits. Therefore, the Court held that the no-fault insurer could not claim a set off for the Medicaid benefits that would have been payable to the injured person if he did not have no-fault coverage.

In *O'Donnell v State Farm Ins. Co.*, the Michigan Supreme Court held that Social Security survivors loss benefits payable under §202 of the Federal Social Security Act were proper governmental benefit set-offs against no-fault survivor's loss benefits payable under MCL 500.3108 of the MNFA.¹⁰⁰ In reaching its holding, the Court reasoned that Social Security survivor's loss benefits and Michigan no-fault survivor's loss benefits were both payable as a result of the decedent's fatal car accident and both benefits served the same purpose. Therefore, the Court held that Social Security survivor's loss benefits were properly deductible under MCL 500.3109(1).

In *Mathis v Interstate*, the Michigan Supreme Court, relying heavily upon its reasoning in *O'Donnell*, held that workers' compensation benefits payable as a result of the same accident were duplicative of certain no-fault benefits, and, therefore, were properly deductible against no-fault work loss benefits under MCL 500.3109(1).¹⁰¹ Notably, there is not any in-depth discussion in *Mathis* as to whether workers' compensation should be considered a government benefit. It appears that the Court assumed that workers' compensation benefits were subject to MCL 500.3109(1) simply because they are mandated to be provided under State law.

In *Thompson v DAIE*, the Michigan Supreme Court also relied upon *O'Donnell* and held that Social Security disability benefits payable to the dependents of the injured person were properly deductible from the injured person's no-fault work loss benefits.¹⁰² In reaching this holding, the Court characterized the Social Security disability benefits received by the injured person's wife and minor children as a substitute or replacement for the injured father's income which would have inured to their specific benefit if the father was not injured. Therefore, the Court held that under MCL 500.3109(1), the social security disability benefits received by the family members were properly subject to set off from the payment of injured father's no-fault work loss benefits.

Despite the relatively straightforward holdings of the foregoing cases regarding governmental benefits, it soon became evident that it is not always clear whether a

⁹⁹ 404 Mich 477 (1979)

¹⁰⁰ 404 Mich 524 (1979)

¹⁰¹ 408 Mich 164 (1980)

¹⁰² 418 Mich 610 (1984)

particular benefit is a governmental benefit and ultimately subject to mandatory set off treatment under MCL 500.3109(1). Simply because something is paid by a governmental source or paid under the powers of a state or the federal government does not necessarily mean it is subject to set off under MCL 500.3109(1). Therefore, the Michigan Supreme Court ultimately established a specific test to determine whether a particular benefit should be subject to set off under MCL 500.3109(1).

1. Government Benefit Set offs Under the Two-Part Test Established in *Jarosz v DAIE*

In *Jarosz v DAIE*,¹⁰³ the Michigan Supreme Court made it clear that a no-fault insurer cannot set off the payment of no-fault benefits under MCL 500.3109(1) simply because the subject government benefit is deemed to be “provided or required to be provided under the law of any or the federal government.” Rather, the Court recognized that if an injured person is receiving government benefits that bear no relationship to the injured person’s no-fault benefits, the government benefits would not be subject to set off under MCL 500.3109(1). Specifically, the Court stated in pertinent part:

“Certainly not all ‘[benefits] provided or required to be provided under the laws of any state or the federal government’ must be subtracted from no-fault personal protection insurance benefits otherwise due. Some governmental benefits bear no relationship whatever to no-fault benefits or to the reason no-fault benefits are paid. Benefits bearing no such relationship are not subject to set off. Our task is to find a formula by which governmental benefits which are required to be set off under § 3109(1) can be distinguished from those which are not.”¹⁰⁴

Accordingly, the Court established a two-part test to determine whether a particular government benefit is subject to set off from the payment of no-fault benefits under MCL 500.3109(1). Specifically, the Court held that in order for government benefits to be subject to set off under MCL 500.3109(1), the benefits must be: “1) benefits which serve the same purpose as no-fault benefits, and 2) benefits which are provided or required to be provided as a result of the same accident. If both criteria are met, the governmental benefit can be said to be duplicative and thus subject to setoff under § 3109(1).”¹⁰⁵

Jarosz involved a complicated set of facts regarding the Social Security retirement benefits at issue, but the Court ultimately applied its two-part test and concluded that the retirement benefits failed both parts of the test. With respect to the first part of the test, the Court reasoned that even though the retirement benefits may have served the same general purpose as no-fault benefits (i.e. wage payments to the injured person), the benefits did not serve the same particular purpose as no-fault work loss benefits. In this regard, the Court reasoned that the purpose of the retirement

¹⁰³ 418 Mich 565 (1984).

¹⁰⁴ *Id* at 573 (1984).

¹⁰⁵ *Id* at 580.

benefits was not to pay the plaintiff disability benefits. Rather, the purpose of the retirement benefits was to supplement the plaintiff's income because of his age and income level after the accident. Therefore, the Court concluded that the plaintiff's retirement benefits did not serve the same specific purpose as the plaintiff's no-fault work loss benefits. With respect to the second part of the test, the Court concluded that the retirement benefits were not payable as a result of the same accident. In reaching this conclusion, the Court reasoned that the plaintiff's entitlement to the retirement benefits was triggered as a result of his age and income level and not as a result of him being injured in an accident.¹⁰⁶

There have been several other cases in which Michigan courts have applied the *Jarosz* two-part test in order to determine whether a particular benefit is subject to set off from the payment of no-fault benefits under MCL 500.3109(1). The Michigan Court of Appeals decision in *Perkins v Riverside Ins. Co.*¹⁰⁷ is an example of the precision with which Michigan courts have applied the *Jarosz* test. In *Perkins*, the Michigan Court of Appeals held that the Michigan State Police pension benefits, which were payable to the widow of a Michigan State Police Trooper who was killed in an off-duty automobile accident, were not governmental benefits subject to set off from the payment of survivor's loss benefits, pursuant to MCL 500.3109(1). In reaching its holding, the court applied the *Jarosz* test and held that the decedent's pension benefits did not serve substantially the same purpose as the plaintiff's no-fault survivor's loss benefits. In this regard, the court reasoned that the retirement pension benefits were technically payable to the decedent's family as a part of the decedent's retirement benefits through his employment with the Michigan State Police and were not payable because the decedent died in a motor vehicle accident. In reaching its holding that these pension benefits failed the *Jarosz* test, the court in *Perkins* stated in pertinent part:

"We agree with the trial court's analysis. No-fault survivors benefits are designed to replace the loss of income or wages that decedent would have enjoyed had he continued his employment No-fault survivors benefits thus duplicate workers' compensation benefits . . . and social security survivors loss benefits Contrary to the defendant's argument on appeal, however, we find that the State Police pension is intended to protect the decedent's retirement contributions and is not intended to replace decedent's wages. MCL 28.107(4); MSA 3.337(4) clearly refers to the pension as a retirement benefit. Under that provision, a spouse is entitled to a pension computed as if the deceased had retired the day preceding his or her death. Further, the pension is referred to as a "retirement allowance" payable to the widow until death only if the trooper had accrued at least 10 years of service . . . the Michigan State Police pension does not duplicate no-fault survivors loss benefits intended to replace income loss. We

¹⁰⁶ *Id* at 582-583.

¹⁰⁷ 141 Mich App 379 (1985).

thus affirm the trial court's refusal to consider Nadine Perkins' pension to reduce her no-fault benefits.”¹⁰⁸

Another example of the precise application of the *Jarosz* test is the Michigan Court of Appeals decision in *Gier v Auto Owners*. In *Gier*, the Michigan Court of Appeals considered whether the \$255 lump sum U.S. social security death benefit payable under the Social Security Act could be set off against the no-fault funeral and burial expense benefit available under MCL 500.3107(1)(a).¹⁰⁹ The Court applied the *Jarosz* test and determined that the death benefit was not a proper governmental set off because it neither served the same purpose as the no-fault funeral and burial expenses, nor was it triggered by the same event. In this regard, the Court stated:

“In this case the two benefits are not triggered by the same event. The no-fault payment is triggered by the funeral and burial of the decedent; proof of expenses incurred by the recipient is required. The lump sum payment, on the other hand, is triggered by the death of an insured person who leaves eligible survivors; no funeral or burial is required, and the payment would be made even if there were no remains to be buried These two payments do not serve the same purpose; therefore, under *Jarosz*, defendant may not decrease this liability by subtracting \$255 from its obligation.”¹¹⁰

On the other hand, in *Moore v ACIA*, the Court of Appeals held that benefits paid under the Railroad Unemployment Insurance Act ("RUIA") were subject to set off as a government benefit under the *Jarosz* test.¹¹¹ The court reasoned that pursuant to the RUIA, these benefits passed the *Jarosz* test because they were payable as a result of the motor vehicle accident and substituted for wages the plaintiff would have made if he was not injured. In reaching this holding, the court in *Moore* rejected the plaintiff's argument that these benefits were no different from regular state unemployment compensation benefits, which are payable only due to loss of employment and not specifically triggered because of a person's injury.

The case law discussed above establishes that in precisely applying the *Jarosz* test, Michigan courts have closely examined the government benefit at issue and analyzed the specific reason and/or purpose of that benefit. It is not necessarily enough for a governmental benefit to become payable at the same time as another seemingly similar no-fault benefit. Rather, a specific comparison must be made between the nature of the particular government benefit and no-fault benefit at issue. Ultimately, under the *Jarosz* test, a governmental benefit is only subject to set off under MCL 500.3109(a) when it can be determined that the governmental benefit serves the same essential

¹⁰⁸ *Id* at 339-340 (citations omitted).

¹⁰⁹ 244 Mich App 336 (2001).

¹¹⁰ *Id* at 340-341.

¹¹¹ 173 Mich App 308 (1988).

purpose as the no-fault benefit and is payable directly as a result of the subject motor vehicle accident.

2. Avoiding the Governmental Benefit Set off under MCL 500.3019(1) for Uncoordinated No-Fault Coverage, Pursuant to the *Leblanc* Hybrid Benefit Doctrine

There have been situations in which a benefit has been determined to be both a government benefit under MCL 500.3109(1) and “other health and accident coverage” under MCL 500.3109a. *LeBlanc v State Farm* was the first case that addressed this situation.¹¹² In *Leblanc*, the Michigan Supreme Court recognized a distinction between governmental benefits, which are subject to set off under MCL 500.3109(1), and other types of benefits payable by the government, but which are more accurately characterized as “health and accident coverage” within the meaning of MCL 500.3109a. In making this distinction, the Court held that because Medicare benefits are, in fact, “other health and accident coverages” within the meaning of MCL 500.3109a, they may be subject to set off only if the injured person is covered under a coordinated no-fault policy. In so holding, the Court stated:

“§3109(1) . . . is clearly addressed to governmental benefits In contrast to §3109(1) is the later enacted §3109a which more specifically speaks to other health and accident coverage. Coverage, a word of precise meaning in the insurance industry, refers to protection afforded by an insurance policy, or the sum of the risks assumed by a policy of insurance. . . .

. . . Medicare constitutes “other health and accident coverage” within the meaning of § 3109a of the no-fault act. Thus, payments made to health care providers pursuant to the Medicare program for expenses arising out of the same accident for which no-fault benefits are also payable may be subtracted from payable no-fault benefits at the option of the insured. Since plaintiff in the instant case did not elect to coordinate his Medicare benefits with his no-fault benefits, payments made on his behalf by the Medicare program may not be subtracted from the no-fault benefits due under the no-fault policy issued to him by defendant.”¹¹³

Based on this analysis, the Court in *Leblanc* recognized that there can be a hybrid or combo benefit that constitutes a governmental benefit within the meaning of MCL 500.3109(1), and constitutes “other health and accident coverage” within the meaning of MCL 500.3109a. The Court reasoned that these types of benefits can only be treated as a set off if the injured person was covered under a coordinated no-fault policy. Therefore, if a person paid a higher premium to purchase uncoordinated no-fault

¹¹² 410 Mich 173 (1981).

¹¹³ *Id* at 204-207.

coverage and is eligible to receive other collateral benefits, the characterization of a benefit as “other health or accident coverage” under MCL 500.3109a immunizes the benefit from set off under MCL 500.3109(1).

It is important to note that in 1980, after *Leblanc* was decided, the United States Congress passed the Omnibus Budget Reconciliation Act that clearly provides that Medicare is always secondary whenever payment has been made or can reasonably be expected to be made under a liability or auto no-fault policy.¹¹⁴ Furthermore, on April 5, 1983, the Health Care Financing Administration (“HCFA”) published final regulations making it clear Medicare benefits are secondary to no-fault insurance policies. In any event, even though Medicare must never pay primary for auto accident-related medical treatment covered by no-fault insurance, the holding in *Leblanc* remains relevant with respect to its discussion of situations where a benefit satisfies both the governmental benefit test under MCL 500.3109(1) and the other health and accident coverage test under MCL 500.3109a.

Since deciding *LeBlanc*, the Supreme Court has confirmed the viability of the hybrid benefit doctrine on a number of occasions. In *Tatum v Government Employees Ins. Co.*, the Michigan Supreme Court held that military medical benefits payable to a member of the armed services, who also purchased an uncoordinated no-fault policy, could not be set off under MCL 500.3109(1) as a governmental benefit.¹¹⁵ The Court reasoned that because these benefits were also “health and accident coverage” within the meaning of MCL 500.3109a, they could not be subject to set off under *LeBlanc*, unless the plaintiff had purchased a coordinated no-fault policy. Therefore, because the plaintiff was covered under an uncoordinated no-fault policy, the military medical benefits, which might otherwise be considered a governmental benefit, were immunized from set off.

In *Profit v Citizens Ins. Co.*, the Michigan Supreme Court held that Social Security disability benefits were properly set off as a governmental benefit under MCL 500.3109(1), where the injured person had purchased an uncoordinated no-fault policy.¹¹⁶ In so holding, the Court reasoned that the Social Security disability benefits were not “other health and accident coverage” within the meaning of MCL 500.3109a. Therefore, there was no issue as to whether the benefits could be set off where a person purchases an uncoordinated policy, pursuant to the *Leblanc* hybrid benefit doctrine. Importantly, however, in reaching this holding, the Supreme Court explicitly refused to overrule the *Leblanc* hybrid benefit doctrine. Therefore, *Profit* serves as further proof of the continued viability of the *Leblanc* hybrid benefit doctrine.

¹¹⁴ 42 USC §1395y(b)(2)(A)(ii)

¹¹⁵ 431 Mich 663 (1988).

¹¹⁶ 444 Mich 281(1993).

Two years after *Tatum*, the continued viability of the *Leblanc* hybrid benefit doctrine was further confirmed by the Michigan Supreme Court in *DeMeglio v ACIA*¹¹⁷. In *Demeglio*, the Court held that no-fault benefits required to be provided under the laws of Pennsylvania to a Pennsylvania resident injured in a Michigan motor vehicle accident were subject to set off from the payment of no-fault benefits under MCL 500.3109(1). In so holding, the Court specifically recognized the *Leblanc* hybrid benefit doctrine and did not disavow it in anyway. Rather, similar to its holding in *Profit*, the Court determined that the hybrid-benefit doctrine did not apply to the given case, because the Pennsylvania no-fault benefits were “benefits” for purpose of MCL 500.3109(1), but did not constitute “other health and accident coverage” for purposes of MCL 500.3109a.

Ultimately, it is clear that the *Leblanc* hybrid benefit doctrine remains viable and must be applied by Michigan courts so that in situations where a particular government benefit is determined to fall under both MCL 500.3109(1) and MCL 500.3109a, the benefit is only subject to set off from the payment of no-fault benefits when the injured person has coordinated no-fault coverage.

F. Consumer Rights and Remedies Under the MNFA

Under the MNFA, motor vehicle accident victims and their medical providers have a clearly established right to bring a private civil cause of action in state court to recover benefits wrongfully denied by a no-fault insurer.¹¹⁸ Notably, there is a very strictly enforced “one-year-back” rule which provides that an action seeking to recover no-fault benefits can do so only with respect to expenses incurred within one year from date the lawsuit was filed.¹¹⁹ Therefore, patients and their providers must exercise due diligence to make sure that suit is filed within one year from the date the unpaid expense was incurred. This stringent one-year limitation makes dealing with coordinated PIP policies more problematic. In this regard, precious time can be wasted waiting for responses from the person’s health insurance company, which then puts the person or provider in a precarious position with regard to the one-year-back rule. This is one reason why some people choose to avoid purchasing coordinated no-fault policies.

It should be noted that the person or provider bringing the action can recover penalty sanctions against the no-fault insurer, but these sanctions are limited to penalty interest and attorney fees.¹²⁰ Attorney fees are only recoverable when there has been an unreasonable denial or delay in paying benefits. A person who has been denied

¹¹⁷ 449 Mich 33 (1995).

¹¹⁸ MCL 500.3145(1). For the right of medical providers to bring their own private cause of action, see *Lakeland Neurocare Ctrs. v State Farm Mut. Auto. Ins. Co.*, 250 Mich App 35, 36-37 (2002) and *Wyoming Chiropractic Health Clinic, PC v Auto-Owners*, 308 Mich App 380 (2014), leave denied by Michigan Supreme Court (May 28, 2015).

¹¹⁹ MCL 500.3145.

¹²⁰ MCL 500.3142 and MCL 500.3148.

benefits can file suit immediately and does not need to go through any review process that is typically required in health insurance disputes. In this regard, the MNFA provides injured people the right to initiate a lawsuit against their no-fault insurers to protect and enforce their rights through the judicial system. However, it should be noted that even though people can take immediate action to initiate a lawsuit against their no-fault insurance company, the MNFA does not impose any specific duties on no-fault insurers to handle claims in good faith. Therefore, one of the biggest weaknesses of the Michigan no-fault system is that the relationships between no-fault insurers and their insureds are often adversarial and contentious.

III. The Intersection of the ACA and the MNFA

A. Michigan No-Fault Coverage is Far Broader Than ACA Coverage

Some people believe that because of the ACA, Michigan no-fault coverage is no longer needed to cover the care, recovery and rehabilitation of motor vehicle accident victims. This is clearly not the case. Even though the ACA provides for relatively broad forms of health insurance coverage, the Michigan benchmark ACA plan contains significant limitations regarding various types of medical products, services and accommodations that are critically important for a motor vehicle accident victim's care, recovery, or rehabilitation, especially for the most catastrophically injured. Some notable examples of products, services and accommodations that are available to auto accident victims under the MNFA but are not available to any extent under Michigan's benchmark ACA plan, include, but are not necessarily limited to, the following:

- long-term/custodial nursing home care (including family-provided attendant care);
- habilitative services¹²¹;
- alternative therapies such as massage therapy and acupuncture;

¹²¹ The ACA allows the states to define the term "habilitative services." The Michigan Insurance Commissioner has defined habilitative services as "*health care services that help a person keep, learn or improve skills and functioning for daily living. Examples include therapy for a child who isn't walking or talking at the expected age. These services may include physical and occupational therapy, speech-language pathology and other services for people with disabilities.*" The Michigan Insurance Commissioner has determined that habilitative services encompasses many types of services, including but not limited to applied behavioral analysis (ABA) for the treatment of autism spectrum disorder. ABA is defined by Michigan law as "*the design, implementation and evaluation of environmental modifications, using behavioral stimuli and consequences, to produce significant improvement in human behavior, including the use of direct observation, measurement, and functional analysis of the relationship between environment and behavior.*"

- guardianship and conservator services;
- case management services;
- medical mileage;
- handicap-accessible transportation accommodations;
- handicap-accessible housing accommodations;

Furthermore, there are substantial limitations within Michigan's benchmark ACA plan for services that are frequently needed for the care, recovery or rehabilitation of seriously injured motor vehicle accident victims and that are covered without quantitative limitations under the MNFA. These services and their respective limitations under Michigan's benchmark plan include, but are not necessarily limited to, the following:

- hospice services (skilled nursing, subacute, inpatient rehabilitation and hospice facility) limited to 45 days per year;
- home health care services limited to 45 days;
- skilled nursing facility (skilled nursing, subacute, inpatient rehabilitation and hospice facility) limited to 45 days per year;
- mental/behavioral health outpatient services (i.e., outpatient mental health services) limited to 20 days per year;
- mental/behavioral health inpatient services (i.e., outpatient mental health services) limited to 20 days per year;
- outpatient rehabilitation service (i.e., rehabilitative medicine services) limited to 30 visits per year;
- chiropractic care (i.e., rehabilitative medicine services) limited to 30 visits per year.

Therefore, given the aforesaid limitations regarding the types and quantities of services available under Michigan's ACA benchmark plan, the coverage available under the MNFA for the care, recovery and rehabilitation of the injuries sustained by motor vehicle accident victims is far broader than the coverage available under the ACA. Accordingly, Michigan no-fault coverage will continue to be necessary for the care, recovery and rehabilitation of seriously injured motor vehicle accident victims, especially those who require extensive rehabilitative therapies, long-term nursing care, handicap-accessible housing and transportation accommodations, or other specialized services such as vocational rehabilitation services, case management services and guardian and conservator services.

It must be also emphasized that, as explained above, there are several categories of individuals who are not required to buy ACA policies. Therefore, if any of these people without health insurance are injured in a Michigan motor vehicle accident, no-fault coverage remains their primary source of coverage for auto-related medical treatment (i.e., assuming they are not otherwise disqualified from no-fault coverage under the relevant disqualification provisions of the MFNA).

Moreover, while the ACA expanded the Medicaid eligibility requirements, Medicaid cannot be held responsible for auto-related treatment. Thus, Michigan no-fault coverage remains the primary source of medical insurance for Medicaid beneficiaries in the event they are seriously injured in a motor vehicle accident. The same is true with respect to Medicare beneficiaries.

It is also important to note that ACA health insurance policies only cover a certain percentage of a person's medical costs. Therefore, if a person, who is insured under a bronze ACA policy that only pays 60% of medical costs, is injured in a motor vehicle accident, he or she will still need to find a way to pay the other 40% of the medical costs related to his or her motor vehicle accident injuries. However, it should be noted that, as explained above, the person's out-of-pocket expenses for Essential Health Benefits ("EHBs") will be capped each year pursuant to the person's cost-sharing limit for EHBs, i.e., in 2015, \$6,350 per person and \$12,700 per family. In any event, no-fault coverage is necessary to help pay an injured person's out-of-pocket costs that are not covered under his or her ACA health insurance coverage.

Additionally, the other benefits available under no-fault coverage (replacement services, work loss benefits, and survivor's loss benefits) are obviously not covered under the ACA. Therefore, no-fault coverage is needed to continue to provide these benefits to motor vehicle accident victims.

B. ACA Coverage Should Only be Subject to Set Off Under Coordinated No-Fault Policies

One of the most significant issues regarding the intersection of the ACA and MNFA is whether ACA coverage should be set off from the payment of no-fault benefits payable under coordinated no-fault coverage, or whether the set off should also apply to no-fault benefits payable under uncoordinated no-fault coverage. Some commentators have suggested that no-fault benefits are subject to mandatory set off under MCL 500.3109(1), regardless of whether the person is insured under an uncoordinated or coordinated no-fault policy.¹²² For the reasons explained below, this article disagrees

¹²² Miller, The Affordable Care Act's Uncertain Impact on Michigan's No-Fault Act, 93 Mich B J 20, (March 2014).

with that position and ultimately concludes that ACA coverage does **not** constitute a governmental benefit under MCL 500.3109(1), and, even if it does, the amounts paid under an ACA policy are only subject to set off from the payment of no-fault benefits in situations involving coordinated no-fault coverage.

1. ACA Coverage is Not Subject to Set Off Under MCL 500.3109(1) Because ACA Coverage is Not “Provided or Required to be Provided” by the Laws of any State or the Federal Government

A benefit can only be subject to set off under MCL 500.3109(1) if it is deemed to be “. . . provided **or** required to be provided under the laws of any state or the federal government”¹²³ As explained above, in *National Federation of Independent Business v Sebelius*, the United States Supreme Court explained that the ACA does not actually require or mandate Americans to buy health insurance. The ACA simply presents people with the choice to either buy a qualified ACA health insurance policy or pay the applicable tax penalty. Based on this reasoning, it is clear that benefits payable under ACA policies are not actually “required to be provided” by the federal government.

Moreover, ACA health insurance coverage is not being “provided . . . under the laws of any state or the federal government.” Rather, ACA coverage is being provided by private health insurance companies. Obviously, there are laws and regulations that apply to ACA health insurance coverage, but that is also the case with any other form of private health insurance. For example, in order for Blue Cross to provide health insurance coverage to the people of Michigan, it must follow certain state laws and regulations regarding health insurance. However, there is no precedent establishing that private health insurance is subject to MCL 500.3109(1) simply because there are laws that regulate how health insurance companies operate and provide health insurance coverage. Accordingly, ACA coverage should not be deemed to be “provided . . . under the laws of any state or the federal government” for purposes of MCL 500.3109(1). Notably, this analysis would be different if the ACA actually created a system of health insurance in which the federal government sold its own health insurance policies and/or administered its own benefits. If this was the case, ACA health insurance coverage would be provided by the government in ways similar to how the government provides health insurance coverage through Medicaid, Medicare, TRICARE military health insurance, etc. However, the system of private health insurance established under the ACA is a direct rejection of that type of government involvement in health insurance. Therefore, ACA coverage is obviously distinguishable from these other forms of government provided health insurance coverage.

Based on the foregoing, ACA coverage is not “required to be provided by or provided under the laws of any state or the federal government” for purposes of MCL

¹²³ Emphasis added.

500.3109(1). Therefore, ACA coverage should not be subject to set off under MCL 500.3109(1).

2. ACA Coverage is Not Subject to Set Off Under MCL 500.3109(1) Because it Fails the *Jarosz* Test

Even if it is determined that ACA coverage is provided or required to be provided under the laws of the federal government, ACA coverage is not subject to set off under MCL 500.3109(1) because it fails the *Jarosz* two-part test explained above. The *Jarosz* test provides that benefits can only be subject to set off under MCL 500.3109(1) if the benefits (1) serve the same purpose as the no-fault benefit at issue; and (2) are provided or are required to be provided as a result of the same accident. The case law discussed above indicates that in applying this test, Michigan courts have closely examined the specific benefit at issue and inquired about the specific reason and/or purpose for the payment of that benefit. For example, in *Perkins*, the court determined that the benefits at issue were technically payable as a part of the decedent's retirement benefits available to him and his family at the time of his death. The benefits were not available to the family because the decedent was killed in an accident. Therefore, the court in *Perkins* determined that these benefits failed the *Jarosz* test. Furthermore, in *Gier*, the court concluded that the social security death benefits at issue failed the *Jarosz* test because the benefits were payable upon the event of the person dying, whereas the funeral and burial expense benefits under the MNFA were payable once the charges were actually incurred for the decedent's funeral and burial services.

Pursuant to *Jarosz* and its progeny, the payment of benefits under an ACA health insurance policy does not serve the same specific purpose as the payment of no-fault benefits under a Michigan no-fault insurance policy. Benefits under an ACA policy are paid pursuant to the private health insurance company's contractual obligation to provide health insurance for the general health and well-being of the insured person. On the other hand, no-fault benefits are paid as part of Michigan's compulsory auto insurance system that seeks to provide comprehensive coverage for the care, recovery and rehabilitation of motor vehicle accident victims, while, at the same time, immunizing at-fault drivers from financial liability for an injured person's medical expenses. Therefore, benefits paid under an ACA policy fail the *Jarosz* test because the purpose of the payment of those benefits is fundamentally different and distinct from the purpose underlying the payment of no-fault benefits.

Furthermore, benefits paid under an ACA policy fail the *Jarosz* test because the payment of those benefits is not triggered by the same event. Benefits are payable under an ACA policy for medical treatment a person requires regardless of the events and/or reasons that cause the person to require the treatment. However, under the MNFA, allowable expenses benefits are payable only when a person requires medical treatment for "accidental bodily injury arising out of the ownership, operation,

maintenance or use of a motor vehicle as a motor vehicle.”¹²⁴ In other words, no-fault benefits become payable strictly when a person sustains injury while engaged in a particular activity (i.e., using a motor vehicle), whereas benefits under an ACA policy become payable whenever a person needs medical treatment. Therefore, the payment of benefits under an ACA policy is not triggered by the same event that triggers the payment of no-fault benefits.

3. ACA Coverage is Not Subject to Set Off Under MCL 500.3109(1) Under the *LeBlanc* Hybrid Benefit Doctrine

Even if ACA coverage passes the *Jaros* test and is also determined to be “provided or required to be provided under the laws of any state or the federal government” for purposes of MCL 500.3109(1), it remains the case that ACA coverage should only be subject to set off in situations involving coordinated no-fault coverage. This is because of the *LeBlanc-Tatum* hybrid benefit doctrine discussed above. Under this doctrine, if a benefit is determined to be a governmental benefit under MCL 500.3109(1) **and** “other health and accident coverage” under MCL 500.3109a, the benefit can only be set off against the payment of no-fault benefits in situations involving coordinated no-fault coverage. There is no question that ACA health insurance coverage constitutes “other health and accident coverage” under MCL 500.3109a. Therefore, even if ACA coverage constitutes a governmental benefit for purposes of MCL 500.3109(1), under the *LeBlanc-Tatum* hybrid benefit doctrine, ACA benefits should only be subject to set off in situations involving coordinated no-fault coverage.

In sum, pursuant to the foregoing reasons, ACA coverage should only be subject to set off in situations involving coordinated no-fault coverage. If the opposite result was reached, there would be great confusion about the amount insurance companies could set off their payment of no-fault benefits in a variety of situations. With regard to a person who has uncoordinated no-fault coverage but failed to purchase health insurance under the ACA, would the no-fault insurance company be entitled to set off the payment of no-fault benefits by an amount that would have been payable under an ACA policy? If so, would the amount of the set off equal the amounts that would have been payable to the injured person under a bronze, silver, gold or platinum ACA plan? For people under 30, would the set off amount be the equivalent of the amounts payable under a catastrophic health insurance plan, given that is the only type coverage people under the age of 30 are required to buy under the ACA to avoid the tax penalty? Also, would the set off apply to no-fault benefit claims brought by children whose parents failed to purchase health insurance for their family? If so, what would be the amount by which the no-fault insurer would be allowed to set off the payment of the injured child’s benefits? Would the set off apply to a person who chooses to pay the tax penalty under the ACA as opposed to buying health insurance? Would the set off not

¹²⁴ MCL 500.3105(1).

apply to no-fault claims brought by the wide-variety of people who do not have any obligation to purchase health insurance under the ACA? These points of confusions can be avoided by Michigan courts correctly holding that it is only in situations involving coordinated no-fault coverage when a no-fault insurance company is entitled to claim a set off against the payment of no-fault benefits by the amounts actually paid under the injured person's ACA health insurance policy.

C. The ACA May Result in More People Purchasing Coordinated No-Fault Coverage

Because coordinated coverage allows an insurance company to pay for an auto accident victim's medical treatment on a secondary basis, it cost less than uncoordinated coverage. Because coordinated coverage costs less, many people end up buying it. However, throughout the years, it has been arguably a better decision for Michigan motorists to buy uncoordinated no-fault coverage. The ACA changes the analysis of whether a person should buy uncoordinated or coordinated no-fault coverage. Ultimately, because of the ACA, more people may purchase coordinated no-fault coverage instead of uncoordinated no-fault coverage.

Perhaps the most significant way in which the ACA may influence more people to buy coordinated no-fault coverage is simply because the ACA will increase the number of people who have private health insurance. Prior to the ACA, if a person did not have private health insurance, he or she would not be eligible to buy coordinated no-fault coverage. Therefore, if a person can now obtain private health insurance under the ACA, he or she can now also buy coordinated no-fault coverage. It should be expected that the vast majority of these people will decide to buy coordinated no-fault coverage simply because it costs less than uncoordinated coverage.

The decision of whether to buy uncoordinated or coordinated no-fault coverage is also significantly affected by the ACA's prohibition on health insurance policies containing any lifetime or annual caps on services that constitute Essential Health Benefits ("EHBs"). Prior to the ACA, there were no laws prohibiting health insurance companies from including annual or lifetime monetary caps within their health insurance policies. For example, health insurance policies could contain a provision stating that the health insurance company is not liable to pay any more than \$1,000,000 (or less) for a person's medical needs throughout the entire time the person is insured under the policy. Therefore, if a person was insured under a coordinated no-fault policy and required extensive medical care for injuries sustained in a motor vehicle accident, the person might not have enough coverage remaining under his or her health insurance policy if he or she happened to become ill or develop another life-threatening disease, such as cancer, at any point in the future. The threat of exhausting health insurance coverage prior to the ACA provided a very compelling reason for people to buy

uncoordinated coverage as opposed to coordinated coverage. However, due to the ACA's prohibition on lifetime and annual caps on EHBs, there is significantly lower risk that a motor vehicle accident victim insured under a coordinated no-fault policy will actually face the problem of exhausting health insurance coverage the person may otherwise need in the future. This reduced risk may make coordinated no-fault coverage more appealing to those who have been previously inclined to purchase uncoordinated no-fault coverage.

It is also worth noting that because the ACA empowers people with significant rights regarding health insurance matters, people may experience more straightforward and fairer treatment from their health insurance company. If people have better experiences dealing with health insurance companies under the ACA, it may help further influence them to buy the less expensive coordinated no-fault coverage instead of the more expensive uncoordinated no-fault coverage.

Based on the foregoing, it is clear that the ACA changes the analysis of whether a person should buy uncoordinated or coordinated no-fault coverage. Ultimately, because of the ACA, more people may eventually purchase coordinated no-fault coverage instead of uncoordinated no-fault coverage.

D. The ACA May Help Lessen the Financial Burdens and Costs of Michigan's No-Fault System

Despite the MFNA's broad scope of coverage for motor vehicle accident victims, there is a seemingly perpetual debate raging in the Michigan Legislature about whether the MNFA should be reformed. At the heart of that debate is whether the MNFA must be reformed in order to ease the financial burdens and costs of Michigan's no-fault system. The cost of auto insurance and the financial reality of the Michigan no-fault system are very complicated issues that this article does not attempt to fully analyze. However, there are some notable observations that can be made regarding how the ACA may help lessen the financial burdens and costs of Michigan's no-fault system.

At the outset, it should be noted that there is nothing within the ACA that should increase the financial burdens of Michigan's no-fault system. In this regard, the ACA does not result in any new cost shifts to no-fault insurance coverage. The ACA also does not further elevate no-fault insurance to any higher order of insurer priority. Furthermore, the ACA does not limit health insurance coverage beyond which was typically provided by health insurance companies prior to the ACA.

There actually appear to be several ways in which the ACA may help lower the financial burdens and costs of Michigan's no-fault system. First, ACA health insurance coverage is generally broader than the coverage that was typically available under health insurance policies prior to the ACA. Notably, the ACA increases the scope and extent of health insurance coverage by guaranteeing coverage for Essential Health Benefits without any annual or lifetime caps, as well as imposing the cost sharing limit

that caps the amount people must pay for out-of-pocket medical costs. Thus, many people with coordinated no-fault coverage now have better health insurance coverage under the ACA that covers a greater amount of treatment and services than were covered under their health insurance plans prior to the ACA. In these cases, the potential liability of the coordinated no-fault insurer that pays secondary to the health insurance company is directly diminished as a result of the person's expanded health insurance coverage under the ACA.

Moreover, as explained above, the ACA may result in more people obtaining coordinated no-fault coverage, as opposed to uncoordinated no-fault coverage. In these situations, if these people are injured a motor vehicle accident, they will now turn to their health insurance company first for all of their medical treatment and no-fault insurance will only have to pay in the secondary position. Furthermore, under the *Dean* doctrine discussed above, these people's medical providers have to accept the discounted rates of reimbursement under the person's ACA policy and are not be able to bill the no-fault insurer for the differential amount that would be payable as a reasonable charge under the MNFA.

The ACA may also lessen the financial burdens of the no-fault system by effectively limiting the right of medical providers to be paid under the "reasonable charge" standard under the MNFA. Based on the growing health insurance market under the ACA, it is anticipated there will be more instances of medical providers contracting with health insurance companies to accept discounted reimbursement rates. As explained above, under the *Bombalski* doctrine, when a medical provider renders auto accident-related medical treatment to a person insured with a health insurance company through which the provider has agreed to accept discounted rates, the provider will only be able to receive payment from the person's no-fault insurance company based on those discounted rates, even if the injured person is insured with uncoordinated no-fault coverage. Therefore, if the ACA impacts the health care industry in such a way that results in more discounted reimbursement rate contracts existing between providers and health insurance companies, there will be more opportunities for no-fault insurers to pay for auto accident-related medical treatment based on those discounted rates.

Another interesting way the ACA could ease the financial burdens and uncertainties of Michigan's no-fault insurance system is based on the ACA increasing the viability of the no-fault PIP "buyout" for the less seriously injured person (i.e., non-catastrophic injury). A buyout is when the no-fault insurer pays the injured person a lump sum of money in exchange for the person forever releasing the no-fault insurer for any future liability for no-fault benefits. No-fault insurance companies are typically interested in finding ways to buyout people's no-fault coverage, because buyouts give the insurance companies certainty about their financial exposure and allow the companies to remove the claims from their books. On the other hand, many no-fault attorneys have been very wary about representing a person in a no-fault buyout deal.

This is because no-fault coverage is too broad and significant for a person to forgo forever. Furthermore, prior to ACA, the person would have a difficult time finding additional health insurance coverage because of the preexisting condition exclusion he or she would likely face as a result of his or her auto accident injuries. Therefore, many no-fault attorneys have typically refused to represent people on buyouts because of malpractice concerns and other complications that could arise as a result of that representation.

The ACA helps limit the potential complications that can arise from a no-fault buyout. The major reason for this is that the ACA prohibits health insurers from denying health insurance coverage based on a preexisting condition. Therefore, if an injured person receives a buyout from his or her no-fault coverage and has enough money to afford an ACA policy, he or she will be able to obtain that health insurance coverage. It would be advisable for the person to put the money from the buyout into a trust account or health-care set aside account to ensure the money will be available for health insurance in the future. Furthermore, it must be emphasized that a buyout of no-fault benefits is much more complicated if the injured person is insured through Medicare or Medicaid. In that situation, Medicare or Medicaid could attempt to deny future coverage by arguing that the buyout compromised its interest by elevating it to the primary pay position. It is not clear whether it would be proper for Medicare or Medicaid to deny future coverage on this basis. Accordingly, the buyout option must be pursued very cautiously when the injured person is covered under Medicare or Medicaid. In sum, carefully crafted buyouts of no-fault benefits for less seriously injured people could help ease some of the financial burdens and uncertainties of Michigan's no-fault system.

Ultimately, before the debate about reforming the MNFA rages on any further, a specific analysis should be conducted by the Department of Financial and Insurance Services regarding how the ACA may impact Michigan's auto insurance rates. Notably, in the landmark no-fault decision, *Shavers v Attorney General*, the Michigan Supreme Court held that because of the compulsory nature of the Michigan no-fault insurance system, due process protections within the United States Constitution and Michigan Constitution require that auto insurance rates in Michigan to be "fair and equitable."¹²⁵ In this regard, the Court in *Shavers* specifically stated:

"In choosing to make no-fault insurance compulsory for all motorists, the Legislature has made the registration and operation of a motor vehicle inexorably dependent on whether no-fault insurance is available at fair and equitable rates. Consequently, due process protections under the Michigan and United States Constitutions (Const 1963, art 1, § 17; US Const, AM XIV) are operative."¹²⁶

¹²⁵ 402 Mich 554 (1978).

¹²⁶ *Id* at 599.

The Court in *Shavers* further indicated that the Legislature, the Judiciary and the Insurance Commissioner all share in the responsibility of making sure auto insurance rates are “fair and equitable.” Ultimately, the assessment of how the ACA may impact auto insurance rates is a necessary part of our government’s constitutional obligation to make sure the people of Michigan are able to buy auto insurance at fair and equitable rates. This point is especially relevant today, considering the extremely high costs of auto insurance in cities like Detroit.

It should also be noted that pursuant to MCL 500.3109a, the insurance commissioner is obligated to make a specific determination of whether the premiums for coordinated no-fault coverage are being “appropriately reduced,” in comparison to the cost of uncoordinated no-fault coverage. Therefore, in addition to the due process constitutional concerns, there is also a specific statutory requirement that obligates the Insurance Commissioner to assess whether the rates of coordinated no-fault policies are being appropriately reduced in light of the scope and extent of health insurance coverage available under the ACA.

Conclusion

Since the MNFA was enacted in 1973, whether they have known it or not, the people of Michigan have been covered under a unique and comprehensive form of health insurance for one of the most perilous hazards we face in our daily life—motor vehicle accidents. This coverage assures that when the people of Michigan are driving in their cars, if something goes wrong, there will be comprehensive coverage for any product, service or accommodation that is reasonably necessary for their care, recovery and rehabilitation. With the passage of the ACA, the people of Michigan are now insured under a relatively broad form of health insurance that establishes more consumer rights in relation to health insurance than have ever existed before in America. The coexistence of these two insurance systems is seemingly good for the health and well-being of the people of Michigan. However, it is incumbent upon Michigan courts to correctly hold that no-fault benefits can only be set off by amounts paid under a person’s ACA coverage when the person is insured under a coordinated no-fault policy. Furthermore, it is incumbent upon the Insurance Commissioner to conduct a detailed assessment of the various ways in which the ACA may bring down the cost of auto insurance in Michigan. Last, but certainly not least, it is incumbent upon Michigan legislators to factor the ACA into the ongoing debate about whether to reform the MNFA.

** Note: this is an overview article intended to provide general guidance. This is not a comprehensive overview of all laws related to the laws reviewed herein.*

The views in this article are the personal views and experiences of the author and do not necessarily reflect the views of the State Bar of Michigan, or of the State Bar of Michigan Health Care Law Section.

**New Business Opportunities, Entrepreneurial Ventures and
Complex Transactions under Health Care Reform**

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New Business Opportunities, Entrepreneurial Ventures and Complex Transactions Under Health Care Reform

Table of Contents

- I. Introduction
- II. New Business Opportunities under Health Care Reform
 - 1. Identifying and Evaluating New Business Opportunities
 - 2. Specific Business Opportunities Under Health Care Reform
 - 3. Accountable Care Organizations
 - 4. Health Care Technology
- III. The Shifting Regulatory Landscape
- IV. Complex Transactions Related to ACA Opportunities and Ventures
- V. The Change Process
- VI. Conclusion

New Business Opportunities, Entrepreneurial Ventures and Complex Transactions Under Health Care Reform

By Michael P. James

I. Introduction

The Patient Protection and Affordable Care Act ("ACA") created sweeping reform to the health care system in the United States. Since its inception, health care Suppliers¹ and Providers² of all sizes have been challenged to navigate the complexities related to health care reform. These complexities include demands and expectations for higher quality; escalating competition that drives the need to reduce waste, lower costs and forge strategic alliances; and multi-dimensional problems that require cross-organizational solutions. To overcome these challenges, Suppliers and Providers have adopted sustainable and continuous improvements that advance care for their customers, enhance health in their populations and reduce the growth of their expenditures. However, these activities require a careful harmonization with the regulatory landscape to ensure that they are implemented through a culture of compliance.

But health care Suppliers and Providers are not the only businesses meeting the challenges of health care reform. Nearly every industry and organization connected to health care has been impacted or influenced by the ACA. In some instances, companies have worked to maintain and strengthen their relationships with Suppliers and Providers by modifying their own products or services, business practices and overall capabilities to meet the evolving needs of the health care industry. In other situations, entrepreneurs and entrepreneurial-minded companies have explored new opportunities afforded by changes in the law and the delivery of care to launch new ventures, products and services. As a result, the number of companies engaged in health care has increased and the scope and breadth of their involvement in the coordination, management and delivery of care has grown.

¹ A Supplier is a physician or other practitioner, or an entity, other than a provider, that furnishes health care services. 42 CFR §400.202.

² A Provider is a hospital, CAH, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice, clinic, rehabilitation agency, public health agency that provides outpatient care, or a community mental health center that furnishes partial hospitalization services as defined by 42 CFR §400.202.

Despite all the uncertainty surrounding health care reform, one thing is clear: change is here. This portion of the White Paper will focus on new business opportunities, entrepreneurial ventures and complex transactions under health care reform. First, I will explore how organizations have identified, evaluated and acted on new business opportunities under the ACA and outline these opportunities. Next, I will examine how the regulatory landscape impacts health care reform initiatives, especially in a constantly-changing environment. After that, I will offer insights into the complex transactions often involved with health care reform opportunities and ventures. Finally, I will conclude with the practical implications of implementing changes related to the ACA.

II. New Business Opportunities Under Health Care Reform

Since the inception of the ACA, I have spent a considerable amount of time working with Suppliers, Providers and numerous other businesses on opportunities related to health care reform. Early on, the primary focus for most organizations was to understand the new framework and determine its impact on their operations, organizational objectives, and overall resources. However, some individuals and entities went beyond these fundamental inquiries. Specifically, these trailblazers wanted to not only comprehend how the ACA was going to change the health care industry, but also develop proactive strategies to leverage these changes. As a result, these Early Adopters³ embraced health care reform and took decisive steps toward implementing initiatives even before the ACA was upheld by the United States Supreme Court or subsequent regulations were finalized.

1. Identifying and Evaluating New Business Opportunities

The health care reform initiatives implemented by Early Adopters were driven by a keen understanding of the opportunities that were emerging from the ACA and the role these opportunities would play in the health care industry. I am often asked how these Early Adopters acquired this knowledge. Although not every Early Adopter followed the same path, I believe that successful individuals and entities followed a similar process. This process involved examining the ACA, evaluating the goals of the business against the objectives of the ACA, and determining the best opportunities for the organization based on the organization's stakeholders. It is worth exploring this process in greater detail.

³ Suppliers, Providers and other businesses who pursued various opportunities during the early stages of the ACA.

First, Early Adopters developed a profound understanding of the fundamental objectives underlying the ACA. Generally, health care reform was designed to:

- 1) Increase the quality of care delivered to patients;
- 2) Improve the performance of Providers and Suppliers;
- 3) Contain and reduce the costs associated with beneficiary expenditures;
- 4) Promote patient engagement in and awareness of his or her own health;
- 5) Support prevention and wellness initiatives;
- 6) Overhaul the health insurance system and expand public programs;
- 7) Establish health insurance exchanges and related programs to facilitate health insurance reform; and
- 8) Implement tax changes to finance health care reform.⁴

Although not every objective directly applied to each Early Adopter, it was important for these businesses to have a comprehensive understanding of the fundamental objectives. In large part, many, if not all, of these objectives are interconnected. If an organization wanted to pursue a business opportunity arising out of one of these objectives, it would likely have to consider the potential impact of the other objectives on the initiative. As a result, the objectives underlying the ACA formed a broad, initial evaluation mechanism for potential new business opportunities.

However, understanding the broad objectives of the ACA was not enough to identify and evaluate the new business opportunities under health care reform. Instead, the Early Adopters needed to dissect the details underlying the ACA objectives. The ACA and subsequent regulations established numerous programs, requirements, incentives, penalties and timelines related to the objectives of health care reform. It was through these specific details and requirements that new opportunities emerged under health care reform. For example, while the introduction of the Health Insurance Marketplace ("Marketplace") was designed to support the broad objective of overhauling the health insurance system, potential business opportunities emerged from the introduction of programs like the Navigator and Web-Broker Entity programs, which were designed to assist individuals with the procurement of health insurance from the Marketplace. Early Adopters interested in pursuing

⁴ Patient Protection and Affordable Care Act of 2010 (ACA), Pub. L. No. 111-148.

Marketplace opportunities related to these programs needed to not only understand the Marketplace generally, but also clearly comprehend the specific requirements needed to participate in the programs and the potential gains and risks associated with participation. Accordingly, the details underlying ACA objectives were critically important to the process of evaluating new business opportunities.

Second, Early Adopters achieved a highly refined understanding of their own organizations. When an organization examines a business opportunity, it is incredibly important for the opportunity to be evaluated against the interests of the various stakeholders of the organization. Stakeholders are those groups of individuals who are affected in some way by the decisions of the business and may include employees, owners, investors, customers, business partners, affiliates, contractors and the overall community. Clearly, health care reform initiatives had, and still have, the potential to have a dramatic impact on some, if not all, of the stakeholders of these organizations. Therefore, it was very important for Early Adopters to make sure they understood the needs of their stakeholders and the impact of a potential health care reform initiative on their stakeholders before acting on the opportunities that emerged from the ACA.

In addition to understanding and gaining support from stakeholders, Early Adopters also had a firm grasp on the resources and capabilities of their organizations. Many of the opportunities arising from health care reform demanded substantial financial commitments to address the infrastructure and technological requirements of the ACA. On the one hand, established organizations needed to plan for these financial commitments while maintaining their existing operations. On the other hand, entrepreneurial ventures needed to secure the necessary funds in an uncertain environment. Both situations involved careful preparation and forecasting. While finances played a critical role in evaluating and planning for ACA business opportunities, the analysis of organizational capabilities went much deeper. Early Adopters needed to ensure that they attracted and retained the human capital necessary to execute health care reform initiatives through a culture of compliance. Furthermore, internal systems and processes needed to be redesigned to conform to the management and reporting requirements of various opportunities. Finally, operations and business practices needed to be reinvented to account for changes in reimbursement models and compensation structures. As Early Adopters prepared to engage in emerging opportunities, it was essential that they understood the resources and capabilities of their organizations so that they were prepared for the evolving nature of ACA opportunities.

Third, Early Adopters sought to identify their position in the applicable local, regional and/or national markets. In order to assess the value of a potential opportunity, one must also be able to effectively evaluate potential threats. This was a challenging process for Early Adopters because it was difficult to gauge whether competitors were pursuing similar ACA opportunities. However, in my experience, a competitor's observable strengths, market focus and experience with the objectives of the ACA were often solid indicators of which health care reform opportunities that competitor may pursue. For example, if a health system or integrated delivery system had a history of coordinating care for its patient populations, there was a higher probability that it would seek approval as an Accountable Care Organization in the Medicare Shared Saving Program. If an Early Adopter was able to reasonably gauge its competitors' interests in an ACA opportunity and their abilities to get their initiatives to market, the Early Adopter likely had a better understanding of the value of a potential opportunity, whether it could obtain a first-mover advantage in the market or whether the opportunity was economically feasible if the Early Adopter was not the first to implement an initiative within an applicable market.

Fourth, Early Adopters harmonized their understanding of the objectives and details of the ACA, their own organizations and the competitive landscape to develop business plans related to ACA opportunities. Through this process, each Early Adopter examined the ACA through its own lens. Their views of the ACA were filtered by their respective organizational histories, cultures, operations, goals, capabilities, resources and applicable competitive landscapes. As a result, not every Early Adopter saw the opportunities under the ACA the same way. Two organizations could look at the same opportunity and reach entirely different conclusions regarding the probability of success, risk factors and overall value. Not surprisingly, the opportunities that emerged under health care reform did not have the same value for each individual and organization that considered them.

The process engaged in by Early Adopters remains relevant for those interested in existing and continually emerging business opportunities under health care reform. Suppliers, Providers and other businesses considering health care reform initiatives need to have a keen understanding of the ACA, a firm grasp on the organic nature of their organizations, and a heightened awareness of their competitive landscapes. Although different opportunities will require modifications to this blueprint, the basic premises remain the same. Through my experiences with Early Adopters, I have learned an important lesson—there is no cookie-cutter, one-size-fits-all answer to health care reform. Each organization needs to evaluate and make decisions about ACA business opportunities from a uniquely individualized perspective. If not, the likelihood of success will diminish

as the framework and requirements of a potential opportunity are determined to be inconsistent with the goals, objectives, resources and overall culture of the organization.

2. Specific Business Opportunities Under Health Care Reform

The new business opportunities that have emerged out of the ACA are expansive. Nearly every business involved in the health care industry has been affected by the seismic shifts that have taken place as a result of the ACA. Generally, health care reform initiatives have been driven by the objectives underlying health care reform. However, as noted above, the specific opportunities have taken shape as a result of the programs, requirements, incentives, penalties and timelines designed to implement the ACA. I have worked with Suppliers, Providers and other businesses regarding numerous opportunities related to health care reform and the ACA. However, here, I would like to focus on a few of these specific opportunities related to the management and coordination of care and utilization of health care technology.

3. Accountable Care Organizations

I have worked with numerous Suppliers and Providers to evaluate and pursue opportunities related to the management and coordination of care. One such opportunity has been the creation of Accountable Care Organizations ("ACO") under the ACA. Generally, ACOs are legal entities intended to promote integrated health care by incentivizing participating Suppliers and Providers to work together to deliver high quality and efficient care.⁵ ACOs are centered around three fundamental principles: 1) to improve care for its beneficiaries; 2) to enhance health in its population; and 3) to reduce the growth of its beneficiary expenditures (collectively referred to as "Triple Aims"). In practice, these principles require ACO participants to utilize evidence-based medicine and promote patient engagement to achieve measured quality improvements. Ultimately, ACOs are held accountable for improving the quality of care for its beneficiary population and reducing the costs associated with its beneficiary population. If an ACO is able to reduce the cost of care and satisfy the performance requirements established by the Centers for Medicare and Medicaid Services ("CMS"), the ACO is eligible to receive a portion of the shared savings it generates.⁶

⁵ ACA, § 3022(a)(1)(A).

⁶ ACA, § 3022(a)(1)(B).

Prior to the ACA, some Suppliers and Providers had a substantial amount of experience related to the coordination of care for patients through a patient-centered, integrated delivery system. CMS desired to partner with these Suppliers and Providers in order to promote changes in the delivery of care to coordinated systems that would enhance care integration, promote patient engagement, improve patient outcomes and reduce the cost of expenditures.⁷ Through this process, CMS hoped to learn what it would take for ACOs to most effectively deliver the Triple Aims.⁸ As a result, the Center for Medicare & Medicaid Innovation ("CMMI") was formed within CMS to manage the Pioneer ACO Model, among other programs.⁹ The Pioneer ACO Model was designed to allow CMS to partner with existing integrated systems to test new payment and service delivery models that may have the potential to reduce Medicare expenditures while maintaining or improving the quality of care for beneficiaries.¹⁰

The ACA also established the Medicare Shared Savings Program ("MSSP").¹¹ Early Adopters with experience in the coordination of care were permitted to participate in the MSSP, instead of the Pioneer ACO Model. However, CMS encouraged Suppliers and Providers that were new to coordinated care to pursue a path toward integration through participation in the MSSP via an ACO. To accomplish this, MSSP ACOs had less rigid requirements than their Pioneer ACO counterparts. For example, MSSP ACOs were only required to have 5,000 Medicare beneficiaries assigned to them to participate in the MSSP,¹² whereas Pioneer ACOs were supposed to have 15,000 assigned beneficiaries.¹³ In addition, the MSSP created a participation track for Suppliers and Providers, new to coordinated care, wherein these ACOs would be allowed to achieve a shared savings payment as a result of their performance but did not

⁷ "Pioneer Accountable Care Organization (ACO) Model Request For Application." Centers for Medicare and Medicaid Services.
<http://innovation.cms.gov/Files/x/Pioneer-ACO-Model-Request-For-Applications-document.pdf>.

⁸ *Id.*

⁹ Established under Section 1115A of the Social Security Act, as added by Section 3021 of the ACA.

¹⁰ *Id.*

¹¹ ACA, § 3022.

¹² ACA, § 3022(b)(2)(D).

¹³ "Pioneer Accountable Care Organization Model: General Fact Sheet" (Pioneer FAQ), Centers for Medicare and Medicaid Services.
<http://innovation.cms.gov/Files/fact-sheet/Pioneer-ACO-General-Fact-Sheet.pdf>.

carry the risk of having to refund costs in excess of predetermined benchmarks.¹⁴ Although the MSSP did offer a risk-based model for potential ACOs, the levels of potential risk and savings were lower than comparable risk-based models under the Pioneer ACO Model. Finally, MSSP ACOs were allowed to continue with a fee-for-service reimbursement methodology, whereas Pioneer ACOs would eventually be encouraged to transition away from fee-for-service payments to population-based payments.¹⁵

A third ACO model also emerged from health care reform. CMMI developed the Advanced Payment ACO Model for certain organizations participating in the MSSP. The Advanced Payment ACO Model was designed to provide support to physician-owned and rural Providers who have less access to capital.¹⁶ Specifically, the model provided these ACOs with start-up resources to build the necessary infrastructure to operate an ACO. Participating ACOs received advance payments that were repaid from future shared savings earned by the ACO.¹⁷ The advanced payments were a combination of fixed and variable payments to help these organizations meet the varied needs of launching an ACO and coordinating care for a patient population.

As Suppliers and Providers began to evaluate ACO opportunities under the framework described above, unique trends and baseline commonalities emerged. Not surprisingly, the shared and divergent experiences of organizations that evaluated and pursued ACOs in the early stages of health care reform offer valuable insight for those Suppliers and Providers considering forming an ACO today. As noted above, Early Adopters each saw opportunities under the ACA through a lens that reflected their own, unique organizations. The decision to create an ACO and pursue one of the available programs and risk models was no different. However, different categories of organizations seemed to have slightly different focal points in their decision-making processes.

Organizations with significant experience in integrated systems already had a firm grasp on their ability to coordinate care. As such, the Pioneer ACO Model and MSSP offered these Suppliers and Providers an opportunity to

¹⁴ See 42 CFR 425.604.

¹⁵ Pioneer FAQ.

¹⁶ "Advanced Payment Accountable Care Organization (ACO) Model: Fact Sheet" (Advanced Payment), Centers for Medicare and Medicaid Services. <http://innovation.cms.gov/Files/fact-sheet/Advanced-Payment-ACO-Model-Fact-Sheet.pdf>.

¹⁷ *Id.*

continue to improve their existing operations and leverage some of their current infrastructure and institutional knowledge to drive additional revenues to their organizations. Although these organizations engaged in a process similar to that outlined above to evaluate their internal capabilities, it seemed as if their focus was more heavily weighted toward evaluating risk. Here, the big risk factors involved the potential participation in a risk-based ACO model and the possibility of incurring shared losses, the number of regional competitors that may also form ACOs, and the potential systemic changes to the ACO program and underlying reimbursement methodologies that could result from the continued evolution of health care reform. Each of these risk factors required Suppliers and Providers to develop a long-term, broad view of their own organizations and the health care industry as a whole. Clearly, this posed a difficult proposition given the environment. Ultimately, if the risk involved was determined to be manageable, many of these organizations ended up relying on the tacit knowledge and experiences in coordinating care to make their final decisions.

The second category of organizations that emerged with respect to ACOs were those where the market conditions were ripe for Suppliers and Providers to consider engaging in the MSSP, but the organization did not have a deep history of delivering coordinated care. Here, risk analysis was incredibly important. However, risk was harder to gauge because these organizations did not have past coordinated care performance data against which to evaluate projected operations. Instead, these Suppliers and Providers would be embarking on new business and delivery models. As such, organizations in this category were often laser focused on their internal capabilities. Specifically, these Suppliers and Providers needed to determine whether they had or could develop the internal capabilities necessary to coordinate and improve care for their beneficiaries, enhance health in their populations, and reduce the growth of their beneficiary expenditures. Often, this analysis also involved evaluating opportunities to build strategic alliances and partnerships to establish the depth of integration needed for success. If Suppliers and Providers could not reach a comfort level with their internal capabilities and network, the MSSP was often deemed not an appropriate opportunity for their organizations.

The third category of Suppliers and Providers consisted of organizations that did not have the financial resources to invest in the infrastructure necessary to effectively operate an ACO. The primary need of most of these organizations was the funds to build the technological resources and acquire the human capital necessary to coordinate care in today's health care environment. Some of these organizations were closer to the first category of Suppliers and Providers in that they had a history of coordinating care for their populations. However, they did so

without today's technological capabilities. Other organizations were closer to the second category of Suppliers and Providers in that they found themselves in local environments where market conditions were ripe for MSSP ACOs, but did not have the experience or internal resources for coordinated care. As such, Suppliers and Providers in this category had similar concerns and obstacles as those in the other categories. However, these organizations also had to evaluate the impact of seeking funding for their ACO initiatives. Some of these Suppliers and Providers pursued government assistance under the Advanced Payment ACO Model. Others sought private funding and/or partnerships to build and acquire the necessary resources. Ultimately, the financial commitments involved in pursuing an ACO played a critical role in the decision-making process of these organizations.

Today, organizations considering participating in the MSSP as an ACO face similar challenges. The experiences of existing ACOs over the last several years can help new entrants evaluate the pros and cons of the MSSP and operation of an ACO. A wealth of data exists on the performance of existing ACOs, and the leaders of these organizations are often willing to talk about their specific experiences in the various ACO programs. However, future ACOs will face new and unique challenges as the landscape of health care reform continues to evolve (more on this below). Suppliers and Providers interested in pursuing ACO initiatives will need to evaluate the opportunities in a way that incorporates the lessons from the past, is uniquely tailored to the characteristics of their organizations and is cognitive of the direction the ACO program is headed under continued health care reform.

4. Health Care Technology

The technology involved in the delivery, management and coordination of care has taken quantum leaps in recent years and continues to evolve faster than the speed of business. If the Triple Aims are the heart of health care reform, technology is the blood pumping through the system and bringing life to health care reform opportunities. Nearly every objective of the ACA is driven or substantially impacted by the use and growth of technology. In short, health care reform and the opportunities arising from it, have been made possible, in large part, by the exponential growth in applicable technologies. Ultimately, health care related technologies have been a mixed blessing for Early Adopters.

For Suppliers and Providers, technology has assisted in their pursuit of the Triple Aims. Through new technologies, health care professionals have instant access to patient information and never-ending resources to help shorten

decision-making cycles. Suppliers and Providers are connected and sharing data throughout the state and across the country by way of the rapidly growing spider web of Health Information Exchanges. Suppliers and Providers are increasingly more connected with their patients through telemedicine resources and able to remotely monitor those most in need via devices and apps. Health portals and the explosion of wellness technologies have enhanced patient engagement to unparalleled levels. Clearly, health care technologies have played a critical role in advancing and improving the delivery of care.

However, as the universe of health care related technologies has grown, so too have the costs and overhead associated with these resources. Small practices have struggled with the expenses associated with Electronic Medical Records ("EMR"). Hospitals and health systems have made significant capital investments to overhaul antiquated systems and deploy new resources. Suppliers and Providers have committed substantial amounts of human capital and time into learning new technologies to leverage their capabilities and avoid mistakes. Although technologies may help Suppliers and Providers deliver more efficient and effective care, thus reducing the overall costs of that care over time, the initial investment in health care technologies can be daunting and prohibitive. Furthermore, the life cycle of technologies keeps getting shorter causing Suppliers and Providers to constantly reassess their needs and make new investments.

Early Adopters in other businesses connected to health care have faced similar pros and cons associated with technological advances. On the one hand, the technological needs of the health care industry have created an exponential number of new businesses opportunities for businesses to service those needs. Some businesses have not only filled the gaps in available resources, but they are also driving the continued growth and evolution of available technologies for the health care industry. Data storage, management and transmission companies are providing the backbone for clinically integrated, network-enabled population health. Health Information Exchanges are pushing through competitive barriers to connect Suppliers and Providers and build pathways for the exchange of data and research. Start-up entrepreneurs and established technology leaders are developing apps and devices for individuals to track, manage and share health related data that give Suppliers and Providers unique, real-time insight and feedback on their patients. As the delivery, management and coordination of care continues to evolve through the use of technology and the law continues to promote the use of technological advances, businesses providing these goods and services will realize new opportunities.

On the other hand, businesses connected to health care have also faced increased restraints and requirements in the delivery of their goods and services to Suppliers and Providers. Many of these challenges have been the result of changes in the use of technology. As Suppliers and Providers have implemented technological advances, many businesses have needed to modify their own product and service offerings, business practices and overall capabilities to keep pace with the changes in the health care industry and to continue to meet their clients' evolving needs. In addition, the regulatory environment has continued to expand, often times having a profound effect on businesses connected to the health care industry. For example, an important component of the health care technology boom has been focused on the accessibility, transmission and management of patient data. While businesses involved with patient data have seen growth in potential business opportunities, they have also had to overcome growing regulatory complexities. Health care reform has led to the expansion of the Health Insurance Portability and Accountability Act ("HIPAA") and the implementation of the Health Information Technology for Economic and Clinical Health Act ("HITECH"). Businesses operating as business associates and subcontractors have been required to invest in infrastructure, develop compliance protocols and processes, engage in training and subject themselves to potentially greater exposure in order to operate in the HIPAA and HITECH environment. Overall, the health care reform initiatives for businesses connected to the health care industry have created potential opportunities for financial gains but have also required significant capital investments, increase flexibility and business dexterity, and potential risk exposure to benefit from these opportunities.

The most significant challenge that has been encountered with health care technologies has been associated with the adoption and implementation of new initiatives. For Suppliers and Providers, the challenge has often been related to budget, demonstration of need, life cycle of the technology and integration issues with existing technology. While most organizations understand the value of first-mover advantage or technological leadership, especially within their communities or region, the question usually remains whether the proposed technological adoption will give their organization a competitive edge and help them meet ACA objectives or will it end up costing the organization resources without realizable gains. For other businesses related to the health care industry, their concerns usually mirror those of Suppliers and Providers with an added layer of complexity. Here, these businesses also need to focus on the likelihood of the technology being adopted by the health care industry and its existing customers and consumers. Businesses must make difficult assessments and choices based on their perception of market and the direction of technological changes.

The challenges faced by Early Adopters related to health care technologies continue to impact Suppliers, Providers and other businesses. The solution to these challenges continues to depend, in large part, on the facts and circumstances related to the organization, specific technology and timing involved. In addition to the assessment process discussed above, successful Early Adopters also embraced change management processes to effectively implement their technological initiatives. The change management process will be discussed in greater detail below. However, it is worth noting here that most successful Early Adopters had a clear plan for implementation, communicated the implementation strategy throughout the organization and obtained support from key stakeholders. Although the change management process is important to every health care reform initiative, it is especially important for those focused around health care technologies. Providers, Suppliers and other businesses contemplating initiatives based on technology should follow a similar path to maximize their likelihood for success.

As one can see, Early Adopters of health care reform initiatives needed to carefully assess the new opportunities that emerged out of the ACA through the lens of their own experiences, capabilities and competitive environments. Although this process did not guarantee success, it did help to mitigate risk, refine strategic plans and prepare for change. Suppliers, Providers and other businesses contemplating ACA opportunities should consider adopting the best practices of successful Early Adopters. These practices will not only help organizations evaluate existing opportunities, but they will also help guide organizations through the shifting regulatory landscape of health care reform.

III. The Shifting Regulatory Landscape

The opportunities that have arisen out of health care reform continue to grow and evolve. Part of this evolution is the result of innovation directed at finding more effective and efficient ways of achieving the objectives of health care reform. The other part of this evolution is the result of the ever-changing regulatory landscape. Health care reform has been a learning experience for everyone involved. As part of that learning experience, the ACA has been subject to numerous modifications and revisions designed to clarify and improve upon the existing framework. However, while some of these changes have created new opportunities or improved existing ones, others have added risk to the opportunities that are already present. It is incredibly important to understand both the upside and downside of the shifting regulatory environment. As such, one of the most critical aspects of engaging in health care reform initiatives is to

develop or acquire the human capital and resources necessary to track changes in the law. Without committed monitoring and on-going compliance, initiatives that began as progressive, first-mover strategies can quickly fall behind competitors, or worse yet, be subject to penalties, fines and corrective action plans implemented by the government.

The opportunities generated by continued health care reform have focused on identifying unnecessary, obsolete and/or excessively burdensome regulations to the business of health care. While some of these changes have been directed at pre-ACA regulations, others have been focused on changing recent rules and requirements that were created under the ACA itself. In either case, some changes in the regulatory environment have helped Suppliers and Providers by removing obstacles that are inconsistent with the objectives of health care reform. Without the prior constraints, organizations have been able to broaden, modify or expand their operations in ways that help them achieve the objectives of the ACA. However, as noted above, in order to take advantage of these changes, organizations need to be aware of the evolving regulatory environment.

Conversely, continued health care reform has also added risk to the opportunities that currently exist. In some cases, the baseline requirements for various ACA programs have been modified. The changes to these requirements can force organizations to quickly alter business practices, redraft strategic plans or even terminate their participation in the initiative. At bottom, these shockwaves can dramatically impact budgets and the bottom line and can put an entire organization at risk. In other cases, continued health care reform has resulted in increased monitoring, reporting and hurdles for those participating in ACA initiatives. While these kinds of changes do not usually have the same kind of impact as the first category, they can increase costs, strain existing human capital and impede the previous speed of operations. In order to gauge potential risks resulting from continued health care reform, an organization must be aware of the changes and understand their impact. As such, monitoring the shifting regulatory landscape can be just as, if not more, important for risk factors as it is for potential opportunities.

Almost every ACA opportunity has been impacted in some way by the shifting regulatory landscape. These changes can be seen at both the federal and state levels. Businesses involved in the Marketplace have seen both increased opportunities and enhanced risks as the program continues to learn and evolve from its early experiences. The requirements, options and structure of corporate wellness programs continue to be adjusted by new regulations and

requirements. Suppliers and Providers have witnessed an evolution in the delivery of care as some states have eliminated their face-to-face contact requirements between health care professionals and patients for services appropriately provided through telemedicine. However, the best example of the potential gains and losses related to the shifting regulatory environment is the recent regulatory changes related to ACOs in the MSSP.

On December 8, 2014, CMS published a proposed rule that represented the largest set of changes to the MSSP and the rules governing ACOs since the implementation of the ACA ("Proposed Rule").¹⁸ In the wake of the Proposed Rule, existing ACOs worked diligently to evaluate its impact on their existing operations and strategies. Some of these organizations also began taking proactive steps based on their experiences and understanding of the MSSP. Suppliers and Providers contemplating forming an ACO took particular interest in the Proposed Rule due to its expected changes to the baseline requirements for ACOs, the application process and the participation models. Because of the scope of the Proposed Rule, many organizations examined the potential changes under the same process discussed above for identifying and evaluating new business opportunities.

On June 9, 2015, the Proposed Rule was finalized by CMS ("Final Rule").¹⁹ There are numerous potential new opportunities and improvements to existing opportunities under the Final Rule. First, the Final Rule offers greater flexibility to encourage participation in the MSSP. For example, the rules related to an ACO's initial beneficiary requirement have been relaxed.²⁰ Prior to the Final Rule, an ACO that failed to meet its 5,000 beneficiary threshold after being admitted into the MSSP was issued a warning letter and placed on a corrective action plan. If the ACO failed to increase its beneficiary population to at least 5,000 by the end of the next performance year, the ACO's participation in the MSSP was terminated. The Final Rule allows the ACO adequate time to complete a corrective action plan, if necessary.²¹ As such, an ACO has time to add the participants it needs to increase its patient population. The Final Rule also gives CMS discretion regarding whether to impose remedial measures or to terminate an ACO for failure to satisfy the minimum beneficiary threshold.²² These changes should be viewed favorably by most potential future participants

¹⁸ 79 Fed Reg 72760-72872 (December 8, 2014).

¹⁹ 80 Fed Reg 32692-32845 (June 9, 2015).

²⁰ 80 Fed Reg 32706-32707.

²¹ *Id.*

²² *Id.*

in the MSSP as they evaluate their internal capabilities and patient populations related to this ACA opportunity.

Second, Track 1 MSSP ACOs (upside potential gains only, no downside risk) have been given the opportunity to renew their participation in the upside only model for a second, three year term.²³ Prior to the Final Rule, MSSP ACOs in the Track 1 model were required to transition to the Track 2 model after their first, three-year contract cycle was completed. The Track 2 model includes both upside and downside risk. Both existing Track 1 ACOs and potential future participants in the MSSP will likely consider this change an important component of their overall participation strategy in the MSSP. Clearly, the elimination of potential downside risk for a second, three-year period could dramatically impact an organization's risk analysis, financial projections and overall expectations.

Third, the Final Rule made some modifications to the way an ACO's performance is benchmarked and provided insight into future regulations on benchmarking.²⁴ An ACO's benchmark is the standard against which its future performance will be evaluated to determine if the ACO has achieved shared savings or incurred shared losses, as applicable. In terms of modifications, the Final Rule developed a new benchmark rebasing methodology that includes equally weighing the ACO's historical benchmark years, and accounting for savings generated in the ACO's first agreement period, when setting the ACO's benchmark for its second agreement period.²⁵ Savings generated by the ACO in the first agreement period will only be counted toward the second agreement period if the ACO generated net savings across the three performance years under its first agreement period.²⁶ Taken together, accounting for an ACO's shared savings during its prior agreement period and equally weighing the ACO's benchmark years may gradually lower the benchmarks for ACOs that perform well in the MSSP.

In addition to these changes, CMS is contemplating various alternative methodologies for establishing, updating and resetting ACO financial benchmarks that will be addressed in future regulations later this year.²⁷ For new ACOs, CMS will determine whether it should weigh all three benchmark years equally or follow the current methodology of weighing benchmark year 1 at 10%,

²³ 80 Fed Reg 32763-32764.

²⁴ 80 Fed Reg 32785-32796.

²⁵ 80 Fed Reg 32795.

²⁶ 80 Fed Reg 32789.

²⁷ 80 Fed Reg 32795.

benchmark year 2 at 30% and benchmark year 3 at 60%.²⁸ For ACOs entering their second or subsequent agreement periods, CMS is considering rebasing the ACO's benchmark based on a blend of regionally-trended data and the ACO's recent historic expenditures.²⁹ In the Final Rule, CMS signaled that it will likely put a stronger emphasis on the regionally-trended component.³⁰ This process would likely make ACO benchmarks gradually more independent of the ACO's past performance and more dependent on the ACO's success relative to its local market. The way ACOs are benchmarked in the MSSP is the primary driver of the financial component of this health care reform opportunity. The proposed changes in the Final Rule may be met with mixed results depending on the specific facts and circumstances related to a given ACO. However, many ACOs may welcome the opportunity to be benchmarked against regional data given the potential similarities in patient populations and health conditions.

The Final Rule also includes changes and potential future modifications that may increase the risk of participation in the MSSP. First, as discussed above, the proposed modifications to the way ACOs are benchmarked in the MSSP could be a potential risk for some ACOs. This is especially true for ones with less experience in coordinated care, fewer resources and/or incredibly unique patient populations compared to their regional competitors. These ACOs may prefer that benchmarking continue based on national data to smooth out high performers and unique patient populations in their regions.

Second, as part of an organization's participation in the MSSP, the organization must agree that it will be subject to all statutory and most regulatory changes that become effective during the term of its agreement.³¹ Prior to the Final Rule, an ACO was not subject to regulatory changes related to:

1. Eligibility requirements concerning the structure and governance of the ACO;
2. Calculation of the sharing rate; and
3. Beneficiary assignment.³²

Clearly, this requirement, standing alone, creates risk for ACOs as it allows for a wide spectrum of changes in the MSSP to be automatically incorporated into the

²⁸ 80 Fed Reg 32796.

²⁹ *Id.*

³⁰ *Id.*

³¹ 42 CFR § 425.212(a).

³² 79 Fed Reg 72782.

ACO's agreement with CMS. However, the excluded regulatory changes provided ACOs with some stability regarding a few of the most important aspects of the MSSP related to achieving shared savings.

Under the Final Rule, ACOs are now subject to any regulatory changes related to beneficiary assignments that become effective during an agreement period.³³ However, any final policies that affect beneficiary assignment will not apply until the start of the subsequent performance year.³⁴ In addition, ACOs are subject to regulatory changes regarding ACO structure and governance, and the calculation of the sharing rate, during an agreement period if CMS is mandated by statute to implement such changes by regulation in the middle of a performance year.³⁵ Both existing and future ACOs may perceive these changes as substantial risks. The beneficiaries assigned to an ACO ultimately dictate the benchmarks against which the ACO will be judged in terms of shared savings. The patient population, organizational governance and calculation of the sharing rate also influence the focus of various process improvement initiatives, capital expenditures, recruitment efforts and the overall success of the initiative. The uncertainty involved with changes to the regulatory framework may be too large of a risk for some Suppliers and Providers given their evaluation of the ACA opportunity.

Third, the Final Rule does not offer clarity to the future of the quality performance standards for MSSP ACOs. An ACO is subject to regulatory changes related to the quality performance standard.³⁶ Quality performance standards are measures by which CMS assesses the quality of care furnished by the ACO.³⁷ Ultimately, these standards must be met by an ACO to achieve shared savings. CMS is required to seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures or both for purposes of assessing such quality of care.³⁸ Accordingly, changes to the quality performance standards would likely impact the ability of an ACO to achieve shared savings. The lack of guidance from CMS in the Final Rule regarding the quality performance standards may be perceived by some Suppliers and Providers as a risk due to the uncertainty surrounding the future regulatory environment.

³³ 80 Fed Reg 32732.

³⁴ *Id.*

³⁵ *Id.*

³⁶ 76 Fed. Reg. 67838.

³⁷ 42 CFR § 425.500(a).

³⁸ 76 Fed. Reg. 67897.

As the Final Rule exhibits, the ever-changing regulatory environment of health care reform can create new opportunities or improve current initiatives within existing ACA programs. Conversely, regulatory changes can add specific risks to health care reform opportunities or increase the general level of uncertainty related to an ACA program. The Final Rule also demonstrates the need for organizations engaged in health care reform opportunities to continually monitor the regulatory environment and develop strategic plans that allow for flexibility and adaptability to the shifting landscape. With health care reform initiatives, it is not enough to simply engage in an initial evaluation of the potential opportunity. Organizations should continually identify new regulations related to their initiatives and evaluate the potential impact of proposed and finalized rules. Otherwise, the value of the opportunity could change before the organization has time to determine and implement an appropriate course of action.

IV. Complex Transactions Related to ACA Opportunities and Ventures

Once a Supplier, Provider or other business has identified and evaluated a new business opportunity and determined that the initiative is in line with the goals, capabilities and resources of the organization, the next step toward implementation often involves a series of transactions with various parties. While the relationships under ACA opportunities resembled some common health care transactions, the scope, purpose and statutory requirements underlying these agreements were as new as the legislation that mandated their existence. As a result, transactions in the early stages of the ACA involved agreements that had never been drafted before, as well as relationships that may not have previously existed.

In working with Early Adopters, I primarily encountered four types of contracts related to health care reform initiatives: government contracts, joint venture/partnership agreements, contracts with customers and consumers, and vendor contracts. Government contracting was one of the more challenging aspects of ACA transactions. Often times, Early Adopters wanted to engage in discussions with the government as soon as a potential opportunity had been identified and evaluated. This was difficult for two main reasons. First, the ACA opportunity was not always finalized. Some Early Adopters wanted to obtain a first-mover advantage in the market, and thus, wanted to start the process based on proposed regulations. In these instances, the government did not have a final framework related to the potential opportunity, much less a contract to go with it. Second, even when an opportunity became official, the government was not

always ready to go. The government usually needed time to put the regulations into motion. Once the government was prepared to allow organizations to pursue an opportunity, the process usually involved an application and lengthy review. Finally, when the government was ready to proceed with an engagement related to a health care reform initiative, the government's contract left little to no room for negotiation and customization. This was particularly difficult for organizations that desired to pursue an ACA opportunity in a way that modified the standard framework to meet the unique needs and circumstances of its customers and consumers. In these situations, organizations had to invest additional time in educating the government about the potential modification and how the changes were consistent with the objectives of the specific program and overall ACA. Ultimately, government contracting in the early days of the ACA required a significant amount of patience and persistence.

Joint venture and partnership agreements related to health care reform initiatives most closely resembled non-ACA related health care transactions. Although the specific terms were often unique, the underlying framework of these transactions was similar to other health care related ventures and partnerships. Here, the biggest challenge was ensuring that the partners had a shared understanding of the potential ACA opportunity, a common plan for its implementation and a mutual commitment to the pursuit of the partnership's ACA goals and objectives. As with any venture, the process involved transparency, communication and compromise. However, what made these transactions unique was that, often times, both partners were entering uncharted waters. As such, as one partner's understanding of the ACA and the opportunity evolved, so too did the requested parameters of the venture. If a partnership built around a health care reform initiative was to be successful, the parties eventually needed to move beyond negotiating the terms of their relationship and start focusing on the requirements and details related to the opportunity itself. Sometimes, this was easier said than done, especially in light of the shifting regulatory landscape.

Transactions with customers and consumers were some of the most important agreements related to health care reform initiatives. It was through these agreements that ACA opportunities came to life as the objectives of the ACA were delivered to consumers. As such, customer and consumer contracts required a considerable amount of care and consideration. When preparing these contracts, it was important to clearly outline the obligations of the parties. Many customers and consumers had a limited understanding of the regulatory framework related to the organization's health care initiative. Accordingly, the agreement needed to provide enough information for the customer or consumer to make an informed decision. In addition, it was incredibly important for an

organization's contract to disclaim risks caused by factors outside of its control. To accomplish this, an organization needed to explore the various ways its initiative could be impacted by changes in the law, decisions and actions by CMS, access to information and data, or other relevant factors. Clearly, not every risk can be foreseen. However, the risks that were foreseeable needed to be clearly addressed in the agreement. Ultimately, the agreements used with customers and consumers were often prepared from scratch given the unique relationships of the parties and the applicable regulatory framework.

Vendor contracting under ACA initiatives was similar to that of other health care transactions. However, the biggest obstacle to these transactions was getting the vendor to understand its role in the execution and implementation of the organization's ACA initiative. Many businesses that worked with health care entities in the early stages of the ACA did not understand the full scope of the ACA or the specific role an organization's initiative played within the regulatory framework. If the vendor was going to successfully help the organization accomplish its goals and objectives, the organization had to educate the vendor as part of the transaction process. The education and training process allowed organizations to build strong relationships with vendors to avoid errors, turnover and non-compliance with the applicable objectives and regulations of the ACA.

To successfully navigate these transactions, organizations needed to be creative, flexible, transparent and adaptable, while at the same time stay within the confines of the ACA and the specific requirements of the applicable initiative. Many of these transactions involved creating and documenting entirely new relationships. As new business opportunities continued to emerge from health care reform, the transactions related to these opportunities will require organizations to engage in a similar array of transactions. Thankfully, some of the agreements related to health care reform initiatives have become common place. However, it is likely that organizations will also encounter new relationships that will require innovative ideas to solidify the applicable transactions. The transactions of the Early Adopters should serve as a springboard for future health care reform initiatives.

V. The Change Process

The final stage in the implementation of a health care reform initiative is its execution. Based on the foregoing steps, one may think that execution is the easy part. Unfortunately, that is rarely the case, mainly because of the reality that change is difficult. The changes involved in most health care reform initiatives

were pretty substantial, even for the most progressive Early Adopters. The implementation of an ACA opportunity can involve modifications to every aspect of an organization, its operations, its people and the provision of care. When faced with even a fraction of this upheaval, the path of least resistance is to move forward without adopting and accepting the new set of rules, requirements and regulations. However, without change, Early Adopters would not have been able to take advantage of the opportunities that emerged from the ACA.

The Early Adopters that successfully implemented health care reform initiatives all went through some form of a change process. In fact, aspects of those change processes have been sprinkled through this section of this White Paper. A change process is a deliberate set of events designed to move an organization from its current structure, operations and/or culture to a desired future state. Under the ACA, Early Adopters used change processes to position their organizations to take advantage of the health care reform opportunities. The Early Adopters laid the foundation for the change process by identifying and evaluating potential ACA opportunities. By engaging in this analysis, Early Adopters not only created a sense of urgency in the adoption of ACA programs, but they also established a vision for their organizations after examining the ACA through the lens of their own experiences, capabilities and competitive environments. Ultimately, the driving force behind the change initiated by each Early Adopter was result of a unique analysis and perspective.

An important part of any change process is obtaining buy-in from the key stakeholders of an organization. Support for the initiative should start during the identification and evaluation of an opportunity. It then gains momentum as the organization engages in transactions to build the structure around an initiative and reaches its boiling point as the organization prepares to execute its initiative. Successful Early Adopters were able to continue to build momentum as they prepared to launch their ACA initiatives. In addition, these same Early Adopters were effective in building the right team to lead the organization. Change leaders were important because they kept the organization on task and focused on the end goals.

As Early Adopters engaged in transactions with the government, strategic partners, and vendors, these organizations removed obstacles and made progress toward implementing their health care reform initiatives. At the same time, these organizations worked to remove and address internal obstacles related to the organizations resources and capabilities. Collectively, these actions poised Early Adopters to be ready to engage with customers and consumers and carry out the Triple Aims of the ACA.

Finally, successful Early Adopters created cultures that fostered and encouraged determination and persistence throughout the change process. This persistence was readily observable in Early Adopters that not only sought out business opportunities based on proposed regulations but also saw those opportunities through. In addition, Early Adopters that continue to navigate the shifting regulatory landscape have embedded the change process into their cultures to ensure that their initial ACA successes will continue into the future. It is the shift in culture that embraces adaptability, flexibility, determination and persistence that has allowed successful Early Adopters to execute their ACA initiatives and continue to explore new opportunities.

VI. Conclusion

The ACA created sweeping reform to the health care system in the United States. Since its inception, Suppliers, Providers and other businesses have been challenged to navigate the complexities related to health care reform. A number of Early Adopters have successfully done so and continue to drive change under health care reform. The lessons learned from their processes and actions serve as a roadmap for other organizations to take on the challenges of health care reform. Not only are these lessons relevant to the current opportunities that exist under the ACA, but they are also valuable for entirely new opportunities that may emerge as health care reform continues to evolve and grow.

** Note: this is an overview article intended to provide general guidance. This is not a comprehensive overview of all laws related to the laws reviewed herein.*

The views in this article are the personal views and experiences of the author and do not necessarily reflect the views of the State Bar of Michigan, or of the State Bar of Michigan Health Care Law Section.

**Fraud and Abuse Waivers and Guidance in the ACO World:
What They Are and How to Use Them**

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Table of Contents

- I. Introduction
- II. Accountable Care Organizations
- III. CMS and OIG MSSP ACO Waivers
 - 1. ACO Pre-Participation Waiver
 - 2. ACO Participation Waiver
 - 3. Shared Savings Distribution Waiver
 - 4. The Physician Self-Referral Law ("Stark") Waiver
 - 5. Waiver for Patient Incentives
 - 6. Application and Observations from the Market Place Regarding ACO Success and Use of Waivers
 - 7. A Word of Caution
- IV. IRS Guidance for Tax Exempt Organizations Participation in ACOs
 - 1. ACO Structure
 - 2. Shared Savings Activities
 - 3. Commercial Shared Savings Activities
 - 4. Avoiding Private Inurement or Impermissible Private Benefits
- V. FTC/DOJ Joint Policy Statement on Antitrust Policy Enforcement Regarding ACOs
 - 1. Overview of Antitrust Law
 - 2. The FTC/DOJ ACO Final Policy Statement
 - 3. Voluntary Review
- VI. Conclusion

Fraud and Abuse Waivers and Guidance in the ACO World:

What They Are and How to Use Them

By Steve Bender

I. Introduction

In instituting the Patient Protection and Affordable Care Act,¹ ("ACA") the federal government sought to reform the manner by which health care had been delivered and paid for in the United States over the last half century. This landmark undertaking proposes to shift the underlying reimbursement incentives for providers away from volume-based care to value-based care. This essentially means that over the next few years providers will no longer be rewarded for the number of services they provide to a particular patient and will eventually be rewarded for improving the experience of care, improving the health of populations, and reducing per capita costs of health care.

However, to achieve these significant reforms to the reimbursement model, modifications needed to be made to our existing regulations and new incentives needed to be developed to encourage the nation's providers to pursue the goals and objectives of the ACA. In enacting this legislation, the federal government anticipated that the previously established fraud and abuse laws posed a significant regulatory barrier to widespread implementation of the ACA's value/quality initiative. In order to overcome these barriers, they needed to clear the path for change by issuing specific waivers to these regulations and providing guidance relating to tax and antitrust considerations. By minimizing the regulatory burdens it is now easier for the health care sector to fully embrace key aspects of the ACA, including the participation in Accountable Care Organizations ("ACOs").

However, the government did not stop with the waivers and guidance, they also have continued to refine and adjust the regulations under which ACOs must operate in an effort to make participation more desirable. Evidence of these refinements can be seen in CMS' June 4, 2015 release of the Final Rule² (discussed below) and the June 25, 2015 announcement of the ACO Investment Model,³ which uses pre-paid shared savings as a means to encourage the formation of new ACOs in rural and underserved areas.

¹ 42 U.S.C. 18001 et seq.

² 80 Fed. Reg. 32692.

³ <http://innovation.cms.gov/initiatives/ACO-Investment-Model/>

Unfortunately, these regulatory accommodations and incentives have not yet resulted in the proliferation of ACOs hoped for by CMS⁴. The cause of this disinterest may stem from the cloud of controversy and uncertainty due to the highly politicized nature of the ACA or the Supreme Court's review of *King v Burwell*, which was decided in favorable support of the Act on June 25, 2015.⁵ Given the decision in *King v Burwell* we can only speculate that the number of applications to the Medicare Shared Savings Program will likely begin to increase.

This article provides an overview of those regulatory burdens eased by the government through the issuance of waivers and guidance which can make participation in ACOs easier. In particular, the article discusses waivers and other guidance by the Department of Health and Human Services' Office of the Inspector General ("OIG"); the Federal Trade Commission ("FTC") Antitrust Division of the Department of Justice ("DOJ"); and the Internal Revenue Services ("IRS") ACO guidance for Tax-Exempt Organizations.

II. Accountable Care Organizations

A hallmark of the ACA movement from volume-based health care to value-based health care is the Accountable Care Organization.

An ACO is a health care organization characterized by a payment and care delivery model that seeks to tie provider reimbursements to quality metrics and reductions in the total cost of care for an assigned population of patients. A group of coordinated health care providers forms an ACO, which then provides care to a group of patients. The ACO may use a range of payment models (e.g., capitation, fee-for-service with asymmetric or symmetric shared savings, etc.). The ACO is accountable to the patients and the third-party payer for the quality, appropriateness and efficiency of the health care provided. According to the Centers for Medicare and Medicaid Services ("CMS"), an ACO is "an organization of health care providers that agrees to be accountable for the quality, cost, and overall care of Medicare beneficiaries who are enrolled in the traditional fee-for-service program who are assigned to it."⁶

⁴ <http://healthaffairs.org/blog/2015/01/22/early-evidence-on-medicare-acos-and-next-steps-for-the-medicare-aco-program/>

⁵ *King v Burwell*, *Secretary of Health & Human Servs.* (No. 14-114).

⁶ "Medicare "Accountable Care Organizations" Shared Savings Program—New Section 1899 of Title XVIII, Preliminary Questions & Answers".

Initially, the ACA provided Medicare Shared Savings Program ("MSSP") enrollees with two reimbursement models, which are referred to as Track 1 and Track 2. Under Track 1, shared savings (which are essentially a bonus payment) are calculated for each performance year and the ACO is not held accountable for losses due to the quality of care it provides. It is essentially an "upside only" model with no downside risk to the ACO. Track 2, on the other hand, is for more experienced ACOs that are ready to share in losses in return for the opportunity for a higher share of savings. Under this model, the ACO will be eligible for a higher sharing rate, with a higher performance payment limit, than is available under the one-sided model.

On June 4, 2015 CMS released the Final Rule which provides for significant updates to the MSSP and introduces a third track (Track 3) of participation.⁷ Track 3 offers participants an even greater share of savings in exchange for greater shared losses.⁸

III. CMS and OIG MSSP ACO Waivers

On November 2, 2011, CMS and OIG issued the Final ACO Waiver Rules as an interim final rule (with comment period).⁹ The ACO Waiver Rules are specifically designed to preclude enforcement of the federal Anti-Kickback Statute,¹⁰ the physician self-referral law (commonly referred to as the Stark Law),¹¹ the gainsharing provisions of the Civil Monetary Penalty law (the Gainsharing CMP),¹² and the beneficiary inducement provisions of the Civil

⁷ 80 Fed. Reg. 32692.

⁸ The ACA has been revised and modified four times since its promulgation, which illustrates the federal government's commitment to tweak it as appropriate to ensure its success. In each instance CMS's revisions have been designed to address the wants and needs of the participants in an effort to strike a balance between fairness and operational beneficence. The "Waiver Rules" at issue in this article are one of the most striking examples of the U.S. Department of Health and Human Services' willingness to address the health care sector's needs as it pertains to participating in the change envisioned by the ACA."76 Fed. Reg. 67992.

⁹ *Id.*

¹⁰ 42 U.S.C. § 1320a-7b(b).

¹¹ 42 U.S.C. § 1395 nn.

¹² 42 U.S.C. § 1320a-7a(b)(1) and (2).

Monetary Penalties law (the "Beneficiary Inducement Law")¹³ (collectively, the Fraud & Abuse Laws).

CMS and OIG issued the following ACO Waivers:

- ACO Pre-Participation Waiver;
- ACO Participation Waiver;
- Shared Savings Distribution Waiver;
- Compliance with Stark Law Waiver; and
- Patient Incentive Waiver.

The Waivers apply to ACOs and Pioneer ACOs (collectively "ACOs") seeking to participate in or already enrolled in the MSSP. *The Waivers do not apply to commercial ACOs or any other clinically integrated arrangement that is not an MSSP ACO.* However, CMS did note in the Interim Final Rule that "we are not providing a specific waiver for private payor arrangements at this time, we believe avenues exist to provide flexibility for ACOs participating in commercial plans." ¹⁴ CMS invited comments on the approach to shared savings arrangements with commercial plans, but, thus far, has not yet published further guidance on this issue. From a practical perspective, it is more likely than not that an ACO that both participates in the MSSP and a commercial shared savings plan would have a much stronger argument that the waivers are applicable to both arrangements than an exclusively commercial ACO would if their shared savings distribution model did not meet a specific fraud and abuse Stark exception or Anti-Kickback safe harbor.

Finally, the Waivers are self-implementing, which means that there is no filing requirement or application process to follow. The proposed arrangement need only meet requirements of one of the Waiver Rules in order to be protected from regulatory enforcement.

¹³ These provisions prohibit the offering of inducements to Medicare or Medicaid Beneficiaries and are found at 42 U.S.C. § 1320a-7a(a)(5).

¹⁴ 76 Fed. Reg. 68006.

1. ACO Pre-Participation Waiver¹⁵

The ACO Pre-Participation Waiver protects ACOs (as well as their participants, providers/suppliers, and all of the parties to the arrangement) as they are in the process of forming and before they have been accepted into the MSSP. Specifically, as an ACO is being developed and services, facilities or goods are provided by the ACO (or the soon to be formed ACO), which could include donations or subsidies provided prior to being accepted into the MSSP.¹⁶ In order to meet the Pre-Participation Waiver, these donations or subsidies are protected from fraud and abuse enforcement if the below requirements are **all** met.

- A. Generally speaking, the start-up activities must be undertaken by the parties acting with the *good-faith intent* to develop an ACO and to submit an application to participate in the MSSP in a particular year (the "Target Year");
- B. The parties must take *diligent steps* to develop an MSSP ACO during the Target Year;
- C. The ACO's governing body must make a *bona fide determination* that the arrangement is reasonably related to the purposes of the MSSP;¹⁷ and
- D. Written documentation of the arrangement (which is retained by the ACO for at least ten years), the governing body's determination, and the description of the *diligent steps* taken to develop the ACO must be contemporaneously created; and

¹⁵ The parties to the arrangement may not include drug and device manufacturers, distributors, durable medical equipment suppliers or home health suppliers. See 76 Fed. Reg. 68000.

¹⁶ While CMS and the OIG attempted to provide a rather lengthy list of examples of certain activities that might be covered by the Pre-Participation Waiver, they did ultimately acknowledge that they did recognize "it is impossible to create an exhaustive list of *bona fide* start-up arrangements." 76 Fed. Reg. 68003.

¹⁷ Purposes of the MSSP mean the following aims: (i) promoting accountability for the quality, cost, and overall management for a Medicare population; (ii) managing and coordinating care for Medicare fee-for-service beneficiaries through an ACO; and (iii) encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients. 76 Fed. Reg. 68002.

- E. Documentation that describes the arrangement, but does not include specific financial or economic terms, must be *publicly disclosed* (typically a public website will suffice).

The Pre-Participation Waiver may only be used one time and ends: (i) on the start date of the agreement when the ACO submits an application during the Target Year; (ii) on the date of the denial notice; or (iii) for ACOs that fail to apply to the MSSP, on the date their MSSP application was due (ACO's that fail to submit an application may apply for an extension).

2. ACO Participation Waiver

The requirements of the ACO Participation Waiver are very similar to those of the Pre-Participation Waiver, except that the Participation Waiver covers arrangements that have applied and been accepted in to the MSSP. Specifically, it protects arrangements involving an ACO (their participants, provider/suppliers, and all of the parties to the arrangement) which can avoid fraud and abuse enforcement if **all** of the below requirements are met:

- A. The ACO has entered into a participation agreement and remains in *good standing* under its participation agreement in the MSSP;
- B. The ACO *meets the governance, leadership and management requirements* (notably at least 75% control of the ACO must be held by ACO participants);¹⁸
- C. The ACO's governing body has a *bona fide determination* that the arrangement is reasonably related to the purposes of the MSSP;¹⁹
- D. There is contemporaneously created written documentation of the arrangement (which is retained by the ACO for at least ten years), the governing body's determination, and the description of the *diligent steps* taken to develop the ACO; and
- E. There is documentation that is *publicly disclosed* (typically, a public website will suffice) that describes the arrangement but does not include specific financial or economic terms.²⁰

¹⁸ 42 C.F.R. § 425.106, 425.108.

¹⁹ See footnote 17.

²⁰ 76 Fed. Reg. 68001.

For arrangements that meet these conditions, the waiver period starts on the effective date of the participation agreement and ends six months following expiration or voluntary termination of the participation agreement.²¹

3. Shared Savings Distribution Waiver

The Shared Savings Distribution Waiver prevents ACOs from incurring fraud and abuse liability (specifically, pursuant to Stark, Anti-Kickback, and the Gainsharing CMP) relative to any shared saving distributions by an ACO where the following requirements are met:

- A. The ACO has entered into a participation agreement and remains in *good standing* under its participation agreement in the MSSP;
- B. The shared savings are earned by the ACO pursuant to the Shared Savings Program;
- C. The shared savings are earned during the term of the participation agreement (the distributions can occur after the expiration or earlier termination of the participation agreement); and
- D. The shared savings are:
 - i. distributed among ACO, including their participants, providers/suppliers, and all of the parties to the arrangement); or
 - ii. used for activities that are *reasonably related to the purpose of the MSSP*.²²

When evaluating the appropriateness and applicability of the Shared Savings Distribution Waiver, ACOs must keep in mind that: (i) this Waiver does not protect MSSP distributions made to referring physicians who are not participants of the ACO unless referring physicians are being compensated for activities that are reasonably related to the purposes of the MSSP,²³ and (ii) this Waiver does not prevent liability under the Gainsharing CMP if the shared

²¹ However, if CMS terminates the participation agreement the waiver period ends upon the date of termination.

²² See footnote 17.

²³ See footnote 17.

savings are made directly or indirectly from a hospital to a physician to reduce or limit medically necessary care.²⁴

4. The Physician Self-Referral Law ("Stark") Waiver

The Gainsharing CMP and the federal Anti-Kickback Statute are waived with respect to any financial relationship between or among the ACO, its ACO participants, and its ACO providers/suppliers that implicate the Physician Self-Referral Law, provided **all** of the following conditions are met:

- A. The ACO has entered into a participation agreement and remains in *good standing* under its participation agreement in the MSSP;
- B. The financial relationship is *reasonably related to the purpose of the MSSP*; and²⁵
- C. The financial relationship fully complies with an exception under Stark.²⁶

For arrangements that meet all of the preceding conditions, the waiver period will start on the effective date of the participation agreement and will end on the earlier of the expiration of the of the participation agreement, including any renewals thereof, or the date on which the participation agreement is terminated.

5. Waiver for Patient Incentives

This waiver prevents enforcement under the Anti-Kickback Statute and Beneficiary Inducement Law with respect to items or services provided by the ACO, its participants, providers/suppliers to Medicare beneficiaries, which are free or below fair market value, provided that **all** of the following requirements are met:

- A. The ACO has entered into a participation agreement and remains in *good standing* under its participation agreement in the MSSP;
- B. There is a reasonable connection between the item or service and the medical care of the beneficiary;
- C. The items or services are in-kind (*i.e.*, the ACO may not provide cash or cash equivalent items like gift cards, or

²⁴ 76 Fed. Reg. 68001.

²⁵ See footnote 17.

²⁶ 76 Fed. Reg. 68001.

- waiving of co-payments or deductibles, etc. to Medicare beneficiaries); and
- D. The items or services meet either of the following clinical goals:
- i. They are preventative care items or services; or
 - ii. They advance at least one of the following goals:
 - a. Adherence to a treatment regime;
 - b. Adherence to a drug regime;
 - c. Adherence to a follow-up care plan; or
 - d. Management of a chronic disease or condition.²⁷

For arrangements that meet all of the preceding conditions, this waiver period starts on the start date of the participation agreement and ends on the earlier of the expiration of the term of the participation agreement, including any renewals thereof, or the date on which the participation agreement is terminated, provided that a beneficiary may keep items received before the participation agreement expired or terminated, and receive the remainder of any service initiated before the participation agreement expired or was terminated.

6. Application and Observations from the Market Place Regarding ACO Success and Use of Waivers

There are a variety of examples of goods and services that could be provided and fit within the purview of these waivers. Entities interested in developing MSSP ACOs should feel comfortable incurring costs in the development and operation of an ACO for the benefit of its private participating physicians. Examples of this include the legal and consulting costs associated with startup, implementing and providing the participating physicians with an electronic health record system and/or subsidizing the personnel necessary to function as an integrated organization. Interested participants should not feel that providing such goods, services and benefits is unlawful, as the clear intent in developing the Waiver Rules was to remove the regulatory barriers that potentially limit participation or interest in the MSSP.

However, it does not appear that many ACOs have availed themselves of the opportunity to enter into financial arrangements with their participating providers that previously would have otherwise been prohibited. Anecdotally, it

²⁷ *Id.*

appears that the ACOs which have used Waivers have done so for electronic health records donations which would not have otherwise met the applicable regulatory requirements under Stark or the Anti-Kickback Statute. However, Waiver authority has not been widely utilized to create enhanced shared savings programs, telemedicine programs, designation of preferred ancillary providers, and payment for health and disease management programs through the use of cost free personnel dedicated to assist the participating physicians with these programs, just to name a few types of financial arrangements that are possible through the use of Waivers.

The foregoing may explain the reason why, as of March 2015, only 15 Michigan based MSSP ACOs were registered with CMS. ACO success in Michigan has been mixed; some ACOs have boasted of achieving significant savings, while others have struggled.²⁸ A review of the performance data shows that only a few of the original Michigan MSSP ACOs earned shared savings in their initial year of participation, though the rate of shared savings has increased over time.²⁹ These Michigan ACOs have all opted for Track 1 with limited success initially in generating any shared savings.

Nationally, it is worth noting that 46% of all MSSP ACOs did not reduce spending relative to their predetermined benchmark threshold. This, at least initially, is a sign of failure of the ACO model as it currently exists given that one of the over-arching goals of the ACA was to provide incentives within the health care sector to encourage more cost effective care.

Reportedly, some of the lost revenue for many ACOs in Michigan (and nationally) appears to be the result of patients choosing to treat with non-ACO participating physicians. When this occurs, it becomes very difficult for the ACO participating physicians to assist in coordinating patient care or, in many instances, even receive information about the patient. Worse, a non-ACO participating physician, who is still reaping the rewards of volume-based care, would get the benefit of providing additional services to an ACO patient under those circumstances, possibly at a higher cost, and would cause the ACO to be penalized by eroded potential shared savings.

This problem of patients seeking care through non-ACO entities is one that potentially could be addressed through the use of one or more Waivers.

²⁸ Craine's Detroit Business February 9, 2015.

²⁹ See CMS, MSSP ACO Performance Year 1 Results
<https://data.cms.gov/ACO/Medicare-Shared-Savings-Program-Accountable-Care-O/yuq5-65xt>.

Specifically, strategic use of the Patient Incentive Waiver would allow the ACO to provide its assigned patients with items or services that are associated with preventative care or help manage a chronic condition.³⁰ Examples of this may include massage therapy coupons, discounts for patients with low back pain, or foot therapy for diabetic patients. Such services, which are fully allowed under the Waiver authority, might enable ACO personnel to remain in contact with patients, ensure follow-up care, ensure that prescribed protocols are followed, and promote the kind of patient loyalty that would result in patients not leaving their ACOs to seek care outside of it.

In sum, better use of Waivers could be the key to increased ACO success, as in the alluded example of patient retention.

7. A Word of Caution

The foregoing should not be considered a clarion call for aggressive utilization of the available Waiver Rules, but rather a call for thoughtful and responsible utilization of them while they remain available. Note that the Department of Health and Human Services has acknowledged that the participation waivers may be revised *or restricted* in the future. Specifically, the Interim Final Rule (“IFC”) provided:

“We plan to narrow the waivers established in this IFC unless the Secretary determines that the information gathered through monitoring or other means suggests that such waivers have not

³⁰Beneficiaries will be assigned to an ACO, in a two-step process, if they receive at least one primary care service from a physician within the ACO:

1) *The first step assigns a beneficiary to an ACO if the beneficiary receives the plurality of his or her primary care services from primary care physicians within the ACO. Primary care physicians are defined as those with one of four specialty designations: internal medicine, general practice, family practice, and geriatric medicine or for services furnished in a federally qualified health center (FQHC) or rural health clinic (RHC), a physician included in the attestation provided by the ACO as part of its application.*

2) *The second step only considers beneficiaries who have not had a primary care service furnished by any primary care physician either inside or outside the ACO. Under this second step, a beneficiary is assigned to an ACO if the beneficiary receives a plurality of his or her primary care services from specialist physicians and certain non-physician practitioners (nurse practitioners, clinical nurse specialists, and physician assistants) within the ACO.*

had the unintended effect of shielding abusive arrangements. In particular, if we find that undesirable effects (for example, aberrant patterns of utilization) have occurred because of the waivers, we will revise this IFC to address those problems by narrowing the waivers.”³¹

Also, and as noted above, the Waivers do not apply to individual commercial ACOs or any other clinically integrated arrangement that is not participating in the MSSP. However difficult it may be for the government to justify enforcement against a fully financially and clinically integrated network that is not an MSSP ACO, the reality is that commercial networks that do not participate in the MSSP, at this time, must abide by the Fraud & Abuse rules without the benefit of the Waivers.

IV. IRS Guidance for Tax Exempt Organizations Participation in ACOs

Like CMS and the OIG, the Internal Revenue Service ("IRS") has issued rules that facilitate MSSP ACO formation.

Since the enactment of the Patient Protection and Affordable Care Act of 2010 and the final ACO regulations on November 2, 2011, the IRS has published a Notice (IRS Notice 2011-20 [April 18, 2011]) ("Notice") and then later a Fact Sheet (FS-2011-11 [October 20, 2011]), which generally confirmed the principles articulated in the Notice and relaxed some of the IRS's earlier positions on MSSP and ACOs.

Below is a high level overview of some of the information contained in the Notice and the Fact Sheet that may be helpful when evaluating MSSP ACO business collaborations with nonprofit entities.

1. ACO Structure

An ACO does have to be a separate legal entity from its participants, but it does not have to be structured as a particular type of legal entity.³² Because of this variability, the tax consequences will also differ depending upon the type of legal entity chosen. This is illustrated in the Fact Sheet which provides the following:

³¹ 76 Fed. Reg. 68008 (November 2, 2011)

³² FS-2011-11 at Q3.

- Corporations will be treated as separate taxable entities;
- A partnership's activities are generally attributed to its partners;
- A limited liability company can elect to be treated either as a corporation, a partnership, or a disregarded.³³

In addition to these structures, an ACO may also be a 501(c)(3) tax-exempt organization if it is able to qualify as a charitable entity.³⁴

Additionally, a charitable organization (such as a nonprofit hospital) can also participate in an ACO with private parties (such as individual physicians or groups of physicians), but must ensure that the nonprofit hospital continues to meet its obligations as a tax exempt organization in order to retain its status as a charitable institution. Provided that the nonprofit entity continues to meet these tax requirements, it may avoid claims of private inurement or impermissible private benefit (discussed below) depending upon the facts and circumstances.³⁵

2. Shared Savings Activities

Generally speaking, the shared savings payments attributable to tax-exempt entities will not be subject to unrelated business income tax; provided that, the shared savings are derived from activities that are substantially related to the tax-exempt organizations charitable purpose.³⁶ Thus, if a nonprofit and other for profit entities form a joint ACO as a limited liability company for the purpose of participating in the MSSP, the shared savings payments received by the tax-exempt organization will likely not be subject to unrelated business income taxation as long as the following statements are true and applicable:

- The payments to the tax-exempt entity are substantially related its charitable purpose (which could be, as an example, promoting quality improvements and cost savings associated with providing Medicare benefits, which is considered lessening the burdens of government within the meaning of Treas. Reg. § 1.501(c)(3)-1(d)(2));

³³ FS-2011-11 at Q4.

³⁴ The ACO must be exclusively engaged in activities that accomplish its charitable purpose and meet all other requirements to qualify for tax exemption.

³⁵ FS-2011-11 at Q5.

³⁶ Notice 2011-20.

- The avoidance of any inurement³⁷ or impermissible private benefit³⁸; and
- The ACO meets all of the eligibility requirements established by CMS for participation in the MSSP

3. Commercial Shared Savings Activities

When addressing commercial shared savings activities, the Notice and the Fact Sheet were somewhat contradictory. The Notice stated that commercial shared savings activities may not be consistent with charitable operations when a nonprofit partnered with for-profit providers in a commercial ACO. However, the Fact Sheet, which was published after the Notice, clarified that a nonprofit participating in a commercial ACO could possibly conduct activities that are unrelated to the shared savings program without jeopardizing its tax exemption and whether or not that was the case would depend upon the specific facts and circumstances. The examples the IRS purported to consider were whether or not the non-shared savings program activities: (i) furthered a charitable purpose, (ii) were attributed to the tax-exempt participant, (iii) represent an insubstantial part of the participants overall activities, and (iv) did not result in private inurement or impermissible private benefit.

4. Avoiding Private Inurement or Impermissible Private Benefits

The Notice also clarified that when a nonprofit participates in an ACO with for-profit participants, there are five (5) factors³⁹ that the IRS would take into

³⁷ Private inurement is "likely to arise where the financial benefit represents a transfer of the organization's financial resources to an individual solely by virtue of the individual's relationship with the organization, and without regard to accomplishing exempt purposes" (see GCM 38459, July 31, 1980).

³⁸ The private benefit doctrine is derived from the requirement under section 501(c)(3) of the Internal Revenue Code that an organization be organized exclusively and operated primarily for one or more qualifying exempt purposes (e.g., religious, educational, or charitable). Although "private benefit" is not explicitly referenced in the statute, an organization will fail this requirement if it confers private benefits upon an individual that are more than incidental, quantitatively and qualitatively, to the furthering of its exempt purposes. (See GCM 39862, Nov. 21, 1991.)

³⁹ Note that not all of the five (5) factors need be met to avoid inurement or impermissible private benefit, rather this determination will be made based upon the facts and circumstances.

consideration when determining whether or not the tax exempt entity could be subject to private inurement or impermissible private benefit.⁴⁰

- A. Whether the terms of the tax-exempt organization's participation in the shared savings program through the ACO are set forth in advance in a written agreement negotiated at arms' length.⁴¹
- B. Whether CMS has accepted the ACO into, and has not terminated the ACO from, the Medicare Shared Savings Program.⁴²
- C. Whether the benefits to the tax-exempt organization derived from the ACO are proportional to the benefits it provides to the ACO. In addition, if the exempt organization receives an ownership interest, that interest must be proportional to its capital contributions to the ACO, and all returns of capital, allocations, and distributions must be made in proportion to each owner's interest.⁴³
- D. The exempt organization's share of ACO losses does not exceed its share of economic benefits.
- E. All contracts entered into by the exempt organization with the ACO and its participants are at fair market value.

V. FTC/DOJ Joint Policy Statement on Antitrust Policy Enforcement Regarding ACOs

Much like the IRS guidance, the Federal Trade Commission and the Antitrust Division of the Department of Justice (collectively the "Agencies") issued a joint policy statement detailing how they will enforce U.S. antitrust laws with respect to ACOs. Initially both agencies issued draft policy statements in March

⁴⁰ FS-2011-11 at Q18

⁴¹ The exempt organization's precise share or exact amount of shared savings does not need be specified; rather, only the methodology that will be utilized for purposes of shared savings distributions needs to be specified.

⁴² Termination from the MSSP does not automatically jeopardize the tax-exempt status of the participant. This will be determined based upon the relevant facts and circumstances.

⁴³ Factor #3 allows for consideration of all contributions made by the tax exempt organization and the other ACO participants in whatever form (cash, property, services), and all economic benefits received by the ACO participants.

2011 which invited public comments. Based upon industry input the Agencies issued their final policy statement in October of 2011.⁴⁴

The Agencies agreed that participation in ACOs may allow health care providers to innovate and improve how care is provided to Medicare beneficiaries and commercially insured patients.⁴⁵ However, they also made clear that, left unchecked, there is also the potential that such undertakings could pose risks that ACOs could function in ways that are proscribed by U.S. Antitrust laws.⁴⁶ For example, the Agencies noted that ACOs could reduce competition and harm consumers through higher prices or by providing lower quality care.⁴⁷ The Final Statement is guidance and establishes parameters that (if followed) would result in procompetitive and patient beneficial ACOs.⁴⁸

1. Overview of Antitrust Law

Section 1 of the Sherman Antitrust Act prohibits activities or arrangements that unreasonably restrain trade. This would include price-fixing schemes and collusive activities, which unreasonably restrain trade and, depending upon the facts and the egregiousness of the conduct, may be deemed to be per se illegal. Conversely, for activities that are not deemed to be “per se” illegal, the courts apply the “rule of reason” test to evaluate whether or not the alleged activities being perpetuated by market competitors are anti-competitive. In these instances, the application of the rule of reason test revolves around whether the alleged anticompetitive activities are outweighed by other procompetitive benefits.

Thus, when market competitors jointly collaborate to form an ACO and their joint activities include the sharing of sensitive market data and/or joint negotiations with commercial payors, the antitrust laws are implicated. It is for these reasons that the ACA contemplated the need for the FTC and the Antitrust Division of the DOJ to issue a Policy Statement that described the parameters around the manner in which ACOs (comprised of market competitors) may form and undertake collaborative activities that would ordinarily be considered anticompetitive activities, while being free from regulatory scrutiny.

⁴⁴ Final Statement, 76 Fed. Reg. October 28, 2011

⁴⁵ 76 Fed. Reg. 67026

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.*

2. The FTC/DOJ ACO Final Policy Statement

The Final Policy statement incorporated many of the concepts espoused in the draft policy and adopted other critical positions raised by many of the commenters. In addition, the Agencies applied other precepts from previous health care industry guidance.⁴⁹ Specifically, commercial ACOs who are “financially or clinically integrated” may pursue joint price negotiations in those circumstances where such activities are deemed reasonably necessary to accomplish the procompetitive benefits of integration.⁵⁰

The Final Policy Statement also preserved the “safety zone” concept from the draft policy. With some exceptions, an ACO could qualify for safety zone protection if its participating providers provide a “common service” (e.g., the same specialty or the same inpatient service line) and have a combined share of no more than 30% in the “Primary Service Area.”⁵¹ “A Primary Service Area” is defined as “the lowest number of zip codes from which the ACO draws at least 75% of its patients, separately for all physician, inpatient, or outpatient services.”⁵² The safety zones can be a very helpful guide (as can the Voluntary Review provided by the Agencies, *discussed below*) when evaluating arrangements that have the potential to dominate a particular market due to the significant number of participating providers in a geographic area.

The Final Statement also provided detailed descriptions of specific conduct that could raise anticompetitive concerns, which was helpful guidance. This information, when coupled with the Agencies’ previous Health Care Statements, provides a degree of clarity not previously offered by the Agencies. Based upon this information, it will be important to refrain from conduct that may facilitate collusion among ACO participants in the sale of competing services outside the ACO.

To illustrate this concern, competing cardiologists in an MSSP ACO who meet regularly may not share reimbursement rates without running afoul of antitrust laws. Additionally, commercial ACOs may not use their market dominant position to drive up private insurance pricing by improperly leveraging their market power; may not avoid implementing patient incentive programs that would improve health or lower delivery costs; may not engage in improper tying

⁴⁹ U.S. Dep’t of Justice & Fed. Trade Comm’n, Statements of Antitrust Enforcement Policy in Health Care (1996), *reprinted in* 4 Trade Reg. Rep. (CCH) ¶13,153, at §§ (8)(B)-(C) (Sept. 5, 1996).

⁵⁰ Final Statement, 76 Fed. Reg. 67027.

⁵¹ *Id.* At 67028.

⁵² *Id.*

arrangements (e.g., requiring a commercial payor to contract with all of a state-wide hospital system's facilities which may be outside the ACOs Service Area); and may not require participating providers to exclusively contract with a commercial ACO or taking actions that prevent or discourage participation in competing commercial ACOs.⁵³ Other conduct that should be avoided includes placing restrictions on the sharing of enrollee information, which is antithetical to the foundational purposes of the ACA; and conspiring to restrict or exclude certain providers or groups of providers in an effort to drive up prices or obtain greater market share.

Further, the Final Policy Statement makes it clear that in order to jointly negotiate payor arrangements on behalf of a commercial ACO the entity will need to achieve an appropriate degree of clinical and financial integration. This is considered to be a necessary and beneficial element required to overcome the anticompetitive nature of joint price agreements among competing health care providers.⁵⁴ Until the appropriate degree of integration is achieved the participants must refrain from sharing competitively sensitive information.

Conversely, the Final Policy Statement provides that a variety of activities and safeguards that would-be ACOs should implement in order to better insulate themselves from allegations that their actions are anticompetitive. In the developmental stage, ACOs should implement appropriate “firewalls” to ensure that competitively sensitive information is not shared between and among market competitors and should carefully review all documents that are developed by the ACO to ensure that they are devoid of inappropriate statements relative to market position and size (otherwise such document may later be used as evidence to establish bad intent or inappropriate conduct). Another recommended safeguard is to utilize a central point for document collection to review and redact sensitive business information, such as fee related information or employee compensation and to ensure it is not improperly shared with market competitors.

3. Voluntary Review

The Final Policy Statement established a process by which the Agencies would provide newly formed ACOs with a voluntary expedited 90-day review. The draft policy statement suggested that the reviews would be

⁵³ In the MSSP, for those that bill for primary care services, the ACO participant's Tax Identification Number must be exclusive to a single MSSP ACO.

⁵⁴ Norman PHO Advisory Opinion—FTC February 13, 2013.

mandatory, but this was modified in the Final Policy Statement to make such reviews voluntary.⁵⁵

Under this process, newly formed ACOs seeking clarity about the specific antitrust risks associated with their ACO may submit their information to the FTC/DOJ ACO Working Group.⁵⁶ The 90-day review period does not commence until the ACO applicant has submitted all of the required and secondarily requested documentation, which may include the ACO application and all supporting documentation; the business strategies and competition information; and information relating to restrictions of ACO participants from sharing sensitive business information.

ACOs interested in receiving this review should consider the time delays associated with this process and more importantly the potentially invasive aspects of the review, which can involve the ACOs participating providers and their respective businesses. From a practical perspective an agency review likely will not be requested when the ACOs activities do not harm competition. However, in those instances where it is a close call or it is unclear as to whether or not the proposed ACO activities possess materially anticompetitive qualities, such as market dominance or a lack of appropriate integration; recently formed ACOs should be judicious in their willingness to request such a review. The Agencies, given past practices, would be more likely than not to provide an unfavorable analysis, which would later be used as documentary evidence if the ACO continues operation. In some instances consideration may be given to forging ahead without an opinion as it is often easier for the Agency to issue an unfavorable opinion than it is for the Agency to litigate the issues relating to the anticompetitive aspects of the ACO.

VI. Conclusion

Based upon the Waivers put forth by CMS and the guidance proffered by the IRS and the Antitrust Enforcement Agencies, there are new opportunities for all providers to collaborate through the development of ACOs pursuant to financial arrangements that previously would have been met with numerous regulatory barriers. While there is no telling how long the Waivers will last or whether the guidance documents will be revised and made more stringent, the Waivers and Guidance that currently exist present an opportunity for unparalleled creative partnerships worth considering.

⁵⁵ Final Statement, 76 Fed. Reg. 67030.

⁵⁶ 76 Fed. Reg. 67030.

** Note: this is an overview article intended to provide general guidance. This is not a comprehensive overview of all laws related to the laws reviewed herein.*

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