I. INTRODUCTION

The Patient Protection and Affordable Care Act (ACA), Public Law 111-148 (Mar. 23, 2010) was enacted in March 2010. Over the next two years, the constitutionality of ACA was challenged in numerous cases with mixed results in the lower courts. Many legal commentators doubted that the ACA would withstand constitutional review. In addition, there have been many attempts to repeal or modify the law. However, the Supreme Court decision in National Federation of Independent Businesses v. Sebelius, 570 U.S.___, 132 S.Ct. 2566, 183 L.Ed.450 (2012) in June 2012, and the subsequent re-election of President Obama in November, 2012, leaves little doubt that the ACA will be with us for a long time.

Much of the ACA is focused upon healthcare benefits and the relationship of those benefits to the businesses that traditionally have paid for them as well as the individuals eligible for participation. The impact upon businesses and individuals certainly has been the focus of much of the litigation challenges to the ACA. However, the impact upon healthcare providers is at least as significant and may, ultimately, be of greater significance to the healthcare system.

Some of the significant impact upon healthcare providers is a direct result of other aspects of the law. More people should be covered for health benefits than ever before. Similarly, more conditions will be covered and new types of coverage will be available. However, the precise nature of the impact upon healthcare providers depends upon the nature of the provider. There are new rules for physicians and a different set of new rules that apply to hospitals, for example. Certain rules apply only to not-for-profit hospitals, as well. The purpose of this paper is to examine the most significant changes and trends caused by the ACA from the perspective of the healthcare provider and the attorneys who represent them. We will focus on ten significant trends that are based on the ACA that will impact providers. Citations, unless noted, are to the sections of the ACA. Other commonly used abbreviations are CMS for Centers for Medicare and Medicaid Services, HHS for the Department of Health and Human Services, GAO for Government Accounting Office, IRC for Internal Revenue Code, IRS for Internal Revenue Service and OIG for the CMS Office of Inspector General.

II. TREND ONE – NEW PROVIDER TAXES

Healthcare reform will not be inexpensive. The ACA contains provisions that seek to cover some of the costs for the expanded coverage system mandated by the ACA. Some of these revenue provisions take the form of excise taxes on activities that the ACA discourages. For example, ACA §10901 (formerly ACA §9001) imposes an excise tax on high cost employer sponsored health coverage. However, three of these taxes reach certain types of health activities:

A. ACA §10904 (§1405 of the Healthcare Education Reconciliation Act of 2010 [HERA]), codified as IRC 4191, imposes an excise tax of 2.3 percent of gross sales on medical device manufacturers and importers. This tax became effective January 1, 2013. Recent attempts to repeal it have failed. Proposed regulations may be found at 26 C.F.R. §§48.4191-1 and 48.4191-2;

B. ACA §9008 imposes an annual fee on branded prescription pharmaceutical manufacturers and importers. This fee went into effect in September, 2011, *see*, IRS Notice 2010-71; and

C. ACA §10907 imposes a 10 percent excise tax on indoor tanning services.

The first two charges presumably were leveled upon portions of the healthcare industry that Congress concluded could afford the charge. These charges may ultimately get passed on to consumers, but they are now part of the regulatory framework. The excise tax on tanning beds is a modification from an original excise tax on cosmetic procedure, *see*, ACA Original §9017.

III. TREND TWO – NEW HEALTHCARE DELIVERY MODELS

The ACA also attempts to change the way that care is delivered in this country. One of the most significant attempts to do so is the creation of Accountable Care Organizations (ACO). An ACO is a group of healthcare providers that are collectively reimbursed for a patient's care or treatment. For example, an ACO may include primary care physicians, specialists and a hospital. The goal is that such collaborative arrangement will give all of the providers a goal for delivering care in a high quality, efficient and cost effective manner, *see*, ACA §§3002, 3023.

Unfortunately, existing healthcare and other laws not only discourage such collaboration, but in many instances make it illegal. Examples of these legal impediments to collaboration include the Civil Monetary Penalty (CMP), 42 U.S.C. §1320a-7a; Medicare and Medicaid Patient Protection Act of 1987 (AKA), 42 U.S.C. §1320-a-7b; and Section 1877 of the Social Security Act (Stark), 42 USC §1395nn. Antitrust laws and laws pertaining to tax exemption also make collaboration legally difficult. The CMP, AKA and Stark are healthcare specific laws. The antitrust and tax exemption restrictions are laws of general applicability that also operate to make collaboration difficult in the healthcare context.

Under the CMP, civil money penalties may be assessed against hospitals or doctors that knowingly make or receive payments to reduce or limit items or services provided to any federally funded healthcare program beneficiary. Violations are $2,000.00 per occurrence, *see*, 42 U.S.C. §1320a-7a(b)(1) and (2). The concern in the collaboration context is that cost control measures of the collaboration will implicate the CMP.

The AKA imposes potential criminal and civil penalties for payments made to induce referrals of federal program patients, *see*, 42 U.S.C. §1320-7b. It is an intent based statute and a series of safe harbors have been promulgated to protect common business transactions, *see*, 42 C.F.R. §1001.952. However,

exchanges of remuneration between participants in such a collaboration may not neatly fit within such protections.

The Stark law imposes substantial civil penalties upon certain compensation relationships between physicians and providers of certain designated health services that result in referrals from the physician to the provider of the designated health service, *see*, 42 U.S.C. §1395nn. Examples of designated health services include hospital, home health, durable medical equipment and laboratory services, *see*, 42 C.F.R. §411.351. Like AKA, there are certain exceptions available for common transactions, *see*, 42 C.F.R. §411.357. However, once again it is difficult to collaborate within such a framework.

In addition, tax exemption restrictions under IRC 501(c)(3) that prohibit private inurement and limit private benefit make it difficult to collaborate if one of the participants is a tax exempt entity. This is so because arrangements that distribute revenue from a tax exempt entity to for profit participants may subject the tax exempt entity to loss of tax exemption or intermediate sanctions, *see*, *e.g.,* IRC 4958. Finally, the antitrust laws are implicated in certain types of combinations between separate entities within the same market, *see*, 15 USC §1.

The ACA encourages the use of collaborative arrangements and, in an unprecedented measure, actually authorized waivers of the applicability of a number of laws. Thus, in April 2011, a Joint Final Rule was issued by the Center for Medicare Services (CMS) and the Health and Human Services OIG authorizing waivers of CMP, AKA and Stark for certain ACO programs. *See*, 76 Fed. Reg. 19528. Similar relief has been granted under the tax exemption laws, *see*, IRC 501(o), IRS Notice 2011-20 (Mar. 31, 2011), and the antitrust laws *see*, U.S. Department of Justice and Federal Trade Commission Joint Policy Statement, 76 Fed. Reg. 209, p. 67026, *et seq.,* (Oct. 28, 2011), to allow expanded collaboration.

The result has been the creation of an annual application process and encouragement of development of the ACO model. By 2013, it is estimated that there are 428 ACOs throughout the country, *see*, Muhlestein, D., "Continued Growth of Public and Private Accountable Care Organization," (February 19, 2013). The program opens on an annual basis. The window for new applications opened for the Medicare Shared Savings Program (MSSP) was from July 1, to July 31, 2013, with Notices of Intent to apply accepted between May 1, 2013 and May 31, 2013, *see* http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Application.html. It is likely that more collaborative arrangements will be formed. Currently ASOs are more common in some areas of the country, with the greatest number being formed in the Midwest and West, Muhlestein, *id*. The South and Great Plains toward the Mountain West have the least growth of ACOs. In Kentucky, as of May 1, 2013, CMS listed forty-six ACO type model programs that were functioning, *see*, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ACO/. Some function in multiple states.

The impact of the growth of ACOs upon practitioners that represent healthcare providers is that they should be prepared to assist healthcare clients in

considering structuring or reacting to proposed structures for ACOs. This may involve an understanding of the documents under which a physician joins an ACO and a review of the selection process as it becomes apparent that physicians must be exclusive to one ACO, *see*, 42 C.F.R. §425.306(b). There also is a two-step process to determine if a physician can have a beneficiary assignment. This may depend on whether the physician performs a plurality of primary care services based upon Medicare allowed charges, *see*, 42 C.F.R. §425.402(a). In addition, there are a variety of ways to potentially avoid the exclusivity requirement. However, these potentially may implicate other healthcare laws, such as Stark.

Conversely, hospitals will have to determine whether to form or participate in an ACO and how to engage primary care physicians in the arrangement. This may involve development of contracts and applications to join an ACO that will require the assistance of attorneys. Employment of physicians is a potential option. It is interesting to note that a study released in Spring 2013 determined that hospital employment of physicians in Kentucky resulted in significant financial losses for the employing hospital, *see*, Ermer, G. and Bundy D., "The Challenge of Integrating Physician Group Operations-2013 Kentucky Healthcare Industry Survey," Dean, Dorton, Ford and Allen, PLLC (2013). Suffice it to say that as ACOs become more common, analysis of and assistance in developing the business structure of such arrangements will become a significant part of healthcare legal practice.

IV. TREND THREE – NEW REQUIREMENTS FOR IRC 501(c)(3) HOSPITALS

The new requirements for hospitals operating as tax exempt under IRC 501(c)(3) constitute one of the most significant areas of change for healthcare providers. The ACA imposes a variety of new requirements that impact significantly how tax exempt hospitals must operate. The requirements were enacted as §9007 of the ACA. The requirements have been codified as IRC 501(r). Proposed regulations for parts of IRC 501(r) can be found at 77 Fed. Reg. 123, pages 38148, *et seq.* (June 26, 2012).

The new requirements are a response to a number of criticisms leveled at not for profit hospitals in recent years. Essentially, as reimbursement for healthcare services became more commonplace, questions were raised regarding whether the tax exempt hospitals actually should continue to be entitled to tax exemption, since the charitable aspect of some hospitals became suspect. In addition, their billing and collection practices were at best questionable. Specifically, new requirements include provisions to:

- Conduct a community health needs assessment (CHNA) and implementation strategy at least once every three years; IRC 501(r)(1)(A) & IRC 501(r)(3);
- Establish written financial assistance and emergency medical care policies; IRC 501(r)(1)(B) & IRC 501(r)(4);
- Limit charges for emergency and other medically necessary care; IRC 501(r)(1)(C) & IRC 501(r)(5); and
- Make reasonable efforts to determine eligibility for financial assistance before engaging in extraordinary collection efforts, IRC 501(r)(1)(D) & IRC 501(r)(6).

Each will be discussed in turn.

A. CHNA

The CHNA requirement is an attempt to satisfy those who criticized the continued entitlement to tax exemption for tax exempt hospitals in view of the current prevalence of sources for payments for healthcare services. The theory is that through conducting such an assessment and implementation program the tax exempt hospital will better demonstrate that it is operating in accordance with a charitable purpose. The ACA does not provide much guidance on what goes into the CHNA. The IRS issued preliminary guidance in IRS Notice 2011-52 and proposed regulations on April 5, 2013, which are in the comment period as of May, 2013. The guidance issued in Notice 2011-52 may be relied upon for six months after April 3, 2013.

The CHNA is required beginning in 2013 and must be conducted at least once every three years. Penalties for failure to conduct the CHNA can include loss of tax exemption or an excise tax of up to $50,000 per year, per hospital. The IRS has announced an aggressive audit program, targeting 3,377 tax exempt hospitals for review in 2013. It is anticipated that all tax exempt hospitals will be audited for compliance with the CHNA requirement within three years.

Attorneys representing tax exempt hospitals can assist their clients through interpretation of the regulatory requirements, especially as such requirements change, as well as providing assistance in preparation of the CHNA and representation in the audit process.

B. Financial Assistance Policy

IRC 501(r) also requires tax exempt hospitals to have a financial assistance policy. Most tax exempt hospitals have had some form of such a policy for some time. However, there is now a formal requirement. In order to comply with the law, there must be a written policy that includes the following elements: 1) eligibility criteria and whether the policy includes free or discounted care; 2) the basis for calculating the amounts charged to patients; 3) the method for applying for assistance; 4) if the hospital does not have a separate billing/collection policy, actions the hospital may take for non-payment including reporting to collection agencies and collection actions; and 5) publication measures to make certain the policy is widely known in the community.

Although this new requirement will cause tax exempt hospitals to review and likely update current policies, the publication requirement may pose a significant implementation challenge. Under the regulations, patients must be advised of the policy on multiple occasions, *see*, Proposed Regulation (Prop. Reg.) 26 C.F.R. §1.501(r)-4(5) & (6). Meeting this requirement could result in significant changes to current practices.

C. Limitations on Charges

The provision in IRC 501(r) that imposes limitations upon charges may prove to be problematic. In the past, most financial assistance policies that allow for some form of discount or reduction of charges calculated the reduction from gross charges. Gross charges generally are the chargemaster charges and are what is used to calculate reductions given to third party payers in managed care arrangements. The practice of calculating a financial assistance reduction based upon gross charges often operated to cause a reduction in charges that merely reduced the charges to the point that they were comparable to the charges third party payers were paying in the first place.

The new provision imposes a requirement that tax exempt hospitals calculate such reductions not from gross charges, but from the amounts that patients having insurance and their insurance carriers are required to pay. Determining this amount may become quite a problem for tax exempt hospitals. The regulations permit the calculation to be made from the Medicare rate, the best (in terms of the patient) commercial rate or an average of the three best negotiated commercial rates, *see*, Prop. Reg. 26 C.F.R. §1.501(r)-5(b). Compliance with this provision will require the hospital to select a calculation method, perform the calculation and update it at least annually, *see*, Prop. Reg. 26 C.F.R. §1.501(r)-5. Moreover, once a calculation method is selected, the hospital may not change it, *see*, Prop. Reg. 26 C.F.R. §1.501(r)-5(b). While it is not clear that there will actually be reduced collection revenue from imposition of this new requirement, the annual calculation will impose significant new administrative burdens on tax exempt hospitals.

D. Collections

The new IRC 501(r) also prohibits tax exempt hospitals from taking "extraordinary" collection actions until the hospital has made reasonable efforts to determine if the patient is eligible for its financial assistance policy. The two most problematic points may be compliance with the definition of "extraordinary" collection efforts and demonstration of reasonable efforts to determine eligibility. The answers provided by the regulations are not intuitive. Extraordinary collection efforts include efforts such as referral to a collection agency and contacting the patient at home, *see*, Prop. Reg. 26 C.F.R. §1.501(r)-6(b). Reasonable efforts will have to be documented and will include proactive requirements, *see*, Prop. Reg. 26 C.F.R. §1.501(r)-6(c). These new requirements impose significant constraints upon the collection activities of tax exempt hospitals. Moreover, it is quite likely that failure to follow these requirements may be actionable under the Fair Debt Collection Practices Act, 15 U.S.C. §1692, *et seq.,* Counsel for tax exempt hospitals need to assist their clients to comply with these collection requirements.

E. Penalties

Failure to follow the new requirements can lead to revocation of tax exempt status and excise taxes. ACA §4959 includes substantial reporting requirements on the CHNA and requirements for audited or consolidated financial statements. Form 990 has been updated to reflect such requirements and an auditing program is underway. This is likely an area of increasing interest and activity in the next several years.

V. TREND FOUR – NEW REPORTING REQUIREMENTS REGARDING PROVIDER RELATIONSHIPS WITH INDUSTRY

Section 6002 of the ACA imposes a substantial reporting and disclosure requirement upon certain applicable manufacturers and group purchasing organizations making payments to "covered recipients." This provision of the ACA was designed to address the concerns that had been raised by Congress and others about the relationships between physicians and the pharmaceutical and medical device companies. Many feared that physicians' treatment decisions were inappropriately influenced by financial relationships, such as consulting and speaking engagements. The new law and implementing regulations are designed ultimately to create an accessible database of payments made to physicians. Through this effort, healthcare consumers and others will be able to ascertain certain financial relationships of their providers. Regulations were promulgated in February 2013 becoming final in April 2013, *see*, 42 C.F.R. Parts 402 & 403, and tracking and collection of data will begin August 1, 2013. Initial reports will be published September 30, 2014 and subsequent reports on each June 30, thereafter.

The reporting requirements apply to pharmaceutical and medical device manufacturers and group purchasing organizations (GPO), *see*, 42 C.F.R. §403.900, 902. Reports have to be made of any payments of ten dollars or more ($10.00) made by one of the required reporting organizations to a "covered recipient" unless an exemption applies. A covered recipient includes licensed physicians, regardless of whether enrolled in Medicare, and teaching hospitals. Medical residents are excluded. The report is made by the manufacturer or GPO.

The report must include the manufacturer or GPO name, covered recipient's name, including specialty, business address, National Provider Identifier, state professional license number, amount of payment or transfer, date, form of payment (cash or other), nature of payment, name of related drug or device, eligibility for delayed publication (if research related), name of entity that received payment (if not directly to physician), payments or transfers to physician owners or investors, and a statement putting the payment in context, *see*, 42 C.F.R. §403.904. There are special reporting rules for payments regarding clinical and pre-clinical research, *see*, 42 C.F.R. §403.910 and 42 C.F.R. §403.904(f) and continuing education programs, *see*, 42 C.F.R. §403.904(g).

Payments of virtually any nature of ten dollars ($10.00) or more must be reported by the reporting entity. Such payments include: consulting fees, compensation for services, honoraria, gifts, food and beverage, entertainment, travel, education, research, charitable contributions, royalties, current or potential ownership or

investment interests, grants, and compensation for service as a faculty member, *see*, 42 C.F.R. §403.904. Certain payments are excluded, however. Those include payments based upon an existing personal relationship, payments less than ten dollars (except when total annual value of such payments exceeds one hundred dollars [$100.00]), educational materials that directly benefit patients or are intended for patient use, discounts, in kind payments for charity care, product samples, short term (ninety days or less) loans of a device, warranties and dividend or profit distributions, *see*, 42 C.F.R. §403.904(i)(10)-(14).

There are several civil penalties for non-compliance. A penalty of not less than one thousand nor more than ten thousand dollars ($1,000 to $10,000) may be assessed against the entity responsible for making the report per incident to an annual maximum penalty of one hundred fifty thousand dollars ($150,000), 42 C.F.R. §403.912(a). Knowingly failing to submit payment information can result in a civil monetary penalty per occurrence of between ten and one hundred fifty thousand dollars ($10,000 to $150,000) to an annual maximum of one million dollars ($1,000,000), *see*, 42 C.F.R. §403.912(b). Of course, an actual falsified report likely implicates potential criminal liability under 18 USC §1001. The total annual civil penalties are capped at $1,150,000 per violator, *see*, 42 C.F.R. §403.912(c).

The brunt of the enforcement activity appears to be directed toward the pharmaceutical and medical device industry rather than individual physicians or teaching hospitals. However, physicians and the attorneys who represent them need to be aware of the potential reach of the new law and of the new era of transparency that will soon be with us. There is only a forty-five (45) day period in which physicians wrongly reported may seek correction of reports, 42 C.F.R. §403.908(g). These reports will be accessible to patients and other healthcare consumers and providers. The reports also may subject physicians to greater regulatory scrutiny under AKA, Stark and CMP. In the not too distant future, physicians may have to be ready to explain why they received certain payments and justify their course of treatment in that new context.

VI. TREND FIVE – NEW EMPHASIS ON QUALITY

The ACA also has an expanded emphasis upon quality. Improved quality programs have been the focus of a number of healthcare reform activities since the publication of two Institute of Medicine studies over ten years ago. The most significant of the studies from a quality perspective is Crossing the Quality Chasm, Institute of Medicine (2001), published in 2001. This study examined the lack of quality in the United States healthcare system and offered thirteen recommendations for improvement. Much work had been accomplished prior to the ACA to implement some of the recommendations. However, the ACA gives added emphasis to such implementation.

Many of the provisions of the ACA support studies and other research to improve quality. For example, ACA §10303(c) directs the Institute of Medicine to conduct a study to determine best practices for developing clinical practice guidelines and the Department of Health and Human Services will award grants to states to create interdisciplinary teams to support primary care physicians in creation of medical homes, *see*, ACA §3502, as modified by ACA §10321. Grant programs

also were created for development of such matters as the following: curricula on patient safety and quality improvement, ACA §3508; coordination of community based collaborative networks with safety net providers, ACA §10333; creation of state quality hubs under the Primary Care Extension Program, ACA §5405, as modified by §10501; and expansion of patient navigator programs, ACA §3510. The ACA also establishes several new regulatory organizations to assist in quality improvement, including: an Independent Payment Advisory Board which includes providers, ACA §3403, as modified by §10320; a non-profit Patient-Centered Outcomes Research Institute, ACA §6301, as modified by §10602; and, through AHRQ, a Primary Care Extension Program, *see*, ACA §5405.

However, the most immediate impact upon healthcare providers will be the new emphasis upon transparency and quality based payment adjustments. The ACA imposes an unprecedented level of reporting requirements of quality data for healthcare providers and will make such data publicly available. In addition, payments to providers will begin to be based, in part, upon quality metrics. Each of these initiatives will be reviewed in more detail.

A. Reporting

The ACA attempts to promote quality through a series of initiatives requiring reporting and ultimate disclosure of quality data from providers. Physicians are required to participate in the Medicare Quality Reporting System (MQRS) by 2015. Failure to participate will result in a reduction of Medicare payments after that time. However, CMS recently ruled that providers who are not successfully/satisfactorily reporting by the 2013 reporting period (January 1, 2013 to December 31, 2013) will have their Medicare payments reduced by 1.5 percent beginning in 2015 and 2 percent in 2016 and later. Ultimately, the Department of Health and Human Services will develop a program called Physician Compare, a website where Medicare beneficiaries can view quality and patient experience measures for physicians, *see*, ACA §10331.

On the hospital side, a number of entities, including critical access hospitals, ambulatory surgical centers, long term care facilities, rehabilitation and psychiatric facilities, hospice providers and certain cancer hospitals will now be required to report quality data, *see*, ACA §§2703, 3001(b)(1), 3004, 3005, 3006 and 3401(f). This data ultimately will be publicly available, *see*, ACA §10407(b).

B. Payment

Physician payment impact, to date, is limited to penalties for failure to participate in reporting programs, *see*, ACA §3002 (a)-(b). However, hospitals will have more direct payment incentives. First, CMS, through its newly established innovation center, will test new payment models focusing on quality improvement and cost, *see,* ACA §3021. Similar programs are established to develop guidelines for insurance plans to offer value based benefit designs, ACA §1001. There are also programs authorized to establish Medicaid bundled payment demonstration projects, *see*, ACA §§2705, 2706 and 3023, as modified by §10308. In

addition, the ACO program will facilitate the new Medicare Shared Savings Program, ACA §3022. In addition, Health and Human Services is to establish a pilot program for bundled payments, *see*, ACA §3023, as modified by §10308.

All of the foregoing provisions will add performance into the payment equation However, the Medicare Value Based Purchasing Program has had, since October 1, 2012, a direct impact upon payments made to acute care hospitals based upon their performance on certain quality measures, *see*, ACA §3001. Under this program, Medicare payments to acute care hospitals will be based, in part, upon how well the hospital performs in meeting quality measures, *see*, 72 Fed. Reg. 170 (August 31, 2012), pp. 52257-52750. In addition, Medicare payments will be reduced for services related to preventable readmissions and hospital acquired conditions at low performing hospitals, *see*, ACA §§3008, 3025, as modified by §10309, and neither the federal nor state governments are allowed to make payments for hospital-acquired conditions under Medicaid, ACA §2702.

The new emphasis upon quality and transparency will significantly impact the ways that healthcare providers operate. Data ultimately will be publicly available so that consumers can evaluate the performance of healthcare providers from a results standpoint, *see*, ACA §§3015, 3403(a), 2703, and 3013(b). In the not too distant future, providers may get questions from consumers regarding the provider's performance. Payments to hospitals will be adjusted based upon quality performance. It is a new era of transparency with financial consequences.

VII. TREND SIX – PAYMENT REDUCTIONS TO SAFETY NET PROVIDERS

One of the cornerstones of the ACA is a commitment to expand access to healthcare coverage for residents of the United States. Estimates suggest that the percentage of persons not having health benefits in the United States will be reduced from around 16 percent to around 7.5 percent by the time it is fully implemented, *see*, Teitelbaum, Joel B. & Wilensky, Sara E., Essentials of Health Policy and Law, 2d Ed., (2013), Chapter 9 "Health Reform in the United States." However, such implementation does not come without a cost and there are provisions in the ACA designed to limit or shift costs. Two of those provisions are ACA §3133 which is titled, "Improvement to Medicare disproportionate share hospital (DSH) payments," and ACA §2551, "Disproportionate share hospital payments." DSH payments are designed to help compensate certain safety net hospitals for the cost of providing a disproportionate amount of healthcare to Medicaid/Medicare recipients and the uninsured, *see*, 42 U.S.C. §1396r-4. The rationale for this provision of the ACA is that as more persons become covered, either through greater access to health benefits through Health Insurance Exchanges or state expansion of Medicaid Programs, the corresponding need for such supplemental payments would decrease. Thus, the appropriate amount of the supplement paid under DSH should also decrease.

The ACA program envisions that beginning in Fiscal Year 2014, the amount available under both DSH programs would dramatically decrease based on the

concept that, through ACA reforms, fewer individuals will receive uncompensated care, *see,* 42 USC §1395ww. The ACA contemplated a reduction in payments of $14.1 billion from the Medicaid program, *see*, 42 USC §1396r-4(f)(7)(B) and a reduction to twenty-five percent of current levels for the Medicare DSH program, *see*, ACA §3133(2), 42 USC §1395ww(r). The projection is that the Medicare reduction would result in a savings of $22.1 billion between 2014 and 2019, *see* Letter from Douglas Elmendorf, Director of the Congressional Budget Office to Nancy Pelosi, Speaker, U.S. House of Representatives (March 20, 2010).

These reductions initially were scheduled to begin October 1, 2013. However, the limitation in the Supreme Court decision that did not mandate that states expand Medicaid coverage coupled with the delay in implementation of health insurance exchanges likely has postponed the reductions. In April 2013, President Obama requested that reductions be delayed for a year.

VIII. TREND SEVEN – CHANGES IN HOW PHYSCIANS PRACTICE

The ACA will impact how physicians must practice medicine. We have already examined the new healthcare delivery model. However, there are a number of changes brought about by the ACA that will have a significant impact upon physicians regardless of the form of business in which they practice. These include an expanded paying patient base, increase in services for which reimbursement will be available and new physician/patient encounter requirements. Each will be discussed below.

The creation of new forms of health benefit coverage should result in an increase in paying patients for many physician practices. Medicaid eligibility will be expanded in many states and other states are considering alternatives that also will cause more persons to have some form of coverage. Changes in requirements for insurance coverage also will expand the number of persons having benefits. Examples include the elimination of pre-existing condition requirements, *see*, ACA §1101, availability of reinsurance for early retirees, *see*, ACA §1102, and the extension of dependent eligibility to remain on their parents' health plan to age twenty-six (26), *see*, ACA §2714; all should lead to more persons having some form of coverage. Moreover, as health insurance exchanges become operational, access to health benefit programs should be greatly improved which should also result in more paying patients.

More physician activities will be eligible for reimbursement, as well. The ACA expands access to primary care services and general surgery services, *see*, ACA §5501. Medicare coverage is expanded to include an annual wellness visit, *see*, ACA §4103, and other efforts are made to remove Medicare barriers to preventive services, *see*, ACA §§4104, 4105. The ACA also makes changes to the Medicaid program to improve access to preventive services, ACA §4106, provide tobacco cessation for pregnant women, ACA §4107, and create incentives for prevention of chronic diseases, ACA §4108. All of the foregoing should result in new types of reimbursable provider encounters.

However, the ACA also has some compliance related requirements that will change the manner in which physicians practice. In a compliance related move to assure that certain services actually are necessary, there now are face to face

encounter requirements for orders of durable medical equipment (DME) and home health benefits for Medicare beneficiaries, *see*, ACA §6407. The encounter can be with the physician or a non-physician practitioner working with the physician. For home health services, the encounter must be within ninety (90) days prior to the start of care or within thirty (30) days after the start of care. DME face to face encounters also may be made by the physician or a non-physician provider, but must occur within the six month period before the order. This requirement is effective for orders made on or after July 1, 2013. Final rules were published November 8, 2012 (Home Health) and November 16, 2012 (DME), *see, e.g.,* 77 Fed. Reg. 217, p. 67106, *et seq.* (Home Health); 42 C.F.R. §410.38(g) (DME). During the face to face encounter, the provider must evaluate the beneficiary, conduct a needs assessment or treat the beneficiary for the condition that is the basis of the order, *id.* The encounter may be by telehealth, provided that the Medicare telehealth requirements are satisfied. A similar face to face encounter requirement is also imposed for hospice patients under ACA §3132(b). This encounter must occur prior to the patient's 180 day recertification and each subsequent recertification. The encounter must occur no more than thirty (30) days prior to the patient's third benefit period.

Finally, also included as an integrity provision, is a new requirement for physicians to provide documentation regarding referrals to programs at high risk for waste and abuse, *see*, ACA §6406. It is unclear what the nature of such documentation will be and how high risk programs are determined. However, all of the foregoing provisions will require providers to exercise greater vigilance in their practices.

IX. TREND EIGHT – CHANGES IN HOW CLAIMS ARE PROCESSED

The ACA also creates a number of changes in how claims will be processed. Of significant importance, the period of time in which to file a Medicare claim has been reduced to twelve months, *see*, ACA §6404. This new requirement will cause more timely claims submissions and also limit the ability of providers faced with compliance issues to re-bill correctly in a timely manner.

The ACA also requires a single set of operating rules for claims processing throughout the healthcare industry, *see*, ACA §1104(b)(4) (entitled Administrative Simplification). This provision directed the Secretary of Health and Human Services to "adopt a single set of operating rules for transaction with the goal of creating as much uniformity in the implementation of the electronic standards as possible." *Id.* Payers were mandated to adopt new operating rules for eligibility and claims status reporting by January 2013 and new rules for electronic remittance advice and electronic funds transfer by January 2014. The ACA directed the Department of Health and Human Services to select a not for profit organization to promulgate operating rules. HHS selected Committee on Operating Rules for Information Exchange (CAQH CORE) for this task. This organization's website contains details of the new operating rules and can be accessed at www.caqh.org/ORMandate_Eligibility.php.

Providers should see improvement in claims processing as these new operating rules are implemented. Revenue cycle management should improve through automated validation of coverage and eligibility prior to office visits, expedited

confirmation of benefit coverage and improved patient registration, *see*, Price, Renee D., CHBME, CMPE, CHFP, CPA, "New Operating Rules for Claims Processing are Fast Approaching" Healthcare Billing and Management Association, September/October 2012, www.hbma.org. The electronic data exchange (EDI) should result in improvement in the number of denied claims, a decrease in collection time and fewer billing related phone calls, *id.*

Finally, the ACA imposes an industry wide requirement for claims appeals featuring both internal and external review processes, *see*, ACA §10101(g), added as §2719 of the Public Health Services Act. Rules providing for internal appeals of claims denials for plans covered by the Employee Retirement Income Security Act of 1974 (ERISA), 29 USC §1001, *et seq.* have been in place since 2002, *see*, 29 C.F.R. §2560.503-1. However, the ERISA rules never provided for an external review process and the review standard was such that the health benefit plan could often win, *see e.g.,* Yeager v. Reliance Standard Life Ins. Co., 88 F.3d 376, 380 (6th Cir. 1996) (highly deferential standard). Moreover, while a number of states already had statutory review procedures, these claims review procedures varied widely throughout the country.

The ACA requirement applies to all health benefit programs whether covered by ERISA or not. It also includes an external review process applicable to all plans. An interim final rule was promulgated in July 2010 and amended in June 2011. This new rule should impact providers in two ways. First, more payments may be approved as a result of the external review process. A Government Accounting Office study suggested that between 39 and 59 percent of denials were reversed in internal appeals and an additional 23 to 54 percent were reversed in external reviews, *see*, GAO "Report to the Secretary of HHS, Private Health Insurance, Data on Applicable Coverage Denials" (March 2011). In addition, as appeals processes become more robust, providers may find that they are taking a more active role in the appeals process. With a fair review and success actually possible, providers may wish to provide more detailed statements and other support for appeals. It may become a matter of significance to patient relations to do so and failure to participate could become legally problematic for providers.

X. TREND NINE – MORE COMPLIANCE REQUIREMENTS

There are a number of new compliance initiatives in the ACA. These include changes in the rule allowing physician ownership of hospitals, new self disclosure protocols, new rules for dealing with overpayments, programs expanding background checks, consolidation of databases, expansion of audit programs and greater coordination in exclusions between Medicare and Medicaid. This section will review some of the most significant developments.

A. Physician Ownership of Hospitals

ACA §6001 prohibits future physician investments in hospitals and freezes current physician investment as those that existed as of the enactment of ACA, March 23, 2010. This section of the ACA substantially restricts a regulatory exception to the Ethics in Patient Referrals Act, 42 U.S.C. §1395nn (commonly known as "Stark"). Stark prohibits physicians from making referrals for designated health services to an entity in which

they or a close family member have a financial interest, unless the interest fits within a recognized exception, *see*, 42 U.S.C. §1395nn(a)(1). Hospital services are one of the designated health services. The theory is that physicians having a financial interest in the entity that provides the designated health service will be ethically compromised; and, as a result, over utilize the service, *see*, Murer, Cherilyn G., "Stark Reality: Physician Owned Specialty Hospitals May Not Be Whole For Long", www.murer.com.

Physician ownership of hospitals provides a source of capital to establish hospitals and has been especially useful in development of specialty hospitals. There are over two hundred fifty (250) physician owned hospitals in thirty eight states, *see*, www.physicianhospitals.org. Stark has had an exception for certain physician ownership of hospitals, *see*, 42 C.F.R. §411.356(c). To qualify for this exception, the physician needs 1) to have a financial interest in the whole hospital, not just a component part; 2) be allowed to perform services in the hospital; and 3) actually perform such services, *id.* ACA §6001 adds a requirement that the ownership or investment had to exist as of December 31, 2010, and the hospital must have a Medicare provider agreement as of that date. Moreover, future expansion of existing hospitals is limited to certain factors demonstrating a need for growth and the physician ownership or investment will have to be disclosed to patients.

This new provision will make it very unlikely that any future physician owned hospitals will be developed. It also substantially limits the ability of physicians to enter into joint ventures with existing hospitals. As such, it narrows the playing field even further for physician/hospital business relationships. Attorneys representing physicians and hospitals in transactional matters relating to investment in hospitals will need to be aware of this new restriction in order to advise their clients properly.

B. Self Disclosure

In a related Stark issue, ACA §6409 permits healthcare providers to voluntarily self disclose Stark violations in hopes of receiving leniency in penalty assessment. While self disclosure programs for other health law irregularities had existed since the 1990s, *see*, OIG Self Disclosure Protocol, 63 Fed. Reg. 58399 (Oct. 30, 1998), there had been no previous provision for disclosure of Stark violations. While some disclosures were occasionally made, in 2009 the HHS OIG issued a letter requiring disclosures and advising that settlement would not be for less than $50,000, *see*, Dep't of Health & Human Servs., David R. Levinson, Inspector General, "An Open Letter to Health Providers, (Mar. 24, 2009), www.oig.hhs.gov/fraud/docs/openletters/OpenLetter3-24-09.pdf. This caused a chilling effect upon disclosures. Indeed, there was some question that the government had requisite authority to settle.

The new provision changes all of this. ACA §6409(a) requires establishment of a self-referral disclosure protocol ("SRDP") and ACA §6409(b) gives the Secretary of HHS authority to reduce penalties for

violations. The SRDP was issued and ultimately revised May 6, 2011. It may be found at OMB Control Number 0938-1106, available at, Updated to Updated to http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/downloads/6409_srdp_protocol.pdf. The actual disclosure must include a significant amount of information, including a description of the nature of the matter being disclosed, why the disclosing party believes a violation may have occurred, circumstances of discovery, a statement of prior history, a description of existence and adequacy of an existing compliance program, a description of any notices to other governmental agencies, an indication of whether the disclosing party knows if the matter currently is under government investigation, detailed financial analysis and certification, *id.*, at 4-5. The disclosing party must also give the government access to its information for verification purposes, *id.*, at 5-6.

CMS may reduce the amounts otherwise owed, *id.*, at 6. Factors that may be considered in determining whether to reduce the amount owed and determining such amount include: "(1) the nature and extent of the improper or illegal practice; (2) the timeliness of the self disclosure; (3) the cooperation in providing additional information related to the disclosure; (4) the litigation risk associated with the matter disclosed; and (5) the financial position of the disclosing party." *Id.* This provision finally provides a real opportunity to make corrections and seek mitigation. In this respect it should be viewed as a positive development. However, this may also signal an enhanced requirement for providers to make such disclosures, which, when coupled with new overpayment provisions, significantly increases the risk of failing to do so. On a related note, a revised general disclosure protocol was issued in April 2013 updating a prior 1998 version.

C. Disclosure of Certain Interests

In yet another Stark related provision, ACA §6003 enhances an existing disclosure provision to require providers that offer radiological diagnostic tests, such as Magnetic Resonance Imaging (MRI), Positive Emission Tomography (PET) and CT services utilizing equipment in which the physician has an ownership interest, which are currently authorized through what is known as the in office ancillary exception to Stark, to advise the patient, in writing, of the ownership interest and provide the patient with a list of other providers in the area who could provide the same services. This is supposed to deter unnecessary utilization. This provision is codified at 42 U.S.C. §1395nn(b)(2)(B).

D. Overpayments

ACA §6402(a) imposes a new provision that requires that Medicare and Medicaid overpayments must be reported and returned no later than sixty (60) days after it is identified or the due date of any corresponding cost report (if the matter is subject to cost reporting). This provision applies to all providers of services, suppliers, Medicare Advantage organizations, Medicaid managed care organizations and Prescription Drug Plan sponsors. On February 16, 2012, CMS issued proposed rules to

implement this requirement, *see*, 77 Fed. Reg. 9179 (Feb. 16, 2012). Much of the potential controversy and confusion will turn upon when an overpayment is identified, thus starting the refund clock. The proposed regulations makes it clear that the overpayment has been identified when a person has actual knowledge of the overpayment or acted in reckless disregard or deliberate ignorance of its existence, *see*, proposed, 42 C.F.R. §401.305(2). The proposed regulations also detail how overpayments are to be reported and a provision to ask for hardship relief.

E. Payment Suspensions

ACA §6402(h) provides for suspension of Medicare and Medicaid payments pending an investigation of a credible allegation of fraud. On February 2, 2011, CMS issued a final rule, which is set forth at 42 C.F.R. §455.1, *et seq.* (Medicaid); 42 C.F.R. §405.371, *et seq.* (Medicare). These regulations provide additional background on some of the key issues, including what constitutes a "credible allegation of fraud." 42 C.F.R. §455.2 provides guidance that such an allegation must have indicia of reliability. It does require some level of verification, but, in the case of Medicaid, defers the verification process to the various states. There are provisions to lift suspensions and an identification of certain circumstances when suspensions need not be imposed, such as cooperation with law enforcement, *see*, 42 C.F.R. §405.371(b); 42 CFR §405.372. There is a requirement to renew the analysis every one hundred eighty (180) days and a general eighteen (18) month maximum, with recognized extension authority, 42 C.F.R. §405.371(b)(2) & (3). However, while rebuttals may be allowed, 42 C.F.R. §405.372, there is no appeals process. This new provision affords the regulators a significant new advantage, by potentially imposing significant financial hardship upon healthcare providers suspected of fraud.

F. Background Checks

The ACA also contains a significant "carrot" to encourage states to implement background check programs for persons having direct patient access in long term care facilities. ACA §6201 created a grant program for such state programs. The types of facilities eligible for coverage include skilled nursing facilities, nursing facilities, home health agencies, hospice care providers and similar entities providing long term care. As of March 2013, twenty two states have received grants. A new application period ran until May 31, 2013. A Kentucky bill that could have taken advantage of this program failed to make it through the Senate in 2013, *see*, H.B. 73, S.B. 100 (2013).

G. Databases

ACA §6403 attempts to eliminate duplication between the Healthcare Integrity and Protection Data Bank and the National Practitioner Data Bank. Both of these databases need to be reviewed when physicians seek employment or medical staff credentials. Consolidation should expedite the review process. In a related provision, ACA §6401 extends the requirement to access the Excluded Parties List System no less frequently than monthly for a provider or other person with an ownership or control interest who is an agent or managing employee of the provider, *see*, 42 C.F.R. §455.436.

H. Expanded RAC Audits

The Recovery Audit Contractor (RAC) program has been in operation since 2010 for Medicare. It was originally started as a pilot program and utilizes contractors to audit for overpayments. These contractors are paid based upon a percentage of their recovery. ACA §6411 essentially makes this program permanent and expands its scope to Medicaid and SCHIP as well as Parts C and D of Medicare. Medicaid RAC audits began in fiscal year 2012 in Kentucky.

I. Medicaid Exclusion

ACA §6501 closes a potential loophole in excluded provider programs by requiring states to exclude from participation in Medicaid any provider that has been excluded from participation in Medicare or any other state Medicaid program. This provision should eliminate the potential of a questionable provider continuing to receive Federal program dollars by moving to a new state and enrolling as a provider in the Medicaid program of the new state.

XI. TREND TEN – ENFORCEMENT INITIATIVES

Suffice it to say that with the enhanced compliance initiatives under the ACA, enforcement activities also will be strengthened. This is the subject of a separate outline in your material. However, new statutes of limitation, antifraud initiatives, self-disclosure protocols and rules for overpayments will combine to greatly improve the regulators' success in enforcement initiatives.

XII. CONCLUSION

The ACA will dramatically change the way that providers do business. While most of the commentary about the ACA has focused on its impact upon health benefit plans, businesses and individuals, the ACA requires numerous changes that will directly and significantly impact providers. This paper has examined ten trends that will have such an impact. It remains to be seen whether these changes will be received favorably by providers and patients or improve the delivery of healthcare services. However, the rules have now changed and providers must learn to adapt or potentially suffer significant consequences. Legal practitioners who represent providers need to become familiar with these

concepts and stay engaged for additional changes as the rules become fully implemented.