Health Law Issues 2012

1 Healthcare Reform/Supreme Court Ruling on Constitutionality – *Peter Leibold, AHLA*

No one can seriously dispute the number one health law issue of 2012: the constitutionality of the individual mandate and the Medicaid expansion mandates on states contained in the Affordable Care Act (ACA). Over the span of three days, March 26-28, the Supreme Court will hear five-and-a-half hours of oral argument on the following issues:

- whether the Anti-Injunction Act bars the Court from considering the individual mandate's constitutionality prior to its implementation in 2014;
- whether the Commerce Clause gives Congress authority to enact an individual mandate;
- if not, whether the individual mandate is severable from the rest of the law; and
- whether Congress violated basic tenets of federalism and exceeded its authority under the federal spending clause when it required states to cover individuals up to 133% of the poverty level or risk losing all of their Medicaid matching funds.

The Court's decision is expected to be announced as AHLA members gather in Chicago for our Annual Meeting at the end of June. This may be the most important Supreme Court decision in health law ever.

Brief Background

The ACA includes a significant set of reforms for the entire healthcare system, but the Supreme Court's focus will be on two issues, as referenced above: (1) the individual mandate, which uses the Internal Revenue Code's existing tax collection system to implement a penalty for those who elect not to obtain

minimum essential coverage; and (2) the ACA's requirement that states cover a significant number of additional people under their Medicaid programs or lose their federal matching funds for Medicaid.

The Anti-Injunction Act

The first issue for the Court will be whether it can pass judgment on the constitutionality of the individual mandate at all. The barrier to consideration may be the Anti-Injunction Act, which bars suits seeking to restrain the assessment or collection of a tax before the tax has been assessed.

The debate over whether the Act bars pre-assessment constitutional challenges to the imposition of a penalty revolves around the rather arcane issue of whether the penalty in the ACA for failure to obtain minimum essential coverage is a "penalty" or a "tax" for purposes of the Anti-Injunction Act. The legislation called the tax a "penalty," but imposed it through the Internal Revenue Code. The Code mandates that in some sections, penalties should be construed as taxes. But, the ACA-imposed penalty is not in such a section. Thus, the Code is silent on whether the ACA penalty should be construed as a tax. Appellate courts have reached contrary positions, with the majority of courts holding that the Anti-Injunction Act does not bar consideration of whether the individual mandate is constitutional under the Commerce Clause and Taxing Power of the U.S. Constitution. The Supreme Court will provide the definitive answer.

Does the Commerce Clause Authorize the Imposition of an Individual Mandate?

Two constitutional provisions govern the analysis of whether Congress acted within its commerce authority in enacting the individual mandate: the Commerce Clause and the Necessary and Proper Clause. In brief, these two provisions allow Congress to take necessary and proper statutory actions to regulate commerce among the several states.

The parties agree that these provisions govern the constitutional issue, but disagree on virtually everything else. Those who believe the mandate is unconstitutional define the issue narrowly as whether the Commerce Clause and the Necessary and Proper Clause can be used to require an individual to purchase a particular product (health insurance). They then use a slippery slope argument to claim that if the Constitution can be interpreted to force an individual into the stream of commerce in order to regulate such commerce, there is simply no limit on what Congress can do. That scope of power, in their view, was not contemplated by the Constitution and would undermine the protections of individuals enshrined in the Constitution.

Those who support the mandate define the issue far more broadly as whether Congress can take the necessary and proper steps to regulate the economic market of providing healthcare for the nation's citizens. To reasonably regulate the marketplace of insurance, Congress must be able to penalize those who insist on imposing the costs of their healthcare on others by not responsibly insuring for the inevitable costs that will result. Supporters believe that the Constitution allows Congress to penalize those without insurance to regulate the interstate commerce of the healthcare marketplace. If the Supreme Court finds that the Anti-Injunction Act does not bar its consideration, the Court will provide the definitive answer on this question as well.

Is the Individual Mandate Severable from the Accountable Care Act?

The Eleventh Circuit found the mandate was unconstitutional, but held the provision could be severed from the rest of the ACA even in the absence of an explicit severability clause. The panel found that there were hundreds of provisions in the ACA completely unrelated to the individual mandate and even those that were related could operate in the absence of the mandate. The appeals court concluded that opponents of the ACA failed to meet the high burden needed under Supreme Court precedent to rebut the presumption of severability. The National Federation of Independent Businesses disagrees with this analysis and argues that the legislation itself deems the mandate "essential" for several provisions, like community rating and guaranteed issue, and as the centerpiece of the legislation, if it falls, the rest of the statute should fall with it. Again, if the Court strikes down the mandate, it will provide the definitive answer on severability.

Can the Federal Government Threaten the Loss of Medicaid Matching Funds If States Refuse to Expand Their Medicaid Coverage Requirements?

In a surprise to many constitutional scholars, the Supreme Court also granted certiorari on the question of whether Congress may use its expansive power of the purse to "coerce" states to expand their Medicaid coverage criteria. No appellate court has agreed with the states that this amounts to an unconstitutional coercion.

Under the ACA, among other Medicaid changes, states will be required to cover adults under age 65 with incomes up to 133% of the federal poverty level (FPL). States also will be required to provide Medicaid to all children whose families earn up to 133% of the FPL. States will not be able to reduce their Medicaid eligibility requirements until a state insurance exchange has been established.

The Eleventh Circuit's review of the case law indicates that no court has ever struck down a law such as the ACA as unduly coercive. Yet, those opposing these provisions believe that the power of a state to walk away from its Medicaid funding is illusory and that the ACA's requirement to expand

coverage so significantly, with the state expenditures that will entail, amounts to an unconstitutional coercion in violation of the Spending Clause and the Tenth Amendment.

Conclusion

The Supreme Court will have an enormous impact on the direction of federal and state health reform with its decision in the ACA case. This is undoubtedly the number one health law issue of 2012.

2 Accountable Care Organizations –

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Why should a concept that occupies only four of over 2,000 pages in the ACA rank as the second most important health law issue two years in a row? Even after the Centers for Medicare and Medicaid Services (CMS) issued the much-anticipated Final Rule on the Medicare Shared Savings Program (MSSP) on October 20, 2011, and provided the healthcare industry with extensive guidance about the formation, operation, and payment of accountable care organizations (ACOs), these entities remain uncommon and, in most cases, more theoretical than real. ACOs do have, however, the potential of being the most transformative part of healthcare reform.

In simple terms, ACOs are provider-led organizations whose purpose is to manage the full continuum of care and be accountable for the overall cost and quality of care for a defined population. The ACA directs CMS to experiment with a variety of ways to cause providers to assume responsibility for clinical and financial outcomes. Together with medical homes and several new payment mechanisms, ACOs represent a dramatic paradigm shift away from traditional fee-for-service medicine to a more holistic way of delivering and paying for patient care. 2012 will likely be remembered as the year Medicare first recognized the intrinsic value created when providers voluntarily join together and cooperatively manage the care they deliver to beneficiaries. Although the MSSP is still in its infancy and is likely to undergo extensive change in the coming years, its significance has been compared to Medicare's adoption of the Prospective Payment System (based on diagnosis-related groups) in the 1980s. Fee-for-service may not be dead yet, but its days surely seem numbered.

The importance that the Obama Administration has given to ACOs was demonstrated by its coordinated issuance of a series of proposed and somewhat more final rules, policy statements, and notices by several federal agencies in March and October of 2011. Literally hundreds of pages in the *Federal Register* were devoted to addressing the unique fraud and abuse, tax, and antitrust implications of ACOs and their participation in the MSSP. Much of the regulatory landscape that predated ACOs was either at odds with the public policies behind the ACA or unprepared to deal with some of the novel legal questions that the law presents. Congress clearly understood that additional agency guidance would be needed to address these new payment methodologies and provider-to-provider relationships, as well as to answer many legal questions that were neither anticipated nor relevant during the pre-ACO era. Also, of particular interest to health law practitioners are a raft of new health information technology, licensure and certification, state insurance law, and organizational issues that are raised by the creation and operation of ACOs. Fortunately for health lawyers, these and many other aspects of ACOs have been addressed in a new AHLA publication: *The ACO Handbook: A Guide to Accountable Care Organizations*. (www.healthlawyers.org/bookstore)

For some veteran health lawyers, the introduction of ACOs may seem reminiscent of the days when physician-hospital organizations and other kinds of provider arrangements were all the rage. Admittedly, there are a few similarities between ACOs and these older models, but they pale in comparison with major advances in health information technology and cultural changes that make it unlikely that accountable care will turn out to be just a 21st Century version of managed care. There is a growing recognition that today's budgetary pressures can only be addressed by a fundamental realignment of the risks and rewards inherent in the American healthcare system. Indeed, some private payors have indicated they are ready to embrace ACOs even if CMS' experimentation with this concept fails to meet Washington's expectations. This is why ACOs are more than another fad. CMS terminology will surely evolve, as will the particulars of the MSSP, but it is very hard to imagine that the principles of accountable care will end up being scrapped completely.

Therefore, whatever comes of the ACO initiative, health lawyers will be grappling with a fundamentally changed regulatory environment because of this particular aspect of health reform. That reason alone ensures that AHLA will be giving special attention to ACOs in the year ahead.

3 Fraud and Abuse Enforcement: Overpayments and Self-Disclosures –

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Recent regulatory changes promise to make 2012 another dynamic year for federal healthcare fraud and abuse enforcement. One of these changes, included in the ACA, imposed new obligations for reporting overpayments under Medicare and Medicaid. The ACA also authorized a new program for self-disclosure of federal Stark Law violations. Participation in this program suspends the obligation to return overpayments and may reduce penalties.

Under the ACA, an overpayment occurs when a person—defined as a provider, supplier, Medicaid managed care organization, Medicare Advantage organization, or Part D Plan sponsor—receives funds from the Medicare or Medicaid program to which the person is not entitled. The overpayment must be "reported and returned" to the appropriate party by the later of 60 days from the date the overpayment was identified or, if applicable, the date when any corresponding cost report is due.

Although these reporting obligations have been in effect for almost two years, ambiguities remain. For instance, while it is clear that overpayments should be reported and returned as soon as possible, neither the ACA nor federal administrative guidance defines when an overpayment is considered "identified" for purposes of triggering the 60-day reporting period (e.g., awareness of the possibility of an overpayment, as opposed to certainty of an overpayment, as opposed to certainty of the occurrence and amount of an overpayment).

Significant developments also will occur this year in two federal programs that allow self-disclosure of federal fraud and abuse violations, including overpayments. The Office of Inspector General (OIG) operates the first program, the Provider Self-Disclosure Protocol (SDP), for self-disclosed violations of the federal Anti-Kickback Statute (AKS), False Claims Act, and Civil Monetary Penalties Law. Any Stark Law violation disclosures to the SDP must also involve "colorable" violations of the AKS. Additionally, the OIG requires a minimum settlement of $50,000 for AKS-violation submissions. While the OIG encourages participation in the SDP, note that disclosed information can be referred to the Department of Justice (DOJ).

During 2011, the OIG reported eight settlements of self-disclosed AKS violations, ranging from $50,000 to $2,596,014. The OIG's website also listed 26 other settlements in 2011 that resolved self-disclosed violations unrelated to the AKS. In total, the OIG reported to Congress that, from October 2010 to October 2011, self-disclosure settlements exceeded $19 million.

The ACA required CMS to establish the second self-disclosure program, known as the Self-Referral Disclosure Protocol (SRDP). The SRDP, issued in September 2010, is available for self-reporting of potential or actual violations that only involve the federal Stark Law. Participation in the SRDP stays a party's 60-day obligation to return an overpayment until a settlement is reached or until the self-disclosure process is otherwise ended. The SRDP also offers the possibility of settling for a reduced penalty without a lengthy government investigation. But, the SRDP does not guarantee participants a reduced penalty, and that submitted information may be referred to the DOJ and/or the OIG if evidence exists of liability under other laws.

As of September 2011, CMS had received 109 SRDP submissions. However, to date, only four settlement agreements have been announced. First, on February 20, 2011, Saints Medical Center in Lowell, MA agreed to pay $579,000 to resolve its Stark liability, which was estimated to be as high as $14 million. Then, on November 9, 2011, CMS settled several disclosed Stark violations by a critical access hospital in Mississippi for $130,000. Finally, on January 5, 2012, CMS settled Stark violations with a California hospital for $6,700 and with a Georgia hospital for $4,500.

By March 2012, CMS will submit a report to Congress that will enable evaluation of the SRDP program, including the number of SRDP submissions made, the amount of money collected under the SRDP, and the types of violations reported. This report should give health law professionals a more complete perspective on the SRDP and help them advise clients about the SRDP process generally and its potential pitfalls and benefits. (*See* related Member Forum article in this issue discussing strategic approaches and practical tips for the SRDP).

Health law professionals should continue monitoring the development of the overpayment rules and self-disclosure programs this year. With this new information, legal advisors can help healthcare providers fine-tune overpayment compliance policies and navigate the complexities of the self-disclosure process.

4 HIPAA Enforcement – *Bianca Bishop, AHLA*

After the initial ramp up to comply with the privacy and security mandates of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and its implementing regulations, this area of the law has not figured as prominently in health law practices. But with the enactment of the Health Information Technology for Economic and Clinical Health (HITECH) Act as part of the American Recovery and Reinvestment Act of 2009, along with several other recent developments, sentiment seems to be growing that the relatively tranquil HIPAA privacy and security enforcement landscape may be changing.[1] The HITECH Act not only imposed new compliance obligations, and stiffer penalties for non-compliance, on covered entities and their related business associates, it also opened the door for a new wave of enforcement actions by state attorneys general, giving them express authority to file suit in federal district court on behalf of state residents for HIPAA violations. In addition to the HITECH changes, several developments in 2011 seemed to signal a renewed focus on HIPAA enforcement.

In February 2011, the Office for Civil Rights (OCR), which is tasked with enforcing the HIPAA privacy and security rules (OCR assumed oversight of the security rules from CMS in July 2009), imposed a $4.3 million civil monetary penalty (CMP) on Cignet Health Center of Prince George's County, MD for violating the HIPAA privacy rule. Significantly, the CMP was the first ever imposed by OCR on a covered entity since the privacy rule's effective date in April 2005. According to OCR, Cignet denied patients access to their medical records

in accordance with HIPAA-specified timeframes and failed to respond to, and cooperate with, OCR's investigation of the matter. At the time the OCR issued the CMP, Department of Health and Human Services (HHS) Secretary Kathleen Sebelius made clear that the agency "is serious about enforcing the individual rights guaranteed by the HIPAA Privacy Rule."

Also in February 2011, OCR announced that Mass General agreed to pay the federal government $1 million to settle claims of HIPAA violations for failing to safeguard the records of 192 patients. A Mass General employee left the records, which were never recovered, containing the patients' protected health information on a subway train while commuting to work. As part of the settlement with OCR, Mass General also agreed to a corrective action plan, or CAP. And in July 2011, the University of California of Los Angeles Health System agreed to pay $865,500 and enter into a CAP to resolve allegations of HIPAA violations when its employees accessed the records of two celebrity patients.

Another development that has many health lawyers even more focused on HIPAA compliance issues is the start of HITECH-mandated audits conducted by OCR. Beginning in November 2011, OCR launched a year-long pilot program for implementing the new requirement that will include 150 audits of covered entities by December 2012. The compliance audits will focus on a broad cross-section of covered entities initially and later be expanded to business associates. At least at this point, OCR has emphasized the audits "are primarily a compliance improvement activity" to correct potential problems and develop best practices.[2]

While it remains to be seen whether the uptick in enforcement activity in 2011 is a signal of more to come, or what role the new audit program will play going forward, one thing appears certain: health lawyers view this as an area to monitor closely in 2012.

5 Final Rule Issued on Medical Loss Ratio Requirements Under Healthcare Reform –

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Introduction

With an estimated $2 billion in total premium rebates due nationally and tens of millions spent by issuers building the administrative infrastructure to properly calculate and rebate such amounts, the Medical Loss Ratio (MLR) requirements of the ACA are clearly a hot health law topic for 2012. Whether rebates may be paid this year could be a proverbial photo finish, with issuer reporting to the federal government due by June 1 on the amount of rebates owed and payment by August 1, given the projected issuance of the Supreme Court's decision on the constitutionality of ACA in late June.

Background

On December 2, 2011, HHS issued the final rule on the MLR requirements under Section 10101 of the ACA. The final rule,[3] along with additional guidance for non-federal government plans[4] and technical release[5] guidance from the Department of Labor, accomplish three main tasks: (a) clarifying that certain expenses can be excluded from the calculation of the MLR; (b) simplifying the process of rebating if the MLR is not met; and (c) modifying the original mini-med and expatriate plan MLR calculation guidance.

Under Section 10101, insurers must meet new aggregate MLR/medical spending requirements: (1) 85% in the large group market and (2) 80% in the small group and individual markets. Some state insurance departments have sought and obtained adjustments to the MLR standard in their individual markets. The ACA gives HHS the authority to make such adjustments if applying the 80% MLR standard could destabilize the individual market in a state. Failure to meet the MLR would require an insurer to pay rebates to policyholders and potentially enrollees. The MLR is calculated by using the following formula:

$$\text{MLR} = \frac{\text{Claims} + \text{Quality Improvement} + \text{Measures}}{\text{Premiums} - (\text{Taxes} + \text{Fees})}$$

The final MLR rule significantly simplified the rebating process by mandating that rebates for most employer groups be returned to the policyholder instead of the policyholder and the enrollees based upon their respective contribution levels.

Despite the simplification, rebating will be no simple task for either the issuer or the recipient and will have major implications for the entire health insurance industry.

Implications

Issuers

The new federal MLR requirements directly impact issuers in several key ways including building the administrative infrastructure to calculate the rebate as well as properly rebating, if required, to affected group and individual customers. Despite the welcome changes in the December final rule, significant short-term work remains for issuers. Final calculations are due by June 1, payments must be made by August 1, and before any of that is possible, substantial work is necessary to properly allocate administrative and claims costs to the appropriate market segments.

In the long term, issuers must determine how best to approach these new loss ratios through both new utilization management efforts and administrative expense review while at the same time managing the added implementation costs associated with ICD-10 transition efforts and the transition

to the ACA exchange model beginning in 2014. Issuers that successfully meet these challenges while controlling premium increases will be well positioned to enter the ACA-mandated exchange marketplaces.

Employers

Employers receiving the benefit of rebates will also discover that strings are attached to the receipt of the rebated premiums. Most employers that may receive rebates are subject to the Employee Retirement Income Security Act of 1974 (ERISA) and the rebated premiums come with familiar fiduciary obligations regarding the use of such plan assets for the benefit of plan beneficiaries.[6] Other employers are bound by new obligations similar to those of ERISA plans, namely that any rebates received must be used for the benefit of enrollees. Some possible uses may include reducing future premiums for the plan, copayment reductions, and/or funding additional benefits. Employers should begin planning now for how they may wish to utilize any rebated premiums instead of waiting until after receipt.

Some employers may find that they receive no rebates because of the manner in which they are classified as a small or large employer. Federal law differs from most states by determining employer size based on average total enrollees versus state law definitions that may be based upon total enrolled or total eligible employees. The result: some employers on the same policy form type may receive rebates while others do not creating confusion and dissatisfaction.

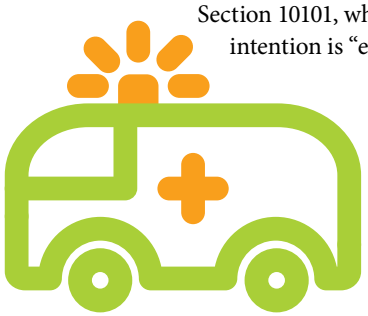
Other Affected Parties

The MLR rules affect many other constituencies including agents and brokers, providers, benefit management companies, and, ultimately, enrollees.

Health insurance agents and brokers have unsuccessfully lobbied both federal and state representatives, Insurance Commissioners, and others to exclude sales commissions from the administrative portion of the MLR calculation. Agents and brokers will likely continue to feel pressure to reduce commissions as issuers comply with the new MLR requirements.

Providers and benefit management companies may have opportunities to assist issuers to meet MLR requirements by building efficient and effective quality improvement programs to manage enrollees' medical conditions. Enrollees ultimately may not only benefit from rebates but also from increased efforts to improve health outcomes as those efforts are encouraged through application of the MLR calculation.

Hopefully, the end result will meet the ultimate goal of ACA Section 10101, which states that the MLR provision's intention is "ensuring that consumers get value for their (premium) dollars."



6 The Responsible Corporate Officer Doctrine—The New World of Healthcare Compliance –

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In October 2011, DOJ celebrated the 25th anniversary of Congress' 1986 False Claims Act (FCA) amendments. The FCA amendments ushered in an avalanche of FCA actions and recoveries. In those 25 years, DOJ has recovered more than $30 billion.

As a result of these settlements, healthcare entities have been radically transformed. As a condition of entering into FCA settlements, the government agrees to waive its ability to exclude healthcare providers from Medicare participation in exchange for companies' entering into detailed corporate integrity agreements (CIAs). As a result of these CIAs and related regulatory pronouncements, most companies in the healthcare industry—hospitals, long term care facilities, research-based pharmaceutical and biotechnology companies, clinical laboratories, and even physician practices—have comprehensive compliance programs.

But now, even as the industry has become accustomed to FCA investigations, lawsuits, and compliance programs, the government has brandished a new weapon to enforce fraud and abuse laws. Specifically, recently federal officials have expressed their intent to revive the responsible corporate officer doctrine, which provides that corporate officers may be held criminally liable for certain offenses relating to public health and welfare, even if the individual officers and managers neither knew of nor participated in the unlawful activity. Additionally, the OIG has announced a new focus on excluding owners, officers, or managers from participation in federal healthcare programs if they should have known of a sanctioned company's misconduct. The OIG announced that the presumption in favor of exclusion may be overcome based on the circumstances underlying the misconduct and the individual's actions in response to the entity's misconduct.

Recently, a notable illustration of this power occurred when the OIG announced the program exclusion of a pharmaceutical company's substantial owner and officer. The exclusion was based upon the guilty plea to criminal charges by the company's wholly owned subsidiary, which paid restitution of approximately $2.3 million and a $23.4 million criminal fine. Notably as a condition of the agreement, the government compelled the officer to withdraw from the company management and divest his ownership interest in the company.

The combination of the responsible corporate officer doctrine and the FCA provides the government with a powerful one-two punch. The FCA's whistleblower, or qui tam, provisions provide an insider with a strong incentive to report suspected fraud and the responsible corporate officer doctrine will require executives—for fear of losing their livelihood by exclusion—to

ensure, at the risk of overreaction, that prompt remedial action is undertaken because the OIG may seek the manager's exclusion if the manager did not appear sufficiently vigilant.

Some, no doubt, will argue that the invocation of the corporate officer doctrine is exactly what is needed to police rampant healthcare fraud and will point to the government's substantial FCA recoveries as proof that the industry is rife with fraud. Others will contend that that the government's massive recoveries typically reflect not the strength of the government's case but the leverage it possesses based upon its ability to exclude companies from participation in Medicare. They will point out that, in fact, the vast majority of whistleblower actions are meritless because historically, since the 1986 FCA amendments, DOJ has refused to participate in approximately 75% of all qui tam actions.

But no matter what position one may adopt, the fact that is beyond cavil is that healthcare executives will be placed in a seemingly impossible bind. They must balance furnishing streamlined, efficient, high quality healthcare and implementing vast regulatory mandates while receiving shrinking healthcare payments. And, at the same time, so as not to risk exclusion from Medicare for failing to identify perceived misconduct and promptly reporting it to the government under the responsible corporate officer doctrine, they will feel compelled to overcompensate by creating and operating resource-intensive compliance programs that will divert dollars from the provision of patient care.

How healthcare executives manage and navigate these contradictory mandates of providing quality care with shrinking reimbursement and reducing costs, while building expansive compliance infrastructures to protect their livelihood and avoid personal liability, will be one of the major issues to watch in 2012.

State-Based Health Law Initiatives –

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Why do states matter? How does their decision making affect the greater healthcare system? Before the ACA, Medicare was the primary federal government tool to influence private sector reform. Now, the industry is looking at state-level decisions because the ACA creates a new era of federal-state cooperation. States are the new driving force behind health system change.

We know that the power of the public purse will loom larger than ever over healthcare services during the next decade. The United States currently spends approximately $2.6 trillion on healthcare. By 2020, this number is expected to grow at an average rate of 5.8%—faster than our projected Gross Domestic Product growth—making healthcare spending a full one-fifth of our entire economy.[7] Nearly half of our future national healthcare spending will be from public funds—explaining why so many law firms and consulting outfits are creating or expanding their healthcare-focused government affairs shops. With only 18% of spending coming from private business, most of the spending will be by the federal government and a full 18% will be state and local spending.

Under the ACA, states face a host of new responsibilities and challenges—the foremost among these changes is the creation of state-based health insurance exchanges and the expansion of Medicaid eligibility.

At this point, many of the ACA insurance market reforms are well underway. The federal government distributed hundreds of millions of dollars to move those reforms along quickly:

- $730+ million to insurance exchange planning and establishment grants
- $150+ million for new or expanded insurance premium rate review programs
- $30+ million to establish or strengthen consumer assistance programs

Twenty-eight states are busy using their grant money to develop new individual and small group insurance marketplaces. HHS has received many more applications for Level I grants—so the number of states applying for money to build insurance exchanges continues to grow. According to a recent Commonwealth Fund report, so far 11 states have enacted legislation to establish health insurance exchanges, while governors in three states—Florida, Louisiana, and South Carolina—have informed HHS their states do not plan on establishing an exchange.[8] Under the ACA, HHS will set up a federally-facilitated exchange in those states that are not certified to operate their own exchange by January 2013.

If the Supreme Court strikes down all or part of the ACA, health insurance exchanges will be difficult but not impossible to implement in the states. In the absence of a mandate and the accompanying insurance market reforms that accompanied them in the ACA, many states still likely will proceed with exchanges in their own way. Additionally, many states already have private health insurance exchanges in place, such as Bloom Health in Michigan and Extend Health.

Medicaid is another huge resource commitment for states. Because Medicaid pays for so many essential services, states cannot realistically opt-out of the program without seriously increasing the number of uninsured and negatively impacting providers. The insurance exchanges offer tax credits to individuals between 133% and 400% FPL, and assume that all those below 133% FPL will be covered by Medicaid. Managing this low-income population's frequent entry to and exit out of the exchanges over the course of a year (often called "churning") will be a significant challenge, and underscores the need for a coordinated electronic eligibility and enrollment platform for both Medicaid and exchanges. Already states are working to

streamline the program and are investing time and resources to update outdated Medicaid information technology enrollment systems. Moving forward, states will need to work with local stakeholders to come up with comprehensive strategies to improve care coordination, control costs, and better manage population health.

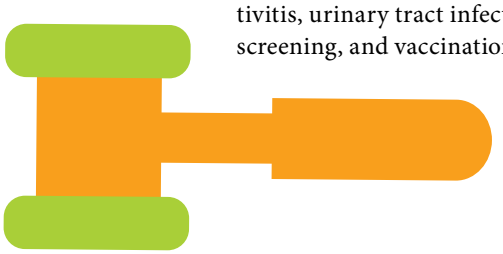
Regardless of the ACA's fate, the new law has already catalyzed significant transformation in the healthcare system. This transformation will continue to be informed and influenced by the key paradigm introduced in the law: a new federal-state partnership for reform.

Retail Health Clinics ("Big Box" Healthcare) –

Cynthia Conner, AHLA

After growing slowly in 2009 and 2010, the number of retail healthcare clinics increased by more than 11% in 2011 and is expected to show similar growth in 2012. Since 2001 when the first retail clinic opened in Minnesota, this segment of the healthcare industry has not grown as quickly as was originally anticipated and in fact, 5% of the operating clinics were closed in 2008 with the financial crisis and the poor real estate market. A recent article in the *New York Times*,[9] however, reports that the number of retail clinics in existence in 2011 jumped to 1,355, fueled in part by the entry of supermarket giants like Safeway and Walmart into the clinic business and an aggressive expansion by CVS Caremark of its MinuteClinics. Several provisions of the ACA may further spur interest in the clinics. For instance, clinics may help fill some gaps in the availability of primary care services, which is already problematic and expected to get worse when coverage expands under the healthcare reform law starting in 2014. Convenient care clinics are also looking to collaborate with ACOs and other integrated health networks to provide a high quality, low cost, and accessible option to physician office and emergency room visits for routine, non-urgent medical care.

These clinics are typically located in large retail settings, such as supermarkets, 'big box' and drug stores. They are staffed by nurse practitioners and/or physician assistants who are authorized under state law to write prescriptions. These providers have access to off-site physicians, although in some instances, clinics will employ physicians to work on site. Generally, the clinics offer care for a limited number of minor ailments, such as strep throat, ear infections, conjunctivitis, urinary tract infections, routine blood screening, and vaccinations and flu shots. A flat fee is charged for these services and price schedules are prominently on display, providing patients with cost transparency that is unique in the healthcare world. Most clinics are open seven days a week, with extended hours on weekdays and limited hours on the weekend. Increasingly, many health insurance plans cover services provided at these clinics and in some instances, waive the co-pay to promote the use of this less expensive treatment option.



A number of federal statutes already govern convenient care clinics, including the Anti-Kickback Statute, the Stark Law, and HIPAA. In addition, an array of state health law issues arise and must be addressed before a clinic can begin operating in a particular jurisdiction, including corporate practice of medicine, fee splitting, scope of practice, and self-referral requirements. At the state level, the legal framework for retail clinics is developing rapidly, as legislatures have begun to regulate them in a variety of ways, most commonly through statutes that authorize the licensure of retail clinics. In other jurisdictions, states are expanding the scope of practice for nurse practitioners, requiring that a physician be on-site to assist, or imposing a ban on tobacco and alcohol sales on the premises. On the horizon are concerns regarding quality, continuity of care, and potential conflicts of interest that may further prompt regulatory efforts.

If its popularity continues to increase as projected, AHLA expects that this new healthcare delivery model will become a growing area of interest for health lawyers. Monitoring industry trends and state legislative initiatives in this area in the year ahead will prepare them for this new area of practice.

Community Benefit, Community Health Needs Assessment –

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One of the top developments for tax-exempt hospitals is that 2012 is the year in which many will have to conduct and report on their first ACA-required Community Health Needs Assessment (CHNA), or at least get ready to do so for their next tax year. This is only one of the provisions Senator Charles Grassley (R-IA) has sought to apply to the nonprofit hospital community, although he ultimately did not vote for the healthcare reform bill that enacted these new requirements into law.

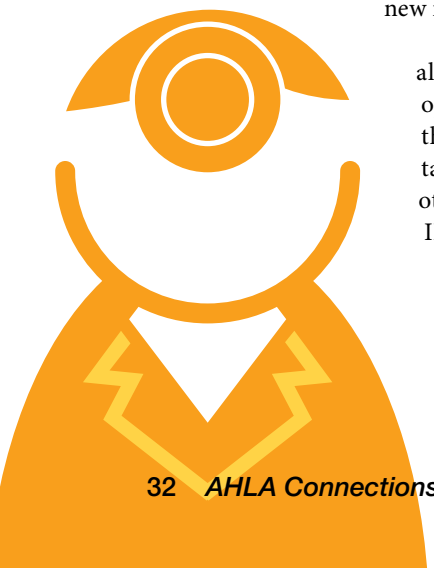
Grassley's idea was not new. New York and California were among pioneering states that required community benefit needs assessments and plans in the early 1990s. The Health Plans and Provider Networks Working Group of the White House Task Force on Health Reform proposed such a requirement in 1993 as part of President Clinton's failed Health Security Act. The Catholic Health Association of the United States did much to translate the idea into a practical planning activity through their Social Accountability Budget docu-

ments. Senator Grassley and his staff, however, made a national CHNA requirement and more detailed reporting of community benefit a reality.

New Code Section 501(r) requires each licensed hospital to conduct a CHNA at least once every three years and adopt an implementation strategy to meet the needs identified through such assessment. The CHNA must take into account input from those who represent the broad interests of the community served by the hospital, including those with expertise in public health, and must be made widely available to the public. Section 6033(b)(15)(a) requires a hospital to describe how it is addressing the needs identified in its CHNA on its Form 990. The CHNA requirement is effective for tax years beginning after March 23, 2012.

Much of the controversy surrounding CHNAs stems from the fact that Congress specified in Section 501(r)(2)(B) that, if an organization operates more than one hospital facility, it must meet the Section 501(r) requirements, including the CHNA requirement, separately for each facility. The Internal Revenue Service (IRS), in Notice 2001-52, signaled its intention to issue regulations requiring that hospitals must document separately the CHNA and implementation strategy for each facility, although they can collaborate with other organizations when conducting CHNAs and developing implementation strategies. One requirement in Notice 2011-52 that has been criticized as unduly restrictive is the IRS statement that it expects to require in regulations that an implementation strategy be adopted by the hospital's governing board by the end of the same year in which the CHNA is conducted.

The other big development that kicks off in 2012, but relates back to 2011, is that all hospitals will have to answer new ACA-driven questions on Form 990, Schedule H. In Notice 2012-4, the IRS notified tax-exempt hospitals that, beginning with the 2011 tax year, Schedule H, Part V, Section B is no longer optional, with the exception of lines 1-7. That means hospitals will have to answer detailed new questions about their financial assistance policy, billing and collections practices, and emergency medical policies. The questions are designed to establish whether each hospital meets the new requirements in Section 501(r).



Perspectives vary, and there will always be some who criticize developments like these. "CHNAs signal the beginning of the end for hospital tax exemption," some say while others believe that's not likely. The IRS has neither the resources nor the interest to do much with CNHA data and has never seriously questioned hospital exemption, only behaviors. The real audience for community benefit information is and always has been the public. By avoiding transparency, the hospital community may allow weaknesses to go unchecked. Tax-exempt hospitals in Illinois probably now wish that some hospitals had not been left to engage unabated in some of their most inventive collection practices. Now, all Illinois property tax exemptions are in jeopardy. Recent news, though, is encouraging. Statewide, tax-exempt hospitals recently doubled the amount of community benefit they provide. They now will have an opportunity to work with the legislature to enact clear standards for exemption. Hospitals in Pennsylvania and Texas who did so years ago are largely happy with the standards they hammered out and with the decreased challenges to exemption.

For those who would prefer not to parse community need and benefit in the harsh light of day, the 1986 loss of exemption by Blue Cross organizations provides a cautionary tale. Many in Congress merely wanted to guide them back to their historical social welfare practices, such as open enrollment and community rating, but it was too late. In the context of overall tax reform, someone needed a revenue raiser and the Blues exemption was gone. Conducting CHNAs and filling out an ever-expanding Schedule H may seem an expensive burden, but the time may come when they earn their keep.

10 Sunshine Act—Payments – *Lisa Salerno, AHLA*

This year was largely a waiting game with regard to implementation of the Physician Payments Sunshine Act. After years of trying to get the legislation passed in Congress, bill sponsors Charles Grassley (R-IA) and Herb Kohl (D-WI) finally were vindicated when their legislation was enacted as part the ACA in March 2010.

Under the physician payment sunshine provisions of the healthcare reform law (Section 6002), drug and medical device manufacturers must disclose to HHS anything of value given to physicians, such as payments, gifts, honoraria, or travel above certain minimum thresholds. The provision also requires disclosure of physician ownership and investment interests in applicable manufacturers and group purchasing organizations (GPOs).

Although CMS was required under the law to establish reporting procedures for applicable manufacturers to submit information by October 1, 2011, the agency did not issue proposed regulations until December 14. In the proposed rule, CMS said it would delay the beginning of data collection from January 1, 2012 until after a final rule is published, but the effective date of the reporting requirement under the law remains March 31, 2013. Comments on the rule are due February 17, 2012.

The rule provides proposed definitions of several key terms and specifies penalties for noncompliance. The rule also proposes exclusions to the requirements for transfers of value

for which applicable manufacturers are not required to submit information. In addition, the proposal sets forth the contents of reports on physician ownership and investment interests, as well as the format for the reports and the mechanisms and timing for report submission, review, and correction.

In the rule, CMS proposes two interpretations of entities that are under "common ownership" with an applicable manufacturer and asks for comments on the issue. The rule is similarly vague in terms of valuation of payments and transfers and preemption of similar state laws.

Some have noted compliance with the regulations is likely to be resource-intensive and expensive for stakeholders and CMS' guidance thus far leaves too many unanswered questions.[10] Once the final rule is issued, applicable manufacturers and GPOs likely will have to ramp up quickly to comply with the new requirements. Health lawyers undoubtedly will play a central role in that effort. C

Endnotes

1 *See, e.g.*, Daniel F. Murphy, *HIPAA—A Paper Tiger No More?*, AHLA Connections, v. 15, no. 6 (June 2011).
2 *See* Joshua J. Freemire and James B. Wieland, *OCR Publishes Its HIPAA Audit Protocol: Focus To Be On Data Gathering And Best Practices*, Health Lawyers Weekly, v. 9, no. 44 (Nov. 11, 2011).
3 76 Fed. Reg. 76574 (2011) (amending 45 C.F.R. pt. 158).
4 76 Fed. Reg. 76596 (2011) (amending 45 C.F.R. pt. 158).
5 Department of Labor Technical Release No. 2011-04
6 Department of Labor Technical Release No. 2011-04
7 Sean P. Keehan, Andrea M. Sisko, Christopher J. Truffer, John A. Poisal, Gigi A. Cuckler, Andrew J. Madison, Joseph M. Lizonitz and Sheila D. Smith, Health Affairs. (July 2011.)
8 The Commonwealth Fund, *State Health Insurance Exchange Legislation: A Progress Report* (Jan. 11, 2012).
9 *More Health Clinics Pop Up Inside Retailers*, New York Times.com, 2012, Jan. 9, 2012.
10 *See* Michael H. Park and Joyce E. Gresko, Alston & Bird LLP, *CMS Issues Proposed Rule to Implement Physician Payments Sunshine Act, Many Questions To Be Answered*, Health Lawyers Weekly, v. 10, no. 1 (Jan. 6, 2012).