Health Law Issues 2013

1 Health Insurance Exchanges

—By Cynthia Conner, AHLA

Calendar years 2013 through 2014 will be populated with major activity relating to the establishment and launch of health insurance exchanges. The Affordable Care Act (ACA) calls for the creation of American Health Benefit Exchanges, which are expected to be the source of health insurance coverage for millions of Americans. Primary responsibility for establishing exchanges rests with the states, although the federal government will step in to create them in states that opt out. The Congressional Budget Office (CBO) estimates that of the 30 million who are projected to gain coverage under the ACA by 2022, nearly half of them will gain coverage in 2014, and the majority of those will be through enrollments in exchanges.

Under the ACA, every state must have an exchange where individuals and small businesses can obtain affordable coverage by January 1, 2014. States have three options for meeting that requirement—(1) running their own state-based exchange, (2) participating in a federally-facilitated exchange (FFE), or (3) partnering with the federal government to share responsibility for running certain functions within an FFE. The Department of Health and Human Services (HHS) extended the deadlines for states to select one of these options, giving states until December 14, 2012 to choose a state-based exchange and until February 15, 2013 to select the partnership model. Beyond the February 15, 2013 date, states that have not opted for either the state or partnership models will default to a FFE. As of this writing, 17 states and the District of Columbia have indicated that they intend to establish a state-based exchange, six states are planning to pursue a

state-federal partnership exchange, and another 17 states have declared that they will opt for a federally-run exchange. Of the remaining 10 states, the partnership model is an increasingly viable strategy, and one that leaves open the possibility of moving to a state-run exchange beyond the January 1, 2014 deadline.

The policy and implementation challenges facing state-run exchanges over the next 10 months are monumental. Most of these states have already established the legal authority for their exchanges, and made decisions regarding the structure (as a nonprofit entity established by the state, as an independent public agency, or as part of an existing state agency), governance, and the type of contractual relationship they will have with qualified health plans. Much remains to be done before the January 2014 deadline however, as these exchanges are responsible for all operations, including developing enrollment systems and information technology infrastructure; adopting plan rating, billing, and other systems; contracting with health plans; and providing consumer outreach and assistance.

At the federal level, and although several states have still not submitted their formal exchange decision to HHS, the government must confront the burden of operating federal exchanges in a significant and growing number of states. Guidance released in May 2012 provided some initial policy decisions, but many important decisions are still to come, not the least of which is what basic benefits will be covered by the plans.

In the state-federal partnership model, the federal government will operate everything from consumer eligibility and enrollment to financial management and risk corridors, while states can retain responsibility for plan management, meaning they will be in charge of qualified health insurance plan certification and reinsurance, data collection, and basic supervision. The states can further choose to be in control of customer service functions, such as in-person assistance. Even where states choose to control those activities, the federal government will oversee websites and call centers where much of the exchange activities will be centered. At present, HHS has issued very little guidance about this vague form of "partnership," meaning that the year ahead will bring major developments in this area, given the launch deadline of January 1, 2014.

As health lawyers know perhaps as well or better than most, an ambitious legislative goal (the operation of health insurance exchanges in all 50 states) and a fast-approaching compliance deadline means that there will be a flurry of activity in government agencies and legislatures across the county in 2013. Monitoring, interpreting, and applying all the rules and standards relating to health insurance exchanges will definitely dominate the practice of health law in the year ahead.

State and Federal Issues Related to Medicaid Eligibility Expansion

—By Joel M. Hamme, Powers Pyles Sutter & Verville PC, Washington, DC

When the February 2012 edition of *AHLA Connections* listed the "Top 10 Health Law Issues" for 2012, it was entirely predictable that the impending review of the ACA by the Supreme Court would occupy the Number 1 slot. What was much less clear was that the Court would invalidate the *mandatory* Medicaid eligibility expansion provisions of the ACA while upholding the core of the ACA and allowing that expansion to move forward if the states did so *voluntarily*. As a consequence, one of the most significant health law issues for 2013 is how state Medicaid programs will approach and decide the expansion issue prior to January 1, 2014 when much of the ACA goes into effect.

Background

One of the overarching goals of the ACA was to attain near universal health insurance coverage in the United States through a multi-pronged approach, including the *mandate* that individuals either purchase health insurance or pay a penalty, *subsidies* to businesses and individuals to help with the costs of coverage, and *expansion of Medicaid eligibility*.

Essentially, under the Medicaid eligibility expansion provisions, states would be required, effective January 1, 2014, to extend eligibility to individuals between the ages of 19 and 65 who have incomes of 133% or less of the federal poverty level (FPL) but are not pregnant, not entitled to or enrolled for Medicare benefits, and not eligible for Medicaid as of December 1, 2009. This newly eligible pool was estimated to be about 16 million of the nation's 50 million uninsured. To help cover the costs of expanding Medicaid eligibility, Congress basically set federal match rates for the newly eligible class at 100% initially with the match then diminishing slightly until it reached 90% in 2020 and thereafter.

The Medicaid eligibility expansion was also deeply intertwined with three other provisions of the ACA: (1) sliding scale refundable tax credits to enable certain non-Medicaid-eligible individuals with household incomes between 100% and 400% of the FPL to purchase health insurance; (2) interim and temporary maintenance of existing eligibility (MOE) standards which, with certain limited exceptions, preclude states from adopting Medicaid eligibility criteria that are more stringent than those in effect on March 23, 2010, the date the ACA was signed;[1] and (3) based on anticipated increases in health insurance coverage, substantial reductions in future disproportionate share hospital (DSH) payments made by Medicare and Medicaid as reimbursement for furnishing uncompensated care.

Medicaid Expansion Issues in the Wake of the Supreme Court's Decision

The Supreme Court's ruling that the Medicaid expansion was unduly coercive but could proceed on a voluntary basis left HHS and the states with a number of thorny questions, many of which have now been resolved administratively but some of which will need congressional examination:

(1) *The uninsured and the individual mandate*—Will individuals who would otherwise have become Medicaid-eligible but who live in states that decide not to expand be subject to the individual mandate even if they are ineligible for tax credits to purchase insurance? HHS quickly indicated that it would use its regulatory authority expansively to grant hardship exemptions from the mandate in these cases.

(2) *Timing, terms, and nature of the eligibility expansion decision*—Must states engage in the full expansion by January 1, 2014 or face the loss of the enhanced federal funding if they do not do so and even if they later decide to expand fully? For states that voluntarily agree to expand eligibility, is the decision irrevocable or may states later decide to do away with the expansion and pare back? May states engage in partial eligibility expansion (e.g., to 100%, 110%, or 120% of the FPL) and receive the enhanced federal funding? HHS has announced that it will treat the states' eligibility expansion decisions as entirely voluntary, both as to the timing of the decision and the ability to retract it later. As such, states may expand Medicaid eligibility to 133% of the FPL at any time and qualify for the enhanced match. Additionally, after expanding eligibility, states may later reduce eligibility without penalty, although there would be no enhanced match even for any individuals who remained eligible. But, expanding eligibility to anything less than 133% of the FPL would *not* qualify for the increased federal match for the new enrollees.

(3) *MOE issues*—Does the Supreme Court's decision effectively invalidate the MOE requirement prior to the times that it is due to expire? HHS has rejected this notion and stated that MOE remains in effect, precluding states from currently cutting back on Medicaid eligibility except in the limited cases permitted by the ACA.

(4) *The curious effect of health insurance tax credits*—The Supreme Court's decision results in an anomaly. Individuals below 100% of the FPL in states that choose not to expand Medicaid eligibility will not be entitled to tax subsidies but those at or above 100% will be. Congress could address this situation, but it is beyond HHS' authority to rectify administratively.

(5) *DSH Payments*—In states that refuse to enlarge Medicaid eligibility, DSH hospitals will continue to see significant numbers of uninsured and underinsured patients and to render comparable amounts of uncompensated care. Yet, their Medicare and Medicaid DSH payments will be cut. As a result, hospital coalitions in many states are lobbying hard for eligibility expansion. But, again, this is a matter that will require congressional attention since HHS has limited authority to address it by administrative fiat.

State of the States

There is now no deadline by which states must declare their intentions regarding Medicaid eligibility expansion so it is impossible to forecast accurately what states will do as of January 1, 2014 or thereafter. Unsurprisingly, many states postponed thinking about the issue while Supreme Court review of the ACA was pending and until the results of the 2012 elections ensured that healthcare reform would not be immediately repealed.

There are many factors that will affect these decisions. The most obvious is political ideology. Many Republican governors and state legislators have challenged the ACA and are either opposed to or reluctant about expanding Medicaid eligibility. Conversely, numerous Democratic governors and state legislators embraced the ACA and are either eager or inclined to engage in eligibility expansion. Practical considerations and, in particular, financial analyses will play a major role as well. What will it cost or save each state to expand eligibility? Available studies suggest that eligibility expansion in particular and ACA implementation in general will result in increased expenditures for some states and savings for others. Thus, the states' expansion decisions may not always fall neatly into the red state/blue state dichotomy.

At this time, the situation remains in flux, and it appears that about 20 jurisdictions will expand eligibility or are leaning in that direction, approximately 14 states will not expand or are currently disposed not to, and the remaining 17 states are undecided. In 2013, states will have to confront the eligibility issue head on and, when they do, the results will differ—perhaps markedly—from current predictions.[2]

Greater Focus on Using, and Protecting the Privacy and Security of, Patient Information—*By Patricia A. Markus, Smith Moore Leatherwood LLP, Raleigh, NC*

2013 promises to be a landmark year, on several fronts, in the use and safeguarding of health information. Increasing numbers of healthcare providers are purchasing, implementing, and beginning to meaningfully use electronic health records (EHRs) to improve patient care outcomes and better track costs and quality of care. The data being generated and exchanged for these purposes is becoming a highly sought after commodity for public health agencies, researchers, individuals, covered entities, and others hoping to sell or otherwise profit from the data.

Innovative technologies that enable electronic exchange of health and other data serve as the backbone of emerging state health insurance exchanges and will be vital to the ability of accountable care organizations (ACOs) to analyze whether quality measures and savings thresholds are being achieved. These technologies also are behind both government and private insurers' significantly increased use of data mining to identify, prosecute, and prevent alleged fraud and abuse within the healthcare delivery system.

Coincident with this increased focus and reliance on health data, 2013 may be remembered as a turning point in health information privacy and security enforcement. The final rule addressing the Health Information Technology for Economic and Clinical Health (HITECH) Act revisions to the Health Insurance Portability and Accountability Act (HIPAA) privacy, security, enforcement, and breach notification rules was released on January 17 and becomes effective on March 26. The final rule is a game-changer for both patients and healthcare industry stakeholders.

Generally speaking, the rule increases safeguards for patients' protected health information (PHI) and expands patients' rights surrounding this data while considerably expanding liability for covered entities and business associates who fail to comply with the requirements. The final rule not only revises the definition of "business associate" to include subcontractors and entities that maintain PHI on behalf of covered entities—which pulls physical and cloud-based record storage facilities within the definition whether or not they actually access the PHI they maintain—but it significantly modifies the test for determining whether breach notification is required after an impermissible acquisition, access, use, or disclosure of unsecured PHI. Whereas the interim final rule required covered entities and business associates to report only those breaches that were determined to pose a substantial risk of harm to the affected individuals, the final rule assumes that an impermissible access, use, or disclosure of PHI will be reported unless the organization can demonstrate there is a low probability that the PHI was compromised. The rule thus shifts the focus of the analysis from the likelihood of harm to the individual to the likelihood that the information was or may be further accessed and misused, and the burden of proving that the information was not further accessed and misused now falls squarely on the entity responsible for the impermissible access, use, or disclosure.

Beyond these transformative changes, the final rule implements an increased civil monetary penalty structure for violations of the privacy and security rules, requires that individuals agree in advance to covered entities' use of their PHI to send them marketing information, prohibits the sale of PHI without patient authorization, requires providers to agree to patient requests that providers not share certain PHI with their insurance companies if the patients pay in full for the care out-of-pocket, and prohibits most health plans from using genetic information for underwriting purposes. Given these features, it is clear that covered entities, business associates, and subcontractors face substantial re-education efforts and re-tooling of their policies and practices to comply with the revised requirements and avoid enforcement activity.

Speaking of enforcement activity, numerous recent six- and seven-figure settlements involving breaches of PHI demonstrate that the industry remains challenged by the requirements to safeguard PHI on mobile devices and to prevent workforce members' unauthorized access to and disclosure of PHI. Covered entities and business associates should learn from these examples, focusing on security risk assessments, workforce training, and encrypting PHI whenever possible. In 2013, more entities likely will face Office for Civil Rights privacy and security compliance audits, state Attorney General or licensing board actions, and class action lawsuits for violating HIPAA or state information privacy and security requirements. And as social media becomes even more pervasive, organizations must address how to benefit from using these technologies while safeguarding PHI, assuring that providers remain professional on social media sites, and adopting employee social media policies that do not chill protected concerted activity.

Additional rules that may be issued in 2013 and present further challenges to organizations' use of health data and technology include:

- The Food and Drug Administration's (FDA's) final guidance on how it will regulate mobile medical applications;
- Stage 3 of the HITECH Act's meaningful use program requirements;
- The final rule addressing revisions to HIPAA's accounting of disclosures rule; and
- Passage of the Telehealth Promotion Act of 2012 or a successor bill.

4 Looming Spending Reductions for Healthcare?

—By Peter Leibold, AHLA

One of the most significant issues of 2013 for the health law bar and for the country will be how the President and Congress address the question of federal spending. Will the federal government reduce spending significantly in 2013? The political camps are split on whether to cut and what to cut. If spending is cut, will the President and Congress focus reductions on the entitlement programs, two of the most important being Medicare and Medicaid? Healthcare clients will have an extreme interest in the outcome of the gigantic fiscal debate that will take place over the next several months.

The prologue for this titanic battle is the vastly different viewpoints that inform the debate on the causes of our slow economic recovery and the best strategy to wake the United States from its economic doldrums.

Progressives believe that the causes of many of our economic problems began with tax cutting that occurred in

2001 and was periodically extended for all taxpayers until the end of 2012. They argue that federal revenues as a percentage of the nation's gross domestic product are at their lowest point in the last 60 years. Fiscal prudence dictates that the nation increases its level of taxation to support the amount of government spending necessary to support the nation's priorities. Progressives believe that Congress and the President have already demonstrated seriousness in cutting spending by passing the Budget Control Act of 2011, which capped the growth of domestic discretionary spending over the next 10 years, saving almost $1 trillion. Progressives generally applaud the recent passage of H.R. 8, the American Taxpayer Relief Act (ATRA) of 2012, which eliminated the extension of many of those tax reductions for individuals making more than $400,000, raising roughly $600 billion in new revenue.

Fiscal conservatives believe that that federal government's deficit problems and the nation's economic sluggishness result from too much spending rather than too little taxation. They point to the growing share of the federal budget spent on the entitlement programs, like Medicare, Medicaid, and Social Security. While discretionary spending remained relatively flat at roughly 9% of Gross Domestic Product (GDP) between 1991 and 2011,[3] spending on mandatory programs increased from 10.1% of GDP in 1991 to 13.6% of GDP in 2011.[4] According to the CBO, these mandatory programs are expected to grow even more quickly in the next 20 years. "The aging of the baby-boom generation portends a significant and sustained increase in coming years in the share of the population that will receive benefits from Social Security and Medicare and long-term care services financed through Medicaid."[5] Fiscal conservatives believe that the top deficit reduction priority is to slow the growth of federal entitlement programs, especially after the tax increases included in ATRA.[6]

As referenced above, the first skirmish in this ideological battle over the budget occurred at the end of 2012 when Congress and the President faced the prospect of huge tax increases on all Americans as the 2001 tax cuts expired and automatic spending cuts required by the Budget Control Act of 2011 would be triggered through a process called sequestration. Pressured by the Armageddon of simultaneous tax increases and spending cuts and the suspected recessionary impact on the economy, the parties waited to the last possible moment, but in the end enacted ATRA into law on January 2, 2013.

ATRA extended the tax reduction provisions of the Economic Growth and Tax Relief Reconciliation Act of 2001 and the Jobs and Growth Tax Relief Reconciliation Act of 2003 for individual taxpayers whose taxable income is below $400,000 ($450,000 for married couples filing a joint return). The legislation also sets the threshold for the phase-out of personal tax exemptions and itemized deductions at $250,000 for individuals ($300,000 for married couples filing a joint return); increases the top, marginal estate tax rate from 35% to 40%; and increases the capital gains tax rate from 15% to 20% for taxpayers whose taxable income is $400,000 or greater. The law also made important changes to the alternative minimum tax, which threatened to hit more taxpayers in the middle class. The law also extended certain credits designed to benefit individuals and businesses.[7]

ATRA also expanded spending in certain areas of significant interest to healthcare clients. The law extended physician payment rates for one year without change. Without this Social Security Act amendment, physician payment rates would have been reduced by 26.5%, which would have been a devastating cut for many physicians. The law also increased and decreased health spending in other ways. It increased spending by extending numerous provisions of interest to particular providers, like ground ambulance services, low-volume hospitals, Medicare-dependent small, rural hospitals, and many others. It reduced spending by reducing payment for certain services, like renal dialysis, multiple therapies on the same day, and certain outpatient services, in addition to numerous other spending reductions.[8]

Most importantly for health lawyers in 2013, the legislation postpones from January 2, 2013 until March 1, 2013 the sequestration required under the Budget Control Act of 2011 to take place by January 15, 2013.[9] The Budget Control Act not only cut domestic discretionary spending by almost $1 trillion, it put in place a procedural, legislative mechanism to force additional spending reductions of $1.2 trillion over 10 years if legislation was not enacted that expressed different spending reduction priorities. This target of $1.2 trillion for additional deficit reduction is at the core of the fiscal debate that continues to rage.

The health community will be lucky if they are only subject to the spending reductions required by sequestration—a 2% reduction in Medicare payments, with Medicaid and the Children's Health Insurance Program exempted, and an 8.2% reduction in all of the discretionary health programs appropriated annually, like programs administered by the Centers for Disease Control and Prevention, the Health Resource Services Administration, and the FDA. While some may see these as significant reductions, they pale in comparison to what may take their place in legislation designed to replace sequestration if fiscal conservatives push for more significant reductions in entitlements and less spending reductions in the defense budget. Health lawyers and their clients should be vigilant in following this debate and informing their clients on proposals targeting reductions in Medicare and Medicaid as Congress and the President engage over the sequestration that will occur on March 1, 2013 absent congressional action.

ACA 2013 Implementation/Regulatory Milestones—*By Bianca Bishop, AHLA*

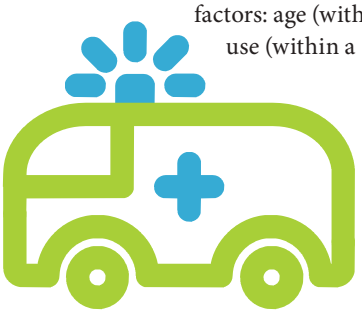
With the influx of millions of Americans into the healthcare system in 2014 through the new health insurance exchanges and the Medicaid expansion, this year promises to be a busy one for ACA implementation activities. In addition to these

major provisions of the ACA (and given their importance, they are considered in separate sections of this year's Top Ten), a number of other healthcare reform milestones are either going into effect or are on the near-term horizon in 2013.

Effective January 1, the ACA requires Medicaid to reimburse family medicine, general internal medicine, pediatric medicine, and related subspecialists on par with Medicare rates in calendar years 2013 and 2014. The Centers for Medicare & Medicaid Services (CMS) issued a final rule implementing the provision in November 2012. Eliminating this increase has come up in debt reduction talks, drawing strong opposition from national and state physicians groups who argue the new payment policy is necessary to help improve access to primary care physicians for existing and newly eligible Medicaid patients. Other ACA provisions that went into effect on January 1 include an increase in the income threshold for claiming itemized deductions for unreimbursed medical expenses from 7.5% of adjusted gross income to 10% of adjusted gross income (the increase does not apply to individuals age 65 and older through 2016); limits on the amount of contributions to a flexible spending account for medical expenses to $2,500 per year (indexed to inflation); increases in the hospital insurance tax rate of 0.9 percentage points on wages over $200,000 for an individual and $250,000 for married couples filing jointly; a 3.8% Medicare tax on net investment income on higher-income taxpayers; elimination of the tax deduction for the Part D subsidy for employers that maintained prescription drug plans for their Medicare-eligible retirees; and a 2.3% excise tax on the sales of certain medical devices.

Also on the radar screen for 2013 is the task of implementing and complying with the long-awaited final rule implementing the Physician Payments Sunshine Act (Sunshine Act), which was signed into law as part of the ACA and requires public disclosure of the financial relationships between physicians and pharmaceutical, medical device, and biologics manufacturers. CMS issued the final rule on February 1. CMS indicated data collection will begin August 1, with the reporting period running through December 2013.

While preparing for the launch of the insurance exchanges will take center stage this year, health insurers will be tracking and implementing a myriad of other new requirements and reforms that go into effect in 2014. Shortly after the presidential election, CMS issued a flurry of proposed rules, including one that would implement ACA provisions on guaranteed-issue coverage, rate reviews, single risk pools, and fair health insurance premiums, which allow insurers to vary premiums in the individual and small group market based only on the following factors: age (within a 3:1 ratio for adults), tobacco use (within a 1.5:1 ratio and subject to wellness program requirements in the small group market), family size, and geography.[10] The comment period for this proposed rule closed on December 26, 2012.



Also in November 2012, HHS issued a proposed rule outlining standards for essential health benefits (EHBs) and for meeting actuarial value requirements.[11] The ACA requires health insurance plans in the individual and small group markets, both inside and outside of the insurance exchanges, to offer a comprehensive package of items and services, known as "essential health benefits." The rule proposed to define EHBs based on a state-specific benchmark plan. States had until December 26, 2012 to make a selection, with the default being the largest small group product in the state. Finally, HHS and the Departments of Treasury and Labor jointly released proposed rules on nondiscriminatory wellness programs in group health coverage to reflect ACA changes.[12] Comments on this rule were due January 25.

This year also will likely see regulatory activity implementing the ACA requirement for a Medical Loss Ratio (MLR) applicable to Medicare Advantage (MA) plans. The ACA requires MA plans to have an MLR of no lower than 85% or to refund a specified sum to the government. Under this provision, MA plans that fail to meet the 85% MLR for three consecutive years will be prohibited from enrolling new members, while those that fail to meet the target for five consecutive years will be terminated from the program.

Starting in 2014, certain employers must offer affordable health coverage to their full-time employees or make an "assessable payment." The Treasury Department and the Internal Revenue Service (IRS) issued December 28, 2012 proposed regulations to implement the "employer shared responsibility" provision of the ACA. Under Section 4980H of the Internal Revenue Code, as added by the ACA, an "applicable large employer" generally is one that employs 50 full-time employees and full-time equivalents. These employers must offer a minimum level of affordable coverage to their full-time employees or pay a penalty if at least one of their full-time employees receives a premium tax credit for purchasing individual coverage in the new insurance exchanges. Comments on the proposed regulations are due March 18.

As this article was going to press, the IRS and CMS also issued proposed regulations relating to the requirement for non-exempt individuals to maintain minimum essential health coverage. IRS is planning a May 29 public hearing on the proposed regulations, which provide guidance on liability for the shared responsibility payment for not maintaining minimum essential coverage and clarifying exemptions to the individual mandate.

As new requirements take effect, and as these rules are finalized, health lawyers will undoubtedly play a key role in ensuring various stakeholders keep pace with ACA implementation.

Quality-Based Healthcare Models: Getting More Bang for Your Healthcare Buck—*By Sarah E. Swank, OBER | KALER, Washington, DC*

Quality activities are not new to healthcare, but this year will bring an increased emphasis on cutting cost and higher quality. What is new is the impact of quality scores on provider reimbursement. Under pay-for-performance models, providers that meet set quality measures are rewarded with greater reimbursement. Certain arrangements are voluntary or contractual, while others target specific provider types, especially in costly care settings.

Accountable Care Organizations and Commercial-ACOs

An example of a voluntary pay-for-performance program is the Medicare ACO shared savings program established under the ACA. ACOs receive a portion of the savings shared, but only if they meet prescribed quality measures. Over the course of their participation in the three-year program, ACOs move from pay-for-reporting to payments based on their performance on required quality measures. In establishing progressive reporting requirements, CMS cited concerns that certain types of providers may need more time to develop quality improvement skills.

This year, the ACO program doubled in size. Many early adopters of the ACO model, especially those required under the Pioneer ACO program through the CMS Innovation Center, are now turning to the commercial market to contract with health plans with ACO-like quality incentives. These arrangements trigger risk-sharing, antitrust, and fraud and abuse laws that are often not obstacles in the Medicare ACO program.

CMS Innovation Center

Last year was a busy one at the CMS Innovation Center. Established under Section 3021 of the ACA, it is charged with testing, evaluating, and spreading new healthcare payment and delivery models in hopes of transforming the healthcare system. The Center's release of new programs slowed down prior to the 2012 election and it is expected to announce several more grants, programs, and other solicitations this year. Based on a U.S. Government Accountability Office (GAO) report (GAO 13-12), the CMS Innovation Center will likely create a process to ensure that providers are not paid for the same service under models in other CMS offices. Although several of the 11 plus CMS Innovation Center programs are ongoing in 2013, two programs may provide the greatest opportunity for participation this year— the Bundled Payment and Dual Eligible programs.

Last year, providers applied to four different models under the Bundled Payment program by setting a price for a single episode of care and then receiving a predetermined discount if the target is met. The CMS Innovation Center contemplated the potential release of four additional models under this program, including additional prospective (or upfront) payments and models that focus on chronic illness, such as diabetes and asthma. Providers also await the state-by-state launch of the *State Demonstrations to Integrate Care for Medicare-Medicaid Enrollees* funded through the CMS Innovation Center. This demonstration focuses on Americans who are eligible for both Medicare and Medicaid (or "dual eligibles") who account for a disproportionate amount of the spending across both programs. This year, 15 states begin programs and CMS seeks Medicare-Medicaid plan applications for a new capitated model.

Value-Based Purchasing

Although the concept of valued-based payments began in 2005, the ACA specifically required the establishment of a hospital value-based purchasing program (Hospital VBP). October 1 of last year kicked-off the Hospital VBP, which provides inpatient hospitals incentive payments based on how closely they follow clinical best practices and how well hospitals enhance the patient care experience. CMS plans to add measures as the Hospital VBP program evolves. For example, the final rule for the Inpatient Prospective Payment System released on August 1, 2012 set out additional payment measures for fiscal year (FY) 2015. Other providers should take note, since CMS ultimately intends to roll out similar payment adjustments and quality programs to providers in the post-acute and outpatient settings. For example, the CMS Innovation Center is currently testing value-based purchasing under the Nursing Home Demonstration.

The Evolving Nature of Quality

Which leads us to the question, what happens when all the low hanging fruit is gone and quality has improved across the country? This year, we may see the impact of "topped out" measures, which means those measures where no statistical difference exists between the 75th percentile and 90th percentile. In addition, CMS will rely on "qualified entities" under the ACA and the rule making process to ensure effective measurement of current, new, and eliminated topped out quality measures. Ongoing evaluation allows CMS to incentivize cutting-edge care and quality improvement consistent with the evolving nature of evidence-based medicine.

Remaining Legal Challenges to ACA—*By Lisa Salerno, AHLA*

The Supreme Court's landmark June 2012 decision in *National Federation of Independent Business v. Sebelius* mostly put an end to the numerous challenges to the so-called individual mandate contained in the ACA. However, as those cases waned following the Court's ruling, litigation over other issues gained steam.

Challenges to the Contraceptive Mandate

One of the most significant sources of ACA litigation in 2013 will be the more than 40 lawsuits that have been filed challenging the "contraceptive" or "preventative services" mandate in the law. The preventative services mandate and its implementing regulations, issued by the Departments of Health and Human Services, Treasury, and Labor, require non-grandfathered health plans to cover, among other things, contraception and sterilization procedures with no cost sharing. The Advanced Notice of Proposed Rulemaking issued by the agencies in March 2012 specifically exempt "religious employers" from the mandate. The agencies also established a temporary enforcement safe harbor until August 1, 2013 for nonprofit employers that did not meet the regulatory definition of a "religious employer" but that professed religious objections to providing coverage for contraceptives. On February 1, 2013, the agencies issued proposed rules simplifying the definition of a "religious employer" and proposing an accommodation for nonprofit religious organizations, such as nonprofit religious hospitals or institutions of higher education, that object to contraception on religious grounds under which enrollees would be provided separate contraceptive coverage with no co-pays, but at no cost to the religious organization.

Plaintiffs in these lawsuits generally allege the coverage mandate places them in a position of either violating their religious beliefs or paying substantial penalties for noncompliance. Specifically, plaintiffs contend the rules violate the Religious Freedom Restoration Act (RFRA), the First Amendment's Free Speech and Free Exercise Clauses, and the Administrative Procedure Act (APA). Plaintiffs generally fall into two categories: secular, for-profit corporations and religious institutions not covered by the exemption. Most cases involving religious organizations have been dismissed on ripeness grounds due to the temporary enforcement safe harbor.

Several federal appeals courts recently issued rulings in cases where secular companies have challenged the law and have reached opposite conclusions, thereby setting up a circuit split, making it somewhat likely that the Supreme Court will take up the issue in 2013.

On December 20, 2012, the Tenth Circuit denied an injunction pending appeal, agreeing with the district court's findings that the secular, for-profit corporations, Hobby Lobby Stores, Inc. and Mardel, Inc., and several individual plaintiffs did not have free exercise rights; the individual plaintiffs were unlikely to prevail on their constitutional claims because the preventative care coverage regulations are neutral laws of general applicability that are rationally related to a legitimate governmental objective; the corporate plaintiffs are not "persons" for purposes of the RFRA; and the individual plaintiffs failed to establish that compliance with the regulations would "substantially burden their religious exercise" under the statute. *Hobby Lobby Stores, Inc. v. Sebelius*, No. 12-6294 (10th Cir. Dec. 20, 2012). The appeals court found that the plaintiffs' contribution of funds to a group health plan that could subsidize someone else's participation in an activity condemned by plaintiffs' religion was likely too attenuated and indirect to establish a "substantial burden" for purposes of their RFRA claim.

However, in a December 28, 2012 decision, the Seventh Circuit reached the opposite conclusion and granted an application for injunction pending appeal after a district court ruled plaintiffs, a construction company and its owners, failed to establish a likelihood of success on their RFRA claims. *Korte v. Sebelius*, No. 12-3841 (7th Cir. Dec. 28, 2012). The Seventh Circuit found the plaintiffs established a reasonable likelihood of success on their RFRA claim that the contraceptive mandate imposes a substantial burden on their religious exercise and that the "government has not advanced an argument that the contraception mandate is the least restrictive means of furthering these interests."

Two other recent district court decisions also split on this issue. On November 16, 2012, the U.S. District Court for the District of Columbia agreed to halt enforcement of the regulations as to Tyndale House Publishers, Inc., a Christian publishing company, that alleged, similarly to the other lawsuits, that the rules violate RFRA, the First Amendment, and the APA. *Tyndale House Publishers, Inc. v. Sebelius,* No. 12-1635 (RBW) (D.D.C. Nov. 16, 2012). The court determined plaintiffs had shown the contraceptive coverage mandate would substantially burden plaintiffs' religious exercise and distinguished its ruling on this issue from the facts in another recent case, *O'Brien v. United States Dep't of Health and Human Servs*., No. 4:12-CV-476 (CEJ) (E.D. Mo. Sept. 28, 2012), in which the U.S. District Court for the Eastern District of Missouri dismissed a challenge to the regulations on the merits after finding plaintiffs failed to demonstrate a substantial burden on their religious exercise. In *O'Brien*, the plaintiffs provided health insurance to their employees through a group health insurance policy that was separately administered by an insurance company, compared to the Tyndale plaintiffs that provide direct coverage to Tyndale employees through a self-insured plan. However, the Eighth Circuit subsequently granted without discussion, a motion for an injunction pending appeal in the *O'Brien* case. *O'Brien v. United States Dep't of Health and Human Servs.,* No. 12-3357 (8th Cir. Nov. 28, 2012). The administration has since filed a notice of appeal with the D.C. Circuit in the *Tyndale* case.

A number of other district courts also have weighed in with different results. *See, e.g., Grote Indus., LLC v. Sebelius*, No. 4:12-cv-00134-SEB-DML (S.D. Ind. Dec. 27, 2012) (denying a preliminary injunction to secular, for-profit manufacturing business with self-insured health plan); *Monaghan v. Sebelius*, No. 12-15488 (E.D. Mich. Dec. 30, 2012) (granting temporary

restraining order to secular, for-profit property management company and its owner and sole shareholder); and *Sharpe Holdings, Inc. v. U.S. Dep't of Health and Human Servs.*, No. 2:12-CV-92-DDN (E.D. Mo. Dec. 31, 2012) (granting motion for temporary restraining order to for-profit corporation).

In addition, other courts have dismissed similar lawsuits without reaching the merits for lack of standing or ripeness. *See, e.g., Wheaton College v. Sebelius,* No. 12-1169 (ESH) (D.D.C. Aug. 24, 2012); *Nebraska ex rel. Bruning v. United States Dep't of Health & Human Servs.*, No. 4:12CV3035 (D. Neb. 2012); *Belmont Abbey College v. Sebelius*, No. 11–1989 (D.D.C. 2012). *University of Notre Dame v. Sebelius*, No. 3:12CV253RLM (JEB) (N.D. Ind. Dec. 31, 2012) (finding lack of standing and claims not ripe for review because of temporary enforcement safe harbor); *Catholic Diocese of Peoria v. Sebelius*, No. 12-1276 (C.D. Ill. Jan. 4, 2013) (dismissing challenge after finding question presented not ripe for judicial review).

It remains to be seen how this issue will ultimately be resolved. The Supreme Court may take up the issue in 2013 if employers still object to the coverage mandate as amended in the proposed rules. The implications of the proposed rules, which were issued as this article was going to press, is unclear at this time.

Low-Income Subsidy for Federally Run Exchanges

Another hotly litigated ACA issue is the availability of federal subsidies for individuals who participate in non-state exchanges. The text of the ACA does not provide for tax credits or subsidies for people who purchase insurance on federally operated exchanges. But the IRS issued a rule that extends the ACA's premium-assistance tax credits to individuals purchasing insurance through a FFE.

A complaint filed September 19, 2012 in *Oklahoma v. Sebelius* (E.D. Okla.) argues the IRS overstepped its authority in promulgating the rule. Congressional Republicans also have repeatedly questioned the IRS' authority under the ACA to extend the tax credits beyond the state-run exchanges. This is an important issue to watch given the non-availability of subsidies in a FFE could have a significant effect on the operation of the exchanges.

Fraud and Abuse Enforcement

—By Jennifer C. Hutchens, Robinson Bradshaw and Hinson PA, Charlotte, NC

Healthcare fraud and abuse enforcement remains a priority for the federal government. In April 2012, the Department of Justice announced a record $4.1 billion in healthcare fraud judgments in fiscal year (FY) 2011. 2012 also saw the largest settlement involving a pharmaceutical company, when GlaxoSmithKline paid $3 billion in fines for illegally promoting its antidepressants for unapproved uses and failure to report safety data involving a diabetes drug. In a recent series of raids in seven states targeting healthcare fraud, over 90 people (including hospital administrators and doctors) were arrested in connection with allegations of fraud totaling over $430 million. This year, healthcare enforcement activity should continue to loom large over the regulatory landscape.

Voluntary Self-Disclosure of Medicare and Medicaid Violations

The CMS Self-Referral Disclosure Protocol (SRDP), released in September 2010, offers providers a way to resolve actual or potential violations of the federal Stark Law at potentially less than the total penalty exposure. In a positive development for providers either currently in the SRDP or considering a submission, CMS said in 2012 that it is willing to limit the "lookback" period to four years, rather than the duration of the Stark violation(s). To date, 16 SRDP settlements have been announced, spanning a broad range of amounts. HHS reported to Congress that as of March 2012, the SRDP had received 150 disclosures, and more have certainly been submitted since. Consequently, 2013 is sure to see more settlement activity for submitted self-disclosures.

Also in 2013, the OIG Provider Self-Disclosure Protocol (SDP), utilized for self-disclosed violations of the federal Anti-Kickback Statute, False Claims Act, and Civil Monetary Penalties Law, will likely be updated. The OIG solicited comments and recommendations for the updated SDP in June 2012. The revised self-disclosure process should address the impact of the 60-day rule.

Release of Final Rule—Physician Payments Sunshine Act

On February 1, 2013, CMS issued the final Physician Payments Sunshine Act rule, requiring pharmaceutical and medical device companies to disclose payments made to physicians in a publicly searchable database. The database should be available by September 2014. With narrow exceptions, all cash and in-kind gifts (e.g., speaking fees, meals, and travel) given by such companies to physicians must be disclosed. The rule also mandates disclosure of physician investment in such companies. Payments for research on new or investigational drugs or devices are delayed from entering the database. The rule gives physicians 45 days to review and, if necessary, correct the information to be posted to the database. Companies that fail to file necessary disclosures may face fines ranging from $150,000 to $1 million.

Healthcare Fraud Prevention Partnership

In July 2012, the Health Care Fraud Prevention Partnership (HFPP) was launched among the federal government, state officials, several private health insurance organizations, and other healthcare antifraud groups to share information and best practices and thereby improve detection of, and prevent payment for, fraudulent healthcare billing. From a long-range perspective, HFPP endeavors to use cutting-edge technology

and analytics on industry-wide data to better predict and identify healthcare fraud schemes. For example, a potential HFPP goal is to target and stop payments billed to different insurers for healthcare delivered to the same patient on the same day in two different cities. In 2013 and beyond, how the HFPP will operationalize its antifraud initiatives remains to be seen.

Case Watch: Stark Law

At least two cases should be monitored in 2013 for their potential impact on the federal Stark Law. *United States ex rel. Drakeford v. Tuomey Healthcare System Inc.,* No. 10-1819 (4th Cir. Mar. 30, 2012), is set for retrial in March 2013. On retrial, the *Tuomey* case may consider critical questions regarding the scope of the Stark Law, including whether, assuming that Tuomey considered the volume or value of anticipated facility component referrals in computing the physician compensation at issue, the part-time employment agreements in question implicated the "volume or value" standard under the Stark Law. Another important Stark Law case is *United States ex rel. Kunz v. Halifax Hospital Medical Center,* No. 6:09-CV-1002 (M.D. Fla. Jan. 10, 2012), which is currently in discovery, and could result in significant rulings on whether the implicated physician employment agreements satisfy the personal services exception under the Stark Law.

9 Supreme Court Review of "Pay for Delay" Agreements—*By Bianca Bishop, AHLA*

The pharmaceutical industry this year will be eyeing closely the Supreme Court's deliberations and decision in the long-standing dispute over the legality of so-called "pay for delay" (also known as reverse payment) agreements to settle patent infringement litigation. Whether these agreements, which involve brand name drug companies settling patent disputes by paying or providing value to generic drug manufacturers in exchange for an agreement to delay market entry of the generic drug, should be considered presumptively anticompetitive under the antitrust laws has divided the federal circuits. While the Eleventh, Second, and Federal Circuits have found a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent, the Third Circuit recently adopted a "quick look rule of reason analysis" that treats "any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as prima facie evidence of an unreasonable restraint of trade." A patent holder could rebut this presumption under the Third Circuit's approach by showing the payment was for a purpose other than delayed entry of the generic or offered some procompetitive benefit.

In December 2012, the Supreme Court agreed to review the Eleventh Circuit decision in *Federal Trade Comm'n v. Watson Pharmaceuticals*, No. 1:09-cv-00955-TWT (11th Cir. Apr. 25, 2012), which affirmed the dismissal of the Federal Trade Commission's (FTC's) challenge to agreements in which a brand name manufacturer paid generic drug makers to delay generic competition to the testosterone-replacement drug AndroGel. The specific question presented to the Court is "Whether reverse-payment agreements are per se lawful unless the underlying patent litigation was a sham or the patent was obtained by fraud (as the [Eleventh Circuit] held), or instead are presumptively anticompetitive and unlawful (as the Third Circuit has held)."

Merck & Co. also petitioned the Court to review the Third Circuit's decision, *In re K-Dur Antitrust Litig.*, No. 10-2077 (3d Cir. July 16, 2012), which revived a class action alleging Schering-Plough Corp. (now part of Merck) and two generic drug manufacturers entered into unlawful reverse payment patent settlements that delayed the market entry of cheaper-priced generics in violation of the antitrust laws. In its petition for review, Merck framed the case as presenting "one of the most significant unresolved legal questions currently affecting the pharmaceutical industry," which "has been percolating in the lower courts for more than a decade." The Court has not ruled yet on that petition.

For years, FTC has argued, mostly unsuccessfully, that such deals are presumptively anticompetitive, saying they cost Americans $3.5 billion annually by delaying market entry of cheaper generic drugs. A position it reiterated in a brief filed with the Court on January 22. In a recent staff report, FTC said the number of potentially anticompetitive patent dispute settlements between branded and generic drug makers jumped from 28 in FY 2011 to 40 in FY 2012. The pharmaceutical industry contends, however, that restricting drug patent litigation settlements will dampen innovation and delay consumer access to affordable medicines. Responding to the recent FTC report, Generic Pharmaceutical Association President and Chief Executive Officer Ralph G. Neas said "[p]atent settlements have never prevented competition beyond the patent expiry, and generally have resulted in making lower-cost generics available months and even years before patents have expired."

While some lawmakers argue pay-for-delay deals subvert the goals of the Hatch-Waxman Act, and legislation to restrict these agreements has gained some traction, Congress has yet to enact such a measure. In 2011, CBO estimated that enacting proposed legislation (The Preserve Access to Affordable Generic Drugs Act) imposing restrictions on pay-for-delay patent settlements would save nearly $4.8 billion over 10 years by accelerating the availability of lower-priced generics. Limiting these types of agreements also has been floated in deficit reduction talks.

With oral arguments in *FTC v. Watson* scheduled for March 25, health and life sciences lawyers will be closely monitoring the outcome of this significant antitrust development.

10 Compounding Pharmacy Litigation Will Come into Focus—*By Jonathan L. Eisenberg, The General Counsel Ltd., St. Paul, MN*

The fungal meningitis outbreak that began in 2012 has led thus far to 678 cases of infection in 19 states, including 44 deaths.[13] Litigation promptly ensued against New England Compounding Company (NECC), its principals, and certain related companies. At least 28 lawsuits are pending, with a motion to consolidate pending before the Judicial Panel on Multidistrict Litigation (JPML).[14] In 2013, we will likely see a decision by the JPML on consolidation as well as decisions related to the onset of discovery and the liability of various parties other than NECC itself.

NECC filed for bankruptcy in December.[15] Therefore, the bankruptcy court will need to determine if the automatic stay of litigation should be lifted.[16] The decision may be influenced by the availability of insurance to cover defense costs as well as at least a portion of the potential liability. The court also may consider the existence of other defendants who are not subject to the automatic stay. Lastly, among other possible factors, the bankruptcy court may take into account which court(s) may be in the best position to identify and marshal additional assets that may be subject to the liability claims as well as to determine whether liability extends beyond the debtor.

Assuming the NECC litigation is allowed to proceed, we will likely see in 2013 at least some of the fruits of the discovery process. A potential fight over confidentiality of internal NECC data may be influenced by the fact that NECC is no longer in business and thus presumably has a weak claim, if any, to trade secret protection. Other defendants may have greater claims to confidentiality protection.

Key issues likely to be explored in discovery, and of great interest to the public and media, would include the extent of internal prior knowledge of deleterious conditions, the role of various individuals and entities in operating if not controlling NECC, and the actions of the state of Massachusetts and the FDA in regulating NECC operations.

If the litigation proceeds, the non-NECC defendants will seek to avoid liability based upon the corporate shield. Plaintiffs will likely try to show individual actions that may lead to separate liability, as well as test various theories under which the "corporate veil" might be pierced. The role and potential liability of various related corporate entities will also likely be explored.

The NECC litigation is not likely to be settled until the potentially responsible parties are determined and the potential assets that may satisfy claims are identified. If liability is ultimately limited to NECC and its insurance, then the cases may come to a prompt conclusion; if not, then the litigation may be expected to be more protracted.

While the NECC litigation probably will not be concluded in 2013, we are likely to see the litigation move forward on some level, with facts unearthed in discovery becoming a focus of media attention and some key rulings on any exposure of non-NECC parties. We may also see new cases asserted against other pharmacy compounding companies, as plaintiffs' lawyers look more closely at the causes of various illnesses in light of the unfortunate history of this industry.[17] C

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Endnotes

1 The MOE requirements expire on October 1, 2019 for individuals under age 19. They expire for adults at the time the health insurance exchange in the state is determined to be in operation (expected to occur in 2014).

2 For those interested in a more detailed treatment of these issues, including legal and other source citations, *see* http://ppsv.com/assets/attachments/167.PDF.

3 Congressional Budget Office, *Budget Infographic–Discretionary Spending* (Apr. 16, 2012), *available at* www.cbo.gov/publication/43155.

4 Congressional Budget Office, *Budget Infographic – Mandatory Spending* (Apr. 16, 2012), *available at* www.cbo.gov/publication/43154.

5 Congressional Budget Office, *Choices for Deficit Reduction* at 5 (Nov. 8, 2012).

6 Jeff Zients, Deputy Director for Management, Office of Management and Budget, blog post (Jan. 1, 2013), *available at* www.whitehouse.gov/blog/2013/01/01/american-taxpayer-relief-act-reduces-deficits-737-billion.

7 Library of Congress, Summary of H.R. 8, the American Taxpayer Relief Act of 2012, *available at* http://thomas.loc.gov/cgi-bin/bdquery/z?d112:HR00008:@@@L&summ2=m&.

8 *Id.*

9 *Id.*

10 *See* William A. Helvestine, A. Xavier Baker, and Jacinta Alves, *CMS Issues Proposed Rules On Rate Review, Risk Pools, Guaranteed Availability And Renewability, And Fair Premiums Under Affordable Care Act,* Health Lawyers Weekly, vol. X, no. 50 (Dec. 21, 2012).

11 *See* Kevin B. Kroeker and Peter Roan, *CMS Proposed Rule On Affordable Care Act Standards For Essential Health Benefits, Actuarial Value, And Accreditation,* Health Lawyers Weekly, vol. X, no. 49 (Dec. 14, 2012).

12 *See* Andrew J. Hefty, Seth T. Parretta, and Allison Ullman, *Agencies Release Proposed Regulations Regarding Incentives for Nondiscriminatory Wellness Programs in Group Health Plans,* Health Lawyers Weekly, vol. X, no. 49 (Dec. 14, 2012).

13 U.S. Centers for Disease Control and Prevention, *Multi-state Fungal Meningitis Outbreak—Current Case Count* (updated Jan. 14, 2013), *available at* www.cdc.gov/hai/outbreaks/meningitis-map.html. For background discussion of the situation, see my prior articles: *Top Ten Things You Need to Know About the Fungal Meningitis Outbreak,* Health Lawyers Weekly, vol. X, no. 42 (Oct. 19, 2012), *available at* www.gcl.com/Docs/Fungal-Meningitis_Top-Ten-Need-to-know.pdf, and *Update on Pharmacy Compounding and the Fungal Meningitis Outbreak,* Health Lawyers Weekly, vol. X, no. 46 (Nov. 16, 2012), *available at* www.gcl.com/Docs/Update-Pharmacy-Compounding-Fungal-Meningitis-Outbreak.pdf.

14 *Defendant New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center's Response to Plaintiffs [sic] Motion for Transfer of Actions Pursuant to 28 U.S.C. §1407 for Coordinated or Consolidated Pretrial Proceedings at 7 filed in In re: New England Compounding Pharmacy, Inc. Product Liability Litigation* (J.P.M.L., MDL No. 2419, Case No. MIE/2:12-cv-14856) (Nov. 7, 2012), *available at* http://cdn.aboutlawsuits.com/wp-content/uploads/2012-11-07-NECC-MDL-Response.pdf.

15 Dawn McCarthy, *New England Compounding Pharmacy, Inc. Files Bankruptcy,* Bloomberg News, Dec. 21, 2012, *available at* www.bloomberg.com/news/2012-12-21/new-england-compounding-pharmacy-inc-files-bankruptcy.html. (New England Compounding Pharmacy, Inc. is commonly known as NECC.)

16 11 U.S.C. § 362. *See, e.g., In re Sonnax Indus., Inc.,* 907 F.2d 1280, 1285-85 (2d Cir. 1990), *available at* https://bulk.resource.org/courts.gov/c/F2/907/907.F2d.1280.89-5023.955.html (reviewing bases upon which Bankruptcy Court's "broad discretion" may be exercised, now known as the "*Sonnax* factors").

17 *See* historical materials, including various warning letters and two FDA "limited surveys" of compounded drug quality, at FDA, *Pharmacy Compounding, available at* www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm.