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Healthcare Reform: Analyzing the Supreme Court Decision

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Today's faculty features:

J. Peter Rich, Partner, **McDermott Will & Emery**, Los Angeles

Christopher M. Jedrey, Partner, **McDermott Will & Emery**, Boston

Amy M. Gordon, Partner, **McDermott Will & Emery**, Chicago

Paul W. Radensky, M.D., Partner, **McDermott Will & Emery**, Washington, D.C.

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PPACA Upheld: Key Payor-Related Issues

July 10, 2012 Strafford Webinar
Healthcare Reform: Analyzing the Supreme Court Decision

J. Peter Rich
McDermott Will & Emery LLP
Los Angeles
jprich@mwe.com

Supreme Court Decision

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- The Individual Mandate is upheld under Congress' taxing authority
- Medicaid expansion is generally upheld, but federal government cannot enforce expansion on states by withholding original Medicaid funding
- Initial reactions from certain state officials on both Medicaid expansion and Exchange implementation

PPACA Upheld: Key Payor-Related Issues

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I. Impact of Decision on Payors

A. Deferring legal compliance with ACA was not an option for payors because so many features of the law governing insurers already have gone into effect, including:

1. Benefit Features (elimination of lifetime limits, reduction in annual limits, full coverage of preventive services, adding dependents to coverage up to age 26)

2. Premium Rate Regulation

(a) MLR rules (first distribution of MLR rebates to occur by August 1)

(b) Premium Rate Increase regulation is in effect (a few health insurers have already been subjected to the "bully pulpit" process by HHS).

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B. Major legal concern prior to Supreme Court's Decision: Would there be guaranteed issue and community rating but no mandate requirement?

Mandate upheld by the Court, so insurers will go forward with (1) guaranteed issue, guaranteed renewability, and no preexisting conditions and (2) community rating

1. Community rating will limit rate variations, which may be based only on plan/policy type (individual or family), rating area (as established by the states), age (age bands permissible), and tobacco use.

2. Maximum differential on rate variations is 3 to 1

3. Although community rating spreads the increased costs, it does not ameliorate health care cost trends.

Scope of the Individual Mandate "Tax"

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C. How is the "Tax" Calculated

1. Exception for people whose income is below the federal poverty line, people for whom the required premium would be greater than 8% of taxable income, or people who don't file a tax return

2. The "tax" is the greater of either a percentage of applicable income or a flat dollar amount

3. The percentage of income will be 1.0% in 2014, 2.0% in 2015, and 2.5% thereafter

4. The flat dollar amount per person is $95 in 2014, $435 in 2015, and $695 in 2016 and beyond; capped per family at 300% of the annual flat dollar amount

6. The overall cap for noncompliance is that the "tax" cannot exceed the national average premium for bronze-level qualified health plans offered through the exchanges

Impact of the Mandate as Health Insurance Costs Rise

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D. Will the Mandate Work?

1. As spread between increasing premiums and the mandate penalty/tax becomes larger, weak mandate may have less of an impact

2. Some two-thirds of surveyed actuaries expect health insurance costs for large group employers and individuals to go up at least 5% and 10% respectively (from Spencer's Benefits Reports)

3. The growth of the mandate tax is indexed to a cost-of-living adjustment which means its impact could further diminish over time

4. Individuals who do not purchase insurance and just pay the tax are likely to be the people with better health status

5. Possible reduction in the number of potential insureds as a result of the Court's ruling on Medicaid expansion (projections were about 16 million new Medicaid insureds as a result of the expansion)

6. Will there be political pressure to delay the effective date of the individual mandate tax, even if the president is reelected?

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E. There will be an expanded pool of insureds (projection was about 32 million new insureds due to ACA) as the quid pro quo for the additional federal regulation and new insurer taxes. BUT:

1. Likely less than projected, due to the weakness of the individual mandate tax.

2. Will the ACA's coordinated open enrollment periods further limit adverse selection? How often should they occur?

3. Will there need to be additional penalties in the form of surcharges on premiums for those who delay obtaining coverage until they have a preexisting condition?

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G. Payor Response to the Affordability Challenge: Move from FFS to New ACO-type Quality Outcome and Value-Based Payment System

1. This phenomenon had already begun with many health insurers, which are developing data systems, provider collaboration arrangements, and new payment techniques.

2. Not dependent upon Medicare ACO formation and Medicare demonstration grants, although these reforms are helping to facilitate the changes needed by insurers with their provider partners.

3. Greater provider/plan integration through direct plan purchases of health care delivery system capacity

4. Creation of benefit/product designs focused on high quality and more cost efficient health care delivery systems

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5. Medicare Advantage already moved in this direction after reduction in MA capitation payment amounts combined with introduction in 2012 of additional revenue sources based on the Star Quality Rating System, to pay bonuses for high achieving plans and permitting greater retention of rebates (challenge for those MA Plans whose ratings remain in the average 3 to 3.5 star range, as opposed to 4-5 Star range, whether they will qualify for bonuses past 2014).

6. Supreme Court Decision will accelerate this ongoing restructuring of provider-payor arrangements; an even greater sense of urgency will occur with both providers and payors now that there is greater certainty.

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7. July 2, 2012 Comment Letter by the Blue Cross Blue Shield Association to CMS, IRS and DOC questioned use of **stop-loss insurance with low attachment points** by group health plans and plan sponsors for small companies (e.g., CIGNA, Assurant).

(a) Could induce small employers to self-insure and thus avoid PPACA's expensive mandates for fully insured plans.

(b) 12-15% of claims exceed stop-loss attachment point.

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(c) In states without stop-loss attachment minimums, coverage could be set at 6,500 per employee.

(d) NAIC considering change to Model Act to raise coverage levels and make it more difficult for small firms to self-insure.

(e) Consumer groups questioned “lasering,” where stop-loss has higher attachment point for members with serious ongoing health conditions.

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II. Impact of Exchanges on Payors

A. Exchange certifies plans for participation but the State Exchanges have authority to create standards beyond the federal minimum. Key areas include

(1) marketing;

(2) network adequacy;

(3) rate review;

(4) benefit design standards.

What are standards and when will payors know?

B. What would be the preference of the payors? Federal vs. State

(1) Dealing with the federal government vs. a locally-based Exchange.

(2) What communications/input mechanisms will there be to ensure that the state/local needs as to health care costs, health care delivery, and uniqueness of marketplace are considered?

(3) Federal regulations allow premium subsidies on state and perhaps federal Exchanges

(4) Critics of the law are arguing that ACA premium subsidies are not available for Federally-run Exchanges based on statutory language.

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C. Will the exchange marketplace be open to all Qualified Health Plans (QHPs)?

During the first year "yes" but will federally operated exchanges move to a competitive bidding model? Will federal exchanges adopt the quality payment models already employed for Medicare Advantage plans?

D. Number of areas to still be addressed in future rulemaking

(1) Defining Essential Health Benefits

-- Even though great latitude given to the states, states need to confirm what is the basic package

-- Actuarial value and other benefit design standards for the silver, bronze and platinum plans that are to be offered on the Exchanges

(2) Health insurers need adequate advance time to develop the products, the rates, the information systems, and the marketing strategies to implement the insurance products to be sold on the Exchanges

2. The Status of the State Exchanges

(a) State Exchange Plans must be approved or "conditionally approved" by HHS no later than January 1,2013 for operation in 2014. By November 16th of 2012, states are required to submit a blueprint for approval indicating whether they plan to run their own exchange or will participate in a federal-state partnership exchange.

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(b) Conditional approval will continue so long as a state continues to meet expected progress milestones. Exchange must be able to:

-- provider consumer support for coverage decisions

-- facilitate eligibility determinations for individuals

-- provide for enrollment in QHPs

-- certify health plans as QHPs

-- operate Small Business Health Options Program (SHOP)

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3. If a state does not meet certain criteria, the federal government will run the exchange but there are three options:

(a) Federally facilitated exchange

(b) State-based exchange where the State operates all Exchange activities

(c) Partnership Model exchange

4. HHS will "certify" health insurers who participate in the Exchange but will still confirm state licensure status with the state as well as compliance with state solvency and similar requirements

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(c) Status of State Exchange Planning – Readiness?

(1) 12 states had halted exchange planning while awaiting a ruling from the Supreme Court

(2) Another 5 states indicated that while they were not pursuing Exchange legislation until the Supreme Court ruled, they were continuing planning for the Exchange,

(3) Six states never began planning for an Exchange and Governors in a few states have recently indicated that they will not implement the Exchanges.

(4) Availability of outside vendors/contractors may be an issue as the time frames become more compressed and the number of states moving forward with their Exchanges grows

New Exchange Funding Opportunities Created by HHS

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- On June 29, 2012, the Secretary of HHS identified 10 additional funding opportunities for states to apply for funding to establish a state-based Exchange
- States can apply for Exchange establishment cooperative agreements through the end of 2014 as they continue to work on their Exchanges
- States participating in federally-facilitated Exchanges may also receive funding to support a transition to a Partnership Exchange or state-based Exchange

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III. The Uncertainty Around Medicaid Expansion and Its Impact on Payors

A. What Will Certain States Do In Light of Supreme Court Decision?

1. Carrot and stick approach is now changed to carrot only, but it is a big carrot.

2. PPACA required states to expand eligibility for Medicaid to all residents earning below l33% of the federal poverty line (estimate around 16-17 million people)

3. Federal contribution is high - federal govt. pays 100% for the first three years (2014-02016) and then moves down to a permanent 90 % contribution by 2020 (not clear yet whether states are locked in perpetuity after they get initial funding at 100% level).

4. State budget limitations on Medicaid spending could be a consideration even with the generous federal funding participation, but hard to say how this will ultimately play out.

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B. What are the implications for the Payors?

1. For Payors who were expecting the 16-17 million insureds, there may now be a lesser number.

2. There will be some overlap in terms of eligibility subsidies under the Exchanges. So, there could be a shift for those persons who earn between 100% and 133% of the federal poverty level to have the option of applying for subsidies on the new exchanges starting in 2014.

3. Will there be enough physicians to serve the new insureds, particularly in rural areas?.

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4. For those individuals who do not qualify for the subsidies (people under 100% of FPL but not covered by State Medicaid program) and who are not covered by an unexpanded State Medicaid Program, who are they and what affect will they have on the ability to manage health care costs within a state?

5. "Churning" phenomenon from State Medicaid programs to Exchanges (as people's income status changes) is influencing many payors who were not in the Medicaid market to consider entry into that market in an attempt to better manage the health care needs of the individual.

6. That strategy may be impacted for those individuals who do not have the expanded Medicaid coverage in that state.

7. Mandate has income exemptions where the required premium amount is 8% or more of the individual's household income. Also, if you are under 100% of FPL then there is no tax penalty for failing to purchase coverage.

8. Cost Shift Impact: hospitals will incur additional bad debt for these individuals and will have a need to make it up on their commercial insured business.

Below the Radar: Potential Adverse Tax Consequences for Risk-Bearing Entities, Their Capitated Medical Groups and Other Affiliates

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- §162(m)(6) of the Internal Revenue Code (added by PPACA) significantly limits deductions that may be taken by a "covered health insurance provider" ("CHIP")
- A CHIP may only deduct up to $500,000 of compensation annually for any employee and certain other providers
- Compensation includes salary, bonus, gains from stock options, vesting of stock options and other forms of incentive pay
  - No exception for performance-based pay
- Generally applies for tax years beginning after 2012
- Appendix 1 sets forth §162(m)(6) in its entirety

Overview of §162(m)(6) Employer Aggregation Rules

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- Employer aggregation rules governing tax qualified plans are applied before determining which entities are part of a CHIP
- Examples of groups under employer aggregation rules include:
  - parent-subsidiary groups
  - brother-sister groups
  - affiliated service groups (A-Org and B-Org)
  - management service organizations
- Entities that are not themselves in the business of health insurance can be subject to §162(m)(6) deduction limits due to these aggregation rules

Overview of §162(m)(6) Legislative Intent

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- PPACA legislative deliberations demonstrate an intention to avoid subsidizing (through tax deductions) health insurers that would receive millions of new customers purchasing their product for the first time
- Statements on the floor alleged that:
  - Significantly less revenue as a percentage of each premium dollar has been spent on patient care over time since the early 1990s
  - this trend translated into a difference of several billion dollars in favor of insurance company shareholders and executives at the expense of health care providers and their patients

Source: 155 CONG. REC. S12,540 (Dec. 6, 2009)

What is a CHIP under §162(m)?

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- A CHIP is a "health insurance issuer" with not less than 25 percent of gross premiums received from minimum essential coverage
  - this definition applies for tax years beginning after 2012
- §9832(b) of the Internal Revenue Code, added by HIPAA and incorporated by reference into §162(m)(6), defines a "health insurance issuer" as an organization that is:
  - either an "insurance company, an insurance service or an insurance organization," including an HMO,
  - "licensed to engage in the business of insurance in a State", and
  - "subject to State law that regulates insurance" (as defined under ERISA)

Insurance and §9832

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- IRS regulations do not interpret what is insurance for purposes of the health insurance insurer definition under §9832(b)

- Key observations regarding §9832(b)
  - not just insurance companies can be a “health insurance issuer”
  - status depends on state law licensing and solvency requirements

- State-licensed/certified (non-HMO/insurance company) risk-bearing organizations engage in certain insurance related activities
  - these entities use risk-shifting (capitation)
  - contracts entered into by these entities cover future contingencies in a manner similar to health insurance

State Laws Regulating Health Care Delivery Models

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- A patchwork of state laws have developed to regulate state-licensed/certified (non-HMO/insurance company) risk-bearing health organizations (referred to below as “Risk-Bearing Organizations”)

- Applicable states include California, Florida, Massachusetts, New Jersey, New York, Ohio, and Pennsylvania

- State law licensing requirements applicable to Risk-Bearing Organizations may impose solvency requirements (e.g., SB 260 in California)

Section 162(m)(6) Risk Factors - Continued

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Examples of representative state insurance/managed care laws that may apply to ACOs and other risk-bearing organizations include:

- California Knox-Keene Act: ACO requires "Limited" Knox-Keene Plan license to assume global downside risk for physician and hospital services
- Florida's Fiscal Intermediary Service Organization Law: Fla Stat § 641.316 (unless owned and controlled by a hospital and/or physicians)
- Massachusetts' recent positions on risk-bearing ACOs taken by Department of Insurance
- New Jersey's HMO laws: N.J. Stat. §§ 26:2J et seq., 17:48H-1 et. Seq. and HMO Regulations: N.J. AC 11:24 et seq.
- Ohio Rev. Stat. Chapter 1751
- Pennsylvania's HMO Act: 40 P.S. §§ 1551-1567 and Risk-Assuming PPO Regulations: 31 Pa Code §§ 152.1 et seq, and 301.314(c); Licensed Organized and Delivery System: 28 Pa Code §§ 9.602, 9.723-9.728.

Risk Factors in Addition to Ambiguity under §9832

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- Supreme Court has broadly interpreted what is a state law which "regulates insurance" for purposes of ERISA preemption
  - Kentucky Assn. of Health Plans v. Miller, 538 U.S. 329 (2003) (any willing provider laws)
- States have taken positions that managed care plans are a form of insurance to avoid ERISA preemption under the savings clause
  - Hewlett-Packard v. Barnes, 571 Fed. 2d 502 (9th Cir. 1978) (Knox-Keene Plan)
- States have different approaches to regulating Risk-Bearing Organizations – it is difficult to predict how these laws will change over time

§162(m)(6) Position

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- Nothing indicates that §162(m)(6) was intended to apply to Risk-Bearing Organizations, including ACOs
- Any insurance-related activity engaged in by Risk-Bearing Organizations is incidental to the primary purpose of providing health care services
- Risk-Bearing Organizations are typically paid capitation amounts and assigned members by an insurance company or organization
- Tax treatment under §162(m)(6) should not vary depending upon how states decide to license and regulate Risk-Bearing Organizations

§162(m)(6) Position

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- Subjecting Risk-Bearing Organizations to §162(m)(6) tax deduction limitations will have a chilling impact on the formation of ACOs
  - §162(m)(6) should not interfere with efforts to develop more efficient forms of health care delivery
- Aggregation rules were likely added to prevent health insurers from avoiding §162(m)(6), and not to penalize Risk-Bearing Organizations
- Entities that might acquire or otherwise affiliate with a Risk-Bearing Organization may be unwilling to do so if there is a material risk of triggering CHIP status under §162(m)(6)

§162(m)(6) Regulatory Process

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- IRS guidance under Notice 2011-2 offered limited relief
  - de minimis rule: an employer will not be treated as a CHIP if the premiums received by the employer for providing health insurance coverage during a year are less than 2% of the employer's gross revenues for that year
  - exemption for independent contractors to a CHIP who also provide services to other several other entities
  - favorable transition relief for entities that do not meet the definition of a CHIP beginning in 2013
  - exemption for premiums paid under certain indemnity reinsurance contracts
- IRS requested comments on several issues, including “the application of the term ‘covered health insurance provider’”

§162(m)(6) Regulatory Process

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- Initial comment letters did not address the treatment of Risk-Bearing Organizations under §162(m)(6)
  - CHIP issues were almost exclusively limited to obtaining relief for captive insurance companies
  - BCBSA also requested that §162(m)(6) deduction limits only apply to health insurance businesses within the employer controlled group
- The formal comment period closed on March 23, 2011
- Treasury/IRS are currently drafting §162(m)(6) proposed regulations
- Recent discussions with regulators suggest that there is openness to considering a regulatory exemption for Risk-Bearing Organizations
- Recent comments from Vanguard and Ardent expressed strong concern about potential impact on ACO-type provider organizations and affiliates

Comment Letter

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- §162(m)(6) authorizes the Secretary to issue "guidance, rules, or regulations as are necessary to carry out the purposes of this paragraph"
- Proposal: revenue received by Risk-Bearing Organizations, whether or not owned by providers, does not constitute gross premiums received from minimum essential coverage in determining CHIP status
- Alternative approaches are problematic given the limited time before the effective date and the IRS issuance of proposed regulations
  - Defining terms under §9832 raises collateral issues and would require joint review by HHS/DOL
  - Defining what is a "premium" would likely require evaluation of other laws

Key Arguments

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- 162(m)(6) was only intended to limit compensation deductions for health insurance company executives, not medical care providers
- Affiliation rules were intended to prevent health insurance company executives from avoiding 162(m)(6) by being employed by an affiliate
- Broad interpretation of 162(m)(6) will discourage healthcare providers from controlling costs through ACOs and other arrangements that involve risk shifting

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Christopher M. Jedrey
McDermott Will & Emery LLP
Boston
617.535.4405
cjedrey@mwe.com

WHAT IS THE CONSEQUENCE OF THE COURT'S DECISION FOR PROVIDERS?

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- Some providers who are "sitting on the sidelines" with respect to ACO-type initiatives might now be motivated to act. Subject to growing antitrust enforcement constraints, this decision will also likely spur additional consolidation initiatives among providers, in order to create networks with the scale and resources to succeed in an "accountable care" world.

GIVEN GROWING PRESSURES ON INSURANCE PREMIUMS AND HEALTH SERVICES COSTS, WHY WOULD PROVIDERS SIT ON THE SIDELINES?

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- Some providers think that the current health reform initiatives will be a repeat of the 1990s, when, after much fuss, the traditional FFS health care remained largely unchanged. Others are in markets where commercial insurors are moving slowly towards value and/or budget-based payment arrangements. In such markets, the federal initiatives under the ACA are important as a driver of delivery system transformation.

WHAT IMPACT WOULD THIS HAVE ON PROVIDER CONSOLIDATION AND MEDICARE/MEDICAID AND COMMERCIAL INSURER ACO-TYPE INITIATIVES?

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- The Medicare ACO provisions (and the associated regulatory waivers) will stay in place, as will the many CMS pilot and demonstration projects. The market and political pressures to control health services costs (and premium increases) by shifting risk to providers will increase for both governmental (including Medicaid) and commercial payors, as will the corresponding desire of providers to consolidate into larger systems to manage those risks and spread the costs of IT and other managed care infrastructure. The latter, however, may be constrained by antitrust reinforcement efforts.

WHAT AFFECT WILL VOLUNTARY MEDICAID EXPANSION HAVE?

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- In states that "opt out" of Medicaid expansion, the greatest impact would be on safety net hospitals (e.g., DS hospitals, other hospitals for whom Medicaid is a major payor and who care for large numbers of uninsured patients) and physician and other providers in poor communities, because such hospitals and other providers would not see anticipated reductions in the number of uninsured patients and corresponding reductions in their bad debt and free care exposure.
- Hospitals in "opt out" – states would still have their EMTALA obligations and mission-related commitments to treat the uninsured, but significant numbers poor, non-disabled adults below 133% of the federal poverty level would remain uninsured. Such hospitals will have to deal with the ACA's Medicare cuts and, for DS hospitals, $14B in additional cuts, but will have the benefit of expanded commercial insurance coverage. However, for many DS hospitals, commercial insurance is not significant. In general, for demographic and socio-economic reasons, hospitals with large Medicaid and uninsured populations tend to have relatively small commercially-insured populations, and vice versa.

WHAT OTHER IMPACTS WOULD THIS HAVE ON SUCH HOSPITALS?

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- Twenty-six states challenged the ACA, but the ACA offers states that "opt in" to the Medicaid coverage expansion: (a) for FY 2014 through 2016, 100% of the costs related to newly-eligible individuals; (b) 95% for FY 2017; (c) 94% for FY 2018; (d) 93% for FY 2019; and (e) 90% for FY 2020 and thereafter. As with some aspects of the federal stimulus bill, some "red" states will be caught between the demands of increasingly strict Republican ideological requirements and the lure of federally-funded benefits for (potential) voters and new revenues for their hospitals and other providers. In most states, the hospitals are among the largest employers and have considerable political clout. For Republican-controlled states, saying no to the largely federally-funded Medicaid expansion will appeal to the Republican base, but may further alienate components of the growing majority/minority population (e.g., Blacks, Hispanics).
- For these reasons, it is likely that most states will not "opt out" of the Medicaid expansion. The current partisan environment may change this, but, in the past, states have seldom rejected federally-funded Medicaid expansions (e.g., 60% of the current program is optional). Also, exclusion of a state from the Medicaid program is a penalty that has existed since 1965, but that has never been used.

WON'T MANY STATES "OPT OUT" OF MEDICAID EXPANSION?

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- Not unless the Republicans maintain a majority in the House, take the White House, and secure a filibuster-proof 60 votes in the Senate. The last of these is very unlikely. As the benefits of the ACA begin to be available to the currently uninsured, and the providers and insurors reconfigure themselves for governmental and commercial value and/or budget-based payment arrangements, repeal of material provisions of the ACA will grow increasingly difficult to accomplish.

WHAT ARE SOME POSITIVE AND NEGATIVE RESULTS OF THE ACA FOR PROVIDERS?

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- Potentially positive results include: (a) Medicare Shared Savings and Pioneer ACOs; (b) quality, access and care coordination incentives; (c) bundled payment pilots; (d) home care demonstration project; (e) prevention funds; (f) training funds; (g) 340B expansion; and (h) SRDP.
- Potentially negative results include: (a) $155B in Medicare cuts; (b) $14B in DS hospital cuts; (c) program integrity/fraud and abuse “enhancements; (d) hospital readmissions and hospital-acquired conditions payment adjustments; (e) expansion of the RAC program; and (f) new IRS CHNA requirements.

WHAT SHOULD PROVIDERS DO NEXT?

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- The court's decision brings greater predictability for providers decision-making. Government and commercial payor initiatives will, over the next few years, complete the transformation of the payment system from FFS to value and/or budget-based payments.
  - If you are a provider system that is making the IT and other managed care infrastructure investments necessary for success in an "accountable care" world, and if you have, or are achieving, the size and scale necessary to support these costs and manage the associated risk, then it is more of the same.
  - If you have been "sitting on the sidelines," your choices may be more limited, e.g.,
    - If you have the financial resources, you should consider developing, or at this point, leasing from a third party, the necessary IT and managed care infrastructure (or portions thereof).
    - If you do not have the financial resources, your only choice may be consolidate with a larger system that does have them, if antitrust enforcement constraints allow such a consolidation.

WHAT SHOULD PROVIDERS DO NEXT? (cont'd)

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- The provider world will increasingly be made up of "haves" and "have nots." The "have nots" are likely to have to forgo increasing amounts of potential reimbursement because of an inability to manage effectively to value or budget-based standards.
- Also, providers who have the benefit of the broad Pioneer ACO regulatory waivers, or the more limited Medicare Shared Savings regulatory waivers, will enjoy a significant competitive advantage because of their greater ability to align financial incentives among their providers.
- The greatest challenge will be managing the transition from FFS to value and/or budget-based payments and, in particular, managing the conflicting incentives of each payment system.
- Bottom Line: Act strategically, act prudentially, but, above all, act now! Providers should have a clear vision of what they will need to be in 2015 and beyond to be successful in an "accountable care" world, and should be making every effort to achieve the desired state.

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Employer Issues under Health Care Reform

Amy M. Gordon
McDermott Will & Emery
Chicago
312.984.6931
agordon@mwe.com

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Employer Actions for 2011

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- No lifetime dollar limits on essential health benefits
- Phase out of annual limits on essential health benefits (plan year beginning on or after September 23, 2010, but before September 23, 2011, the limit is $750,000)
- No retroactive termination of coverage (except under limited circumstances)
- No pre-existing condition exclusions under age 19
- Coverage of adult dependent children to age 26 (differences depending on whether or not the plan is grandfathered)
- Non-discrimination requirements that previously only applied to self-insured plans also apply to all fully insured, non-grandfathered plans (effective date pending further guidance)

Employer Actions for 2011

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- First dollar preventive care coverage (excluding grandfathered plans)
- Choice of providers and coverage of emergency care (excluding grandfathered plans)
- No coverage of over the counter drugs in health savings accounts (HSA), health reimbursement accounts (HRA) and health flexible savings accounts (FSA)
- Group health plan insurers must provide rebates to their customers if their medical loss ratios ("MLRs") are below 85% in the large group market and below 80% in the small group and individual market. This requirement does not apply to self-insured plans

Employer Actions for 2012

McDermott Will & Emery

- Uniform Summary of Benefits Coverage (SBC)- Group health plans must distribute an SBC to all plan participants and beneficiaries beginning on the first day of the first open enrollment period that begins on or after September 23, 2012 (the first day of the plan year beginning on or after September 23, 2012, for those participants and beneficiaries who do not enroll in coverage through an open enrollment period, including individuals who are newly eligible for coverage or who are eligible for special enrollment under the Internal Revenue Code)
- Phase out of annual limits on essential health benefits (plan year beginning on or after September 23, 2011, but before September 23, 2012, the limit is $1.25 million)

Employer Actions for 2012

McDermott Will & Emery

- $2,500 Limit for health flexible spending accounts (FSA) that do not operate on a calendar year basis- The maximum annual contribution limit permissible under a Health FSA, effective for plan years on or after January 1, 2013, is reduced to $2,500. FSA Plans with plan years other than a calendar year basis, may need to reflect the $2,500 limit prior to the January 1, 2013 effective date
- Quality of Care Reporting - Health and Human Services is required to develop reporting requirements regarding the quality of care (applies only to non-grandfathered plans)

Employer Actions for 2012

McDermott Will & Emery

- Summaries of Material Modifications - If a group health plan makes any material modification to the terms of the plan or coverage, and the modification is not reflected in the most recently provided summary of benefits and coverage, the plan must provide notice of the modification not later than 60 days prior to the date the modification becomes effective
- W-2 Reporting - Employers are required to report the value of group health plan benefits on their employee's annual Form W-2 beginning with the 2012 taxable year (the W-2 due in January 2013)
- Comparative Effectiveness Research Fee - For plan years beginning after September 30, 2012 through 2013, self-insured health plans and fully-insured health plans (through the insurer) will be assessed a $1 per participant fee to fund research regarding patient centered outcomes for medical treatment

Employer Actions for 2013

McDermott Will & Emery

- $2,500 Limit for health flexible spending accounts (FSA) - The maximum annual contribution limit permissible under a Health FSA, effective for plan years on or after January 1, 2013, is reduced to $2,500
- Loss of Medicare Part D Subsidy Deduction- the deduction for the portion of health care expenses that are reimbursed to the employer through the Medicare Part D subsidy program will no longer be available. The Retiree Drug Subsidy will remain in existence, however an employer's ability to deduct the amount of the subsidy will end.

Employer Actions for 2013

McDermott Will & Emery

- Phase out of annual limits on essential health benefits (plan year beginning on or after September 23, 2012, but before December 31, 2013, the limit is $2 million)
- Notice of State Insurance Exchanges- By March 1, 2013, plans must provide notice to employees and new hires of the upcoming existence of state insurance exchanges, which are to be established by all states in 2014

Employer Actions for 2013

McDermott Will & Emery

- FICA Medicare Tax Increase- For tax years beginning after December 31, 2012, the FICA Medicare tax rate will increase by 0.9% for wages over $200,000 ($250,000 for married couples filing jointly). FICA taxes are comprised of Social Security and Medicare taxes, thus this change increases the employee's portion of the FICA Medicare tax from 1.45% to 2.35% for wages over $200,000 ($250,000 for married couples filing jointly). An employer will be required to collect the employee's portion of this FICA Medicare tax
- Compensation Deduction Limit- A deduction limit of $500,000 will be applied to officers, directors, employees and service providers of health insurers for taxable years beginning after 2012 with respect to services performed after 2009. This will apply to current compensation and deferred compensation

Employer Actions for 2014

McDermott Will & Emery

- Elimination of Pre-Existing Condition Exclusions- Plans may not impose preexisting condition exclusions on any participant
- Annual Limits- Plans are restricted from imposing annual limits on essential health benefits
- Waiting Periods- Plans are not permitted to have eligibility waiting periods that are greater than 90 days
- No Eligibility discrimination- The same nondiscrimination rules that currently apply to health plans under the Health Insurance Portability and Accountability Act (“HIPAA”) are now statutorily included in PPACA

Employer Actions for 2014

McDermott Will & Emery

- HIPAA Wellness Incentive Cap Increase- The current cap on certain wellness incentives under is 20%. This cap will increase to 30%, in 2014, with an option of increasing the incentive to 50% based on HHS' discretion
- No Discrimination As To Health Care Providers- Group health plans may not discriminate against a provider who is acting within the scope of his/her license. However, this does not mean that the plan must contract with any willing provider. (applies only to non-grandfathered plans)
- Automatic enrollment- Employers with more than 200 full time employees that offer at least one health plan benefit option must automatically enroll all new employees in a benefit option and continue the enrollment of current employees in a health benefit plan offered by the employer (the effective date on this is unclear, but we think it is likely to be 2014)

Employer Actions for 2014

McDermott Will & Emery

- Cost Sharing Limits- Certain cost-sharing requirements under health plans must be satisfied. The annual out-of-pocket maximum may not exceed $5,000 (single) or $10,000 (family) (indexed); the annual deductible maximum may not exceed $2,000 (single) or $4,000 (family)
- Clinical Trials- A plan may not deny a qualifying individual's participation in certain clinical trials or deny the coverage of routine patient costs for items and services furnished in connection with the clinical trial (only applies only to non-grandfathered plans)
- Creation of Exchanges- States are required to establish a health insurance exchange through which individuals may purchase health insurance beginning in 2014

Employer Actions for 2014

McDermott Will & Emery

- Notification of Exchange- Employers are required to notify each employee at the time of hiring
  - The existence of the exchange,
  - That the employee may be eligible for a subsidy under the exchange if the employer's share of the total cost of benefits is less than 60%; and
  - That if the employee purchases a policy through the exchange, he or she will lose the employer contribution to any health benefits offered by the employer

Employer Pay or Play Mandate Effective 2014

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- Applies to all plans with 50 or more full time employees (FTEs)
- Non-deductible excise tax applies for no coverage
  - Penalty if one FTE obtains a tax credit or cost sharing assistance is $2,000 per FTE in excess of 30 employees
- Non-deductible excise tax for providing "unaffordable coverage."
  - Penalty of $3,000 per FTE who receives a federal subsidy capped at $2,000 per FTE in excess of 30 employees
  - Unaffordable coverage means it exceeds 9.5% of the individual's house hold income (proposed Regs. include a safe harbor)
  - the employee falls within 100%-400% of the federal poverty level; and
  - the plan's share of allowed costs under the plan is less than 60%

Employer Actions for 2015

McDermott Will & Emery

- Employer Reporting of Health Insurance Coverage- Every person who provides minimum essential coverage to an individual during a calendar year will have to file a special return

Employer Actions for 2017

McDermott Will & Emery

- Health Insurance Exchanges will be Expanded to Allow Large Employers- States will be able to permit large employers to purchase coverage through health insurance exchanges

Employer Actions for 2018

McDermott Will & Emery

- Cadillac Tax- A nondeductible 40% excise tax will be imposed on the value of high cost coverage in excess of $10,200 for single coverage and $27,500 for family coverage, indexed for inflation

Tax Issues

McDermott Will & Emery

- Medicare Part D Subsidy no longer deductible (2013)
- Non-taxable coverage of adult dependent children up to age 26 (2011)
- Early Retiree Reinsurance Program (temporary subsidy for retiree health benefits (2011 to 2012, when the funds were exhausted)
- Increase in excise tax on nonqualified withdrawals from HSAs from 10% to 20% (2011)
- Comparative effectiveness research fee (2013-2019)
- Pay or Play Mandate Tax (2014)

Tax Issues

McDermott Will & Emery

- Cap on Health FSAs to $2,500 (2013)
- Elimination of ability to submit reimbursement for OTC drugs to HRAs, HSAs and FSAs (unless prescribed by a physician) (2011)
- FICA Medicare Tax Increase to 2.35% for wages over $200,000 ($250,000 for married couples filing jointly) (2013)
- Compensation Deduction Limit (2013)
- Cadillac Plan Tax ($10,200/$27,500) (2018)

Reporting and Disclosure Requirements

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- W-2 reporting of aggregate value of employer provided health care (2012 W-2)
- Uniform Summary of Benefits Coverage (SBC) (2012)
- Notice of material modifications sixty days before effective date (2012)
- Notice of State Insurance Exchanges (2013)

Reporting and Disclosure Requirements

McDermott Will & Emery

- Notice to employees of existence of Exchange (2014)
- Summaries of Material Modification (2012)
- Health care reporting to IRS and to covered individuals (new Code Section 6055, effective 2014)
- Quality of Care reporting (2012)

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ACA and the Supreme Court: Implications for Life Sciences Companies

Paul Radensky, MD, JD
McDermott Will & Emery LLP
Washington, DC
202.756.8794
pradensky@mwe.com

ACA and Impact on Life Sciences Companies

McDermott Will & Emery

- The Affordable Care Act (ACA) includes 3 types of provisions that impact Life Sciences companies:
  1. Expansions in covered lives and covered services
  2. Changes in coverage or payment policies for Medicare or Medicaid, and
  3. Non-health-plan-related provisions directly related to revenues or operations of Life Sciences companies.

Expansion: Impacts on Numbers of Covered Lives and Benefits

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- Expansions in covered lives
  - Adoption of the insurance exchanges
  - Coverage of dependent children until age 26
  - Guaranteed issue
  - Removal of preexisting coverage exclusions
  - Expansions in Medicaid for states that elect to do so

Expansion: Impacts on Numbers of Covered Lives and Benefits

McDermott Will & Emery

- Expansions in services
  - Minimum essential health benefits
    - Benchmark plans
  - Preventive and wellness services

Medicare and Medicaid Payment Reforms

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- Moving away from fee-for-service models
  - Shared savings programs (Accountable Care Organizations)
  - Bundled payment demonstrations
  - Center for Medicare and Medicaid Innovation

Medicare and Medicaid Payment Reforms

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- Payment limitations
  - Independent Payment Advisory Board
  - Fee schedule and prospective payment system cuts
- Comparative effectiveness research—Patient-Centered Outcomes Research Institute

Non-Health-Plan-Related Provisions: Reduction in Net Revenues

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- Medical device and pharmaceutical excise taxes and fees
- Expansions in the 340B pharmaceutical pricing program
- Changes to the Medicaid Drug Rebate program
  - Increase in rebate percentages
  - Expansion to Medicaid Managed Care Organizations
- Coverage gap (“donut hole”) reduction—manufacturer rebates
- Adoption of a biosimilars pathway for approval of biologicals

Non-Health-Plan-Related Provisions: Increase in Operating Costs

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- Sunshine Act reporting
- Rx samples reporting

Implications/Recommendations for Life Sciences Companies

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1. Review estimates of expansions in covered lives for products on the market or in pipeline for 2014 and on
   - Assess implications under evolving scenarios of expansion of Medicaid covered lives
   - Assess implications on revenues from products on market
   - Assess implications for products in pipeline
2. Identify those provisions of ACA that are expected to impact the rates paid to providers from private payers, Medicare, and Medicaid for drugs/devices/diagnostics. Estimate likely downstream implications for vendor purchasing contracts from providers depending upon how their payment rates change

Recommendations (cont'd)

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3. Identify those provisions that directly impact bottom lines, like the biosimilars law, medical device excise taxes, pharmaceutical fees, Medicaid rebate increases/expansions, 340B expansion. How will these provisions change your estimated revenues? Consider ways to address impact on revenues.
4. Identify those provisions that increase operating costs, like the Sunshine Act, and reporting of Rx samples. How will these provisions increase your operating costs? Consider ways to address impact on operating costs.

Questions/Discussion

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