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Responding to Health Care Reform: How Pharma and Device Manufacturers Can Participate – Strategic, Legal and Compliance Implications

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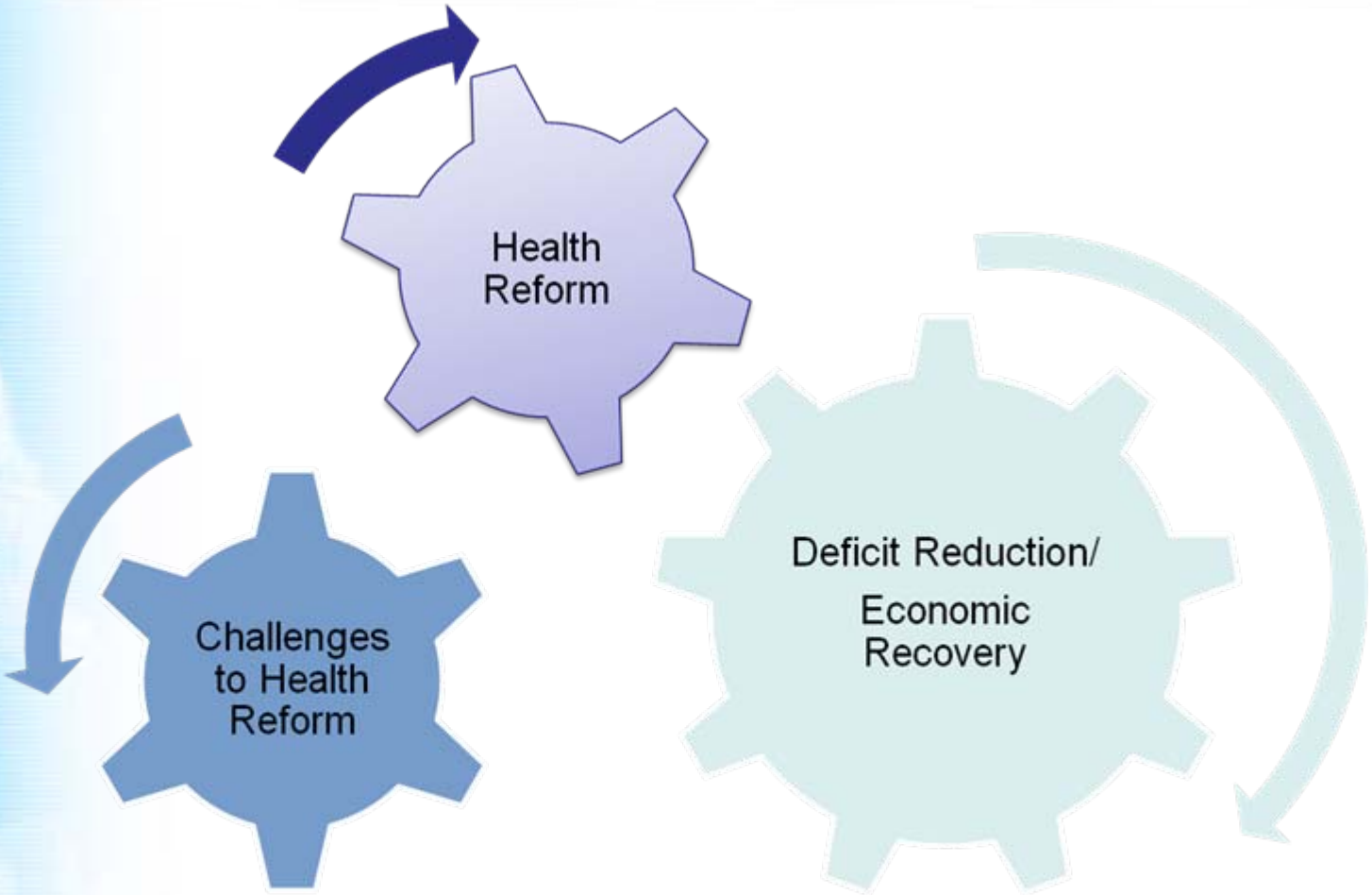
Agenda

- Current Federal Health Care Reform
  - Current Landscape
  - PPACA Implementation Timeline and Challenges
  - Debt Ceiling; Deficit Reduction
- Health Care Reform Initiatives Underway and Potential Responses
  - Themes
  - New Patient Care Models
  - Essential Health Benefits
  - Drug Pricing and Reimbursement

Current Federal Health Care Reform

Current Landscape



PPACA Implementation Timeline

2010
•Review of Health Plan Premium Increases
•Changes in Medicare Provider Rates
•Qualifying Therapeutic Discovery Project Credit
•Medicaid and CHIP Payment Advisory Commission
•Comparative Effectiveness Research
•Prevention and Public Health Fund
•Medicare Beneficiary Drug Rebate
•Small Business Tax Credits
•**Medicaid Drug Rebate**
•Coordinating Care for Dual Eligibles
•**Generic Biologic Drugs**
•New Requirements on Non-profit Hospitals
•Medicaid Coverage for Childless Adults
•Reinsurance Program for Retiree Coverage
•Pre-existing Condition Insurance Plan
•New Prevention Council
•Consumer Website
•Tax on Indoor Tanning Services
•Expansion of Drug Discount Program
•Adult Dependent Coverage to Age 26
•Consumer Protections in Insurance
•Insurance Plan Appeals Process
•Coverage of Preventive Benefits
•Health Centers and the National Health Service Corps
•Health Care Workforce Commission
•Medicaid Community-Based Services

2011
•Minimum Medical Loss Ratio for Insurers
•**Closing the Medicare Drug Coverage Gap**
•Medicare Payments for Primary Care
•Medicare Prevention Benefits
•Center for Medicare and Medicaid Innovation
•Medicare Premiums for Higher-Income Beneficiaries
•**Medicare Advantage Payment Changes**
•Medicaid Health Homes
•Chronic Disease Prevention in Medicaid
•CLASS Program
•National Quality Strategy
•Changes to Tax-Free Savings Accounts
•Grants to Establish Wellness Programs
•Teaching Health Centers
•Medical Malpractice Grants
•Funding for Health Insurance Exchanges
•Nutritional Labeling
•Medicaid Payments for Hospital-Acquired Infections
•Graduate Medical Education
•Medicare Independent Payment Advisory Board
•Medicaid Long-Term Care Services

Source: Kaiser Family Foundation, Health Reform Implementation Timeline, *available at* http://healthreform.kff.org/Timeline.aspx.

PPACA Implementation Timeline

2012

- Accountable Care Organizations in Medicare
- Medicare Advantage Plan Payments
- Medicare Independence at Home Demonstration
- Medicare Provider Payment Changes
- Fraud and Abuse Prevention
- **Annual Fees on the Pharmaceutical Industry**
- Medicaid Payment Demonstration Projects
- Data Collection to Reduce Health Care Disparities
- Medicare Value-Based Purchasing
- Reduced Medicare Payments for Hospital Readmissions

2013

- State Notification Regarding Exchanges
- Closing the Medicare Drug Coverage Gap
- Medicare Bundled Payment Pilot Program
- Medicaid Coverage of Preventive Services
- Medicaid Payments for Primary Care
- Itemized Deductions for Medical Expenses
- Flexible Spending Account Limits
- Medicare Tax Increase
- Employer Retiree Coverage Subsidy
- **Tax on Medical Devices**
- Financial Disclosure
- CO-OP Health Insurance Plans
- Extension of CHIP

2014

- **Expanded Medicaid Coverage**
- Presumptive Eligibility for Medicaid
- Medicare Advantage Plan Loss Ratios
- Individual Requirement to Have Insurance
- Health Insurance Exchanges
- Health Insurance Premium and Cost Sharing Subsidies
- Guaranteed Availability of Insurance
- No Annual Limits on Coverage
- **Essential Health Benefits**
- Multi-State Health Plans
- Temporary Reinsurance Program for Health Plans
- Basic Health Plan
- Employer Requirements
- Wellness Programs in Insurance
- Fees on Health Insurance Sector
- **Medicare Independent Payment Advisory Board Report**
- Medicare Disproportionate Share Hospital Payments
- Medicaid Disproportionate Share Hospital Payments
- Medicare Payments for Hospital-Acquired Infections

Source: Kaiser Family Foundation, Health Reform Implementation Timeline, *available at* http://healthreform.kff.org/Timeline.aspx.

PPACA Implementation Timeline

2015	2016	2018
•Increase Federal Match for CHIP	•Health Care Choice Compacts	•Tax on High-Cost Insurance

Source: Kaiser Family Foundation, Health Reform Implementation Timeline, *available at* http://healthreform.kff.org/Timeline.aspx.

Challenges to Health Reform Law

- The Supreme Court is widely expected to provide the final word on the law's constitutionality during the current term, which began in October 2011 and runs through June 2012
  - A decision is expected by June 2012
  - The court has two very strong reasons to take the case:
    - There are two circuit courts that have ruled in opposite directions on the constitutionality of the law's individual mandate (challenges considered by six circuit courts)
    - Because the Obama administration lost in the 11th Circuit ruling, the DOJ has filed an appeal to the Supreme Court
      - The Supreme Court rarely turns down such requests from the federal government, especially on an issue with the scope of the health reform law

But…
Private Health Insurance Reforms became effective September 23, 2010
and
State Health Reforms are underway

Debt Ceiling Debates

- On July 31, 2011, Congress reached an agreement to reduce the deficit and avoid default on the national debt
- The agreement:
  - Cuts $917 billion over 10 years in exchange for increasing the debt limit by $900 billion
  - Establishes a joint committee of Congress that would produce debt reduction legislation by **November 23, 2011** to cut at least $1.5 trillion over the coming 10 years and be passed by December 23, 2011
    - The committee will have12 members, 6 from each party
  - If Congress fails to produce a deficit reduction bill with at least $1.2 trillion in cuts, then Congress can grant a $1.2 trillion increase in the debt ceiling but this would trigger across the board cuts ("sequestration") of spending equally split between defense and non-defense programs
    - Across the board cuts would apply to mandatory and discretionary spending in the years 2013 to 2021
    - Across the board cuts would apply to Medicare, but not to Social Security, Medicaid, civil and military employee pay, or veterans
  - The debt ceiling may be increased an additional $1.5 trillion if either one of the following two conditions are met:
    - A balanced budget amendment is sent to the states
    - The joint committee cuts spending by a greater amount than the requested debt ceiling increase

Entitlement Spending under Deficit Reduction

- Potential options for cutting Medicare/Medicaid spending:

Increase efforts to curb Medicare fraud and abuse	Nursing homes/home health cuts
Raise the Medicare eligibility age	Premium support pilot program
Restructure Medicare benefits	Medicaid block grants
New rules for Medigap plans	Medicaid “blended” matching rate
Raise Medicare Part B premiums	Drug rebates for Medicare-Medicaid “dual eligibles”
Cut hospital payments for bad debts	Repeal the CLASS Act

- If the Super Committee does not come up with a plan, hospitals, doctors and other health care providers will face a 2 percent cut in Medicare payments under the automatic “trigger” created in the debt limit deal
  - The 2 percent cuts could begin as early as 2013

Deficit Reduction Proposals

- The President's Plan for Economic Growth and Deficit Reduction (Sept. 2011)
  - Includes a sequester of Medicare payments to providers and plans, if by 2014 the debt-to-GDP ratio is projected to exceed 2.8% for 2015-2019
  - Includes proposals, resulting in $320 billion in health savings, that would:
    - Increase income-related premiums under Medicare Parts B and D and cost sharing under Medicare Part B
    - Lower the Independent Payment Advisory Board target rate for Medicare spending from GDP+1% to GDP+0.5%
    - Require drug manufacturers to provide rebates to Part D plans for dual eligibles and low-income subsidy beneficiaries
    - Improve Medicare integrity programs
    - Reduce Medicare payments for advanced imaging, bad debts, indirect medical education, rural add-ons, critical access hospitals, and post-acute care providers

Medicare / Medicaid

- "Dual eligible" individuals
  - Persons who are entitled to Medicare (Part A and/or Part B) and who are also eligible for Medicaid
    - Chronically ill frail elderly
  - Total number – 9.2 million in 2008
  - CMS recently reported that the amount spent annually on dual eligibles is now approximately $300 billion
  - Solutions offered include Shared Savings Models and Program for All-Inclusive Care for the Elderly (PACE)

Source: CMS Fact Sheet, Details for: People Enrolled in Medicare and Medicaid (May 11, 2011), *available at* http://www.cms.gov/apps/media/press/factsheet.asp?Counter=3954&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date.

Where are the Uninsured?

By State 2009

Total Non-Elderly Uninsured: 49.9 million

Almost 50% of the Uninsured

California	7.0 million
Texas	6.2 million
Florida	3.8 million
New York	2.7 million
Georgia	1.8 million
Illinois	1.7 million

Source: Kaiser Family Foundation, State Health Facts, Health Insurance Coverage of Nonelderly 0-64, states (2008-2009), U.S. (2009), *available at* http://www.statehealthfacts.org/comparetable.jsp?typ=1&ind=126&cat=3&sub=39.

Who Are the Payers?

Private Payers

Employers
– self-funded or not
Unions
Health Plans
– Blue Cross/Blue Shield Plans
– United Healthcare
– Aetna US Healthcare
– Anthem Wellpoint
– Others

Public Payers

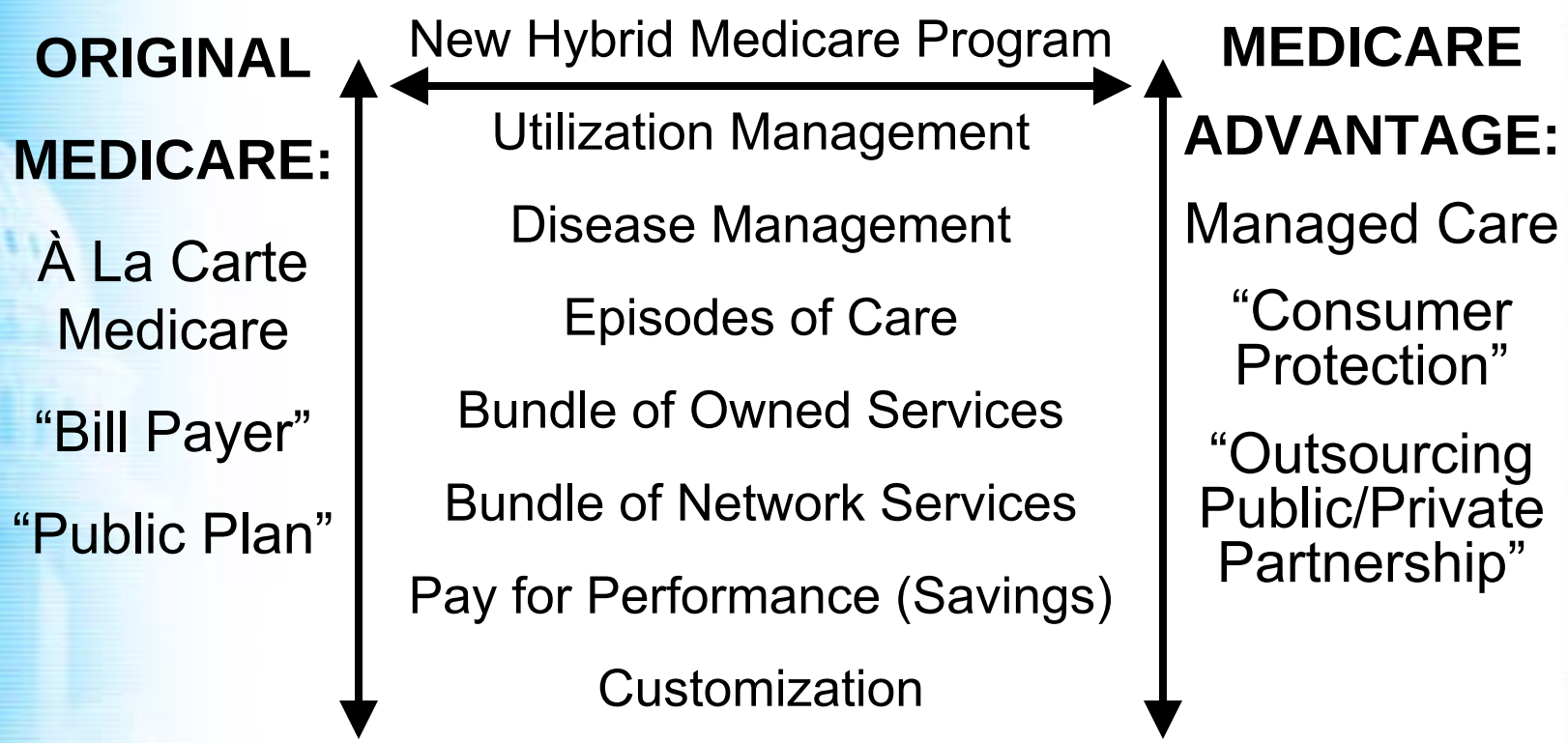
Medicare (federal)
– seniors, disabled, ESRD
Medicaid (federal/state)
– indigent, women, children, indigent seniors, chronically ill
SCHIP (federal/state)
– children
TriCare (federal)
– military and dependents
Veterans Administration (federal)
– veterans and their dependents
Federal and State employees health benefit plans
Others

Health Care Reform Initiatives Underway and Potential Opportunities and Responses

Overall Themes of Health Reform – Entitlement Spending

- Payment "Reforms" are Medicare reductions to hospitals and physicians on fee-for-service covered benefits
- Delivery "Reforms" are Medicare payments to hospitals and physicians to reward:
  - Population Health Management
  - Improved Quality/Outcomes
  - Integrated/Coordinated Care
  - Efficiencies

Themes for the Medicare Program



Medicare *"as we know it"*

Themes for Private Payers

- Pricing pressures on payers and providers built into federal health reform of the private health insurance market
  - Unreasonable Premium Review
    - Federal and state review of "unreasonable" premium increases
    - Massachusetts example
  - Medical Loss Ratios
    - MLR of 80% for individual and small group insurers (1-100 employees; state option to define as 1-50 employees ends 01/01/16) and 85% for large group insurers (101+ employees), with refunds due to policyholders
  - New Coverage Obligations
    - No annual or lifetime limits; no pre-existing condition exclusions; adult dependent coverage; coverage of preventive health services
    - Essential Health Benefits
  - “Cadillac Tax”
    - Excise tax on insurers of 40% of the value of plans that exceed $10,200 for individual coverage and $27,500 for family coverage beginning Jan. 1, 2018
      - Threshold values indexed to the consumer price index for urban consumers (CPI-U) beginning in 2020
      - Boeing example: shifting costs to employees because of “cost pressure” from excise tax

Themes for Health Plans and Hospitals

Health Plan Executives Identified these Top Issues in 2011:

- Administrative Mandates
- Care Management, Data Analytics, and Informatics
- Health Insurance Exchanges and Individual Markets
- New Provider Payment & Delivery Systems
- Bend the Cost Trend

Hospital Executives Identified these Top Issues in 2011:

- Financial Challenges
- Healthcare Reform Implementation
- Governmental Mandates
- Patient Safety and Quality
- Physician-Hospital Relations

Source of Health Plan Data: Managed Care Executive Group, Top 10 Issues for Health Plans in 2011 (Apr. 6, 2011), *available at* http://www.govhealthit.com/news/top-10-issues-health-plans-2011.

Themes for Health Plans and Hospitals

Health Plan Executives Identified these Top Issues in 2011:

- Medicare and Medicaid
- Health Information Exchanges and EMRs
- Consumer's Role in the Modernization of Healthcare
- Reform Uncertainties
- Payer/Provider Interoperability

Hospital Executives Identified these Top Issues in 2011:

- Care for the Uninsured
- Patient Satisfaction
- Personnel Shortages
- Technology
- Capacity

Source of Hospital Data: Joe Carlson, Modern Healthcare, "What Really Matters to the CEO" (Jan. 24, 2011); ACHE, American College of Healthcare Executives Announces Top Issues Confronting Hospitals: 2010 (Jan. 24, 2011), available at http://www.ache.org/Pubs/Releases/2011/topissues.cfm.

Potential Opportunities – Patient Care Models

- PPACA includes a number of provisions that allow for testing of Medicare payment mechanisms that may increase coordination of care, improve quality, and reduce costs
  - Examples of new Medicare Patient Care Models include:
    - » Accountable care organizations (CMS issued a Final Rule on October 20, 2011)
    - » Payment bundling during an episode of care
    - » Patient-centered medical homes
    - » Value-based purchasing programs

Potential Opportunities - Private Payers

- AHIP: Innovations in Recognizing and Rewarding Quality
  - Describes new payment models created by health insurance plans to make health care more affordable and to improve value and safety
  - Highlights innovative approaches to advance quality of care and efficiency through the recognition and reward of physicians and hospitals for achieving national benchmarks, demonstrating outstanding performance, and making measurable improvements over time
  - March 2009 Report available at: http://www.ahip.org/content/default.aspx?docid=26393

Potential Opportunities – What the Blues are Doing

- Blue Cross Blue Shield released an action plan providing specific recommendations to improve healthcare quality and reduce costs
  - The action plan is based on the experience of 39 Blues Plans in all 50 states
  - An independent economic analysis of the recommendations estimates that the action plan, if adopted, will achieve more than $300 billion in federal savings over the next 10 years
- The proposal lays out specific, actionable steps the government should take in four key areas:
  - Reward Safety
  - Do What Works (i.e., pay for quality rather than quantity of services)
  - Reinforce Front-Line Care
  - Inspire Healthy Living
- BCBS, Building Tomorrow's Healthcare System: The Pathway to High-Quality, Affordable Care in America (Oct. 2011), *available at* http://www.blueadvocacy.org/plans

Potential Opportunities – What the Blues are Doing

- Plans are managing pharmacy benefits and promoting medication safety by:
  - Implementing a Medication Reconciliation Outreach Referral program that focuses on patient transition from hospital to home
  - Supporting and promoting the Drug Enforcement Agency's National Drug Take-Back Day in 2011 to increase patient safety through proper handling and disposal of unused medication
- Blue Cross and Blue Shield of Massachusetts launched an Alternative Quality Contract (AQC) in January 2009
  - Replaces the typical fee-for-service model with a modified global payment model, designed to encourage cost-effective, patient-centered care by paying participating physicians and hospitals for the quality, not the quantity, of the care they deliver
- Plans are reducing medication costs while ensuring safety and efficacy by:
  - Educating patients about increased risks for medication-related problems and the importance of reviewing all medications with health care providers
  - Offering incentives for members to move from prescription drugs to over-the-counter alternatives
- Plans are coordinating care to better manage chronic illness by:
  - Developing a Patient-Centered Medical Home pilot that provides "high-risk" employees with access to a care team and a personal registered nurse to develop an integrated care plan
  - Paying for traditionally non-covered care coordination activities such as telephonic consultations and outreach to patients who may need assistance taking medications or keeping doctor's appointments
  - Providing one-on-one nurse health coaching and outreach through disease management programs

Essential Health Benefits

- PPACA provides the Secretary of HHS with the discretion to determine the scope of the "essential health benefits" package that is the core product of the federal health reform legislation
- HHS must "ensure that the scope of the essential health benefits…is equal to the scope of benefits provided under a typical employer plan" – *see* Department of Labor Report published April 15, 2011, available at http://www.bls.gov/ncs/ebs/sp/selmedbensreport.pdf
- PPACA Benefit Categories include:
  - Ambulatory patient services
  - Emergency services
  - Hospitalization
  - Maternity and newborn care
  - Mental health and substance use disorder services, including behavioral health treatment
  - ***Prescription drugs***
  - Rehabilitative and habilitative services and devices
  - Laboratory services
  - Preventive and wellness services and chronic disease management
  - Pediatric services, including oral and vision care
- HHS public rulemaking is expected

Source: Lynn Snyder, et al., "The Importance of Stakeholder Participation in the Process to Define the 'Essential Health Benefits Package'", *available at* http://www.ebglaw.com/showarticle.aspx?Show=13830.

IOM Report on Defining the Essential Health Benefits

- The Institute of Medicine (IOM) issued its report on defining the essential health benefits on October 7, 2011
- The report does not recommend which specific services should be covered, but rather discusses what the process should be for defining the essential benefits
- The IOM's recommendations include:
  - Developing a premium target – HHS should determine what the national average premium of typical small employer plans would be in 2014 and match the benefits to that premium cost
  - Defining priorities – HHS should hold a series of small group meeting around the country to discuss the benefits and costs of different plan designs, including coverage-specific services and cost-sharing
  - Ensuring appropriate care – HHS should only cover medically necessary services and the definition of "medically necessary" should depend on individual circumstances
  - Promoting state-based innovations – HHS should grant states' requests to adopt alternatives to the EHB package only if the alternatives are consistent with ACA requirements and the criteria specified in the IOM report, and they do not vary significantly from the federal package
  - Updating the EHB – HHS should update the EHB package annually, beginning in 2016; advances in medical science and cost should define the updates; and a National Benefits Advisory Council should be appointed to offer external advice

Source: IOM Committee on Defining and Revising an Essential Health Benefits Package for Qualified Health Plans, *Essential Health Benefits: Balancing Coverage and Cost* (Oct. 2011).

Drug Rebates

- Medicaid Drug Rebate
  - Increases the Medicaid drug rebate percentage for brand name drugs to 23.1% (except the rebate for clotting factors and drugs approved exclusively for pediatric use increases to 17.1%) and to 13% of average manufacturer price for non-innovator, multiple source drugs
  - Extends the drug rebate to Medicaid managed care plans
  - Implementation: January 1, 2010 for increase in Medicaid drug rebate percentage; March 23, 2010 for extension of drug rebate to Medicaid managed care plans
- Regulations anticipated ….

340B Drug Discount Program Integrity

- Expansion of Drug Discount Program
  - Expands eligibility for the 340(B) drug discount program to sole-community hospitals, critical access hospitals, certain children's hospitals, and other entities
  - Implementation: Applications accepted beginning August 2, 2010
- PPACA requires HRSA to establish procedures for manufacturers to refund overcharges to covered entities
  - Includes "routine instances of retroactive adjustment" as well as "exceptional circumstances such as erroneous or intentional overcharging for covered drugs"
  - Sales at the 340B price are generally excluded from other federal drug pricing calculations such that there could be a ripple effect on the other calculations
  - Regulations anticipated …

Prescription Drug Manufacturer Fee

- Annual Fees on the Pharmaceutical Industry
  - Imposes new annual fees on the pharmaceutical manufacturing sector
  - On August 15, 2011, the Internal Revenue Service issued temporary regulations that provide guidance on the annual fee imposed on pharmaceutical companies
- Compliance challenges include potential issues regarding interplay between drug pricing program restatements and the allocation of federal program sales as basis for calculation of fee
  - VA FSS price reduction = overpayment of fee
  - Best Price restatement ↑ = underpayment of fee

Drug Reimbursement

- On September 22, 2011, CMS issued a "Draft Guide" and a file containing Federal Upper Limits ("FULs") for approximately 700 different drugs, as well as the weighted monthly Average Manufacturer Prices ("AMPs") from which they were calculated
  - PPACA modified previous statutory provisions that establish a FUL on multiple source drugs
  - Effective October 1, 2010, the Secretary is required to calculate FULs as no less than 175 percent of the weighted average (determined on the basis of manufacturer utilization) of the most recently reported monthly AMP
  - CMS issued draft FUL reimbursement files and the draft methodology used to calculate the FULs
    - The guide states that CMS is accepting comments, but no deadline was provided for the submission of comments
- CMS has not yet issued regulations regarding the manner in which manufacturers must calculate AMP, in light of changes made by PPACA
- *See* CMS, Draft Affordable Care Act Federal Upper Limit Methodology and Data Elements Guide to the Draft FUL Files, *available at* https://www.cms.gov/reimbursement/05_federalupperlimits.asp

QUESTIONS?

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