Patient Protection and Affordable Care Act: Implementation Update

November 2, 2012
Agenda

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Healthcare Reform in Context
Mechanisms for Valuation of Medical Technology are Changing

Historically:

Innovation

- Value associated with “newness” of technologies
- Charge based payment

Currently:

Provision of Care

- Fee for service approaches
- Global payment based on disease/condition

Future:

Value for Money

- Value-based payment
- Quality/outcome measurement
- Evidence based medicine

Health reform taps into a broader on-going desire to secure greater value for healthcare services. Certain health reform elements are designed to spur transition to a value-based purchasing system.
Health Reform Is An Attempt to Address Each of These Issues

One way to attempt to address all three simultaneously is to focus on VALUE
Implementation Update
The Patient Protection and Affordable Care Act (Affordable Care Act, or ACA): A Mix of Coverage, Payment Reform, New Entities, Revenue, and Other Provisions

The coverage elements get a lot of the attention but the payment reform and new entity provisions have the potential to change the way medical devices are evaluated and paid.
The Major Coverage Provisions of the ACA Have Not Yet Been Implemented

Access to Preventive Services

• Requires group health plans and health insurers offering group or individual health insurance coverage to cover and impose no cost sharing on items or services that have a rating of “A” or “B” by the U.S. Preventive Services Task Force

• Also includes requirements for immunizations and preventive care and screenings for infants, children, and adolescents

Medicaid Coverage Expansions

• Expands Medicaid to all individuals not eligible for Medicare under age 65 with incomes up to 133% of the federal poverty limit

• Provides enhanced federal matching payments for newly eligible beneficiaries

State Health Insurance Exchanges

• Creates state-based health insurance exchanges through which individuals and small business with up to 100 employees can purchase qualified coverage

Individual Mandate

• Requires all U.S. citizens and legal residents to have qualifying health coverage

• Phased-in tax penalty for those without coverage

• Specifically targeted for repeal

The outcome of the Supreme Court ruling in June 2012 most significantly impacts Medicaid expansion: States have the option to “opt out” of this provision without penalty. Prior to the ruling, if a State decided not to expand eligibility, it would lose all of its Federal Medicaid funding.
The Patient-Centered Outcomes Research Institute and the Center for Medicare and Medicaid Innovation Have Already Begun Distributing Funding to Meet Their Objectives

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<th>Patient-Centered Outcomes Research Institute</th>
<th>Center for Medicare and Medicaid Innovation</th>
<th>Independent Payment Advisory Board</th>
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| • Funds research that will provide evidence-based information (i.e., CER) needed to make informed health care decisions  
• Has developed national priorities for research and a research agenda  
• Is developing research methods that will include patients in the research process | • Created to test innovative payment and service delivery models to reduce program expenditures while improving quality of care  
• Issues healthcare innovation awards (up to $1 billion in grants to applicants who meet these aims)  
• Has 15 active programs (not including innovation awards) | • Beginning in 2013, the CMS Chief Actuary will determine the per capita growth rate for Medicare for the next two years  
• If the projection exceeds a target growth rate, IPAB must develop a proposal to reduce Medicare spending in the implementation year  
• The first proposal that could be submitted is in January 2014 to take effect in 2015 |

The Congressional Budget Office projects that Medicare spending will not eclipse growth targets for years, thus IPAB won’t be responsible for drafting a savings plan through at least 2021 if expected trends hold. *(American Medical Association opposes IPAB)*
The 2.3% Tax on Medical Devices is Set to Go into Place January 1, 2013

- Imposes a 2.3% device on sales of medical devices except for devices that are generally purchased by the general public at retail for individual use (e.g., hearing aids, eyeglasses, contact lenses)

- While medical device trade associations (e.g., MDMA, AdvaMed) are working towards repeal, the tax is set to go into place in 2013

- Legislation to repeal the tax passed the House in June with 37 Democrats joining Republicans to support the measure, although it is unlikely to receive Senate consideration this year

- The problem with this - or any change - is finding another area to make up the loss of revenue
Payment Reform

Accountable Care Organizations
Value-Based Purchasing
Bundled Payments
Hospital Readmissions Reduction Program
Community-Based Care Transitions Program
Medicare Shared Savings Program: Accountable Care Organizations (ACOs)

CMS
CMS and the ACO enter into a shared savings contract

ACO Leadership and Management
The ACO contracts with eligible providers; ACO leadership has the ability to influence care at the point of service

ACO Participating Providers
Beneficiaries assigned based on plurality of primary care services and given the opportunity to decline to share claims data

Participating Medicare Beneficiaries

The Pioneer ACO Program is an initiative by the CMS Innovation Center to test different payment models (i.e., per-beneficiary per month payment amount versus fee-for-service)
The ACO Medical Director will be Responsible for Clinical Management and Oversight of Providers Participating in the ACO

Traditional payer/provider relationships leave clinical management up to each individual provider.

The ACO Medical Director will act as an intermediary, ideally ensuring that quality, seamless care is provided at lower costs.

Based on historical spending for participating beneficiaries, ACOs will receive a percentage of Medicare savings (“shared savings”).
Medicare Hospital Value-Based Purchasing Program

1. 1% of DRG base payments is withheld from hospitals participating in the Hospital VBP program.

2. Participating hospitals are awarded achievement and improvement points to total a performance score based on specified quality measures.

   **Achievement**
   
   Awarded by comparing an individual hospital’s rates during the Performance Period with all hospitals’ rates from the baseline period.

   **Improvement**

   Awarded by comparing a hospital’s rates during the Performance Period to that same hospital’s rates from the baseline period.

3. Hospitals are ranked by total performance score and value-based payments are distributed from “pool” of withheld DRG payments. Payment is made as an adjustment to the hospital’s base DRG payment in the following fiscal year.
The FY 2013 Hospital VBP Program began on October 1, 2012

- Hospitals earn their scores during the July 1 2011 to March 32 2012 performance period
- The FY 2013 baseline performance period is July 1, 2009 to March 31, 2010
- Examples of Clinical Process of Care Measures:
  - Primary PCI Received within 90 Minutes of Hospital Arrival
  - Blood Cultures Performed in the Emergency Department (ED) Prior to Initial Antibiotic Received in Hospital
  - Prophylactic Antibiotic Received within One Hour Prior to Surgical Incision
- Examples of Patient Experience measures
  - Nurse Communication
  - Hospital Staff Responsiveness
  - Pain Management

Measures: Efficiency and Outcomes (including HAC) measures were added for the FY 2014 program
The Center for Medicare and Medicaid Innovation is Running the Bundled Payments for Care Improvement Initiative

• In this program, Medicare will link payments for multiple services patients receive during an episode of care
  - e.g., instead of a surgical procedure generating multiple claims from multiple providers, the entire team is compensated with a “bundled” payment that provides incentives to deliver health care services more efficiently while maintaining or improving quality of care
  - Providers have flexibility to determine which episodes of care and which services would be bundled together

• There were originally four models of bundled payments proposed by the CMMI
  - Retrospective Bundled Payments
    - Model 1: Retrospective Acute Care Hospital Stay Only
    - Model 2: Retrospective Acute Care Hospital Stay plus Post-Acute Care
    - Model 3: Retrospective Post-Acute Care Only
  - Prospective Bundled Payments
    - Model 4: Acute Care Hospital Stay Only

• However, on October 24, 2012, CMS decided to suspend Model 1 because there were not enough applicants to support moving forward with the program
The FY 2013 Hospital Readmissions Reduction Program began on October 1, 2012 and includes AMI, Heart Failure, and Pneumonia

- The Hospital Readmissions Reduction Program requires CMS to reduce payments to acute inpatient hospitals with excess readmissions, effective for certain discharges beginning on October 1, 2012

- For FY 2013, the relevant discharges are for Acute Myocardial Infarction (AMI), Heart Failure (HF) and Pneumonia (PN)

- A “readmission” is defined as an admission to a qualifying acute inpatient hospital within 30 days of a discharge from the same or another qualifying acute inpatient hospital

- The excess readmission ratio is a measure of a hospital’s readmission performance compared to the national average for the hospital’s set of patients with that applicable condition
The Community-based Care Transitions Program is also being Run by the Center for Medicare and Medicaid Innovation

- The CCTP, launched in 2011, will run for 5 years. Participants will be awarded two-year agreements that may be extended annually through the duration of the program based on performance

- Community-based organizations (CBOs) will use care transition services to effectively manage Medicare patients' transitions and improve their quality of care

- Up to $500 million in total funding is available for 2011 through 2015

- The CBOs will be paid an all-inclusive rate per eligible discharge based on the cost of care transition services provided at the patient level and of implementing systemic changes at the hospital level
  - CBOs will only be paid once per eligible discharge in a 180-day period of time for any given beneficiary
Implementation Timing and Political/Budgeting Implications
All of the Major Provisions of the ACA are Set to be Implemented by 2015

- **2010**
  - Community-Based Care Transitions Program
  - Coverage of Preventive Benefits
  - Center for Medicare and Medicaid Innovation

- **2011**
  - Pioneer ACO Program
  - Medicare Shared Savings Program: Accountable Care Organizations
  - Medicare Hospital Value-Based Purchasing Program

- **2012**
  - Medicare Bundled Payment Pilot Program
  - Medicare Hospital Readmissions Reduction Program

- **2013**
  - Medical Device Tax
  - Medicaid Coverage Expansions, State Health Insurance Exchanges, Individual Mandate

- **2014**
  - Implemented
  - Not Yet Implemented

- **TBD**
  - Independent Payment Advisory Board

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# Impact of Election on Health Reform

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<th>OBAMA</th>
<th>ROMNEY</th>
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| - *Obama has pledged to carry it out, but fiscal concerns and political pressure could drive him to alter provisions*  
  
  - Many of the most sensitive coverage elements come up during a potential second term (individual mandate, state health exchanges)  
  
  - Obama may be more open to working with Congress to tweak provisions of the law that have raised concerns (i.e., individual mandate) in second term  
  
  - Adjustment could be part of a larger deal to reduce the federal deficit (i.e., scale back subsidies)  | - *Romney’s vow to repeal the law is unlikely to be realized, but he could still have a strong impact on it*  
  
  - Repeal and replace difficult to pull off if Democrats control Senate  
  
  - Romney could attempt to weaken program but given constitutional concerns (i.e., must enforce law) he cannot completely undermine it  
  
  - More likely he will choose to give states more flexibility (i.e., waivers) and not to enforce certain elements (i.e., tax component of individual mandate) |

Many of the payment reform concepts and new entities with implications for medical device manufacturers are not directly in cross-hairs of repeal/modification efforts
The Failure of Congress to Find $1.2 Trillion in Savings will Result in Sequestration, or Automatic, Across-the-Board Cuts in Government Spending including Health Reform Related Spending

- The Budget Control Act of 2011 cut $1 trillion in government spending over the next 10 years, and made it the responsibility of Congress to find another $1.2 trillion in savings.

- An report issued by the Administration identified that the following cuts will result from sequestration, if it is to occur:
  - 9.4% reduction in non-exempt defense discretionary funding
  - 8.2% reduction in non-exempt nondefense discretionary funding
  - 2.0% cut in Medicare non-administrative payments
  - 7.6% cut to other non-exempt nondefense mandatory programs
  - 10.0% cut to non-exempt defense mandatory programs

- This includes a 7.6% (or $66 million) reduction in grants to States for setting up exchanges under the Affordable Care Act.

- Congress has until the end of the year to come up with a budget that would avoid sequestration.
Conclusions
Result of Payment Reform Measures is Shifting Financial Risk from Payers and Employers to Providers

Current System

Adoption Decision-making

Manufacturers

Hospitals

Physicians

Payers

Employers

Financial Risk

The medical device industry will still call on same customers but will need to communicate the value of the products in different ways in a system where that adoption decision-maker is also at financial risk
Increasing demand for evidence-based value requires innovators to appraise, demonstrate and communicate their value.
Key Takeaways

• Immediate direct impact (i.e., taxes, cost-cutting) elements will impact system before coverage gains

• Value-based payment concepts, demonstration projects and new payment model testing may eventually alter the payment system

• Common themes:
  - Overall shift in financial risk holding from payers to hospitals and physician organizations
  - Moving away from fee-for-service payment to outcome based payment
  - Emphasis of quality and value

• New payment models reward cost reduction while maintaining quality
  - Manufacturers should attempt to align products and positioning with quality metrics
  - Less emphasis on per-procedure payment more focus on clinical outcomes and provider-focused health economic story

• Some products will need to differentiate themselves based on possible clinical impact by producing outcomes/evidence data
Thank You

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