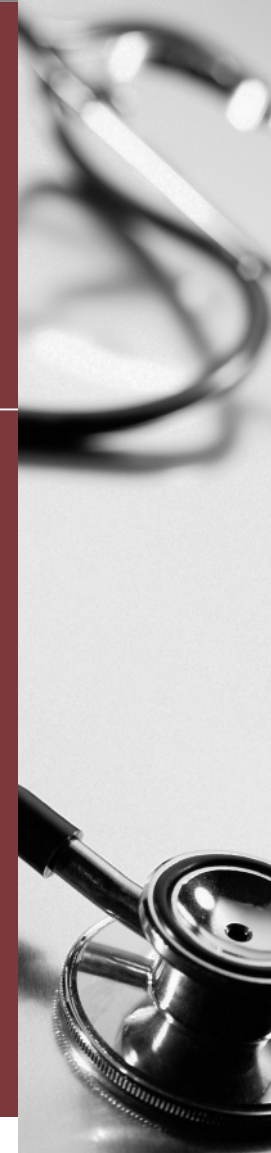


# Impact of Obama's Health Reforms on Reimbursement for Drugs and Devices

*Jayson Slotnik*





**“Government scientists announced a big breakthrough:  
Someone finally figured out how Medicare works!”**

# Outline

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- Overview/ Background
- Potential Congressional Action
  - Must pass legislation versus broader health reform issues
- Centers for Medicare and Medicaid Services' (CMS) role
  - Agency trends likely to continue regardless of Congressional activity
- Role of other agencies
- What does it mean for you?

# Overview/Background

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- Health care expenditures are projected to be about 17% of the gross domestic product (GDP) in 2009, increasing to nearly 20% by 2017
- Stark contrast between spending and quality of care delivered. Across 37 indicators, the U.S. achieves a score of 65 out of 100 on 2008 Commonwealth Fund Commission National Scorecard:
  - 75 million adults (42%) uninsured or underinsured
  - U.S. ranks last of 19 countries on mortality amenable to medical care
  - U.S. health insurance administrative costs are 30-70% higher than in countries with mixed private/public insurance systems
- Deficits are growing—Federal and state governments will remain under significant pressure to reduce health care costs
- Health reform a high priority for new Democratic Congress and Administration

## Perspective Based on Recent Events

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- Federal spending accounts for 1/3 of overall health care spending.
- Medicare and Medicaid programs expected to grow from \$720 billion in 2009 to about \$1.4 trillion in 2019.
- 90 million elderly, disabled, and low income Americans access CMS's programs.
- Loan guarantees for JP Morgan's purchase of Bear Stearns was \$29 billion. That is about 2.5 weeks of spending for CMS.
- The loan package for AIG was initially \$85 billion. That is about six weeks worth of CMS spending.
- The bank rescue package was several hundred billion dollars. That is about one year of spending for CMS.

# Innovation is Expensive

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- Typically between 1.1 -- 1.7 billion dollars spent on research, regulatory submissions and launch of new drug/biotech therapy.
- Reimbursement must also covers failures.
- Trends show that these costs will continue to rise.
- Demand for better and more specific clinical and safety data will increase costs.
- Increased competition can shorten product's lifecycle—especially for devices.
- Societal pressures on healthcare costs.

# Reimbursement's Role in the Company

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- Reimbursement decisions by either Congress or CMS impact many aspects of the company.
  - Regulatory—do we need to reassess our clinical trial design and/or FDA labeling strategy?
  - Investor relations—how well did the investor community react?
  - Public relations—how do we promote/control the scope of the decision?
  - Business development—what does this decision mean for future licensing opportunities?

# Why Is Reimbursement Important?

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- Providers are unlikely to buy technologies that are not reimbursed
- Investors request reimbursement strategies and timelines
- Reimbursement is not automatic upon Food and Drug Administration (FDA) approval
- Reimbursement strategies can be employed early to facilitate coverage and reimbursement upon FDA approval
- Increasing health care costs are driving reforms and decreasing reimbursement rates
- Reimbursement landscape is constantly changing
- Private payers look to Medicare for coverage and payment of new technologies

# The Changing Path to Success

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- Yesterday

FDA Approval = Commercial Success

- Today and Tomorrow

FDA Approval + Evidence-Based Value

+ Reimbursement = Commercial Success

# The Missions of FDA and CMS

## U. S. Food and Drug Administration (FDA)

### “Safe and Effective”

- Mission to promote and protect the public health by helping safe and effective products reach the market in a timely way
- To monitor products for continued safety after they are approved for marketing
- To provide the public with accurate, science-based information needed to improve health

## The Centers for Medicare & Medicaid Services (CMS)

### “Reasonable and Necessary”

- Mission to ensure healthcare security for beneficiaries
- Administers the Medicare program
- Develops Medicare coverage and reimbursement policies for the Medicare program
- Works in partnership with States to administer the Medicaid program and the State Children’s Health Insurance Program (SCHIP)

# Two Agencies, Two Distinct Missions--One Business Plan

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- Regulatory pathway requires different business models for devices and drugs.
  - PMA versus NDA
  - 510(k)
- Relates to ability for premium pricing
- The FDA approved 24 NME in 2008, compared with 18 in 2007, 22 in 2006 and 20 in 2005.
  - Few, however, are likely to be traditional blockbusters.
- Rise of post market studies—will there be a trade for pre versus post market study?

# What are Medicare and Medicaid

- Medicare--Federal program established in 1965 to provide health insurance coverage to the aged, disabled, and those with end-stage renal disease.
  - Medicare is a defined benefit creating alphabet soup—important to understand under which benefit your product will be covered.
- Medicaid--A joint federal-state program providing health care coverage for certain groups of low-income individuals and families.
  - *KFF—In 2006, combined federal and state Medicaid spending on services was \$304 billion. On average, states spend about 17% of their general funds on Medicaid.*
- Ability to set launch price still exists within these programs, however, other market and regulatory forces often dictate launch price and price increases.
- Congress writes the laws—healthcare is very political.

# Congressional Players

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- Many “cooks in the health reform kitchen”--fundamental distrust of physicians, insurance companies and innovators.
- Committees of Jurisdiction
  - House of Representatives
    - Energy and Commerce–Jurisdiction over Food and Drug Administration (FDA) and CMS. New leadership at Energy and Commerce.
    - Ways and Means–Jurisdiction over CMS, tax and trade issues. Many new members on both sides of the aisle.
  - Senate
    - Finance Committee–Jurisdiction over CMS, tax and trade issues. Senators Grassley and Baucus have good working relationship.
    - Health, Education, Labor and Pensions (HELP)–Jurisdiction over FDA and other HHS agencies. What is Sen. Kennedy's role?
- Significant challenges exist to manage the process for health reform
  - Growing deficits
  - Parts of Medicare are silos, creating scoring challenges
  - Congressman Stark recently stated that reform unlikely until 2010

# Congress in 2009

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There are at least three health care vehicles in 2009:

1. House \$800 billion plus stimulus package includes:
  - \$87 billion in enhanced Federal Medical Assistance Percentages (FMAP) to help states deal with the increased Medicaid enrollment due to the economic crisis.
  - \$20 billion is allocated toward health information technology—electronic medical records.
  - \$3.0 billion for preventative care, which includes funding hospital infection prevention programs, block grants for state and local public health departments, immunization programs and evidence based disease prevention.
  - \$1.1 billion for comparative effectiveness research into the existing entities that are already conducting research -- Agency for Healthcare Quality and Research (AHRQ) and National Institute of Health (NIH).
2. Children's Health Insurance Program (SCHIP)
  - Funding set to expire at the end of March 2009.
  - Reauthorizing legislation already passed both chambers—can be an opportunity.
3. Physician Payment
  - Physician payments are scheduled to be reduced by approximately 20% on January 1, 2010

# Comparative Effectiveness Senate Version

- Create new institute charged with identifying the “most pressing gaps in clinical knowledge.”
- Would be private, non-profit corporation with a Board of Governors appointed from the public and private sectors by the U.S. Comptroller General.
- Will contract with other Federal agencies such as AHRQ and NIH to conduct the research.
  - Goal of research would be to help patients, providers, and payers of health care to make more informed clinical decisions.
- Funded by mixture of general funds, a tax on self-insured and other health plans, and \$1 per Medicare beneficiary.

# Other Congressional Issues

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- Driven by budgetary issues, Congress likely will focus on pharmaceutical/device industries for sources of money:
  - Increase current Medicaid rebate
  - Require Medicaid-type rebates on Medicare Part D drugs
  - Decrease or freeze reimbursement rates
- Congress may permit/mandate price negotiations.
- Congress may permit drug importation on a larger scale.
- Senator Grassley already announced that he plans on reintroducing the Sunshine Act that will require greater transparency from device and pharmaceutical manufacturers regarding sales and marketing activities.
  - Price reporting requirement for device companies, similar to Average Sales Price, also discussed.
- Create greater latitude for innovators to be sued in state court and pathway for generic biologicals.

# The Administration

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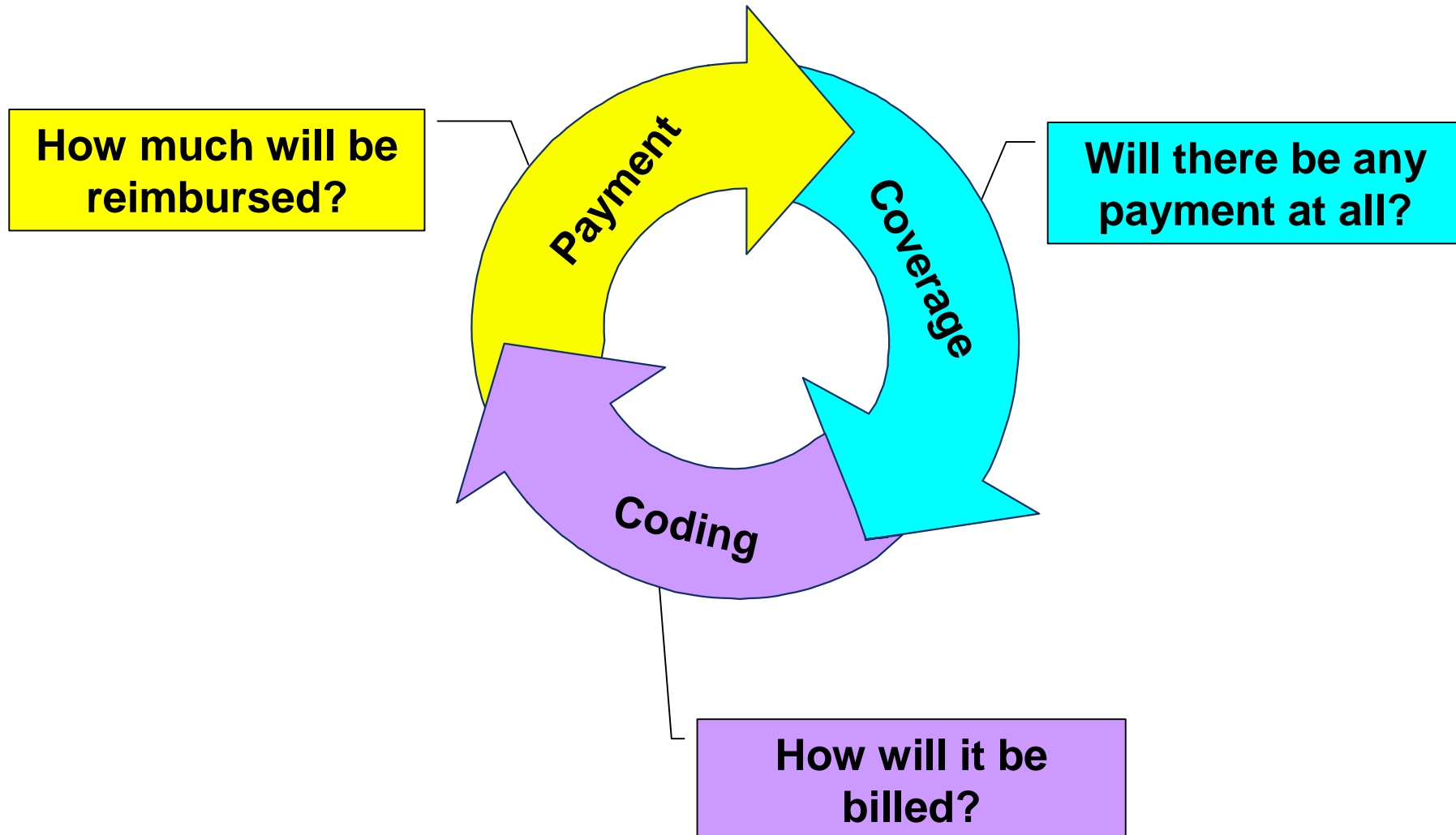
- Early signs indicate an increased role for government in making coverage and perhaps payment decisions.
- Establishing a strong and diverse health care team to hopefully fulfill the many campaign promises in this area.
  - Focus on background of each nominee, many familiar faces.
- The leaders of CMS and FDA will still influence reform process regardless of “health care board.”

# General Principles

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- Administration will be more focused on the beneficiary's Medicare and Medicaid experience.
  - Expand coverage to all Americans.
- Invest in a national health information technology systems.
- Reward health providers that provide high quality and coordinated care.
- Continued focus on preventative care and new delivery models.
  - Approximately 1 in 3 children born today will develop diabetes in their lifetime.
  - Only 4 cents out of every healthcare dollar is spent on prevention and public health.
  - Expand disease management programs.
- From Transition Team Participant Guide--“lower drug costs by increasing the use of generic drugs, and taking on drug companies that block cheaper generic medicines from the market.”

# Three Independent Issues at CMS



## CMS—The Future Already May Be Here

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- For both drugs and devices, the scrutiny on the product's effectiveness for the Medicare population no longer makes FDA approval a guarantee of Medicare coverage.
- CMS is more focused on the quality and type of the clinical data.
- This is evident in all three principal functions of the agency – coverage, coding, and payment.

# Medicare Coverage

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- For FDA-approved products, Medicare payment is prohibited for any item or service that “is not *reasonable and necessary* for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”
- CMS has not further defined by regulation what is *reasonable and necessary*.
- Most coverage decisions are made at local level, however, CMS recently issued a list of potential national coverage decision (NCD) topics.
  - Descriptions of proposed topics focus on clinical outcomes of Medicare beneficiaries.
  - Many descriptions focus on off-label uses, particularly for devices.
- Medicare Part D---similar to private plans, formulary placement is focus.

# Coverage Trends Continued

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- CMS is currently transitioning to fewer Medicare contractors at local level.
- Evolution of fail first policies at the local level—requiring beneficiary to fail on an oral product before covering an infused formulation.
- Coverage is expanding, however, in other areas—CMS recently increased the number of compendia.
- Coverage with Evidence Development—Will CMS continue to use it under a new administration?

# Increased Focus on Quality

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- CMS continues to expand quality initiatives within sites of care and for a broader range of items and services.
  - CMS will not pay for hospital acquired conditions under certain circumstances in the inpatient setting.
  - Recent rulemaking explored possibility of expanding to outpatient and physician office setting.
- Physician Quality Reporting Initiative (PQRI)—Incentive payments for eligible professional who satisfactorily report data on quality measures for covered services. The 2009 PQRI consists of 153 quality measures and 7 measure groups.
- Value-based Purchasing—Applies to hospitals paid under the IPPS and builds on the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program.
  - Goals of program are to improve quality, reduce adverse events, encourage more patient-centered care, stimulate investments in IT, and make the results transparent.
- The more the provider does, the more the provider gets paid--shift from pay for reporting to pay for performance.

# Coding Issues

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- For drugs, coding issues fairly straightforward.
- Similar to coverage, strength of clinical evidence seems to be affecting ability to receive unique code for devices.
- Coding applications for permanent J-codes and temporary and pass-through status focus on quality and quantity of clinical data.
- CMS is reluctant to issue new permanent individual codes because of downstream implications on payment.

# Current and Future Payment Issues

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- Inpatient Hospital Setting

- Transition is complete from charge based reimbursements to cost based reimbursements creating greater granularity within MS-DRG system.
- Still very difficult to receive new technology add-on payment.
- Bundled hospital payment demonstration project recently announced.

- Hospital Outpatient Setting

- Older drugs and biologicals will be paid ASP plus 4% in 2009.
- CMS eager to increase packaging.
- No major changes for devices, however, harder to get unique temporary or permanent code.
- New technology Ambulatory Payment Classification (APC) payment is still an option.

- Physician's Office

- Drugs and biologicals will still be reimbursed at ASP plus 6% per statute.
- Brief review of 1847A grandfather provision as an example of the interactions of coverage, coding and reimbursement.
- Will the Competitive Acquisition Program return?

# Other Agencies

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- Other agencies will greatly influence the debate.
  - Budget agencies:
    - Congressional Budget Office (CBO) is responsible for “scoring” various pieces of legislation. Given budget environment, its better to save money than cost money.
    - CBO recently issued two health reform documents that could serve as a guide to which provisions are included in upcoming legislation.
    - Office of Management and Budget (OMB) serves similar function for administration. OMB signs off on agency regulations to ensure the regulation meets policy and financial goals of the administration.
  - Medicare Payment Advisory Commission (MedPAC) advises Congress on Medicare payment issues.
  - AHRQ is the current agency that conducts certain types of quality reviews either in-house or through its network of academic institutions.
  - Greater collaboration expected between FDA and CMS.

# What Does It Mean for You?

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- What is your exist strategy—be true to yourself.
- Understand the value of your product and ability for commercialization.
- Outcomes data increasingly important.
- Look for opportunities to tie product use to clinical guidelines or quality measures.
- Monitor NCD potential topics list and contractor reform.
- New options for prevention and screening.
- Contemplate marketing in payment systems with more packaged services.
- Case study discussion: oral versus infused drug/biological product.

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