EPSTEIN BECKER GREEN

EMBRACING CHANGE:

WHAT ARE THE IMPLICATIONS TO THE HEALTH CARE INDUSTRY OF THE REFORM LEGISLATION?

April 13, 2010

The Yale Club
50 Vanderbilt Avenue
New York, NY 10017

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- Health reform is a process, not an outcome
- Continuous public opportunity to shape health reform

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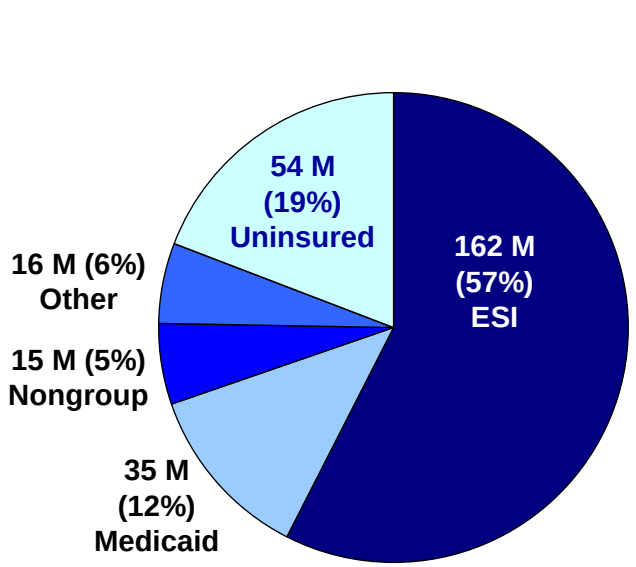
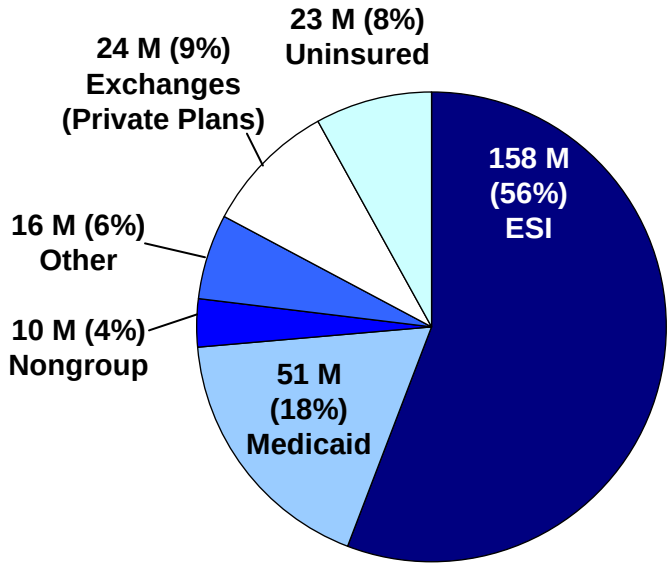
Source of Insurance Coverage Under Current Law and Under the Federal Health Reform Act, 2019

Among 282 million people UNDER AGE 65



Current Law



Health Reform Act

Note: ESI is Employer-Sponsored Insurance.
Source: Cost Estimate for the Amendment in the Nature of a Substitute for H.R. 4872, Incorporating a Proposed Manager's Amendment Made Public on March 20, 2010, Congressional Budget Office Letter to the Honorable Nancy Pelosi, March 20, 2010, http://www.cbo.gov/doc.cfm?index=11379.

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- Federal Agency Involvement
  - Reorganizations, new offices, new government officials
  - Proposed Final Regulations, Interim Final Regulations, Issuances, “Letters”
- Potential Litigation Challenges
  - Constitutional
  - Administrative Procedures Act (regulatory)
- State Implementation Activities
  - Exchanges, Medicaid, other programs
- NAIC and other Key Players
- New Commissions and Boards

PANEL I

HEALTH CARE REFORM:

INNOVATION & NEW IDEAS

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I. A VIEW FROM CAPITOL HILL

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- Congress now and moving forward
  - Reaction in the Districts
  - District influence in D.C.
  - Oversight of health reform implementation
  - Likely 2010 activities related to health reform and health care
    - Amendments
      - Timing
      - Topics
- November Elections
  - Likely outcomes
  - Implications for future legislative achievements for the Obama Administration

EMBRACING CHANGE – PANEL I

II. A CMS PERSPECTIVE

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- Access for the Uninsured
  1. Young invincibles
  2. Poor
  3. Uninsurable
  4. Qualifies for Assistance
  5. Undocumented Aliens

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Access: Uninsured Demographics

Hispanics	41.5%
Non-Hispanic blacks	19.9%
Non-Hispanic whites	11.6%
All Adults	16.0%
Ages 18-29	27.6%
Ages 30-44	20.3%
Ages 45-64	14.4%
Ages 65+	3.6%
South	19.7%
West	18.7%
Midwest	13.5%
East	10.5%

Men	17.8%
Women	14.4%
Less than $36,000	28.6%
$36,000-$89,999	8.8%
$90,000+	4.5%

Source: National Journal

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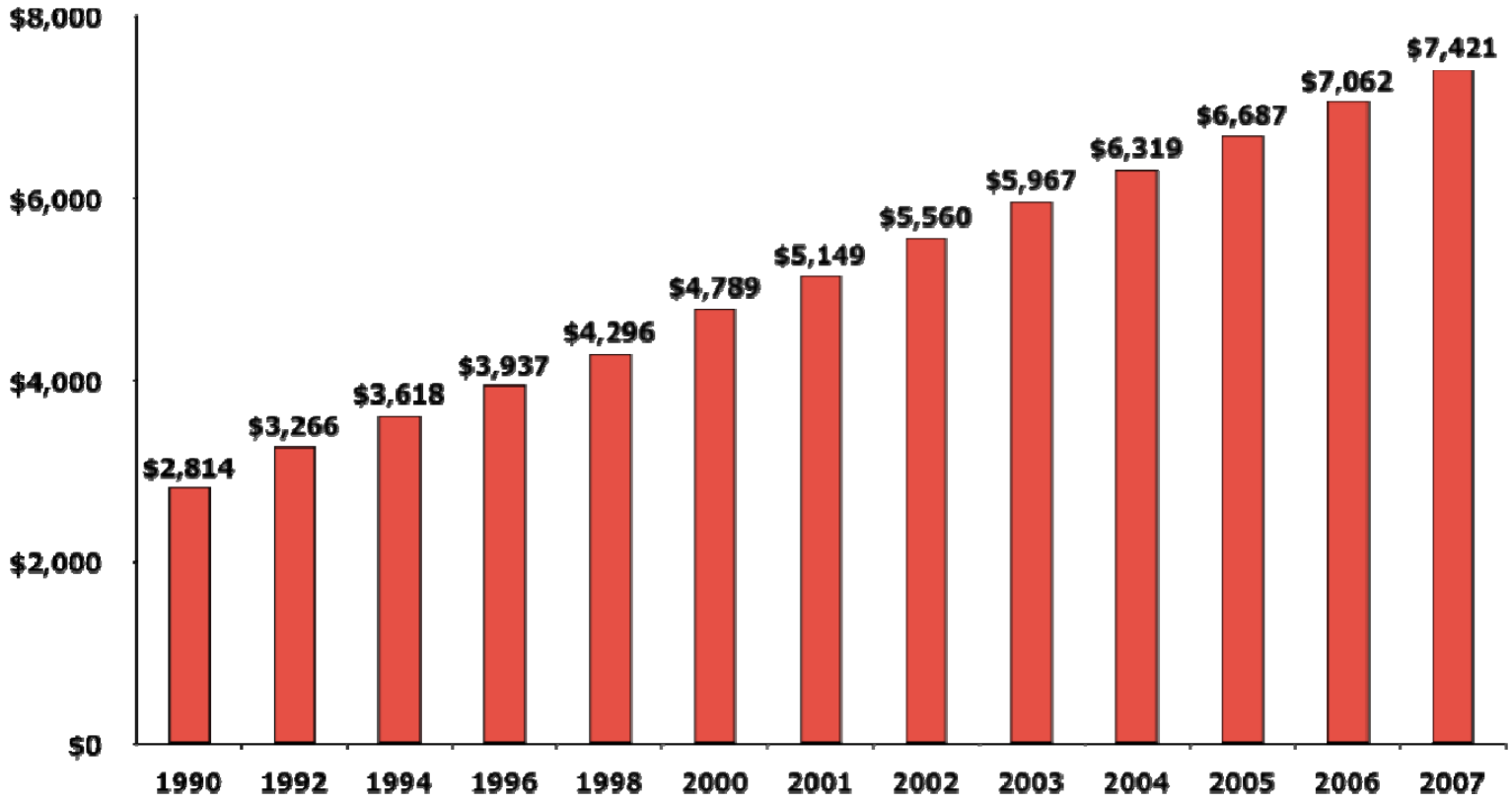
National Health Expenditures per Capita, 1990-2007



Source: Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group, at http://www.cms.hhs.gov/NationalHealthExpendData/ (see Historical; NHE summary including share of GDP, CY 1960-2007; file nhegdp07.zip).

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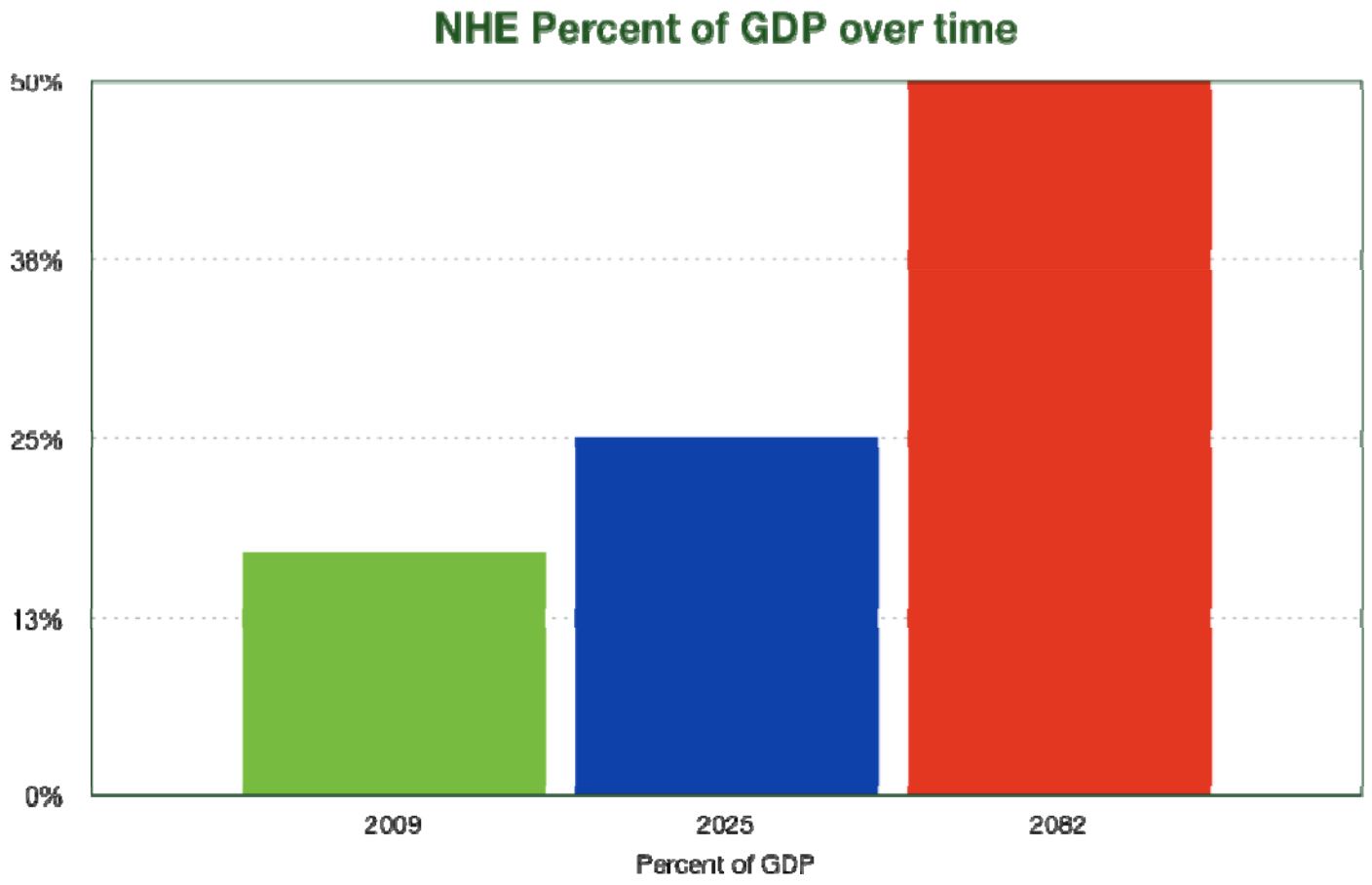
Projected Growth



Source: CBO

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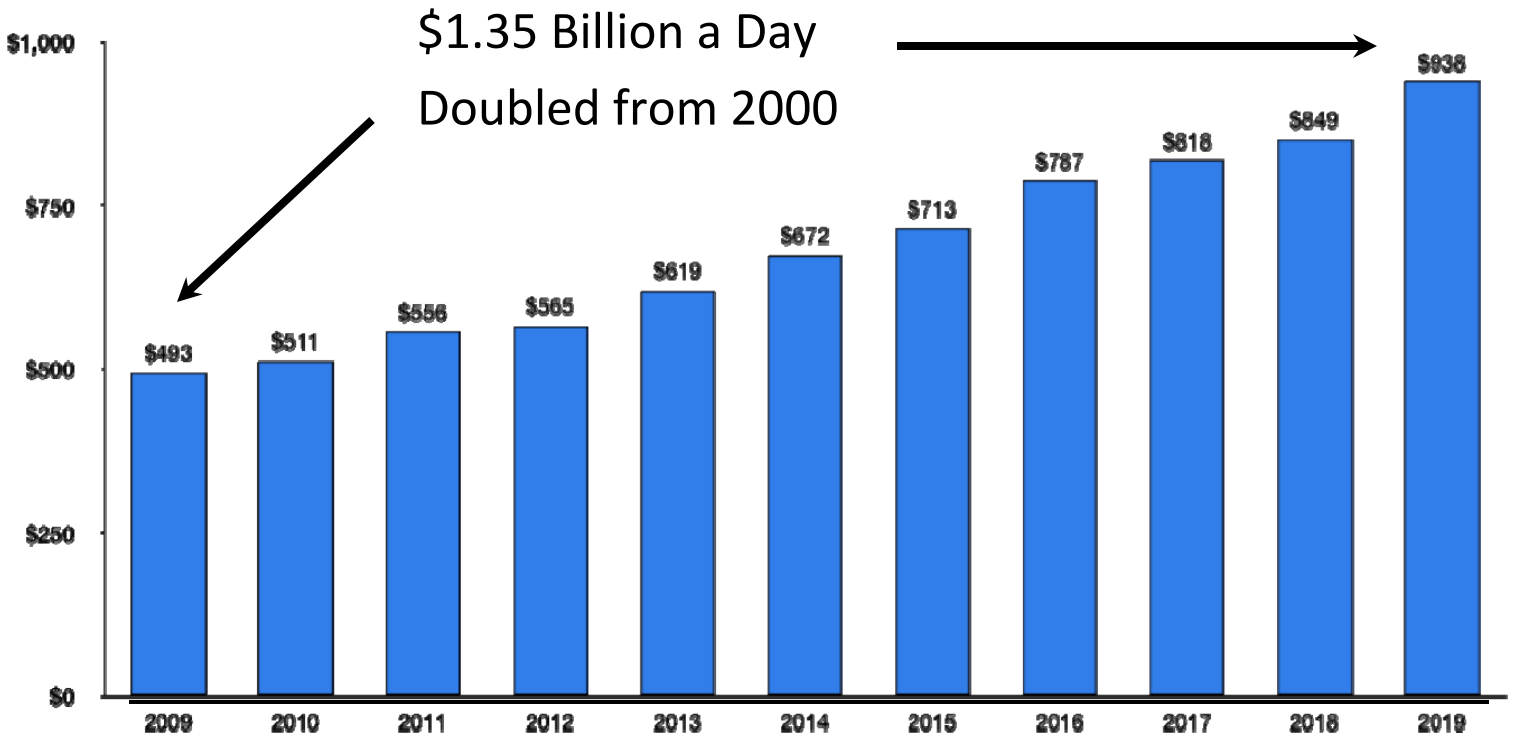
Projected Medicare Outlays, 2009-2019

Total Outlays (Billions)



	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Share of Federal Budget:	14%	16%	17%	17%	17%	18%	18%	19%	19%	19%	20%
GDP:	3.5%	3.5%	3.7%	3.6%	3.7%	3.9%	4.0%	4.2%	4.2%	4.2%	4.5%

NOTE: Numbers have been rounded to nearest whole number.
SOURCE: Kaiser Family Foundation, based on data from Congressional Budget Office, The Budget and Economic Outlook: An Update, January 2008, and A Preliminary Analysis of the President's Budget and an Update of CBO's Budget and Economic Outlook, March 2009.

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- Cost of Medicare – “Bend the Cost Curve”
  - Market Basket minus Productivity Adjustment
  - Comparative Cost Effectiveness
  - “Super” MedPac
  - Innovation Center at CMS

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- Cost of Medicare
  - Antiquated Payment Systems – Difficult to Reform through Legislation
  - New Ideas via Voluntary Pilots
  - Accountable Care Organizations
  - Bundled Payments
  - Gainsharing

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- Cost - Chronic Care
  - 23% of all Medicare Beneficiaries:
    - Have 5 or more Chronic Conditions
    - See 12 or more physicians a year
    - Take 50 or more prescriptions a year
    - Cost 68% of the Medicare Budget

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- Cost of Medicare
  - Chronic Care Management
    - Support Primary Care
    - GME Reform
    - Medical Home Models

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III. SEIZING OPPORTUNITY

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YES, BUT NOT ALONE

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- Current State of the U.S. Health Care System
  - The problems are widely recognized
    - Fragmented care
    - Uneven, unsafe practices
    - Unsustainable costs
  - *Crossing the Quality Chasm*, 2001
    - Quality = care that is safe, effective, efficient, patient-centered, timely and equitable

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"Our fee-for-service system, doling out separate payments for everything and everyone involved in a patient's care, has all the wrong incentives: it rewards doing more over doing right, it increases paperwork and the duplication of efforts, and it discourages clinicians from working together for the best possible results."

— Atul Gawande, "Testing, Testing," The New Yorker, 12/14/09

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- Solution to the Current State of Health Care Delivery
  - Better coordinated care, more transparent to the consumer, using evidence-based measures to achieve better outcomes, greater patient satisfaction and improved cost efficiency
  - Or, in other words, “accountable care”
  - “Accountable care organization” (ACO) means a provider-based organization comprised of multiple providers with a sufficient level of clinical integration to deliver accountable care
  - Both the payment system and delivery system need to change together to achieve accountable care

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- Payment and Delivery Reform: It's Only a Matter of Time
  - There is great consensus in the policy community, in both parties and in both houses of Congress, as to the current problems and the endpoint goals — the challenge is the transition, but it has begun
  - Under the PPACA, both payment and delivery reforms are phased in over time
  - Further changes can be attached to regular budget and Medicare legislation and CMS actions
  - States are actively implementing new programs based on accountable care principles
  - Private sector accountable care innovations between payers and providers are taking place in a number of locations throughout the country

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- Key Accountable Care Provisions in the Senate Bill
  - Formation at the Centers for Medicare & Medicaid Services of an Innovation Center that would be required to test and evaluate patient-centered delivery and payment models – Section 3021; by 1/1/11
  - Recognition of accountable care organizations (ACOs), which would be allowed to qualify for incentive bonus payments; among other requirements, an ACO would have to have a formal legal structure to allow it to receive bonuses and distribute them to participating providers – Section 3022; by 1/1/12
  - A hospital value-based purchasing program in Medicare that moves beyond pay-for-reporting on quality measures to paying for hospitals actual performance on those measures – Section 3001; 10/1/12

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- Key Accountable Care Provisions in the Senate Bill (cont.)
  - The establishment of a bundled payment pilot program involving multiple providers to cover costs across the continuum of care and entire episodes of care; if the pilot is successful, it would be made a permanent part of the Medicare program – Section 3025; 10/1/12
  - Reductions in Medicare payments to hospitals with preventable readmissions above a threshold based on appropriate evidence-based measures – Section 3023; by 1/1/13

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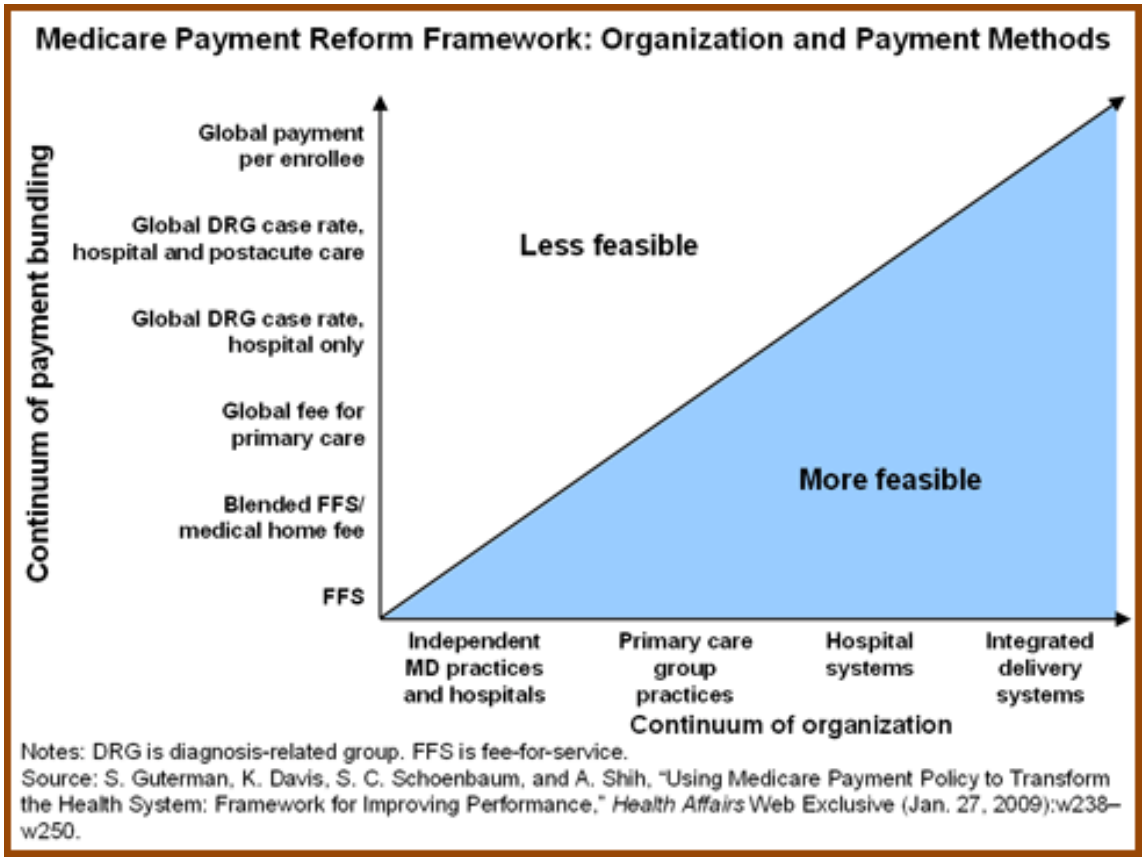
The Accountable Care Framework



"To change the way health care is organized and delivered, we need to change the way it is paid for — to move from fee-for-service payments to bundled payments."

– Gutterman, Davis, Schoenbaum and Shih, 2009

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- Payment Reform – Volume to Value
  - Pay for performance
  - Inpatient bundling
  - Episode of care bundling
  - Per enrollee shared savings
  - Partial or full global payment per enrollee

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- ACO Structure Options
  - Contractual models
  - Partial or virtual integration models
  - Fully integrated models

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- Senate Bill Criteria for ACOs
  - Agree to become accountable for overall care for their Medicare fee-for-service beneficiaries
  - Have a formal legal structure that would allow the organization to receive and distribute payments to participating providers
  - Include primary care physicians for at least 5,000 Medicare fee-for-service beneficiaries

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- Senate Bill Criteria for ACOs (cont'd)
  - Have arrangements in place with a core group of specialist physicians
  - Have in place a leadership and management structure, including with regard to clinical and administrative systems
  - Define processes to promote evidence-based medicine, report on quality and cost measures, and coordinate care

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- Brookings/Darmouth Key ACO Criteria
  - Can provide or manage the continuum of care for patients as a real or virtually integrated delivery system
  - Are of sufficient size to support comprehensive performance measurement and expenditure projections
  - Are capable of internally distributing shared savings and prospectively planning budgets and resource needs

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- Legal Issues
  - Stark, antikickback, CMP
  - Antitrust
  - Corporate practice of medicine
  - State regulation of risk transfer
  - How to define clinical integration
  - How to distinguish good collaboration from bad

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- In Search of Accountable Care – Part II
  - Why might ACOs and global payments work now when similar concepts did not in the 1990s?
    - There is greater recognition of the urgency of the cost and quality problems
    - The implications of evidence-based medicine are more widely understood and accepted
    - There is greater understanding that good outcomes, patient satisfaction and cost-efficiency are linked
    - We have learned from past experience with provider integration efforts and risk contracting
    - Consensus measures and IT infrastructure have advanced significantly
    - Early pilots and demonstrations show promise

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The Benefit of Pilots and Demonstrations

"The history of American agriculture suggests that you can have transformation without a master plan, without knowing all the answers up front…Transforming health care everywhere starts with transforming it somewhere."

- Atul Gawande, "Testing, Testing," The New Yorker, 12/14/09

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- Who Are the Potential ACO Drivers?
  1. CMS
  2. States
  3. Purchasers / Employers
  4. Payers
  5. Providers
  6. Consumers

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- Conclusion
  - Payment and delivery reform is the pathway to improving quality, bending the cost curve and, ultimately, paying for greater access
  - Payers and providers need to work together more than ever, and they ignore this imperative at their peril
  - Failure to do so will put more onus on government to regulate prices on both parties and potentially micro-manage contract provisions
  - If the promise of accountable care is realized, purchasers, payers, providers and consumers all should benefit

PANEL II

INDUSTRY PERSPECTIVES:

CHALLENGES & OPPORTUNITIES

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I. PAYOR PERSPECTIVE

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Quality and Access

- Individual Mandate
  - Begins after 2013
  - Penalties are phased in and subject to exceptions
- Employer Responsibility
  - Starting 1/1/14, employers with more than 50 employees must provide coverage or pay a fee for each employee who receives a tax credit for health insurance purchased through an exchange

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Quality and Access (cont'd)

- Exchanges and Co-Ops
  - By 1/1/14, each State is required to establish an exchange to facilitate the purchase of qualified health plans by individuals and a small business health options exchange to assist qualified small employers in enrolling their employees
  - Plans must be certified to be offered on an exchange
  - Creates a payment mechanism that provides increased reimbursement or other incentives for improving health outcomes through various initiatives, including disease management, treatment compliance, preventing hospital readmission, patient safety, reduction of medical errors, implementing wellness programs and activities designed to reduce health disparities
  - Establishes the non-profit Consumer Operated and Oriented Plan to foster the creation of non-profit health insurers to offer plans in the individual and small group markets
  - Multi-state plans – national offering similar to FEHBP's

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Quality and Access (cont'd)

- Market Reforms
  - Immediate underwriting changes
    - Prohibits rescission except in limited circumstances
    - Prohibits the application of pre-existing conditions to children (regs expected to extend this to guaranteed issue for children this year)
    - Imposes limits on waiting periods
    - Requires that dependents be covered up to age 26
  - 1/1/14: major insurance reform, including
    - Guaranteed issue
    - Prohibition of pre-existing condition exclusions
    - Elimination of annual and lifetime maximums

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Quality and Access (cont'd)

- Quality Programs
  - Demonstration projects in public programs, including testing alternative payment models and health plan reporting
  - Wellness programs, including rewarding behavior and other demonstration programs

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Cost and Pricing

- Establishment of Minimum Loss Ratios, effective 1/1/11
  - 85% large group
  - 80% small group and individual
  - Ratios do not include taxes and federal and state fees
- Review of "Unreasonable" Rate Increases
- Additional Premium Taxes
- Fees for Exchanges and Reinsurance Programs
- Tax on "Cadillac" health plans
- Extensive Minimum Benefit Packages with Requirements for Coverage Levels
- No Provisions Addressing Health Care Costs

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Compliance Challenges & Opportunities

- Grandfathered Plans – unclear scope
- Regulations Required
  - Consistency with statute will be reviewed closely
- Federal vs. State Regulators
  - How will they work together?
- Interstate Health Insurance in 2016
  - Insurers may offer products across state lines
  - Regulators in states where offered can enforce, but based on home state's laws

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Compliance Challenges & Opportunities

- New Requirements
  - Standardization of coverage documents within 12 months
  - New transaction requirements
    - Health plan ID
    - Eligibility and health status
    - Electronic funds transfer and remittance advice
    - Claims attachments
      - Minimum benefit requirements, including cost sharing changes and restrictions on annual and lifetime requirements
      - Dependent coverage up to 26
      - Rescission restrictions

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Significant Implications

- Immediate revision and rework of all products required
  - Note: large groups currently being sold now for 2011
- Large investment in information technology to implement all of the requirements
- Innovation regarding bringing value and providing the administrative services within the medical loss ratios
- Innovation regarding products and payment methodologies to bend the trend, including integration of payor and provider functions
- Non-traditional partnerships
- May bring more consolidation

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II. PROVIDER PERSPECTIVE

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Quality

- Innovation/regulation
  - Establishes, for example:
    - Center for Medicare and Medicaid Innovation
    - Center for Quality Improvement and Patient Safety (§3501)
  - Various pilots test and plans—
    - bundling,
    - ACOs,
    - Medical Homes,
    - Independence at home project (§3024)
  - EHR; telemedicine

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Access

- Coverage is broader, for example
  - Pediatric dental and vision care must be covered; psychiatric treatment; drug addiction
  - Community Health Centers
  - Home and Community-Based Services (HCBS)
  - CLASS (community living assistance for severely disabled)
  - Nursing home and long term care

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Cost and Payment

- Many fewer uninsured patients
- Reduces Medicare disproportionate share hospital (DSH) payments.
- Reduces market basket updates for all providers

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Quality- Cost and Payment

- Pay for Quality
  - "Rewarding Quality through Market-Based Incentives"
  - Physician Quality Reporting Initiatives (PQRI) and use of "value based modifier" to adjust payments based on quality
  - Reduces Medicare payment for some hospital readmissions, effective 2012
  - Payment adjustments for conditions acquired in hospitals, effective 2015
- Transparency
  - Post at "Physician Compare" and "Hospital Compare" websites

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Quality

- Not-for-Profit Hospitals must conduct community needs assessment and limit collection of fees from indigent
- Graduate Medical Education (GME) changes
- Workforce advisory commission on allocating resources for training primary care health care providers

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Compliance and Enforcement

- Substantially enhanced provider enrollment screening
- Enhanced oversight of providers and suppliers
- Disclosures of affiliations of excluded providers

EMBRACING CHANGE – PANEL II

Compliance and Enforcement

- Eliminates the need to have knowledge of the AKS or of an intent to violate the AKS as a defense
- Claims resulting from a violation of the AKS are covered under the False Claims Act
- Failure to return overpayments within 60 days of their being identified and potentially subject to the False Claims Act

EMBRACING CHANGE – PANEL II

Compliance and Enforcement

- Enforcement enhancement aimed at Providers
  - Authorizes CMP for certain activities
    - Knowing false statement
    - Failing to grant the OIG timely access to information for purpose of audits
    - Failure to report and return a known overpayment

EMBRACING CHANGE – PANEL II

Compliance and Enforcement

- Stark Law Changes
  - OIG Self-Disclosure Protocol for Stark violations and possible lowering of penalties
  - In office ancillary services—Group Practice exception to Stark—requires the referring physician to supply patient with list of others who provide services in area
- Prohibits physician ownership of hospitals without a provider agreement in place on 12/31/2010—limited grandfathering exceptions

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Compliance and Enforcement

- Enforcement initiatives
  - Suspension of payment pending investigation with a credible allegation of fraud
  - Data mining
  - Audit cooperation
  - EHR

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Compliance and Enforcement

- Mandatory Compliance Programs
  - Regulations are forthcoming
  - Likely to vary based on types of providers
  - Given enforcement initiatives—compliance programs will be essential tool to limit financial and legal exposure

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III. MANUFACTURER PERSPECTIVE

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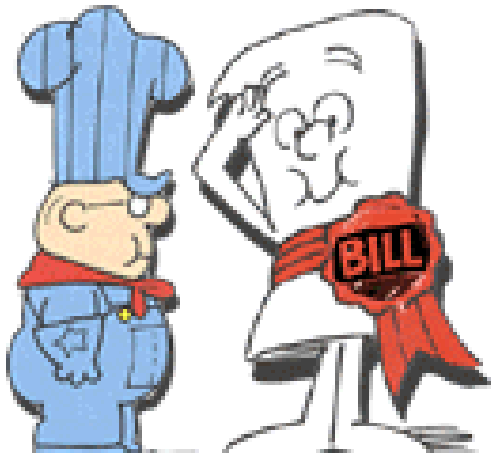
I’m just a pill,
Yes, I am only a pill,
I look for friends on Capitol Hill



“And if they vote for me on Capitol Hill
Well, then I'm off to the White House”

“I’m just a Bill,” Schoolhouse Rock

EMBRACING CHANGE – PANEL II

Access

- Reduces Medicare Part D Beneficiary Co-insurance Coverage Gap
  - By 2020, beneficiary coinsurance for branded drugs reduced from 100% to 25%
    - Brand name drug manufacturers will be required to offer 50% discount to beneficiary at POS for its drugs, effective 2011
    - Discount will be a requirement to have drugs covered under Part D program
    - DHHS must issue a model agreement within 6 months of enactment
  - By 2020, beneficiary coinsurance for generic drugs reduced from 100% to 75%
    - Phase-in commences 2011
  - $250 coverage gap rebate (administered quarterly), effective for 2010
  - Increase initial coverage limit by $500, effective for 2010

EMBRACING CHANGE – PANEL II

Access (cont'd)

- Expands Medicaid Benefits
  - Prohibits excluding smoking cessation agents, barbiturates and benzodiazepines
  - Includes counseling and pharmacotherapy for smoking cessation to pregnant women, effective 2011

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Cost and Pricing

- Changes to Medicaid drug rebates, effective 1/1/10,
  - Basic rebate for “S” and “I” drugs (generally “branded” and authorized generic products) increased to 23.1% of AMP (from 15.1%)
  - Clotting factor and exclusively pediatric indications to 17.1% of AMP (from 15.1%)
  - Basic rebate for “N” drugs (generally “generic” products) increased to 13% of AMP (from 11%)
  - Additional rebate for new formulations of “Oral Solid Dosage Form” products
- Extends Medicaid drug rebates to Medicaid MCOs, effective 3/23/10

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Cost and Pricing

- Re-defines AMP, effective 10/1/10, to more accurately reflect retail pharmacy acquisition cost
  - Average price paid to the manufacturer for the covered outpatient drug in US by (1) wholesalers for drugs distributed to retail community pharmacies; and (2) retail community pharmacies that purchase drugs directly from the manufacturer
  - More limited definition than the current regulatory definition that includes, among other things, hospital outpatient sales, mail order pharmacy sales, physician sales, LTC and various other purchasers
  - Note - retail does not include mail order, hospital or LTC pharmacies
- Requires public disclosure by DHHS on web of weighted average of AMP for multisource drugs only, effective 10/1/10
  - NACDS injunction may delay publication until December at earliest

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Cost and Pricing

- Changes the 340B outpatient drug discount program
  - Expands participation to additional purchasers including cancer hospitals, certain children's hospitals, critical access and sole community hospitals and rural referral centers
    - These additional purchasers do not appear to be subject to GPO purchasing restrictions
  - Does not include expansion to any inpatient purchases
  - Adds "integrity" provisions for manufacturers and covered entities
    - Among other items, manufacturers must refund for overcharges
  - Adds a "must sell" provision and reporting obligations

EMBRACING CHANGE – PANEL II

Cost and Pricing

- Changes to Medicaid outpatient FFS drug reimbursement for generics known as FULs, effective 10/1/10, among other things:
  - FULs for multiple source drugs if 2 or more equivalent products in class (e.g., 3 or more drugs) shall be “no less than” 175% of the weighted average (based on utilization) of the most recently reported monthly AMPs” for the group of equivalent products “that are available for purchase by retail community pharmacies on a nationwide basis”

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Cost and Pricing

- Provides funding for programs to study alternative reimbursement strategies, such as bundled payments and outcomes-based payments
- Requires OIG to study and issue reports on numerous topics including drug prices under Medicare Part D and Medicaid and part D formularies inclusion of commonly used drugs by dual eligibles

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Cost and Pricing

- Imposes an annual fee, which is not tax deductible, on pharmaceutical manufacturers of branded prescription drugs
  - Fee imposed on manufacturers and importers
    - "Importers" not defined
  - Other fees imposed on insurers (effective 2014, $8 billion industry fee allocated on market share, with certain rules for nonprofits and others)
  - Medical device manufacturers (effective 2013, a 2.9 % excise tax on taxable medical devices, with certain exceptions)
- Total fee of $2.5 billion divided among the industry for 2011
  - Increases to $4.1 billion by 2018
  - Drops to $2.8 billion from 2019 forward
- Tax is imposed relative to share of annual sales "to any specified government program"
  - Medicare Parts B and D, Medicaid, VA, DoD, TRICARE

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Cost and Pricing

- Percentage of annual sales taken into account

Aggregate Sales	% of Sales Taken into Account
Not more than $5M	0%
More than $5M, less than $125M	10%
More than $125M, less than $225M	40%
More than $225M, less than $400M	75%
More than $400M	100%

EMBRACING CHANGE – PANEL II

Quality

- Grants for five-year demonstration projects including proposals likely to enhance patient safety by reducing medical errors and adverse events
- Establishes a regulatory approval pathway for biosimiliars, effective immediately
  - Biologic may not be licensed until 12 years after the licensing of the reference product and must not have any clinically meaningful difference in safety, purity or potency

EMBRACING CHANGE – PANEL II

Compliance

- Physician Payment Sunshine Act, first report due 3/31/13
  - Requires annual disclosure of payments and other transfers of value made to physicians and teaching hospitals by manufacturers and distributors of drugs, devices, biologicals, and medical supplies
  - Must report the name, address, payment amount, date, form of payment, nature of payment and product
    - Certain exclusions including de minimis payments, samples to patients, discounts and short-term loans of devices
  - Reported information will be made available to the public
    - Delayed publication for payments made in connection with research
  - Partial preemption of state marketing and disclosure laws
- Additional PBM, health benefits plan and GPO transparency provisions
- Additional PDMA sample reporting to DHHS for manufacturers and authorized distributors

EMBRACING CHANGE – PANEL II

Compliance

- Enhanced fraud and abuse provisions
  - The "knowing or willful" requirement of the AKS amended to provide that a person need not have actual knowledge or specific intent to commit a violation of the AKS
  - AKS amended to provide that a claim for items or services that violates the AKS or FDCA is a False Claim under FCA regardless of who submits the claim
  - Provisions to reduce fraudulent billing include Medicaid prescription drug profiling
  - Changes to the civil monetary penalty law
- False Claims Act
  - Extended to apply to payments made by, through or in connection with the private exchange plans if such payments include federal funds

EMBRACING CHANGE – PANEL II

Significant Implications

- Impact on pharmaceutical marketing
  - Payor presentations vs. physician detailing
  - Comparative effectiveness research
    - Patient-Centered Outcomes Research Institute will fund "research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items . . ."
- Impact on rebate contracting/negotiations
  - Negotiations with new entities
  - Negotiations with current customers
    - Shifting of populations (Medicaid MCO, Part D RDS …), expansion of benefits

EMBRACING CHANGE – PANEL II

Significant Implications

- Impact on Government program pricing
- Impact on compliance
- Relationships with business partners
- Relationships with customers
- Increased scrutiny on industry from enforcement

EMBRACING CHANGE – PANEL II

Significant Implications

- Research and development business strategy
  - Tax incentives
  - Coverage
  - Pricing
- Prepare for and be involved in the potential changes in delivery system and reimbursement models

EMBRACING CHANGE

MODERATED

QUESTIONS & ANSWERS