Georgia Bio

The Impact of Health Care Reform Legislation

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Health Reform: Barely Hanging On All Winter

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But in the End…

- Patient Protection and Affordable Care Act (H.R. 3590) – *signed into law on March 23, 2010*
- Health Care and Education Reconciliation Act of 2010 (H.R. 4872) – *signed into law on March 30, 2010*
- Culmination of 30 years of work and significant expenditure of political capital (tremendous accomplishment– *unless you pay taxes!)*

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Overview

- General Review
  - Coverage expansion
  - Revenue raisers (.9% HI / 3.8% Unearned income). Punted on "Cadillac Tax"
- Significant Changes for Pharma
  - Increases to Medicaid rebates
  - Closing of Part D donut hole
  - Creation of approval pathway for biosimilar drugs
  - Comparative clinical effectiveness research

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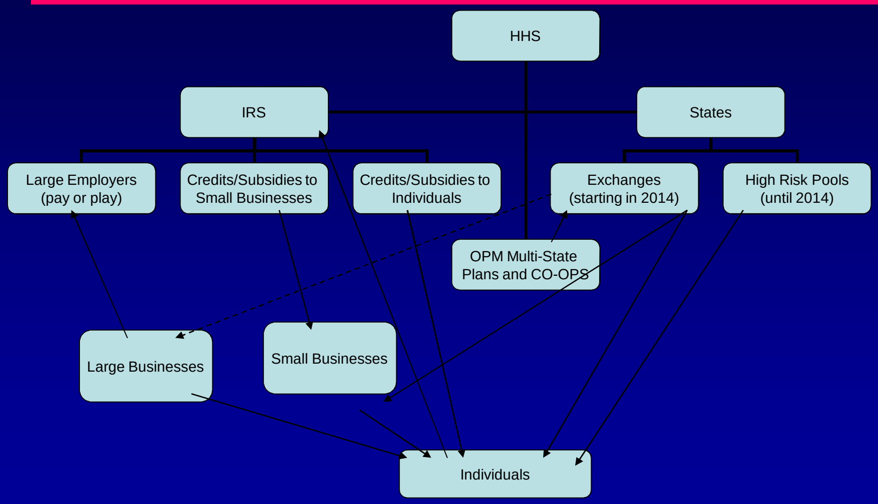
Coverage Expansion

- 32 million more Americans to be covered by 2019
- Immediate $5 billion infusion for state high risk pools (some states may move faster than 20154)
- State run health insurance Exchanges required by 2014
- Medicaid expansion to 133% FPL
  - 100% federal share for expansion
  - Includes childless adults
- Insurance reforms are pretty mainstream
- Large businesses (ERISA) largely untouched; very slow phase in to exchanges will slowly erode employer coverage

Coverage Expansion in 2014



Revenue

- Increase in Medicare (HI) Payroll Tax (0.9% increase); Tax on unearned income, 2013 (3.8% increase)
- Industry Fees and Taxes
  - Pharmaceuticals (share of $27 billion/10 yrs)
  - Devices (2.3% tax; raises $20 billion/10 yrs
  - Health plans (share of $60.1 billion/10yrs)
- Excise Tax on High Cost Health Plans (Cadillac plan tax) – 2018 implementation – (a joke)
- Medicare Cuts
- "Independent Payment Advisory Board"
  - Hospitals exempt until 2020
  - May recommend payment reductions for MA-PDPs and PDPs

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Medicare

- Fills in the Part D donut hole by 2020
  - $250 rebate for beneficiaries in donut hole in 2010
  - Brand name drugs:
    - 50% discount from brand manufacturers starting in 2011
    - Additional 25% covered through subsidies phased in starting in 2013
  - Generic drugs:
    - 75% subsidies phased in starting with 7% in 2011
- Impact
  - Makes Part D higher revenue business
  - Complex implementation options for CMS

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Medicaid

- Expansion of Medicaid
- Rebates (CMS issued a guidance letter to State Medicaid Directors concerning these drug rebates on April 22, 2010)
  - Increases rebate for outpatient single source and innovator multiple source drugs from 15.1% to 23.1%
  - Increases rebate for non-innovator, multiple source drugs from 11% to 13%
  - Applies an additional rebate for new formulations of existing drugs that are line extensions of a single source or innovator multiple source drug that are in oral solid dosage form
  - Expands Medicaid rebates to Medicaid MCOs
- Federal Upper Limit
  - Changes the Federal Upper Limit (FUL) to no less than 175% of the weighted average of the most recent Average Manufacturer Prices (AMPs) for pharmaceutically and therapeutically equivalent multiple source drugs available nationally through commercial pharmacies

Other Pharma Issues

- Biosimilars
  - Secretary must establish an approval pathway for biosimilar biological products
  - Must develop recommendations for user fees for the review of these applications (sense of the Senate that these should be collected as of October 1, 2012)
- Expands 340B discounts to other covered entities
- Drug Labeling
  - Secretary must determine whether summaries of the benefits and risks of drugs should be included in promotional labeling or print advertising for drugs
  - Permits certain changes to generic drug labeling

Other Pharma Issues (cont'd)

- Patient-Centered Outcomes Research Institute
  - Will conduct comparative clinical effectiveness research
- Protected Classes
  - Codifies the six protected classes
  - Removes current language used to identify protected classes
  - Grants the Secretary authority to identify other classes through rulemaking
- Transparency
  - Requires prescription drug sample transparency
  - Requires covered drug manufacturers to submit transparency reports, including information about physician ownership

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PBM Transparency

- Requires reporting on:
  - Percentage of prescriptions provided through retail v. mail order pharmacies
  - Percentage of prescriptions where generic was available and dispensed
  - Aggregate amount and types of rebates, discounts, and price concessions
  - Difference between the amount a plan pays the PBM and the amount the PBM pays the retail and mail order pharmacy

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Employer Issues

- Employer Mandate
  - Large employers (more than 50 employees) required to pay if:
    - Do not offer full-time employees minimum essential coverage; and
    - At least one full-time employee receives a credit or subsidies.
    - Employees who work 30 hours or more defined as full time
- Requires employers to notify employees of coverage options; provide “exchange options’.
- Will be slow erosion of ERISA/employer plans as they dump

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Employer Tax Issues

- Limits salary contributions to HSAs and FSAs
- Excludes OTC drugs and products from HSA/FSA reimbursement
- Eliminates deductibility of Medicare retiree drug subsidy (2013)
  - Costs will increase for employers as Part D becomes plusher benefit and employers have to match.
  - Loss of tax free status of 28% subsidy ($200/person)
- Drives employers to dump retirees into Part D

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What Does this Mean for the Fall Elections

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Part II
Where is this New Market Going?

- Big program expansions in Medicaid (15-20 Million new beneficiaries!!!!)
- Longer term, but HUGE private plan expansions via Exchanges (2013-14)
- Much more state and federal regulation and oversight of commercial markets
- Likely a significant consolidation, by region, of insurance market players as the strong get bigger and stronger (see Part D)

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HEALTH SECTOR IMPACT??
Despite whining, health sector BIG winner

- GREAT expansions of coverage for the bulk of health care sector
- VERY few tough calls made on anything
- It is a UNIVERSAL COVERAGE bill, not “health reform”

- **Big Winners:** Hospitals

- **Big Losers:** Insurance Agents and Brokers
  – TAXPAYERS with AGIs over $200,000
  – The long term structural deficit!!!

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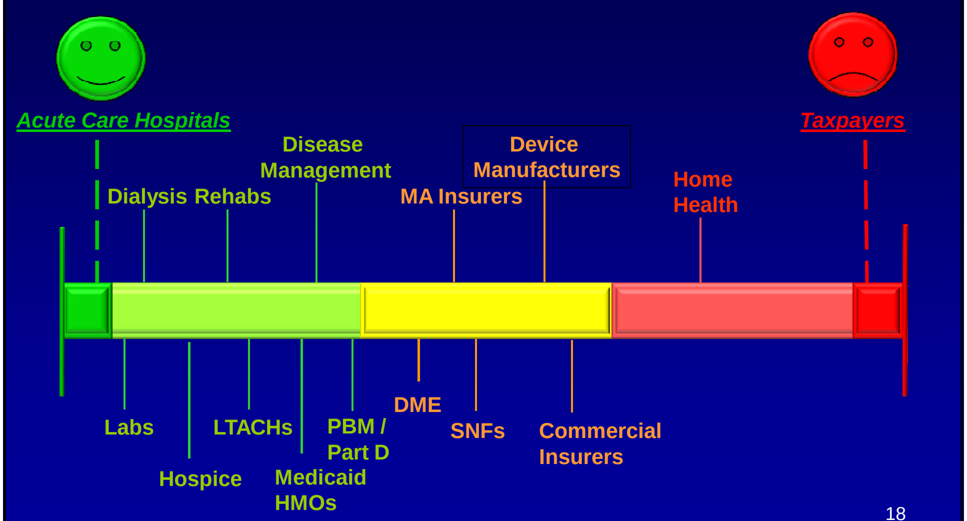
Impact Overview



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THE BIG PICTURE: FY 2009 Federal Deficit

($ - billions)	2004	2005	2006	2007	2008	2009
Fiscal Year Totals						
Receipts	**1,880**	**2,153**	**2,407**	**2,568**	**2,524**	**2,105**
Outlays	**2,293**	**2,472**	**2,655**	**2,729**	**2,978**	**3,522**
Deficit	**(413)**	**(319)**	**(248)**	**(162)**	**(455)**	**(1,417)**
Percentage of GDP						
Deficit	(3.5%)	(2.6%)	(1.9%)	(1.2%)	(3.1%)	(9.9%)

RECEIPTS AND OUTLAYS AS A PERCENTAGE OF GDP

SOURCE: CBO, FY2009 Monthly Budget Review, November 2009.

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YIKES! Where's The Money!

($ - billions)	2007	2008	2009	% CHANGE 2008/2009
Major Source				
Individual Income	**1,163**	**1,146**	**915**	**(20.1%)**
Corporate Income	**370**	**304**	**138**	**(54.6%)**
Social Insurance	**870**	**900**	**891**	**(1.0%)**
Other	**164**	**173**	**160**	**(8.0%)**
Total	2,568	2,524	2,105	(16.6%)
Percentage of GDP	18.5%	17.5%	14.8%	N/A

SOURCE: CBO, FY2009 Monthly Budget Review, November 2009.

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Wrap Up

The Bill: Ain't All that Bad … *at least for healthcare?*

- This is a COVERAGE EXPANSION BILL—not a Reform Bill
- There WILL be big changes in the insurance system—but survivable- and probably good for large plans; MA and PDPs will be fine
- Fees and Taxes on insurers, devices, etc are necessary because they punted on the tough calls (Tax cap and Hospitals)
- Exchanges will start slow and ramp fast
- Medicaid will expand explosively
- Hospitals and many providers got off easy—will see windfall
- -- Much more regulation --More Health spending

GOOD FOR EVERYONE IN HEALTHCARE

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very rough on taxpayers!

How to Pay for "Reform"

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