

2011 Legislative Landscape

An Overview and Analysis

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2011 on the Hill



Issues to Watch For

- Health Reform
- PDUFA Reauthorization
- Medicare “Doc Fix”
- Biosimilars Rulemaking
- Congressional Investigations



2011 on the Hill

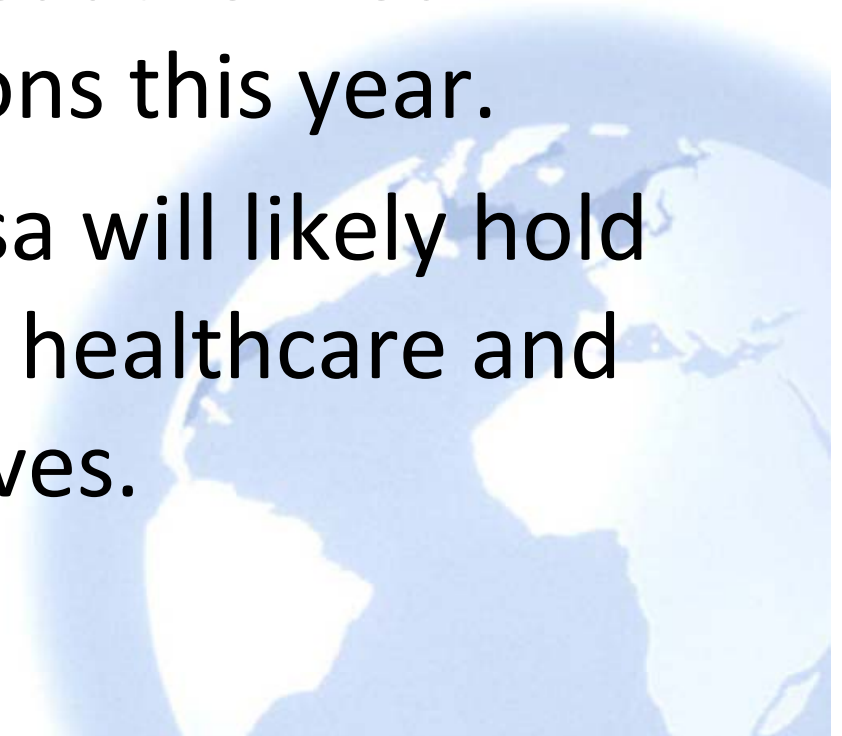
- Health Reform

- Republican push in the House to repeal PPACA.
- Failing full repeal, small moves over 2011 to scale back controversial parts of the law (*e.g.* IPAB).



2011 on the Hill

- Congress must vote on the Medicare Doc Fix before it expires later this year.
- PDUFA must be fully reauthorized in 2012. Expect discussions this year.
- Investigations Chair Issa will likely hold numerous hearings on healthcare and other spending initiatives.



2011 in the Executive Branch

- FDA has received public comment on the approval pathway for biosimilars. New rulemaking will begin to percolate.
- HHS must begin to establish rules for the implementation of the federal Sunshine law.
- DEA rulemaking on controlled substance return programs.



2011 in the States



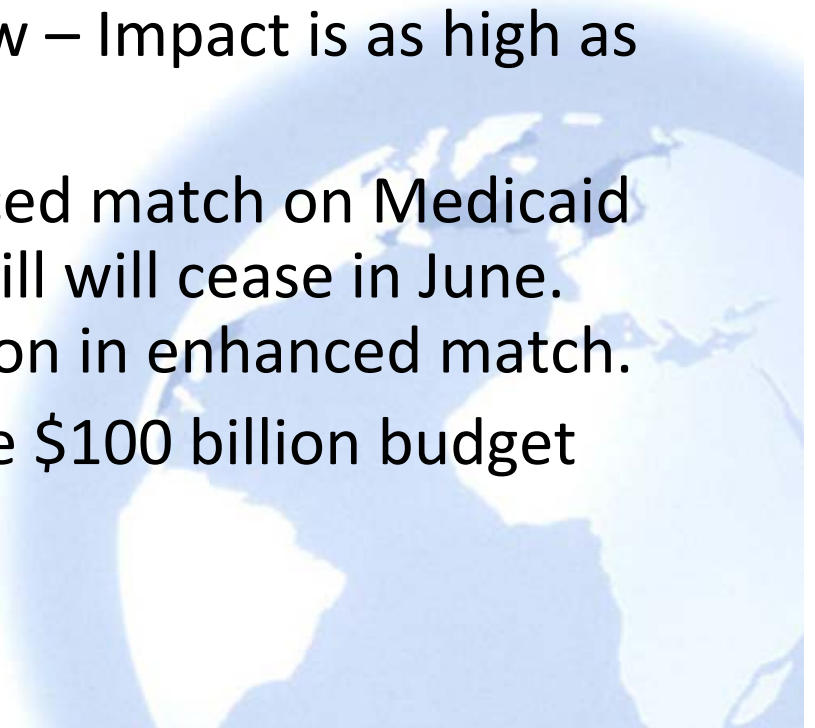
Major Legislation Expected

- Medicaid Access and Funding
- General Cost Control Measures
- Health Reform Implementation Measures
- Pharmaceuticals in the Environment/Take-back



Medicaid Legislation

- Medicaid Expansion
 - Largest expansion in the history of the program.
 - Medicaid will cover all individuals, including childless adults, at or below 133% of the FPL starting in 2014.
 - States must start planning now – Impact is as high as 23 million new enrollees.
 - Federal Government's enhanced match on Medicaid payments from the stimulus bill will cease in June. States will lose about \$26 billion in enhanced match.
 - States already face a collective \$100 billion budget deficit for the next fiscal year.



Medicaid Legislation

- Non-AWP Reimbursement Models
- Cuts in Benefits (*e.g.*, pharmacy benefits for adults, PT/OT care, dental benefits)
- Rebate Expansion (MCO and beyond)
- Expanded Drug Negotiation Authority
- Formulary Restrictions



Medicaid Legislation

What Are States Doing?

- **Texas**: The state Health and Human Services Commission has proposed an across-the-board 2% reimbursement cut on all physician-administered drugs and certain other services.
- **New York**: Governor Cuomo has indicated he will find \$2.1 billion in cuts (about \$4 billion in combined federal and state funds) to the state's Medicaid program during the upcoming fiscal year.
- **Arizona**: The state Medicaid agency recently eliminated coverage for certain organ transplant procedures and related follow-up care. (Note: May be reversed legislatively this session).
- **Montana**: Has initially explored expanding Medicaid drug pricing to all state residents.

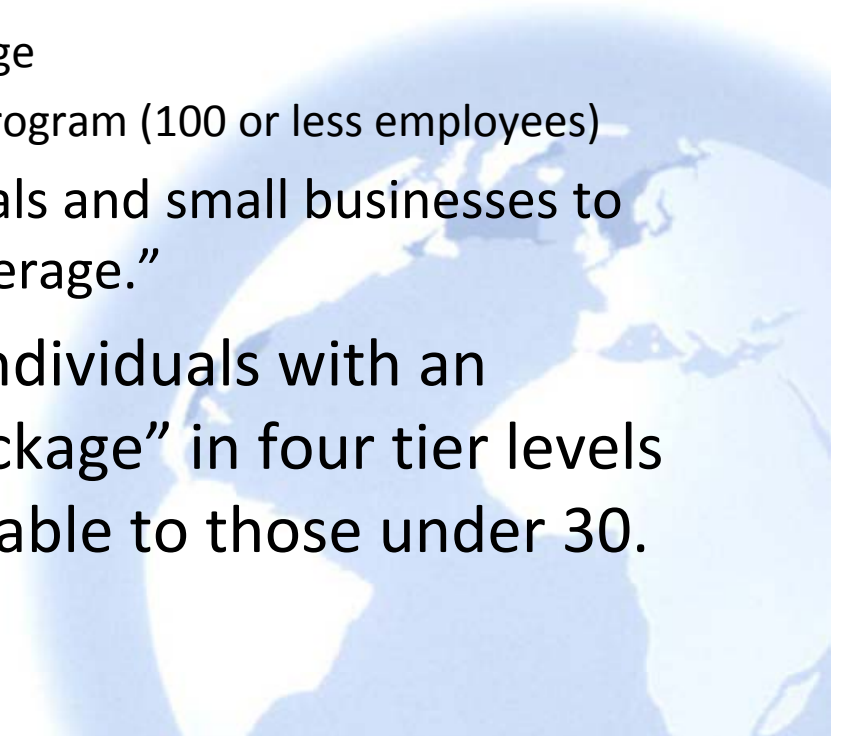
Health Reform Implementation

- Health Insurance Exchange Set-up
 - Federal/State Issue: Benefit Design
- Medicaid/Insurance Administrative Simplification Mechanisms
- Health IT Measures
- Expanded Wellness Programs
- Comprehensive Delivery Pilots



Health Reform Implementation

- State-Based Health Insurance Exchanges
 - Each state must establish a state insurance exchange by 2014.
 - Two types of exchanges:
 - American Health Benefit Exchange
 - Small Business Health Options Program (100 or less employees)
 - Exchanges will permit individuals and small businesses to purchase “qualified health coverage.”
 - Exchanges must provide all individuals with an “essential health benefits package” in four tier levels plus a catastrophic plan available to those under 30.



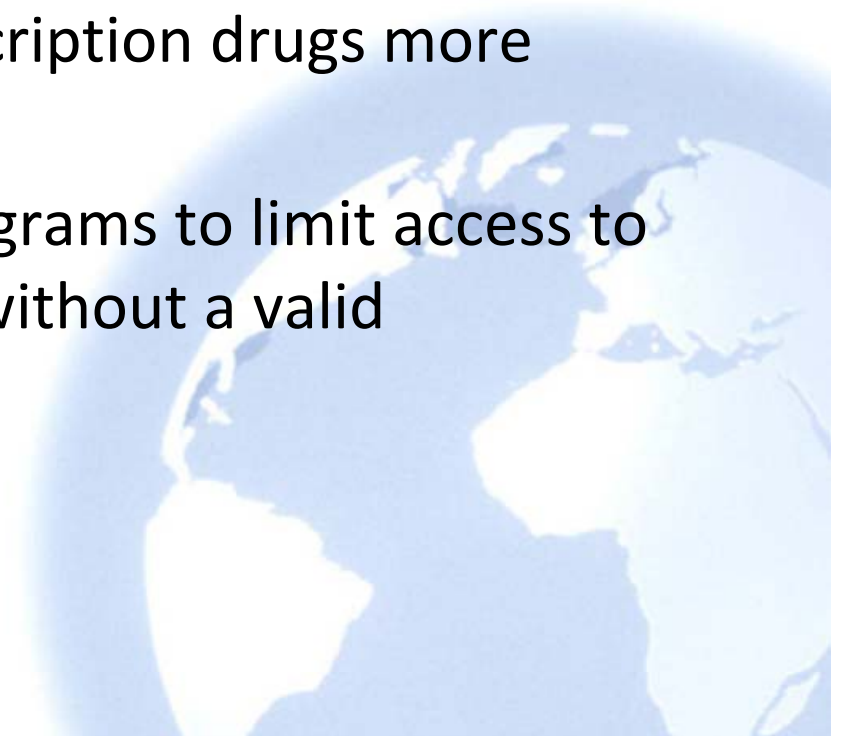
Health Reform Implementation

- State-Based Health Insurance Exchanges
 - NAIC model bill expected to be widely followed.
 - BIO supports many of the provisions in the model bill.
 - Big Question: what will the benefit design look like from HHS?
 - BIO supports robust access at all benefit tiers for innovative and life-saving biologic treatments.
 - State Action: California, Montana, North Dakota, New Mexico.



Pharmaceuticals in the Environment

- Expected to be one of the most active areas of state legislative activity in 2011.
- Generally based upon the notion that unwanted prescription medications present a hazard to the environment and make prescription drugs more accessible to teens.
- BIO supports reasonable programs to limit access to prescription drugs by those without a valid prescription.



Pharmaceuticals in the Environment

- What has legislation looked like so far?
 - Company-funded pharmaceutical take back programs
 - Company-funded sharps take back programs
 - Prohibitions on flushing unused medicine
 - State-sponsored pharmaceutical drop-off programs

- State Activity
 - 15 states introduced some type of legislation in 2010.
 - 5 state, including Indiana, have introduced some form in 2011.

- The federal government passed a law in 2010 that would make controlled substance take back easier.



Questions?

