2008 NCSL Legislative Summit
Federal Health Update

Joy Johnson Wilson
Health Policy Director, NCSL
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Legislation
FY ’09 HHS Appropriations

- **Highlights**
  - **Medicaid** - Senate bill would amend the nominal price exception to the Medicaid Drug Rebate Program to include non Title XX Family Planning Clinics and college health centers. This means the discounted prices provided to those facilities would not be included in the calculation of the Medicaid "best price".
  - **SCHIP** - Senate bill would delay implementation of the August 17th CMS Directive scheduled to become effective August 17, 2008.
  - **Health Care Fraud and Abuse Control (HCFAC)** - Both bills provide $198 million in discretionary funds for program integrity initiatives for Medicaid and Medicare.
FY ’09 HHS Appropriations cont.

- **Health Care Access Initiatives**
  - **State High Risk Pools** - House bill would provide funding, but the Senate would not.
  - **State Access Grants** - House bill provides $75 million for this competitive grant program. The Senate provides no funding for this initiative.
Enacted Legislation - Highlights

- Appropriations - Supplemental Appropriations, 2008 (P.L.110-252)
  - Delays six Medicaid rules until April 1, 2009
  - Appropriates $25 million in each of FY 2009 and FY 2010 to reduce Medicaid fraud
  - Requires states (not territories) to implement an asset verification program permitting access to information held by financial institutions for the purposes of determining and redetermining Medicaid eligibility
Medicare Improvement for Patients and Providers Act of 2008 (P.L. 110-275)

- Blocked reduction in reimbursement for Medicare docs
- Delays implementation of the Durable Medical Equipment (DME) competitive bidding program
- Delays implementation of Medicaid rule regarding the HHS Departmental Appeals Board
- Temporarily extends TMA and QI
- Delays implementation of some DRA Medicaid pharmacy reimbursement provisions
Enacted Legislation-Highlights cont.

- Food and Drug Administration Amendments Act (P.L. 110-85)
- Genetic Information Nondiscrimination Act (P.L. 110-233)
- Food, Conservation, and Energy Act of 2008 (P.L. 110-246) "Farm Bill"
Pending Reauthorizations

- Community Health Centers (H.R.1343, S. 901)
- Federal Reimbursement for Emergency Health Services Furnished to Undocumented Immigrants (no bill yet)
Pending Health Legislation

- Economic Stimulus (FMAP increase?)
- Mental Health Parity
- Interstate Sales of Tobacco Products
- FDA Regulation of Tobacco
- Health Information Technology
- Indian Health Improvement Act
- Ryan Haight Online Pharmacy Consumer Protection Act of 2007
Mediaid Prescription Drug Reform

- DRA established a new federal upper payment limit for Medicaid multi-source prescription drug reimbursement.
- Proposed rule published 12/22/06. Final Rule (with limited comment) published 7/17/07.
- National Association of Chain Drug Stores successfully sued HHS to halt the implementation of these reforms
- P.L. 110-275 delays implementation
Supplemental Appropriations, 2008

- Supplemental Appropriations, 2008 (P.L. 110-252) delays implementation of the following Medicaid rules until April 1, 2009---
  - Intergovernmental Transfers (IGTs)
  - Health Care Related Taxes
  - Graduate Medical Education (GME)
  - Rehabilitative Services
  - School-Based Health Care Services
  - Targeted Case Management
Regulations??

CMS August 17th Directive
The letter, issued August 17, 2007, imposed controversial changes to the State Children’s Health Insurance Program (SCHIP), resulting in some states (New York, New Jersey) filing suit to halt the proposed changes.

May 2008 letter provides additional "clarification" of last year's letter.
CMS August 17th Directive

- GAO and CRS independently found that CMS exceeded its authority in issuing the directive
- On July 18, 2008, Senator Rockefeller (D-WV) introduced a Senate Joint Resolution of disapproval (S J Res. 44)
U.S. Supreme Court

Decisions
Rowe v. N.H. Motor Transportation Association

- Under Maine law, mail-order tobacco product retailers must require their delivery service to verify that the purchaser is not a minor. Delivery services are deemed to know that a package contains tobacco products under certain circumstances. The New Hampshire Motor Transport Association and others challenged the Maine law arguing the law is preempted by the Federal Aviation Administration Authorization Act of 1994 (FAAAA).
- **State law is preempted.**
The Prevent All Cigarette Trafficking (PACT) Act (S. 1027) amends the Jenkins Act to revise provisions governing the collection of taxes on and trafficking in tobacco products and enhances the ability of states to both collect taxes and enforce state laws regarding underage purchasing of tobacco products.
Riegel v Medtronic

In 1996, a catheter burst during Charles Riegel’s angioplasty. Riegel and his wife filed a product liability complaint against the catheter’s manufacturer, Medtronic, Inc. A federal district court dismissed the complaint, holding that the Medical Device Amendments (MDA) preempted most of the claims. The U.S. Court of Appeals affirmed. The MDA generally forbids states from imposing requirements on devices that received pre-market approval from the Food and Drug Administration (“FDA”).
Because the complaint depends on state law, Medtronic argues that letting it proceed would impose state requirements, usurp the power of the FDA, and stifle innovation in the medical field. Mrs. Riegel, who was substituted as plaintiff after her husband died, argues that while Congress gave the FDA power to regulate medical devices, it never meant to stop private citizens from suing negligent manufacturers.
Riegel v Medtronic – Key Question

■ Does the preemption provision in the MDA preempt state law claims seeking damages for injuries caused by medical devices that received pre-market approval by the FDA?

■ State law is preempted.
H.R. 6381 was introduced on June 26, 2008 by Representative Pallone (D-NJ), Chairman of the Health Subcommittee on the House Committee on Energy and Commerce.
U.S. Supreme Court

Pending
Wyeth v. Levine

- This fall, the U.S. Supreme Court will determine whether FDA approval of a drug's label preempts state-law claims of inadequate warning.
SCHIP Reauthorization

Current Status
Reauthorization Status

- The current extension of SCHIP expires April 1, 2009.
- Challenges abound----
  - New Administration
  - Many new members of Congress
  - Bad economy