

# Legislative & Regulatory Issues Their Implications for Pharmacy

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# Priority Issues for 2009

- AMP
- Health Care Reform
- DMEPOS
  - Accreditation
  - Surety Bonds
- Importation
- Part D
  - Price Negotiations
- Pedigree/Wholesaler Registration
- Generics

# AMP Reimbursement Formula

- A legislative fix is necessary to reform the Average Manufacturer Price (AMP) reimbursement system for generic drugs in Medicaid, which was created under the Deficit Reduction Act of 2005.
- Cuts were delayed under the Medicare Improvements for Patients and Providers Act (MIPPA) last year, but only through September 30, 2009.
- If no action is taken before September 30th, the consequences will be severe.
  - AMP cuts could reduce pharmacy reimbursement > 30%
  - Paying one-third below pharmacy's cost for many commonly prescribed generic drugs.
  - PriceWaterhouseCoopers analysis =
    - over 11,000 pharmacies – 20 percent of all pharmacies nationwide -- may have to close.
    - closures would disproportionately impact rural and inner city areas where many Medicaid beneficiaries reside, and where access to healthcare services is often limited.

# AMP Reimbursement Formula

- Remains delayed in courts (NACDS/NCPA litigation – December 2007)
  - Implementation of AMP-based FULs is delayed.
  - Publication of AMP – and sharing of AMP information with the states – is also delayed.
- Even with a best-case outcome from the courts, legislation needed
  - To require CMS to use a weighted average of AMPs in setting FULs.
  - To provide a more adequate markup percentage.
  - To make improvements to dispensing fees.

# Legislative Fix

- Health Care Reform will not pass before 9/30/09 deadline
- Need stand alone vehicle for delay or fix
  - Delay more likely – but still difficult

# Summary of Medicaid Pharmacy Reimbursement Language in H.R. 3200

- The generic reimbursement is set at 130% of the weighted average AMP, a change from 250% of the lowest AMP as stipulated in the Deficit Reduction Act.
  - We do support the language that would base federal upper limits (FULs) for generic drugs using the weighted average AMP rather than the lowest AMP, as required by the Deficit Reduction Act of 2005 (DRA.) Use of the lowest AMP will not reflect the wide range of market prices for generic drugs, where a weighted average AMP will. Using a weighted average ensures that the AMP is an appropriate metric for pharmacy reimbursement.
  - Preliminary analysis suggests the 130% proposed in the draft legislation would not be sufficient to ensure pharmacies are reimbursed adequately. The “multiplier” needs to be high enough to ensure reimbursement covers pharmacies’ costs and provides an incentive to dispense low cost generics, which will help save Medicaid money in the long run.

# Summary of Medicaid Pharmacy Reimbursement Language in H.R. 3200

- AMP definition is redefined to more accurately reflect retail pharmacy acquisition costs
- Prices which are excluded from the AMP calculation include:
  - customary prompt pay discounts to wholesalers
  - bona fide service fees paid by manufacturers
  - reimbursements for recalled, damaged, expired or otherwise unsalable returned good
  - sales directly to, or rebates, discounts, or other price concessions provided to PBMs, MCOs, HMOs, Mail Order Pharmacies not open to the public insurers
  - sales directly to, or rebates, discounts, or other price concessions provided to hospitals, clinics, and physicians
- Continues the pre-DRA FULs in effect through December 31, 2010.

## Summary of Medicaid Pharmacy Reimbursement Language in H.R. 3200

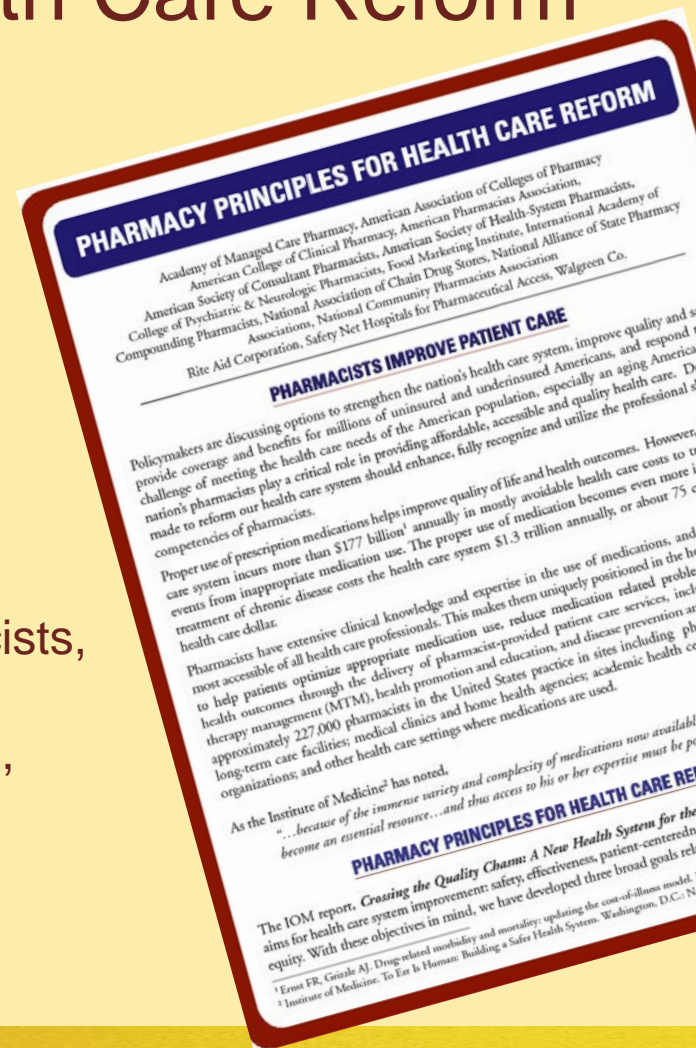
- Weighted average of brand and generic AMP data will be posted on a public website.
  - We feel the posting of AMPs is of no real value to either payers or consumers and has the potential to distort the marketplace and reduce incentives for manufacturers to discount drug prices

# FMI Activity

- Engaged with coalition to support legislative fix or delay prior to 9/30/09
  - Delay most feasible
- September Hill visits
- Grassroots Activity

# Pharmacy Principles for Health Care Reform

- 15 member coalition
  - Academy of Managed Care Pharmacy,
  - American Association of Colleges of Pharmacy,
  - American College of Clinical Pharmacy,
  - American Pharmacists Association,
  - American Society of Consultant Pharmacists,
  - American Society of Health-System Pharmacists,
  - College of Psychiatric & Neurologic Pharmacists,
  - **Food Marketing Institute,**
  - International Academy of Compounding Pharmacists,
  - National Association of Chain Drug Stores,
  - National Alliance of State Pharmacy Associations,
  - National Community Pharmacists Association,
  - Rite Aid Corporation,
  - Safety Net Hospitals for Pharmaceutical Access,
  - Walgreen Co.



FMI  
Supermarket Pharmacy  
Conference

# Reform Principles

- Improve Quality & Safety of Medication Use
- Assure Patient Access to Needed Medications and Pharmacy Services
- Promote Pharmacy and Health Information Technology Interoperability

# Coalition Activity

- Press Conference – February 2009
- Joint Hill Visits
- Numerous letters to CMS, Senate, House
- Secured champion for MTM language in Health Care Reform bills.



**FMI**  
Pharmacy  
Conference

# DMEPOS Suppliers

- FMI and numerous pharmacy and patient stakeholder groups are urging Congress to exempt community pharmacies from the September 30 accreditation requirement and October 2 surety bond requirement needed to continue providing durable medical equipment, prosthetics, orthotics and supplies to Medicare patients.
- Pharmacies and pharmacists are licensed and highly regulated by the states through comprehensive state laws and regulations that stringently oversee pharmacies and pharmacists. Requiring accreditation and surety bonds is duplicative and unnecessary, and will lead to loss of patient access to valuable healthcare services.
- H.R. 3200, America's Affordable Health Care Choice of 2009, included provisions in their health care reform bill.
  - we'll be working with our coalition partners to get the House language incorporated into the Senate bill.
- Key Members of Congress have written to the Centers for Medicare and Medicaid Services asking that pharmacies be exempted.

# DMEPOS Suppliers

- We support H.R. 1970, the Preserve Patient Access to Reputable DMEPOS Providers Act
  - seeks a conditional exemption for pharmacies from the requirement to have a surety bond to provide Medicare Part B durable medical equipment, orthotics, prosthetics, and supplies (DMEPOS) and Part B drugs to Medicare beneficiaries.
  - Pharmacies were not exempted from the surety bond as were most other healthcare providers.
- We support H.R. 616, the Access to Durable Medical Equipment Act
  - seeks a conditional exemption for pharmacies and pharmacists from the requirement to be accredited to provide DMEPOS to Medicare beneficiaries.
  - Pharmacies and pharmacists are the only licensed healthcare professionals that CMS did not conditionally exempt from the accreditation requirement.

# DMEPOS Suppliers

- At this time you should still be proceeding as though you need to comply with both requirements.

# Importation

- More of a political issue than a policy anyone actually wants to see enacted.
- Language from the 110<sup>th</sup> Congress reappears:
  - Senator Vitter (R-LA) – failed in Senate
  - Senators Dorgan (D-ND) & Snowe (R-ME)
- An issue to watch for in 2009 and beyond
  - especially during re-election season

# Medicare Part D Price Negotiations

- Language included in House Healthcare Reform legislation.
- For plan years beginning 2011:
  - directs that, “the Secretary shall negotiate with pharmaceutical manufacturers the prices (including discounts, rebates, and other price concessions) that may be charged to” Part D plan sponsors.
- FMI will watch closely for possible impact on retail pharmacies.

# Pedigree/ Wholesaler Registration

- Legislation did not advance in the 110th Congress.
  - Congressmen Buyer and Matheson remain committed to language requiring pharmaceutical manufacturers, distributors and pharmacies to implement technology that would allow them to electronically track and trace individual prescription medications sold within the United States.
- Not a top priority in 111<sup>th</sup> Congress
  - Though Buyer and Matheson remain open to listening to our concerns and suggestions.

# Pedigree/ Wholesaler Registration

- FMI supports:
  - adoption of a peer-to-peer drug traceability system that is efficient, cost-effective and complements current business operations.
  - Benefits of this traceability system include
    - creating a system that will allow traceability of drug products at the steps in the supply chain from manufacturer to wholesaler to dispenser,
    - providing an efficient means to determine the source of prescription drug products,
    - providing data security within each company, with company ability to provide data on demand to approved authorities without the need for external databases,
    - preventing security breach risks associated with central databanks.