Federal Legislation

NCPA Priority: passing state and federal legislation to address transparency and delay in pricing/reimbursement updates

- H.R. 244, the MAC Transparency Act of 2015
  - Reps. Doug Collins (R-GA-9) and Dave Loebsack (D-IA-2).
  - Addresses problems in Medicare Part D, DoD’s TRICARE program and the Federal Employees Health Benefits program (FEHB)
  - Currently has 41 co-sponsors (35R/6D)

- On February 22, 16 members of congress issued a letter requesting a hearing on H.R. 244 to the Energy and Commerce, Armed Services and Ways and Means Committees.

- PCMA has recently increased opposition to this legislation, likely in preparation for NCPA's Legislative Summit
Federal Legislation Continued...

**Preferred Networks** – “Any Willing Pharmacy” having access to Medicare Part D networks

- House, AWP legislation (H.R. 793)
  - Currently 95 co-sponsors (57R/38D), including 14 members of the Energy and Commerce Committee and Chairmen of House Judiciary and Appropriations Committees.

- Senate, AWP legislation (S. 1190)
  - First preferred network legislation introduced
  - Currently 10 co-sponsors (7R/3D), including the Chairmen of the Senate Small Business and Appropriations Committees.

- Both bills would allow independent pharmacies the ability to participate in preferred networks if they can meet the terms and conditions of the network contract if located in a medically underserved or Health Professional Shortage Areas as defined by: Health Resources and Services Administration (HRSA)

2016 Priorities Continued...

**Pharmacists as Providers** – Permits pharmacists in medically underserved communities to both provide and be reimbursed under Medicare Part B for services outlined in their state’s existing scope of practice.

- Provider Status legislation in the House, H.R. 592, currently has 284 co-sponsors (156R/128D), well in excess of the House majority of 218.

- The Senate companion, S. 314 currently has 44 co-sponsors (25D/19R).

Other Legislative Action

- **Comprehensive Addiction and Recovery Act (CARA) S.524**
  - Senate approved a bill designed to address opioid abuse (94-1)
  - Contained an amendment allowing Medicare Part D plans to lock beneficiaries at risk of drug abuse into sole prescribers and pharmacies to fill Schedule II controlled substances. NCPA was successful in ensuring the amendment exempts LTC patients and that community pharmacists be included in the stakeholder group who will work with CMS to determine lock in criteria.

  House shows no intention of moving S. 524 but instead is taking up their own opioid abuse prevention legislative efforts

  Week of **May 9** dubbed “Opioid Week” in the US House
  - Legislation authorizing partial fills of Schedule II controlled substances
  - Legislation setting requirements related to the OTC sale of products containing dextromethorphan (i.e. i.D.Check)

  NCPA working to ensure that burdensome requirements are removed from these bills. As next steps, conference with Senate will need to occur.
Pharmacy “DIR” Fees

- “Direct and Indirect Remuneration” (DIR): Priority issue at both the state and federal levels.
  - Term coined by CMS related to drug manufacturer rebates that would affect gross Rx drug costs of Part D plans “that were not captured at point of sale.”
  - Pharmacy “DIR” fees are now used as a “catch-all” term to retroactively recoup additional dollars from community pharmacy.
  - DIR fees are starting to become more prevalent and now obscure true reimbursement amounts to pharmacy, and to skirt state MAC transparency laws and federal regulations.
  - Types of DIR Fees:
    • “Pay to Play” DIR Fees
    • Payment Reconciliation DIR Fees
    • Performance Metric DIR Fees

NCPA Steps to Address the Issue

- NCPA is keeping in regular contact with CMS regarding proposed guidance on transparency at POS.
- Working with and educating the Medicare Payment Advisory Commission (MEDPAC) on this.
  - Who’s MEDPAC? The Medicare Payment Advisory Commission is an independent US federal body. The Commission’s 17 members bring diverse expertise in the financing and delivery of health care.
  - Issued 2 letters detailing recommendations for addressing the relation of DIR fees to Part D bids.
  - Issued multiple congressional letters that call for CMS to finalize.
  - Preemptive state efforts: OK, LA.

2016 Part D MAC Enforcement

- January 1, 2016 Part D Plans/PBMs must:
  - Provide network pharmacies access to MAC prices in advance of use for reimbursement.
  - Update MAC prices every 7 days.
  - Ensure MAC prices reflect “market price.”
- NCPA has been in ongoing dialogue with CMS to discuss examples of potential non-compliance.
Medicaid: AMP FULs/NADAC/AAC

• 2012 CMS Proposed Rule requiring states to pay Medicaid pharmacies based on “actual acquisition cost” plus a “professional dispensing fee”
  • 2016 Final Rule: Defines AAC (§447.502) to mean the agency’s determination of the pharmacy providers’ actual prices paid to acquire drug products marketed or sold by specific manufacturers.
  • Examples of how a state can implement an AAC model of reimbursement include, but are not limited to, the following:
    • A state survey of retail pharmacy providers’ pricing (AAC).
    • A national survey of retail pharmacy providers’ pricing, such as the National Average Drug Acquisition Cost (NADAC).
    • Published compendia prices, such as the Wholesale Acquisition Cost (WAC) (States will be expected to make adjustments to this benchmark to reflect discounts and other price concessions in the marketplace).
    • Average Manufacture Price (AMP) based pricing (the states can determine the relationship between AMP and other marketing factors).

• States may use AMP-based federal upper limits (FULs) OR survey pharmacies to determine actual acquisition cost OR use the National Average Drug Acquisition Cost (NADAC) – CMS pricing benchmark based on average invoice costs

Final AMP Rule

Issued early February 2016: Includes several provisions that NCPA advocated for:

• National Average Drug Acquisition Cost (NADAC) will serve as a reimbursement "floor" — or that in instances where the FUL is below acquisition cost — NADAC value will be used.
• CMS is requiring states to consider both the ingredient cost reimbursement and the "professional dispensing fee" when proposing changes of the reimbursement for Medicaid covered drugs. NCPA has long advocated for a dispensing fee commensurate with a pharmacist’s time and services.

• State can use, but are not limited to, one of the following methods to establish their professional dispensing fee:
  • National survey/data
  • Regional/neighboring state survey/data
  • State-specific survey/data

• State Medicaid Agencies without an already established actual acquisition cost reimbursement must submit a SPA with an effective date no later than April 1, 2017, thereby providing a one-year timeframe for compliance.

• States must already have implanted the now updated FULs

Total National State Victories as of 2016

• Fair Pharmacy Audit: 35
  
  • MAC Transparency: 31
    • New York law contains only a defined appeal rights
  
  • AMMO: 8

• DIR / Fee Reform: 2

• Med-Synch: 13
2015 NCPA State Activity

• Continued successful enactment of state MAC transparency legislation
  ✓ 2015: 2 states included as part of state budget provisions (OH/WI)
  ✓ 2015: 1 state included transparency to plan sponsors (OH)
  ✓ 2015: 1 state addressed all “multi-source generic drugs” and not only “MAC” (GA)
  ✓ 2015: 1 state included language prohibiting the requirement for pharmacies to dispense at a loss and regulating unfair PBM self compensation (AR)

• First year that states attempted to strengthen existing MAC transparency laws due to PBMs circumventing the intent of previously existing laws

• Medication Synchronization continued to gain traction requiring insurer recognition and coverage for med-synchronization while prohibiting prorating of dispensing fees

• Washington state enacts scope of practice/provider status legislation that requires recognition and insurer compensation for pharmacist services

• Preventing biosimilar legislation from including unnecessary reporting requirements

Updated NCPA model legislation:
• PBM Pricing Disclosure & Pharmacy Benefit Pricing Transparency (New MAC Model)

2016 Notable State Activity

• Highlights:
  ✓ Maine: MAC transparency
  ✓ New Jersey: Generic drug pricing transparency
  ✓ Wyoming: MAC, Audit PBM registration
  ✓ Kansas: MAC transparency
  ✓ Tennessee: Strengthens generic drug pricing transparency law
  ✓ Washington: Strengthens generic drug pricing transparency law
  ✓ Kentucky: Strengthens generic drug pricing transparency law
  ✓ Oklahoma: Strengthens pricing transparency and includes DIR protections
  ✓ Louisiana: Fee and Chargeback protection legislation and notable media campaign against Clawbacks

Expected State Action for 2016

Legislation/Regulation
• Emphasis on expanded and enforceable pricing transparency laws
• Strengthening previously enacted pricing transparency laws to close available loopholes
• PBM oversight and enforcement (Enforcement must be a priority!)
• AAC/NADAC/FUL implementation
• DIR/Fee Protections
• Patient choice
• Medication Synchronization
• Scope of Practice and pharmacist recognition expansion

National Influence
• NCPA participation with the update to the National Association of Insurance Commissioners (NAIC) Prescription Drug Benefit Model Act – Model #22
• NCPA testifies before NAIC National Convention