Date: Tuesday, October 15, 2013
Time: 1:45 pm – 3:15 pm
Location: The Walt Disney World Swan and Dolphin Resort
Northern Hemisphere Salon E1-E2
Title: NCPA Advocacy Center, Regulatory and State Government Affairs Update
Activity Type: Knowledge-based
Speaker: Steve Pfister, Senior Vice President of Government Affairs, NCPA
Ronna Hauser, PharmD, Vice President of Policy and Regulatory Affairs, NCPA
Susan Pilch, Senior Director, Public Policy and State Government Affairs, NCPA
Matt DiLoreto, Director of State Government Affairs, NCPA
Pharmacist Learning Objectives:
Upon completion of this activity, participants will be able to:
1. Identify current federal and state legislative and regulatory activities that affect community pharmacy.
2. Discuss how efforts to regulate PBMs will increase transparency and the ability to negotiate with PBMs.
3. Discuss NCPA’s model state pharmacy legislation.
Technician Learning Objectives:
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Disclosures:
Steve Pfister declares no conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.
Ronna Hauser declares no conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.
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NCPA Advocacy Center, Regulatory, and State Government Affairs Update

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Overview

- What's Happening in Washington
- Regulatory Update
- NCQA State Affairs Update
- NCQA Legislative Initiatives
- Affordable Care Act Implementation

WHAT'S HAPPENING IN WASHINGTON

OCTOBER 1ST...THE DAY WE SHUT DOWN THE GOVERNMENT TO SHUT DOWN OBAMACARE! A DAY THAT WILL LIVE IN HISTORY!

OR MORE LIKE IRONY
Shutdown

- Since October 1st the federal government has been partially shut for the first time in 17 years. Only federal employees who are deemed essential by their supervisor are allowed to report to work. The House passed a bill to compensate furloughed federal workers for the lost pay during the shutdown, but the Senate has yet to take it up.
- At this point it appears House Republicans, Senate Democrats and the Administration will continue the shutdown into mid-October when the debt ceiling will have to be raised to avoid default. Obviously outside factors, i.e. fluctuations in the stock market could change the lack of negotiations going on right now but we will have to see how it all plays out.

Government Shutdowns, 1987-Present

<table>
<thead>
<tr>
<th>Year</th>
<th>1987</th>
<th>1990</th>
<th>1995-96</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitting President</td>
<td>Ronald Reagan</td>
<td>George H. W. Bush</td>
<td>Bill Clinton</td>
<td>Barack Obama</td>
</tr>
<tr>
<td>Beginning Approval Rating (Gallup)</td>
<td>48% (Dec 7-9, 1987)</td>
<td>67% (Sept 27-30, 1990)</td>
<td>52% (Nov 6-9, 1995)</td>
<td>45% (Sept 23-26, 2013)</td>
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<tr>
<td>Ending Approval Rating (Gallup)</td>
<td>48% (Dec 22-25, 1987)</td>
<td>54% (Dec 11-14, 1990)</td>
<td>52% (Nov 2-5, 1995)</td>
<td>TBD</td>
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<tr>
<td>Congressional Control (Gallup)</td>
<td>Democratic</td>
<td>Democratic</td>
<td>Republican</td>
<td>GOP House, Dem Senate</td>
</tr>
<tr>
<td>Congressional Approval Rating (Gallup)</td>
<td>42% (Aug-Sep 1987)</td>
<td>28% (Oct 1990)</td>
<td>30% (Sep 1995)</td>
<td>TBD</td>
</tr>
</tbody>
</table>

Note: Approval ratings are based on Gallup surveys unless otherwise noted.
Post-World War II Midterm Elections Following Presidential Reelection

<table>
<thead>
<tr>
<th>Year</th>
<th>President</th>
<th>Party</th>
<th>In-Party Seat Change: House</th>
<th>In-Party Seat Change: Senate</th>
</tr>
</thead>
<tbody>
<tr>
<td>1958</td>
<td>Eisenhower</td>
<td>Republican</td>
<td>-5</td>
<td>-13</td>
</tr>
<tr>
<td>1966</td>
<td>Kennedy/Johnson</td>
<td>Democrat</td>
<td>-9</td>
<td>-4</td>
</tr>
<tr>
<td>1974</td>
<td>Nixon/Ford</td>
<td>Republican</td>
<td>-8</td>
<td>-3</td>
</tr>
<tr>
<td>1980</td>
<td>Reagan</td>
<td>Republican</td>
<td>-7</td>
<td>-2</td>
</tr>
<tr>
<td>1988</td>
<td>Reagan</td>
<td>Democrat</td>
<td>+5</td>
<td>0</td>
</tr>
<tr>
<td>2004</td>
<td>G. W. Bush</td>
<td>Republican</td>
<td>-30</td>
<td>-6</td>
</tr>
</tbody>
</table>

AVERAGE: -29, -6

2014 Senate Races

(2012 Obama Performance vs. Romney Performance)

Obama +15 or Greater Obama +6 to +14.9 Obama +6 to Romney +6.8 Romney +6 to +14.9 Romney +15 or Greater

DEMOCRATS (20)

<table>
<thead>
<tr>
<th>States</th>
<th>Obama +15</th>
<th>Obama +6 to Romney +14.9</th>
<th>Romney +6 to +14.9</th>
<th>Romney +15 or Greater</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iowa</td>
<td>Obama</td>
<td>Romney</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ohio</td>
<td>Obama</td>
<td>Romney</td>
<td></td>
<td></td>
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<tr>
<td>Nevada</td>
<td>Obama</td>
<td>Romney</td>
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<tr>
<td>New HK</td>
<td>Obama</td>
<td>Romney</td>
<td></td>
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<tr>
<td>New MI</td>
<td>Obama</td>
<td>Romney</td>
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<tr>
<td>New MO</td>
<td>Obama</td>
<td>Romney</td>
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<tr>
<td>New OR</td>
<td>Obama</td>
<td>Romney</td>
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<tr>
<td>New PA</td>
<td>Obama</td>
<td>Romney</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New WA</td>
<td>Obama</td>
<td>Romney</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

REPUBLICANS (15)

<table>
<thead>
<tr>
<th>States</th>
<th>Obama +15</th>
<th>Obama +6 to Romney +14.9</th>
<th>Romney +6 to +14.9</th>
<th>Romney +15 or Greater</th>
</tr>
</thead>
<tbody>
<tr>
<td>Idaho</td>
<td>Obama</td>
<td>Romney</td>
<td></td>
<td></td>
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<tr>
<td>Kansas</td>
<td>Obama</td>
<td>Romney</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maine</td>
<td>Obama</td>
<td>Romney</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New MI</td>
<td>Obama</td>
<td>Romney</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New OR</td>
<td>Obama</td>
<td>Romney</td>
<td></td>
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<tr>
<td>New PA</td>
<td>Obama</td>
<td>Romney</td>
<td></td>
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</tr>
<tr>
<td>New WA</td>
<td>Obama</td>
<td>Romney</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2014 US Senate Ratings

Total Number of Seats: 35

- Solid Democrat: 7
- Likely/Lean Democrat: 10
- Toss Up Democrat: 1
- Solid Republican: 11
- Likely/Lean Republican: 5
- Toss Up Republican: 1

To regain a majority, Republicans would need to win 6 seats.
Fewer Competitive House Districts

The House is more partisan than ever...

Only 17 Republicans represent districts carried by President Obama.

Only 9 Democrats represent districts carried by Mitt Romney.

2014 House of Representatives Ratings

Source: The Cook Political Report

- Solid Republican: 205
- Likely/Lean Republican: 28
- Toss Up Republican: 1
- Solid Democrat: 163
- Likely/Lean Democrat: 29
- Toss Up Democrat: 9

218 Needed for Republicans to retain Majority
Challenging Atmosphere for Community Pharmacy

Massive debts and yearly deficits in the federal government and state governments increases pressure on the public health programs

The entirety of our reimbursement and general business are now affected by middlemen PBMs

Current Community Pharmacy Issues

Federal

- Compounding/Track and Trace
- Part D/PBM Issues
- Medicare Part D MTM Expansion
- DTS/Medicare Part B
COMPOUNDING & TRACK AND TRACE LEGISLATION

NCPA Impact

"Mr. Speaker, this bill upholds the current section 503(a) of the law, and provides it with the clarity that FDA needs by eliminating the unconstitutional provisions. The bill also requires FDA to engage in meaningful communication with State boards of pharmacy. Further, under this bill, entities engaged in sterile drug compounding can voluntarily register with FDA and operate under FDA regulation. Finally and importantly, this bill protects traditional pharmacy compounding that occurs in community pharmacies across the country. That’s why the bill has the support of the National Community Pharmacists Association, and I would like to thank them for working with us so closely."

Chairman Fred Upton, Energy and Commerce R-MI

Drug Compounding/Track and Traceability Timeline

9/21/12- NECC Outbreak

11/14/12 – House Energy and Commerce holds first hearing on Meningitis Outbreak

11/15/12 – Senate HELP Committee holds first hearing on the outbreak

5/09/13 – Rep. Latta (R-OH) introduces House Track and Traceability bill
Drug Compounding/Track and Traceability Timeline

5/13/13 – Senator Harkin (D-IA) introduces Drug Compounding bill, Senator Bennet (D-CO) introduces Track and Traceability

5/22/13 – Senate HELP considers and reports Sen. Harkin (D-IA) drug compounding bill and Senator Bennet (D-CO) track and traceability bill by voice vote. These bills were then combined into one legislative vehicle

6/03/13 – Rep. Latta's Track and Traceability bill passed the full House by voice vote

8/01/13 – Senate recesses for the August Work Period without considering the combined bill

8/16/13 – House Reps. Griffith (R-VA), DeGette (D-CO), and Green (D-TX) introduced H.R. 3089 and NCPA came out in strong support of the bill. It would have protected our member's ability to compound sterile drugs for office use inter-state up to 5% of total drugs dispensed – there was no cap in the bill for non-sterile compounds.

9/27/13 – House E&C Chairman Upton (R-MI) and Rep. Waxman (D-CA) introduce H.R. 3204, Drug Quality and Security Act. This bill contained Drug Compounding and Track and Traceability. We support this package and the compounding section of the bill contained over 90% of our request.

9/28/13 H.R. 3204 passed the House by voice vote.

PART D / PBM REFORM
Part D PBM Reform

The Medicare Prescription Drug Program Integrity Act of 2013 (S. 867)

- Sponsors: Sens. Mark Pryor (D-AR) and Jerry Moran (R-KS) – additional co-sponsors are Sens. John Boozman (R-AR), Thad Cochran (R-MS), Tim Johnson (D-SD) and Roger Wicker (R-MS)
- To date there has yet to be a companion bill introduced in the House. Americans for Tax Reform and Citizens Against Government Waste (D.C. based groups) have again come out in opposition to the Senate bill. We strongly believe that these groups are being subsidized by large mail order pharmacies and their association. Right or wrong, these groups are supported by many conservatives and that has caused many of the Republican Members of Congress we have asked to lead on the bill to hesitate.
- We will obviously continue to seek a lead Republican for this measure.

Part D PBM Reform

Key Provisions of S. 867:

- Greater choice of pharmacies for consumers.
- Greater transparency to Medicare and for pharmacies regarding generic drug payment rates.
- Fair standards for PBM pharmacy audits to assure that any recoveries are returned to Medicare and not kept by the PBMs.

Reforming PBMs for Patients & Pharmacies

The Preserving Our Hometown Independent Pharmacies Act of 2013 (H.R. 1188)

- Sponsors: Reps. Tom Marino (R-PA) and Judy Chu (D-CA) – additional co-sponsors are Reps. Lou Barletta (R-PA), Howard Coble (R-NC), Doug Collins (R-GA), Jeff Fortenberry (R-NE), Walter Jones (R-NC), Mike Michaud (D-ME), Martha Roby (R-AL), and Ted Yoho (R-FL)
- Key Provisions:
  ✓ Promote competition by providing independent pharmacies similar leverage as large chains and allowing independents to collectively negotiate third-party contracts.
  ✓ Allow independents to form negotiating entities that are no larger than 25% of all retail pharmacies in a Part D plan region.
MEDICARE PART D / MTM EXPANSION

Medicare Part D MTM Expansion

The Medication Therapy Management Empowerment Act of 2013 (S. 557/H.R 1024)

• Senate Sponsors: Sens. Kay Hagen (D-NC) and Pat Roberts (R-KS); 28 co-sponsors
• House Sponsors: Reps. Cathy McMorris Rodgers (R-WA) and Ron Kind (D-WI); 142 co-sponsors
• Key Provision:
  ✓ Increases the number of Medicare Part D beneficiaries who qualify for MTM services with a licensed pharmacist to any patient with a chronic medical condition, such as diabetes or hypertension. Currently, only those patients suffering from specific multiple chronic conditions are eligible.

DTS/MEDICARE PART B
DTS Home Delivery Bill

- Rep. Peter Welch introduced a bill on July 26th that would allow our members to home deliver DTS at no cost to the federal government. It currently has six bipartisan co-sponsors.

- Before the fiscal cliff (H.R. 8, as amended by the Senate) bill was enacted in early January, there was a higher reimbursement for home delivery. Now all parties are reimbursed at the same amount regardless of method.

- That is why we believe that all rationale for prohibition of delivery is gone and we appreciate Mr. Welch taking the lead on this issue.

Other Issues to Watch

- Hydrocodone Rescheduling
  - Educate Members of Congress that rescheduling hydrocodone combination products will not necessarily alleviate abuse of the drug and could cause patient access problems.

- Pharmacy Crime
  - Support pharmacy investment to prevent crimes against pharmacies, support increased penalties for pharmacy crime.

- Long Term Care
  - There are a few proposals which would affect LTC pharmacies, including new agents for the treatment of antipsychotic use in LTCs, and DEA Drug disposal regulations.

- Provider Status
  - Sixteen health professions are officially recognized by Medicare as providers, but not pharmacists. Through patient counseling on the proper use and adherence to prescribed medications, pharmacists are improving patient health and lowering costs. We believe that all federal health programs and private plans should recognize pharmacists as providers to enable them to do even more to improve health outcomes and reduce costs for their patients.

REGULATORY UPDATE
Drug Quality and Security Act

• Compounding Provisions
  – Establishes voluntary category of “outsourcing facilities” overseen by FDA
  – Maintains current law and Board of Pharmacy oversight for traditional compounding pharmacies
  – Enhances communication between FDA and State Boards of Pharmacy

Drug Quality and Security Act

• Federal Track and Trace Legislation

  Phase I—January 1, 2015—
  – Sets federal standards for wholesale distributors
  – Requires dispensers to receive certain information about the products they receive from their wholesaler (Language specifically allows wholesaler to “hold” required information
  – Manufacturers start serializing products (unique product identifier)
  – FDA starts series of five public meetings and issues guidances about any additional requirements in Phase II (presumably requiring some use of the unique product identifier)

Drug Quality and Security Act

• Track and Trace Phase II

  Includes critical provision that establishes that no additional requirements can be place on small dispensers (25 or fewer FTE) until such time as an independent third party firm determines that the necessary hardware and software are accessible, not cost prohibitive and can be integrated into existing pharmacy operating systems
Medicare Part D – 2014 Call Letter

Provides guidance to plans for 2014 structure:

• Preferred/Non-Preferred Pharmacy Networks

CMS indicates that the regulations that permit lower cost sharing at some network pharmacies also require that it not increase CMS payments to plans. CMS questions reverse pharmacy “pay to play” payments and higher unit costs in preferred networks.

• Plan Communications to LIS Beneficiaries

CMS states that plans cannot inform LIS beneficiaries that they must fill prescriptions at preferred pharmacies to get LIS copay.

Medicare Part D – 2014 Call Letter

• “Automatic Prescription Refills by Mail Order”

CMS requires that a pharmacy must obtain patient consent prior to each new/refill prescription. CMS questions auto-ship refill programs.

Excerpt from Medicare & You Handbook

“...some automatic delivery services were creating waste and unnecessary costs for people with Medicare and the Part D program. By January 2014, to make sure you still need a prescription before they send you a refill, prescription drug plans should get your approval to deliver a prescription, new or refill, before each delivery, except when you ask for the refill or request a new prescription... This new policy won’t affect refill reminder programs where you go in person to pick-up the prescription and it won’t apply to long-term care pharmacies that give out and deliver drugs.”

Medicare Part D – 2014 Call Letter

• “PDE Guidance on Post-POS Claim Adjustments”

CMS finding retrospective audits of prior claims are resulting in complete recoupment of amount originally paid to pharmacy when non-financial data on claims transaction (prescription origin code, prescriber ID) were erroneous.

CMS is concerned that growing post-audit total claim recoupments from pharmacies is distorting Part D payment, compromising Part D data integrity.
Medicare Part D CY 2014 Implementations

• 10/1/13 Part D Marketing Underway
• 10/7/13 Plan Ratings Revealed
• Open Enrollment October 15-December 7
• There will continue to be Medicare Part D plans that feature “preferred networks”.
• CMS stated in the 2014 Call Letter that the Agency “strongly believe[s] that including any pharmacy that can meet the terms and conditions of the preferred arrangements in the sponsor’s preferred network is the best way to encourage price competition and lower costs in the Part D program. Doing so would also likely mitigate some beneficiary disruption and travel costs, especially in rural areas.”

Medicare Part D CY 2014 Implementations

• Daily Cost-Sharing Rate
  – Rate will apply to anything less than a month’s supply
  – Voluntary
  – Trial fill or med sync uses

Excerpt from Medicare & You Handbook
“Usually, the amount you pay for a covered prescription is for a one-month supply of a drug. However, starting in 2014, you can request less than a one-month supply for most types of drugs. You might do this if you’re trying a new medication that’s known to have significant side effects or you want to synchronize the refills for all your medications. If you do this, the amount you pay is reduced based on the quantity you actually get. Talk with your prescriber to get a prescription for less than a one-month supply.”

Part B Changes on July 1, 2013

• Further Medicare Part B Reimbursement Cuts
  The American Taxpayer Relief Act of 2012 equalized Medicare payments for DTS obtained through retail settings with payments made under the National Mail Order Program to $10.41/box of 50 diabetic strips.

• Prohibition on Home Delivery and Delivery to ALFs
  CMS altered the definition of “mail order” under the National Mail Order Program so that independent pharmacies will be prohibited from providing home delivery and delivery to ALFs of diabetic testing supplies.

• DME Face-to-Face Documentation Requirement - DELAYED
  The 2013 Part B Final Rule requires a face-to-face encounter as a condition of payment for certain Durable Medical Equipment items for orders.
FDA Hot Topics

• Compounding
• Drug Shortages
• Biosimilars
• Track and Trace Supply Chain Security
• Utilizing Innovative Technologies and Other Conditions of Safe Use to Expand Access to Nonprescription Drugs
• Medication Guides/Patient Medication Information
• REMS for opioids

DEA Hot Topics

• Disposal of controlled substances rulemaking
• Arbitrary wholesaler/supplier controlled substance quotas and DEA’s response
• EPCS
• Dispensing of controlled substances to residents at long-term care facilities
• Reminder forms vs. pre-populated prescriptions

Long Term Care Pharmacy Issues

• Short Cycle Dispensing/Reporting Requirements
• Nurse-as-Agent
• Hospice vs. Medicare Part D
• Consultant pharmacist separation
**CMS Medicaid Update/Pharmacy Benchmarks**

- **Weighted AMP:**
  - Average monthly weighted AMP for a multiple source drug
  - This will be used to set FULs for generics
  - Multiple draft FUL updates so far; No set date for final draft
  - CMS delays release of final AMP rule until January 2014

- **RSP – “Retail Survey Price”**
  - “Out the Door” price based on data compiled by Myers and Stauffer
  - Only includes retail (cash/Medicaid/third party)
  - CMS suspended this summer

- **NADAC – National Average Drug Acquisition Cost**
  - Random selection of 2000-2500 pharmacies monthly

- **AAC – State Administered Acquisition Cost Surveys**
  - 6 states already have an AAC process
  - Others are beginning the process – or considering it

- **OIG Report Analyzes State MAC programs in relation to CMS Federal Upper Limits**

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**AFFORDABLE CARE ACT “ACA” IMPLEMENTATION**

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**Exchanges/Marketplaces**

- Creates a state-based, state-federal partnership and federally facilitated Health Benefit Exchange for individuals to purchase coverage as well as a separate Small Business (SHOP) exchange for small businesses to purchase coverage

- All health plans offered in the Marketplace must cover ten essential health benefits (EHB): ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services.

- Rather than having the federal govt. provide the details and parameters of each of these “essential benefits,” the federal govt. instead asked each state to choose a “benchmark” plan to serve as a template for each of these elements. The default plan is the largest small group plan in the state. Each states benchmark plan can be found on the CMS website.

- To date, CMS has resisted imposing any network adequacy requirements or restrictions on mandatory mail order. CMS has stated that it is their intent to simply establish the framework for the greater availability of commercial insurance (not establish another government-run entitlement program)
Health Insurance Marketplaces: What are States Doing?

- 16 states and the District of Columbia are pursuing their own state exchanges
- 7 states are pursuing a state-federal partnership exchange
- 1 state (Utah) is pursuing a state-run small business exchange and a federally-run individual exchange
- 7 states are pursuing a Marketplace Plan Management Option. The exchange will be federally facilitated; however—the state will be responsible for the plan management functions
- 19 states are pursuing a federally facilitated exchange—HHS has indicated intent to incorporate reviews conducted by state insurance departments into health plan certification decisions for inclusion in the federally facilitated exchange

Parallels Seen Between Rollout of Part D/Exchanges

- Former HHS Sec./Michael Leavitt authored an editorial outlining similarities between the two programs: Both required:
  - New regulations and information technology systems
  - Approval of insurer bids and plans
  - Coordination with federal depts and state govs.
  - Education of millions of Americans

Lessons Learned from Part D

- Leavitt identifies three key areas of concern
  - Insufficient education: 78% of Americans lack awareness about the new law (prior to Part D implementation, 66% of seniors did not understand what the program would do for them)
  - Technology breakdowns: Success of exchanges will depend on technical infrastructure used to connect/transfer data between government agencies and private entities
  - Subsidy errors: Decisions on 2014 subsidies—based on 2012 tax data

Source: The Commonwealth Fund
Medicaid Expansion

- On June 28, 2012, the Supreme Court ruled in favor of the ACA but ruled that states cannot be required to expand Medicaid up to 133% of the FPL and for individuals between the age of 18 and 65.

- 26 states have decided to move forward with Medicaid expansion; 22 states are not moving forward at this time and three are still debating Medicaid expansion.

- Arkansas will expand Medicaid through alternative option—state will use Medicaid expansion $ to purchase private insurance.

- IN, IA, OK, and PA are all considering expanding through alternative model (approaches considered include: premium assistance model, health savings account model, placing expansion population in state or federally facilitated exchanges).

Medicaid Expansion Prescription Drug Coverage

- Prescription drug plans will be required to offer a minimum of one drug in every USP category and class and the same number of drugs in each category and class as an essential health benefit benchmark plan.

- The above policy was a reversal of an initial CMS proposed rule that would have required the same generous rx drug coverage found in traditional Medicaid for those under Medicaid expansion. Most believe this reversal was designed to make expansion more palatable to states “on the fence”

- Cap on patient co-pay will be $4 for generics and $8 for non-preferred drug for beneficiaries who earn less than 150% of the poverty line.

ACA Emerging Trends

- Premiums in the Exchanges Lower than estimated so far.

- Newly insured likely to deepen primary care doctor gap.

- Lower insurance premiums likely at the cost of fewer provider choices.

- Large employers transitioning employees to private exchanges (Sears, IBM, Time Warner).

- Accountable Care Organizations (ACO’s) (Full implementation begins 2015-2020 when its expected virtually all Medicare payments to providers will flow through ACOs).
Implementation Deadlines

- October 1, 2013: Open enrollment begins for the individual and small business exchanges
- January 1, 2014: Coverage begins
- March 31, 2014: Open enrollment closes
- January 1, 2015: Employer mandate of coverage for employer’s who have more than 50 employees begins

PBM Transparency Within ACA (section 6005)

- PBM reform requires PBMs in exchanges and Part D to report:
  - PBM retail vs. mail-order generic dispensing rates
  - Aggregate PBM manufacturer rebates earned and passed through to the plan
  - Aggregate payments from plans to PBMs and subsequent payments to pharmacies
  - CMS will not require PBMs to publicly disclose this information. PCMA states that this is necessary for their members to negotiate lower prices
Past Years State Action

- NCRA State Legislative & Policy Concentration:
  - Fair Pharmacy Audits (Approx. 16 States Ran Legislation)
  - MAC Transparency (Approx. 8 states ran legislation)
  - Anti-Mandatory Mail Order "AMMO" (Approx. 5 states ran legislation)
  - PBM Reform / Transparency (Approx. 10 states ran legislation)
  - Compounding (Approx. 19 states ran legislation)
  - Expanded Scope of Services (Immunization / Provider)

Wins

- Fair Pharmacy Audits: 6 States
  - SD, MT, CO, TX, OR, NH
- MAC Transparency: 5 States (+1 Iowa rulemaking)
  - ND, KY, OR, AR, TX
- Anti-Mandatory Mail Order Legislation: 2 States
  - PA, HI
- PBM Reform/Registration: 1 State
  - OR
- Strengthened Pharmacy Audit Laws: 7 States
  - UT, GA, MS, MD, ME, NC, TN

Highlights

- Highlights from past years state legislative season!
  - MAC Transparency: First time states have enacted strictly MAC Transparency provisions.
  - Montana Fair Pharmacy Audit Legislation (S.B.235):
    - PBMs stayed neutral on the final version.
  - Hawaii AMMO and PBM Reform (H.B.62 & H.B.65):
    - AMMO Law does not contain "Same terms and conditions..." language
    - Requires some level of PBM reporting
    - Simultaneously enacted PBM law preventing private patient information from being utilized to market services.
  - Oregon PBM Reform Legislation (H.B.2123):
    - PBMs stayed neutral on the final version.
    - First bill to encompass PBM Registration, Fair Audit Standards and MAC Transparency.
  - Texas MAC Transparency & Audit Reform:
    - PBMs stayed neutral on both bills.
Looking Ahead

- MAC Transparency
  - GER?
- Fair and Uniform Pharmacy Audits
- Patient Choice (AMMO – Restricted Networks)
- Expanded Scope of Practice/Provider Status
- Medication Synchronization
- Pro-rated Dispensing Fee
- PBM Registration/Licensure
- NADAC/FULs

NCPA is seeing many states combine many of these issues into 1 bill. “Hybrid bills.”

QUESTIONS?