

# Medicaid Drug Rebate:

## Briefing for Medicaid Health Plans of America

**Webinar**

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**Kip Piper, MA, FACHE**



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# Agenda

1. Basics of the Medicaid Drug Rebate
2. Operation of Medicaid Drug Rebate Program
3. Changes to Medicaid Drug Rebate Under PPACA
4. Implications and Issues in Extension of Rebates to Medicaid Health Plans
5. Preliminary Answers to MHPA Questions on Drug Rebate Equalization

Caveat: Presentation is based on PPACA language, limited CMS guidance, and preliminary views regarding likely federal and state policies and pharma industry responses. Therefore, the following is subject to change based on federal and state decisions.



# Basics of Medicaid Drug Rebate Program

- ✓ Average Manufacturer Price
- ✓ Best Price
- ✓ Federal Rebate Agreements
- ✓ Supplemental Rebates
- ✓ Calculating Minimum Rebates

# Average Manufacturer Price (AMP)

- Average Manufacturer Price (AMP) is average price wholesalers pay manufacturers for drugs that are sold to retail pharmacies.
- Section 1927 defines AMP as “the average price paid to a manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.”
- To arrive at the actual price paid by wholesalers, AMP is calculated net of cash discounts, volume discounts, rebates, and other price concessions.
- AMP for each drug is therefore unique and fluctuates. Manufacturers report AMP monthly to CMS and share with the states.
- Specific AMP numbers are confidential but subject to federal audit.
- PPACA requires CMS to disclose online the weighted average of the most recently reported monthly AMP for multiple-source drugs.

# Medicaid Best Price

- Best Price is the lowest manufacturer price paid for a prescription drug by any purchaser or payor.
- This includes any retailer, wholesaler, or commercial health plan.
- Exceptions include prices charged to Medicare drug plans, certain federal agencies (e.g., Veterans Affairs, Public Health Service, Indian Health Service), 340B discount program participants, state pharmaceutical assistance programs.
- Also exclude nominal prices if less than 10% of AMP (e.g., drug company patient assistance programs).
- Like AMP, Best Price is net of financial cessations (e.g., rebates, discounts).
- The Best Price for each drug is reported to CMS and shared with states, but otherwise confidential.

# Federal Rebate Agreements with Drug Manufacturers

- To ensure Medicaid coverage of their outpatient prescription drug products, pharmaceutical manufacturers must sign a rebate agreement with CMS.
- Applies to generic and brand name drugs, whether dispensed by pharmacy or physician administered.
- About 550 pharma companies, including all large manufacturers, have rebate agreements.
- If a manufacturer has a rebate agreement, its drugs are covered nationwide in Medicaid. Exceptions for drugs broadly excluded from Medicaid (e.g., fertility drugs)
- Agreement specifies:
  - Calculation of rebate amounts.
  - Reporting of Best Price and Average Manufacturer Price for each drug.
  - Payment of rebates to state Medicaid agencies.
  - Dispute resolution.
  - Confidentiality of Best Price and AMP data (federal and state eyes only).

# Supplemental Rebates and Preferred Drug Lists (PDLs)

- State Medicaid agencies may negotiate supplemental rebate agreements with drug manufacturers.
- For bargaining power, state may leverage Preferred Drug Lists (Medicaid formulary). Increasingly, states join together in multi-state drug purchasing.
- Under these, drug maker agrees to pay state a rebate higher than the minimum required under the federal rebate agreement.
- Total rebates (federal minimum plus state-negotiated supplemental) average about 40%.
- Drug maker unwilling to offer supplemental rebates may see their drug placed on non-preferred list. Non-preferred drugs require some prior authorization and may include a higher beneficiary co-payment.
- Most states use PDLs for some but not all therapeutic classes.

# Calculating Minimum Federal Rebate Percentage

- **For brand name or innovator drugs**, the federal minimum drug rebate for a drug is the greater of:
  - a. Average Manufacturer Price minus percentage set in statute.
  - b. Difference between AMP and Best Price (AMP minus Best Price).
- If a brand drug's AMP increases faster than inflation, minimum rebate increased based on change in AMP compared to Consumer price Index (CPI).
- **For generic drugs**, the minimum federal rebate is Average Manufacturer Price minus percentage set in statute.
- These are the federal minimum rebate percentages. State may negotiate **supplemental rebates** with drug manufacturers.

# Operation of Medicaid Drug Rebate Program

- ✓ Utilization Reporting Process
- ✓ Payment of Drug Rebates to States

# Utilization Reporting Process

- Drug manufacturers report their Best Price and AMP figures to CMS. Monthly or quarterly.
- Using this, CMS calculates and provides to states the minimum federal rebate percentage for that quarter for each covered drug.
- Before PPACA, increasingly rebate amounts were based on difference between AMP and Best Price. Instead of the “AMP minus X%” minimum.
- States determine Medicaid drug utilization for the quarter and report the data to drug manufacturers and CMS.
- Utilization data are based on NDC codes for all outpatient drugs, including physician administered drugs (typically biologics).
- States must report utilization data to manufacturers within 60 days after each quarter.

# Payment of Rebates to States

- Using state utilization data, manufacturers calculate rebates owed and pays rebate amounts directly to the states.
- Rebate payments are due within 30 days of receiving state utilization figures.
- Drug makers may dispute state utilization data.
- Rebates to states include the federal minimum rebate amount and the supplemental rebate, if any.
- States then report to CMS on rebate revenues received.
- States share all rebate revenues with CMS, based on state's respective FMAP for fiscal year rebates received.

# Changes to Medicaid Drug Rebate Program

- ✓ New Minimum Rebate Amounts for 2010
- ✓ Equalization – Extension to Medicaid MCOs

# New Minimum Rebate Amounts in 2010

## Effective January 1, 2010:

- **For Most Brand Name Drugs:** Increased minimum rebate from 15.1% Average Manufacturer Price (AMP) to 23.1% of AMP.
- **For generic drugs:** Increased minimum rebate from 11% of AMP to 13% of AMP.
- **For Clotting Factors and Pediatric Indication Drugs:** Increased minimum rebate from 15.1% of AMP to 17.1% of AMP.
- **For new formulations of brand oral drugs:** Sets method of determining rebate. Applies to line extensions, time-release versions.
- **Maximum rebate for brand drugs set at 100% of AMP**, regardless of Best Price. (Applies to entire Medicaid rebate program, both FFS and MCO brand utilization.)

# Extension of Rebates to Medicaid Health Plans

## Drug Rebate Equalization (DRE):

- PPACA extends Medicaid drug rebate to Medicaid MCO drug utilization starting March 23, 2010.
- States required to include Medicaid MCO drug utilization in quarterly drug utilization reports to drug manufacturers and CMS.
- Medicaid MCOs must report covered drug utilization by Medicaid beneficiaries using National Drug Codes (dosage form, strength, and package size).
- Excludes drugs already discounted under federal 340B program.
- “Actuarial Soundness” requirement still applies.
- CMS: “MCO capitation rates must be based on actual cost experience related to rebates” and subject to actuarial soundness.

# Key Effective Dates to Remember

There are two effective dates for changes to the Medicaid drug rebate:

- **January 1, 2010:** Increase in Rebate Amounts Paid by Drug Manufacturers
- **March 23, 2010:** Extension of Medicaid Drug Rebate to MMCO Utilization

# Implications and Issues in Extension of Medicaid Drug Rebate to MCOs

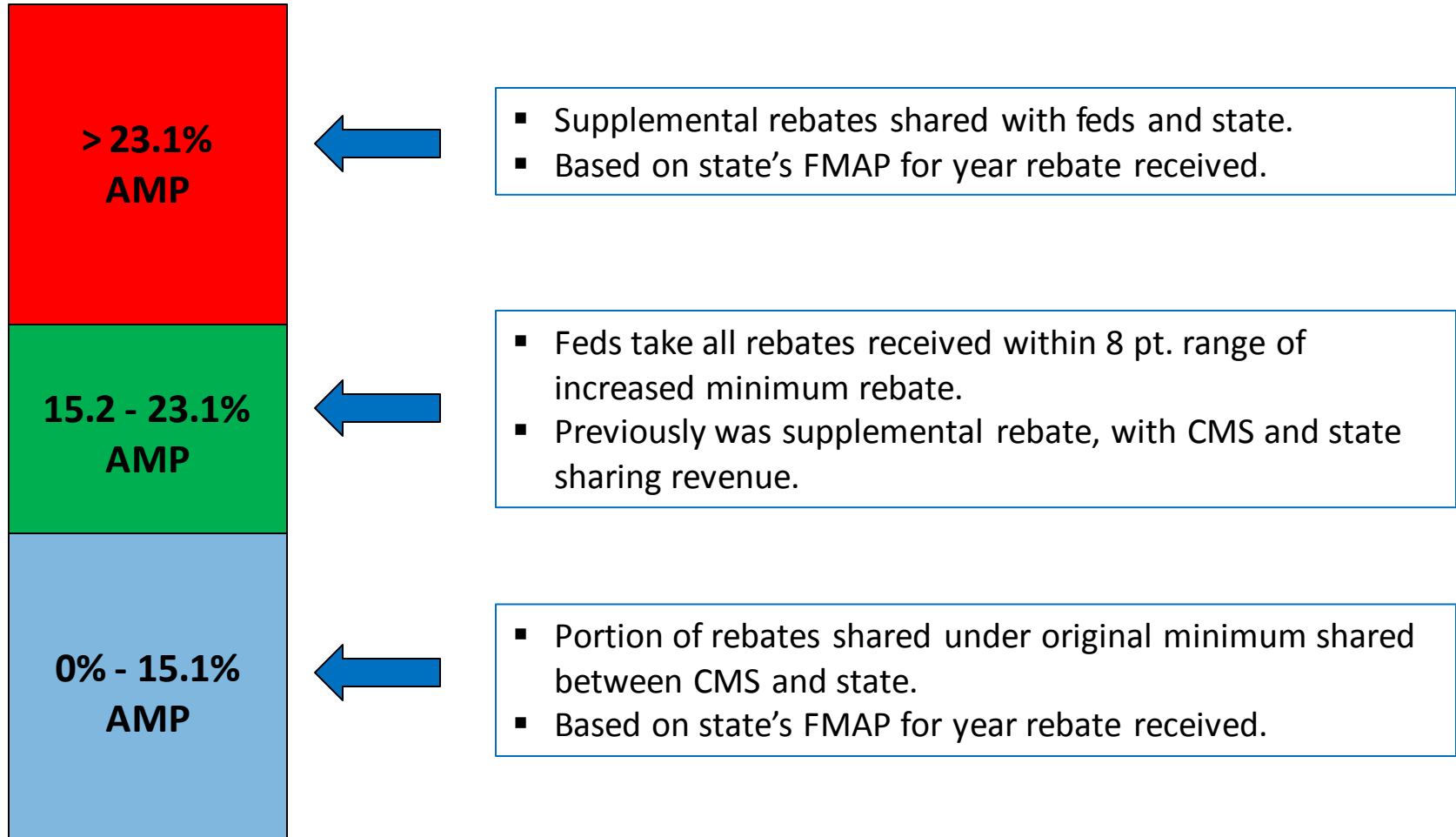
- ✓ Federal Retention of Increased Rebates
- ✓ Operational Issues in Utilization Reporting
- ✓ Impact on MCO Pharmacy Practices
- ✓ Likely Changes to State Practices

# Federal Retention of Increased Rebates

- Congressional Budget Office (CBO) projects \$38 billion in federal savings from rebate changes in PPACA.
- CMS is taking the entire rebate amount between 15.1% and 23.1% – for both FFS and MCOs. CMS taking difference between 11% and 13% on generics.
- For MCO brand drugs, states and feds will share between 0% and 15.1%, then feds get everything from 15.1% to 23.1%, then states and feds share anything above 23.1%.
- For MCO generic drugs, states and feds will share between 0% and 11%, then feds get everything from 11% to 13%, then states and feds share anything above 13%.
- For FFS brand drugs, states will lose the state share of savings of all existing rebates between 15.1% and 23.1%.
- That is, states lose state share of 8 percentage points in brand drug price concessions previously received via Best Price, supplemental rebates, multi-state negotiations. States lose 2 percentage points on generics.



# Example: Allocation of Rebate Savings for Brand Drugs



# Operational Issues in Drug Utilization Reporting

- Drug utilization reporting by MCOs will raise operational issues. For example:
  - ✓ State concerns regarding reliability of existing pharmacy encounter data.
  - ✓ Need for detailed unit volume reporting based on full 11-digit NDC codes.
  - ✓ Quick turnaround time needed so states receive clean MCO utilization data in time for quarterly reporting to CMS and drug manufacturers.
  - ✓ Initial break out of dates of service on and after March 23, 2010 effective date.
  - ✓ Reporting of utilization data for physician-administered drugs or biologics. Also reported by NDC.
  - ✓ Where applicable, distinguishing utilization between Medicaid and CHIP enrollees and between s. 1927 and s. 340B drugs.
- Expect federal and state audit of drug utilization reporting. MCOs and their PBMs / contractors must be prepared for tight oversight.



# Impact on MCO Pharmacy Practices

- Medicaid MCO drug benefit designs and rebate negotiations are not changed (directly).
- Medicaid health plans may continue to negotiate with drug manufacturers for rebates.
- Naturally, manufacturers will work to avoid risk of “double dipping” by states and the MCOs. Rebates are driven largely by ability of payor to drive market share.
- Therefore, PPACA changes will likely disrupt and complicate current MMCO contracts with drug makers.
- Overtime, MCO drug benefit practices may get disrupted by the severe policy disconnect between the objectives of utilization management and the narrow objectives of the drug rebate. Contrary to vision of value-based benefit design.
- “Carve-in” states may use contracts to reach into and steer MCO pharmacy benefit policies to maximize supplemental rebates. Many scenarios for added complications.

# State Practices Likely to Change

- To leverage and synchronize buying power across FFS and MCO, states may use MCO contracts to limit MCO flexibility with pharmacy benefit design and Preferred Drug Lists.
- Medicaid supplemental rebate agreements for FFS drugs are often very prescriptive, with state agreeing to refrain from utilization controls on preferred drugs. States may seek to extend same expectations to MCOs.
- Extension of rebates to MCO utilization gives states with large managed care enrollment and no carve-out significant new leverage in therapeutic classes with low FFS volume and consequently low rebates.
- States will need to find savings to back-fill for federal take-back of large portion of FFS drug rebates.
- Further use of bulk or group purchasing by states is highly likely.
- With MCO drug utilization data, creates opportunity for states to conduct more detailed comparisons of MCO performance. Ultimately, perhaps extending physician and pharmacy profiling beyond FFS.



**Preliminary Answers to  
MHPA Questions on  
Drug Rebate Equalization (DRE)**

# Impact on State Rate Setting

**Question:** How will DRE affect state MCO rate setting and capitation levels?

**Answer:**

- Of course – in theory at least – MCO capitation rates must be actuarially sound and based on actual cost experience related to rebates.
- State should increase MCO rates to reflect loss of MCO's supplemental rebate bargaining power under DRE. That is, reflect MCOs expected higher post-rebate drug costs.
- Estimating this will be difficult and a state may choose to be slow in increasing rates to reflect impact of DRE. States are angry at federal take-back and will be reluctant to diminish DRE savings.
- States typically include a modest bump for administrative cost of MCO rebate administration. Reason for this largely removed by DRE (assuming MCO supplemental rebates drop). But MCOs will have new cost of reporting drug utilization.
- Impact on Medicaid/CHIP contracts will vary by state and depend on degree of program separation and rate methodologies.
- Long range, improved accuracy of pharmacy data reporting may have significant impact on how states set pharmacy portion of capitation rates.

# MCO Negotiated Supplemental Rebates, “Double Dipping”

**Question:** How will DRE affect ability of MCOs to negotiate their own supplemental rebates? Does DRE create possibility of “double dipping” of rebates?

**Answer:**

- Nothing in the law prohibits states and MCOs from both negotiating supplemental rebates from drug manufacturers. But market forces will rule and work to minimize direct rebates to MCOs.
- Naturally, manufacturers seek sales volume and drive to maximize marginal revenues, but must navigate PDLs, Best Price, Average Manufacturer Price, competitor pricing, generics, etc.
- States will have the leverage with drug companies. States will also prefer to see rebate savings directly where possible, rather than indirectly through adjustments to MCO capitation rates.
- DRE will limit MCO leverage with manufacturers. Drug makers are under severe pricing and profit pressures, increased by PPACA. They will work hard to moderate supplemental rebates and avoid paying rebates to both states and MCOs for same utilization.
- In own rebate negotiations, MCOs may leverage volume effect of their better management.
- Law clarifies that 340B drug utilization in MCOs is excluded from Medicaid drug rebates.



# State Supplemental Rebate Negotiations

**Question:** How will DRE affect state supplemental rebate negotiations?

**Answer:**

- Fiscally, DRE is good news for the “carve-in” states.
- The “carve-in” states will be eager to capture MCO drug utilization to receive associated rebates and thus negotiate higher supplemental rebates for that utilization. However, drug makers have limited understanding, poor relationships with states.
- Given different utilization and brand/generic mix under MCOs vs. FFS, DRE will increase state bargaining power for select therapeutic classes and generics.
- Given the federal take-back of a large portion of previously negotiated supplemental rebates, the increase in federal minimum AMP-based rebates is large budget hit for most states.
- Expect combination of DRE, increased minimum rebate, and federal take-back to increase state use of PDLs and bulk/group purchasing.
- State will be very concerned about accuracy and timeliness of MCO drug utilization reports. Expect many pharma company disputes, at least initially in 2010-2011.



# Impact on DRE on State Pharmacy Benefit Carve-Outs

**Question:** How will DRE affect state carve-out / carve-in policies?

**Answer:**

- Fortunately, drug rebate equalization does remove the perverse incentive for state Medicaid programs to carve out drug benefits.
- DRE will likely slow down states considering the carve-out option. DRE may provide added argument for reversing earlier full or partial carve-outs.
- Likely easier in partial carve-out states and perhaps those facing large expansion of Medicaid enrollment in 2014. New utilization reporting may increase state comfort level in MCO rate setting, removing one of the rationales used to defend carve-outs.
- However, we expect state drug benefit policies (both pharmacy and medical sides) to continue to evolve. Includes concern over cost and use of biologics, generic dispensing rates, expanded use of PDLs and group purchasing to secure supplemental rebates.
- Combination of DRE savings and budget hit from federal take-back of portion of rebate revenues may encourage states to steer MCO pharmacy practices via contracts.



# Impact on MCO Drug Utilization Management Practices

**Question:** Will DRE change or restrict MCO drug utilization management practices?

**Answer:**

- PPACA doesn't change or restrict MCO drug utilization management practices.
- With DRE, states will want MCO volume to maximize state-negotiated supplemental rebates where possible. (And presumably, net pharmacy benefit cost.)
- Over time, states may be eager to influence or even mandate certain practices inside MCOs to synchronize MCO and FFS practices to shift utilization in way that increases rebates. Especially given prescriptive nature of many FFS rebate agreements with manufacturers.
- The reverse is another (hopeful) possibility – states incentivized to align FFS practices with MCO practices or use MCOs more broadly in managing benefits. Important to make the case for FFS to follow MCO, rather than other way around.
- Unfortunately, the incentives for rebates will likely skew state decision making and may complicate or compromise care management and value-driven benefit designs by MCOs.

# Drug Utilization Reporting Requirements

**Question:** How will MCO drug utilization reporting work?

**Answer:**

- New reporting requirement, notwithstanding existing encounter reporting. More data, different timing, different use of data, role of data in rebates, and possibility of manufacturer challenges.
- Starts with dates of payment on and after March 23, 2010.
- Applies to all Medicaid covered dispensed drugs and physician-administered drugs.
- Report total number of units using full 11-digit NDCs to identify drug, dosage form, strength, package size, and manufacturer or labeler. Likely also number of scripts per NDC and total amount paid per NDC.
- Medicaid rebate does not apply to 340B drugs. However, reports likely to include 340B drugs, with 340B drugs and s. 1927 rebate drugs delineated for state tracking and compliance.
- Timing and accuracy are critical. States need data to report Medicaid-wide data quarterly.
- Many states and their actuaries are concerned about accuracy of MCO pharmacy encounter reporting. These concerns are likely to spill over to rebate related reporting.



# Physician Administered Drugs

**Question:** Are physician-administered drugs included in DRE? How will this be operationalized?

**Answer:**

- Yes, physician-administered drugs are included in the Medicaid drug rebate and therefore also the DRE. Medicaid MCOs will need to report to states on Medicaid beneficiary utilization of physician-administered drugs.
- Like pharmacy-dispensed drugs, the utilization must be reported using full 11-digit NDCs and number of NDC units on date of payment. In addition to HCPCS codes and units.
- MCOs will need to instruct physician offices, clinics, and outpatient hospitals to include NDC coding and NDC units in claim submissions for Medicaid enrollees.
- For format, suggest you model after existing state guidance to physicians on FFS reporting. A HCPCS-to-NDC crosswalk likely necessary initially given March 23, 2010 effective date.
- States must report utilization and collect rebates on top 20 physician-administered drugs. CMS identifies top 20. However, states may go beyond the top 20, are motivated by rebate savings, and the specific 20 change often. So expect states to require report for virtually all physician-administered drugs in any outpatient setting.

# Data Elements for Utilization Reporting

**Question:** What data elements are states likely to require?

**Answer:**

- Total number of units reimbursed during the quarter. Paid claims.
- Units reported using by full 11-digit NDCs to identify specific drug or formulation, dosage form, strength, package size, and manufacturer or labeler.
- Per NDC, total number of prescriptions and total amount paid during the quarter.
- Include all outpatient drugs, including physician administered drugs in any outpatient setting.
- Distinguish between Medicaid and CHIP eligibles, as necessary.
- Distinguish between Medicaid covered drugs and 340B drugs.
- Some states may require additional data elements (e.g., utilization arrayed against benefit design).

# Administrative Cost of Implementing DRE

**Question:** What are some of the administrative costs of implementing DRE in MCOs?

**Answer:**

- Implementation requires several new activities by MCOs and their contractors / PBMs.
- Includes, for example:
  - ✓ NDC-level utilization reporting of both pharmacy dispensed and physician administered drugs.
  - ✓ Fast and timely reporting to meet state need to report utilization within 30 days of each quarter.
  - ✓ Changing provider instructions. Modifying claims system to require NDC codes on claims for physician-administered drugs in outpatient settings.
  - ✓ Initial cross-walk of claims (HCPCS to NDC).
  - ✓ Ensuring reliability of data, cleaning up and fixing reporting problems.
  - ✓ Assisting state and state fiscal agents in responding to manufacturer disputes and federal audits.
  - ✓ Responding to federal and state audits.



# Status of CMS Guidance to States

**Question:** What is status of further CMS guidance to states? What are behind-the-scenes conversations between NASMD, NGA, et al with CMS?

**Answer:**

- NASMD and NGA have been in frequent conversations with CMS staff. Mostly focused on the federal take-back of rebate revenues from states, which is very controversial.
- CMS has been collecting questions from states on PPACA issues, including DRE.
- CMS believes that the PPACA requirements on DRE are relatively straightforward, with law self implementing. FFS side of Medicaid rebates has become highly systematized.
- CMS' April 22, 2010 SMD letter contains baseline guidance. CMS expected to release modified reporting forms to states soon, following OMB approval.
- Guidance via rules seen as not essential. CMS will eventually publish a proposed and final rule to conform drug rebate rules with PPACA changes.
- We are closely monitoring informal and formal guidance from CMS to states.



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## Questions and Discussion



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**Sellers Dorsey**  
**[www.SellersDorsey.com](http://www.SellersDorsey.com)**

**Nancy Hardy**

Senior Vice President  
nhardy@sellersdorsey.com

**Christopher Labonte**

Principal  
clabonte@sellersdorsey.com

**Kip Piper, MA, FACHE**

Senior Consultant  
kpiper@sellersdorsey.com