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Overview of Government Pricing Implications Within PPACA/HCERA

Jerry Wolf

Navigant Consulting, Inc.

October 22, 2010

The 11th Annual Pharmaceutical Regulatory Compliance Congress and Best Practices Forum

The Legislation

- The Patient Protection and Affordable Care Act (PPACA)
  - P.L. 111-148
  - Enacted on March 23, 2010
  - 906 pages in pdf format
- The Health Care and Education Reconciliation Act of 2010 (HCERA)
  - P.L. 111-152
  - Enacted on March 30, 2010
  - 55 pages in pdf format
- Together, called/referred to as the Affordable Care Act (ACA)

A few changes

- Revised Medicaid Rebate Program AMP definition, calculation, and reporting requirements
- Increase in minimum Medicaid rebate percentages and calculations
  - » Alternative Unit Rebate Amount (URA) calculation for new formulations of some brand name drugs
  - » URA capped at 100% of AMP
- Rebates required for drugs dispensed to Medicaid Managed Care Organization (MCO) beneficiaries

A few *more* changes

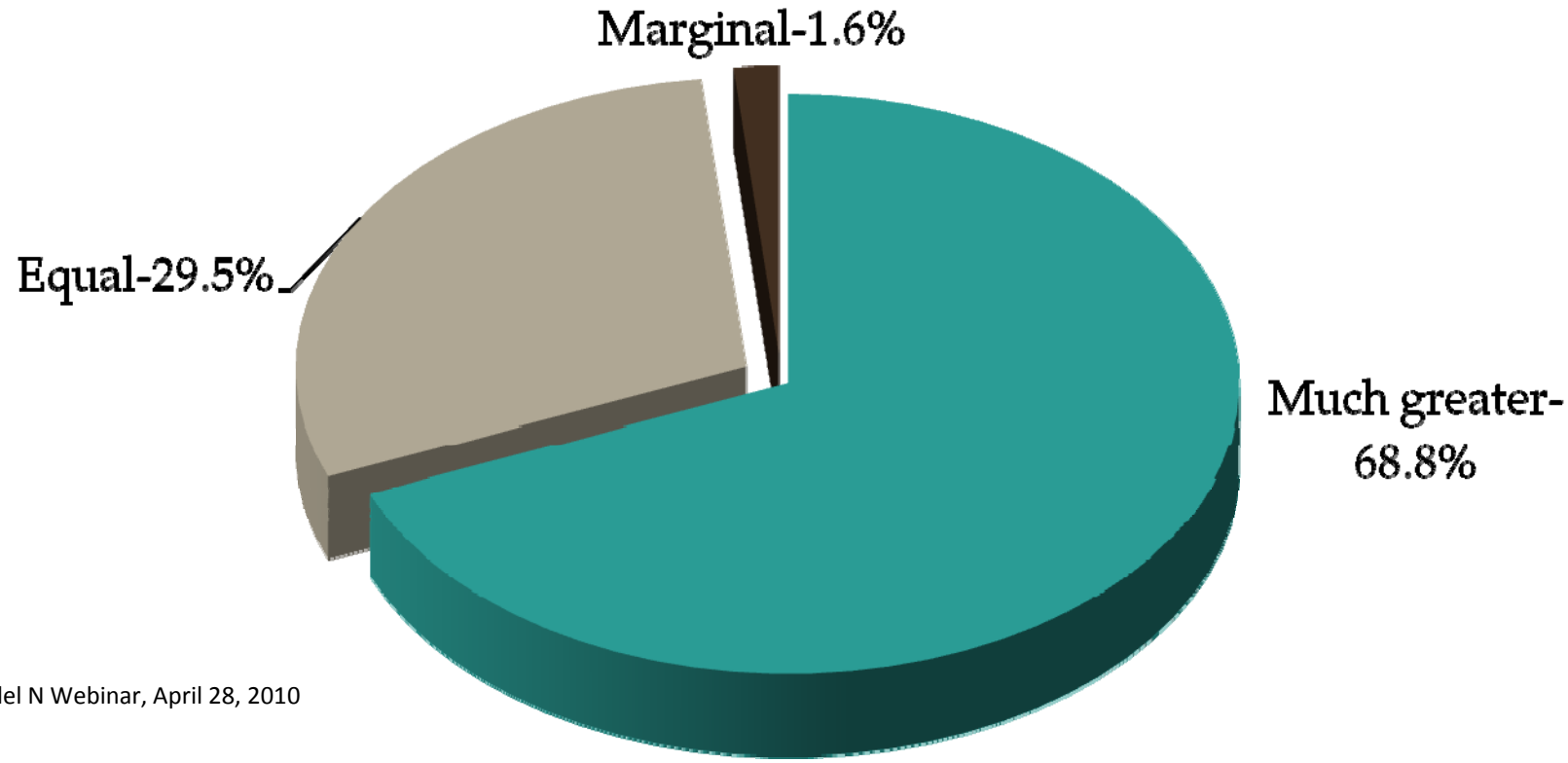
- Expansion of 340B Drug Pricing Program
  - » Retroactive discounts to newly eligible entities
- 340B Drug Pricing Program ceiling price reporting
- Pricing restatement requirements
  - » subsequent to changes in AMP/BP that impact URA
    - ceiling price = AMP - URA

Some implications for manufacturers

- Financial
  - » Increase in minimum Medicaid rebate amount and changes in AMP calculations may result in higher URAs
    - may be offset by existing supplemental rebate agreements
  - » Downward pressure on prices from commercial customers
  - » Increase in Medicaid utilization from inclusion of MCO claims
    - potential for duplicate discounts
  - » Refunds to 340B entities resulting from AMP/BP restatements and changes
  - » Increase in eligible covered entities
- Systems, processes, and resources
- Many unanswered questions on how to implement
  - » AMP calculation methodology
  - » Restatement of Baseline AMP?
  - » Data integrity of MCO utilization?

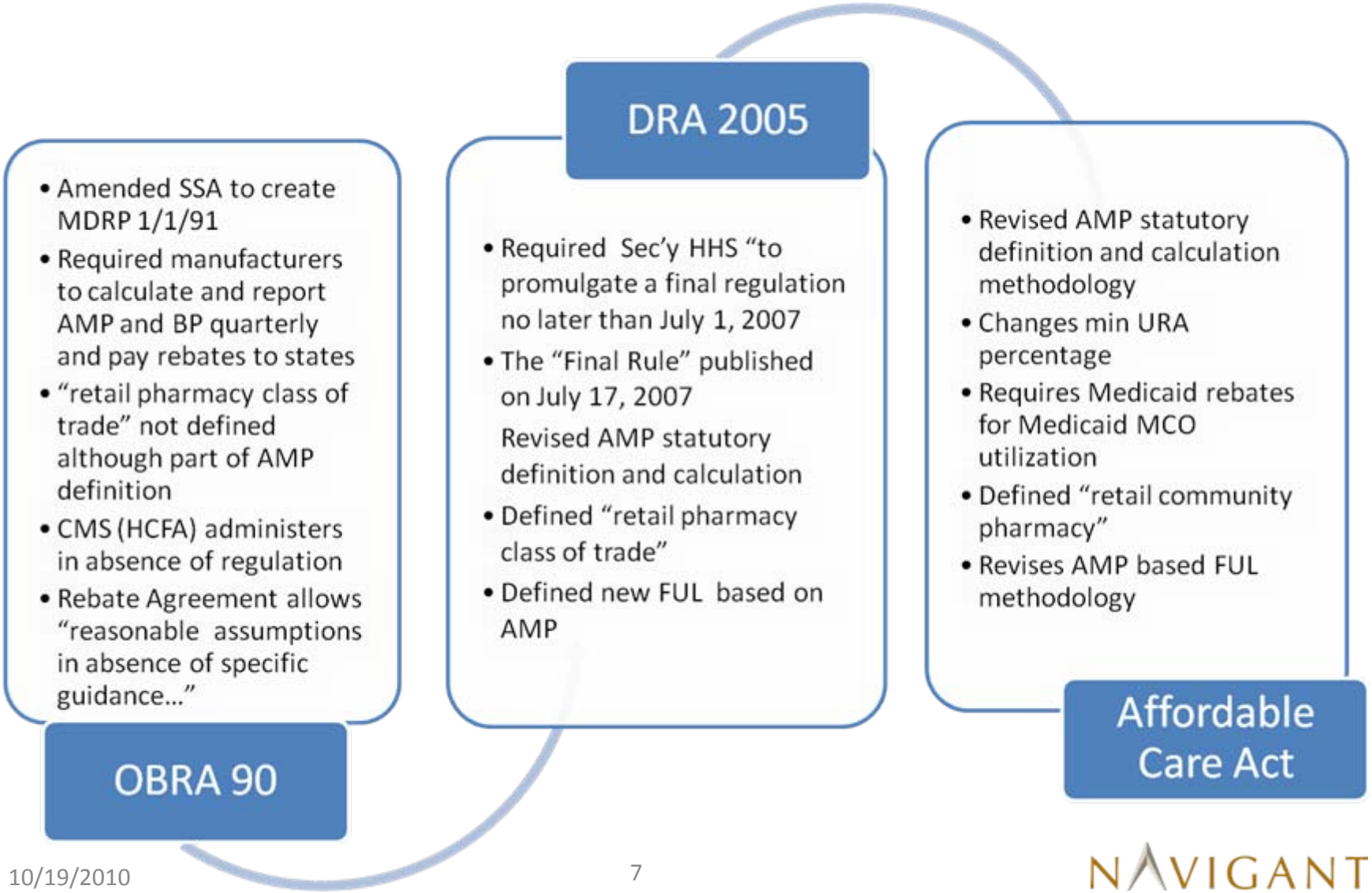
Responses to poll by Model N, Inc.—April 2010

Compared to the Deficit Reduction Act of 2005, how do you see healthcare reform impacting your operational processes and systems?



CBI/Model N Webinar, April 28, 2010

A brief historical perspective



AMP definition and calculations—OBRA '90

OBRA 90	• Average price paid to the manufacturer in the State by wholesalers for drugs distributed to the **retail pharmacy class of trade** (excluding direct sales to hospitals, health maintenance organizations, wholesalers where the drug is relabeled…" FSS prices are not included in the calculation of AMP. • Must be adjusted by the manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.	• **Retail pharmacy class of trade not defined** in statute or proposed regulation published September 1995. • CMS Release 29 (1997) specifies that sales to nursing home/primary contract pharmacies, **mail order pharmacies, and hospital outpatient pharmacies are INCLUDED in AMP.** • All sales to wholesalers are included EXCEPT those **"which can be identified as being subsequently sold to any of the excluded sales categories"**

CMS Release 29—1997

AVERAGE MANUFACTURER PRICE/BEST PRICE CALCULATIONS

SALES	INCLUDED IN AMP	INCLUDED IN BP	REBATES DUE	ADDITIONAL INFORMATION
Direct Hospital Sales	No	Yes	Note 1	Sales discussed in this chart may be affected by subsequent sales to an excluded/included entity for AMP/BP purposes.
HMOs (Drugs Dispensed Under Capitated Rate)	No	Yes	No	
HMOs (Drugs Dispensed Under Fee-for-Service)	No	Yes	Yes	
Mail Order Pharmacy	Yes	Yes	Yes	Note 1 - Yes, if the drug is used in the outpatient pharmacy and the Hospital bills Medicaid for reimbursement for dispensing the outpatient drug. Otherwise, no.
Retail Pharmacy	Yes	Yes	Yes	
PHS Covered Entities	No	No	No	
State-Funded Only - Pharmacy Assistance Programs	No	No	No	Note 2 - Yes, except for sales to wholesalers which can be identified with adequate documentation as being subsequently sold to any of the excluded sales categories.
VA/DOD Excluded Sales	No	No	No	
Federal Supply Schedule Sales	No	No	No	
Nursing Home Primary/Contract Pharmacy Sales	Yes	Yes	Yes	
Sales to Other Manufacturers Who Repackage/Relabel Under the Purchaser's NDC	No	No	No	Additional note - All pricing adjustments affecting the price of any sales must be taken into account if the sales were included in the calculation of AMP/BP.
Sales to Other Manufacturers Who Act as Wholesalers and Do Not Repackage/Relabel Under the Purchaser's NDC	Yes	Yes	Yes	
Wholesalers	Note 2	Note 2	Note 2	

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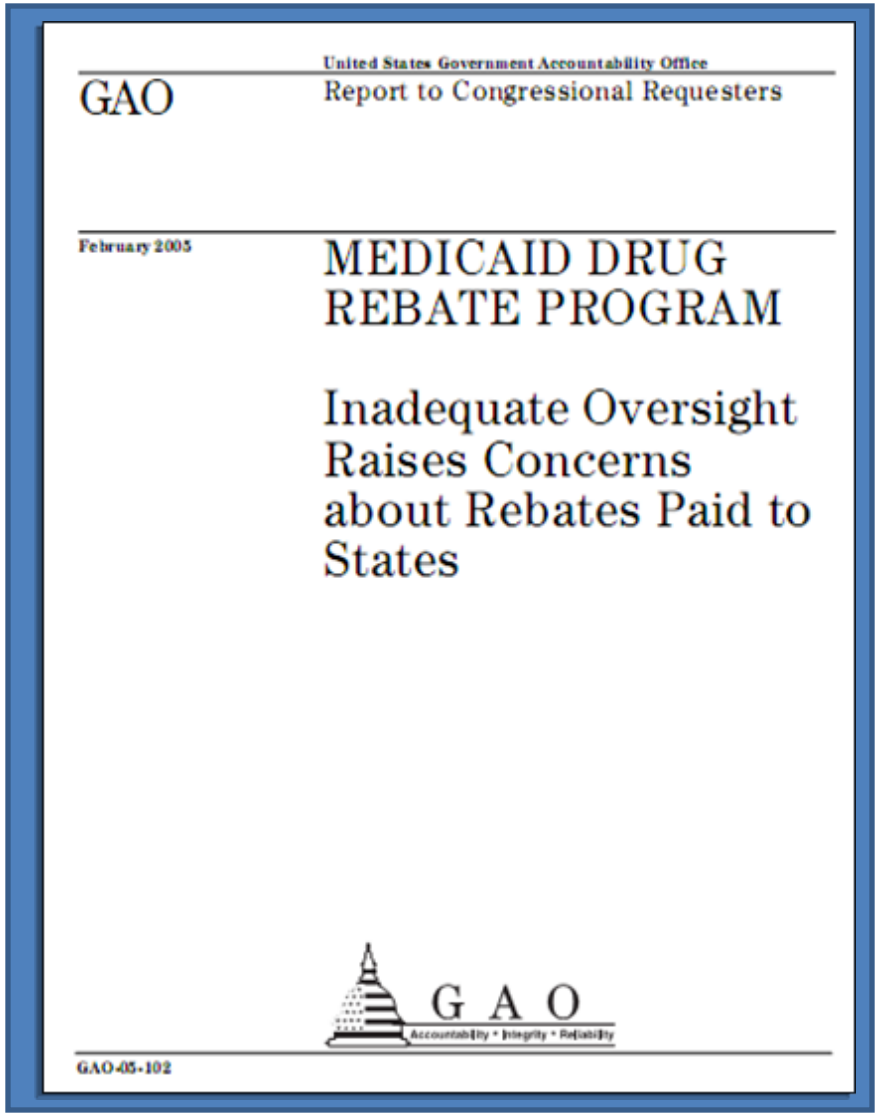
GAO Report—February 2005


United States Government Accountability Office

GAO

Report to Congressional Requesters

February 2005

MEDICAID DRUG REBATE PROGRAM

Inadequate Oversight Raises Concerns about Rebates Paid to States

GAO

Accountability * Integrity * Reliability

GAO-05-102

- *"OIG officials told us that, despite the program releases issued by CMS, they remain* ***unable to evaluate AMP because of the lack of clear CMS guidance, particularly related to the retail pharmacy class of trade..."***
- *"There was* ***considerable variation in the methods that manufacturers used*** *to determine best price and AMP... "*
- ***"Current rebate program oversight does not ensure that manufacturer reported prices or price determination methods are consistent with program criteria specified in the rebate statute, rebate agreement, and CMS program memoranda."***

DRA 2005 and Final Rule July17, 2007 –"the AMP rule"

DRA 2005 Final Rule

- Average price paid to the manufacturer in the State by wholesalers for drugs distributed to the retail pharmacy class of trade…
- Prompt pay discounts excluded from AMP
- **Monthly AMP to be used as basis of FUL instead of "published prices".**
- Calculation incorporates "smoothing" of lagged discounts over 12 months *ala* ASP
- May revise AMPs ***except*** when due to data for lagged price concessions.
- Quarterly AMP = weighted average of monthly AMP
- Retail pharmacy class of trade defined as "Any independent pharmacy, chain pharmacy, **mail order pharmacy**, or other outlet that purchases drugs from a manufacturer, wholesaler, distributor…"
- **AMP includes all sales to wholesalers except for those sales that can be identified with adequate documentation as being subsequently sold to any of the excluded entities**
- Long list of excluded entities, mostly easily identifiable, including inpatient hospital sales, HMOs, LTC facilities, hospices, prisons, FSS
- Includes **mail order pharmacies, hospital outpatient pharmacies, specialty pharmacies, home healthcare, physicians, clinics**

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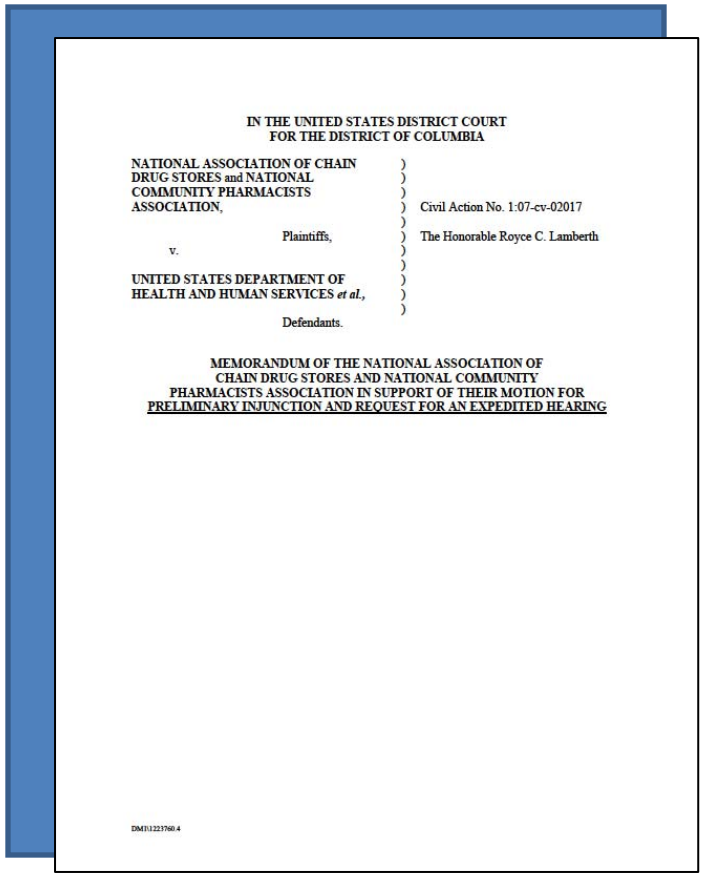
Never mind that AWP = "Ain't what's paid"…

AMP =

Ain't My Price !!

Retail pharmacy—CMS lawsuit November 7, 2007



IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF CHAIN DRUG STORES and NATIONAL COMMUNITY PHARMACISTS ASSOCIATION,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES *et al.*,

Defendants.

Civil Action No. 1:07-cv-02017

The Honorable Royce C. Lamberth

MEMORANDUM OF THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES AND NATIONAL COMMUNITY PHARMACISTS ASSOCIATION IN SUPPORT OF THEIR MOTION FOR PRELIMINARY INJUNCTION AND REQUEST FOR AN EXPEDITED HEARING

DM1\1223760.4

- *…"the AMP rule includes a significant number of transactions that do not belong in the calculation of AMP because they are not prices paid to manufacturers by wholesalers for drugs distributed to the retail pharmacy class of trade…*
- *"…the AMP Rule completely reverses the statutory test for AMP by requiring a manufacturer to include virtually all prices unless the manufacturer has "adequate documentation" which proves that the price should be excluded."*
- *FULs calculated on these "flawed AMPs" result in reimbursement rates for generic drugs that will be cut by a "staggering 78.7%..." and…"well below the prices retail pharmacies pay for drugs."*
- *"...an estimated 10,000 to 12,000 pharmacies are expected to be forced to reduce their hours, refuse Medicaid beneficiaries, or close their doors…"*

AMP Calculation—March 2010 PPACA/HCE

- Average price paid to the manufacturer…by wholesalers for drugs distributed to **retail community pharmacies** and retail community pharmacies that purchase drugs directly from the manufacturer.

AMP Includes:	• sales and discounts to wholesalers for drugs distributed to retail community pharmacies • sales and discounts to retail community pharmacies that purchase drugs directly from the manufacturer
AMP Excludes:	• sales and discounts to any other entity that does not conduct business as a wholesaler or a retail community pharmacy

AMP Calculation—March 2010 PPACA/HCE

- Defines **"retail community pharmacy"** as
  - an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices.

- Does NOT include a pharmacy that
  - dispenses prescription medications primarily to patients through the mail,
  - nursing home pharmacies,
  - long term care facility pharmacies,
  - hospital pharmacies,
  - clinics,
  - charitable or not-for-profit pharmacies,
  - government pharmacies,
  - or pharmacy benefit managers.

AMP Calculation—March 2010 PPACA/HCE

- Minimal guidance provided to manufacturers for identifying sales by wholesalers to excluded entities (i.e., those other than retail community pharmacies)
  - » DRA 2005 Final Rule acknowledged that manufacturers typically cannot otherwise reliably track sales from wholesalers in the absence of a lagged discount transaction
- No requirement for wholesalers to provide such sales information to manufacturers or data consolidators.
- No requirement for retail community pharmacies or any other purchasers to provide sales information to manufacturers or data consolidators.
- What about drugs that typically aren't sold to retail pharmacies?
- Does "adequate documentation" provision of DRA 2005 Final Rule still apply?

Retail pharmacy letter to CMS—July 20, 2010

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

NCPA NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

July 20, 2010

Donald Berwick, M.D.
Administrator, Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Subject: Implementation of Medicaid AMP Pharmacy Reimbursement Provisions of P.L. 111-148

Dear Dr. Berwick:

Congratulations on your appointment as Administrator of the Centers for Medicare and Medicaid Services (CMS). We look forward to working with you during your tenure at the agency. Community retail pharmacies are a critical access point to health care services for Medicaid beneficiaries. In 2009, approximately 300 million prescriptions were dispensed to Medicaid beneficiaries by community retail pharmacies. Pharmacies will become an even more important source of health care related services for Medicaid beneficiaries as new health care reform provisions are implemented.

As you move forward with implementation of the Patient Protection and Affordable Care Act (PPACA), the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) are writing to provide our views on Section 2503 of PPACA, *Providing Adequate Pharmacy Reimbursement*. Due to its complexity, we urge you to utilize formal rulemaking with a reasonable public comment period, as opposed to a sub-regulatory guidance, to implement this important provision. We believe this rulemaking should be completed before CMS implements Section 2503, even if a delay in the October 1, 2010 effective date is required. The agency used this approach when implementing the pharmacy reimbursement provisions of the Deficit Reduction Act (DRA), and we believe this method of implementation is appropriate in this case as well.

It is in the spirit of strengthening the link between community pharmacy and the Medicaid program that we offer the attached recommendations on the implementation of Section 2503. In particular, our comments focus on:

- Average Manufacturer Price (AMP) Calculations
- Whether to Calculate a Federal Upper Limit (FUL)
- Amount of FUL
- Whether a FUL Applies to Particular Drug Products
- Public Availability and Posting of AMPs and Retail Survey Prices (RSPs)

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In providing clear guidance to drug manufacturers on the calculation of AMPs, we believe it is of the utmost importance to reverse the "adequate documentation" provision of the AMP rule. *See* 72 Fed. Reg. 39142 (July 17, 2007). This provision states that manufacturers should include all sales in the calculation of AMPs unless they have adequate documentation proving the sales should be excluded. This provision of the AMP rule does not comply with current law. PPACA clearly sets forth sales that should not be included in AMP calculations. Including this adequate documentation provision in rulemaking or other regulatory guidance would be in conflict with the intent of Congress in passing PPACA and inconsistent with current law. Instead, CMS should provide guidance in rulemaking that sales should be excluded from AMP calculations unless manufacturers have adequate documentation to show that the sales fit the statute's definition of AMP.

We appreciate the opportunity to share our views, and are committed to working with you to implement these important provisions in a manner that complies with current law and maintains access to prescription drugs and services for Medicaid beneficiaries.

Sincerely,

Douglas Hoey, R.Ph., MBA
Acting Executive Vice President and CEO
National Community Pharmacists Association

Steven C. Anderson, IOM, CAE
President and CEO
National Association of Chain Drug Stores

cc: The Honorable Max S. Baucus
The Honorable Charles E. Grassley
The Honorable Henry A. Waxman
The Honorable Joseph L. Barton

Cindy Mann, Director, CMCSC, CMS
Larry Reed, CMS Medicaid Pharmacy Team
Carol Steckel, Commissioner, Alabama Medicaid / Chair, NASMD
Ann Kohler, Director of Health Services, NASMD

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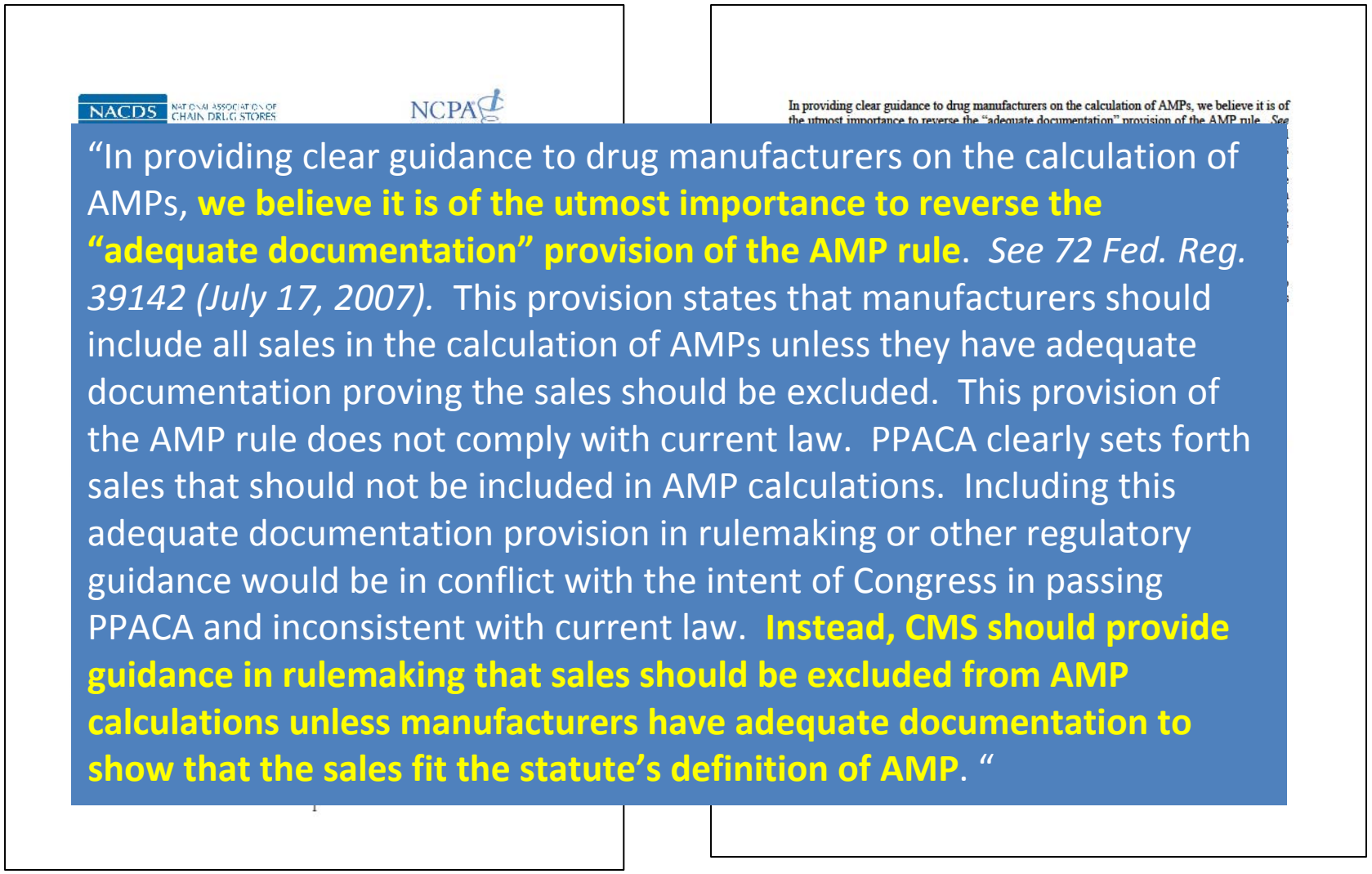
Retail pharmacy letter to CMS—July 20, 2010



"In providing clear guidance to drug manufacturers on the calculation of AMPs, **we believe it is of the utmost importance to reverse the "adequate documentation" provision of the AMP rule**. *See 72 Fed. Reg. 39142 (July 17, 2007).* This provision states that manufacturers should include all sales in the calculation of AMPs unless they have adequate documentation proving the sales should be excluded. This provision of the AMP rule does not comply with current law. PPACA clearly sets forth sales that should not be included in AMP calculations. Including this adequate documentation provision in rulemaking or other regulatory guidance would be in conflict with the intent of Congress in passing PPACA and inconsistent with current law. **Instead, CMS should provide guidance in rulemaking that sales should be excluded from AMP calculations unless manufacturers have adequate documentation to show that the sales fit the statute's definition of AMP**. "

AMP Re-defined by HR 1586—August 10, 2010

- The "five I's" provision
- AMP further re-defined to exclude payments and rebates from or discount provided to entities other than retail community pharmacies …

*"unless the drug is an **inhalation**, **infusion**, **instilled**, **implanted**, or **injectable** drug that is not generally dispensed through a retail community pharmacy"*

- Does not define what is meant by "generally"
- Likely to result in *lower* AMPs for these drugs compared to previous calculations

CMS Issues Proposed Rule—September 3, 2010

- CMS proposes to withdraw two provisions of DRA 2005 "Final Rule"
  - » the determination of Average Manufacturers Price (AMP)
  - » the Federal Upper Limits (FULs) for multiple source drugs

- CMS advises manufacturers "to base their AMP calculations on the definitions set forth in section 1927 of the Act, including changes made by section 2503 of PPACA as amended by HCERA, ***instead of on the AMP related definitions provided in existing regulations and guidance.***"

Manufacturer implications—AMP

- Effective October 1, 2010; monthly AMP due to CMS on November 30, 2010

- AMP calculations still subject to management certification
  - » even if data used in the calculations is from multiple wholesalers or data consolidators?
- "Reasonable assumptions" provision of Medicaid Drug Rebate Agreement still in effect

Manufacturer implications—AMP

- Minimal guidance from CMS
- Interpretations vary on intent and methodology:
  - » Include all sales except those where there exists "adequate documentation" that they should be excluded? (as described in Release 29 and DRA 2005 Final Rule)
  - » Exclude all sales from AMP calculations unless manufacturers have "adequate documentation" to show that the sales are to retail community pharmacies only? (as suggested by NACDS and NACP)
    - what is "adequate documentation" when there is no chargeback or rebate?
- Retail pharmacy (NACDS/NACP) influence on CMS regarding manufacturers' AMP calculation methodology
  - » What if FUL were based on some other factor than 175% of the weighted average monthly AMP?

Medicaid rebate percentages

	Previous	Affordable Care Act

Minimum rebate-innovator drugs	• 15.1% of AMP	• 23.1% of AMP except…
		  • 17.1% of AMP for drugs approved by the FDA exclusively for pediatric indications
		  • "Synagis", "Pulmicort Respules"
		  • 17%.1 of AMP for clotting factors for which separate payment is made under Medicare Part B
		  • list posted on CMS web site
		  • URA specific to new formulations (line extensions) of a brand name drug that is an oral solid dosage form, e.g., extended release formulations (see below)

New formulations of certain brand name drugs 	• N/A	The higher of: • the highest additional rebate expressed as a percent of AMP for any strength of the original brand name drug • The total URA (basic plus additional) calculated for the new drug

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Medicaid rebate percentages

	Previous	Affordable Care Act
Minimum rebate—non-innovator	• 11% of AMP	• 13% of AMP
Maximum rebate	• N/A	• 100% of AMP

Rebates for Medicaid MCO drugs

- Manufacturers must pay rebates to the states for drugs dispensed to individuals enrolled with a Medicaid MCO if the MCO is responsible for coverage of such drugs
- States must include utilization reported by each Medicaid MCO to the states when invoicing quarterly rebates to manufacturers and in their quarterly utilization reports to CMS
- No assignment of responsibility for data integrity issues associated with MCO utilization
- No impact on MCO plan formularies (recently addressed by CMS)
- State PDLs?

A few 340B Drug Pricing Program changes

- Increase in eligible "covered entities"
  - » Certain children's hospitals
  - » Free-standing cancer hospitals
  - » Critical access hospitals
  - » Sole community hospitals
  - » Rural referral centers
- Mandatory refunds to covered entities for historical price changes from AMP/BP restatements
- Mandatory reporting of ceiling prices
- Numerous other program integrity provisions
  - » dispute resolution process
  - » "spot checking" of manufacturer calculations

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Contact:

Jerry Wolf
Navigant Consulting, Inc.
(215) 832-4465
(609) 923-7572 (mobile)
jerry.wolf@navigantconsulting.com