FOLEY

FOLEY & LARDNER LLP

Medicaid Drug Rebate Program

The Final AMP and Best Price Rule: Making Sense of the New Requirements

Lena Robins, Foley & Lardner LLP

March 11, 2008

Miami, Florida

Outline

- Pharmacy/Medicaid Drug Rebate Program Overview
- DRA Background
- Final AMP Rule:
  - Determination of AMP
  - Determination of Best Price
  - Reporting Requirements
  - Federal Upper Limits
  - Physician-Administered Drugs and Dispensing Fees
- Future Issues

FOLEY

FOLEY & LARDNER LLP

3

Medicaid Pharmacy Reimbursement Overview

- States set their own drug reimbursement policies. Payments are required to approximate drug acquisition costs plus a reasonable dispensing fee.
- Most States use one of two metrics to estimate acquisition costs:
  - Average Wholesale Price (AWP) = specified %
  - Wholesale Acquisition Cost (WAC) = + specified %
- Federal and State cost containment programs also limit reimbursement:
  - Federal Upper Limit (FUL). Applies in aggregate to multi-source drugs (generics).
  - Maximum Allowable Cost (MAC). State-set limits for select drugs.

FOLEY
FOLEY & LARDNER LLP

4

Medicaid Rebates and Average Manufacturer's Price

- Under the Medicaid Drug Rebate Program, manufacturers pay rebates to States for the drugs dispensed to Medicaid beneficiaries equal to:
  - 15.1% Average Manufacturer's Price (AMP)
  - Difference between AMP and Best Price
- AMP was created solely for purposes of Medicaid Drug Rebate Program to approximate acquisition costs to retail class of trade
  - Drugs (brand or generic) have an AMP

FOLEY
FOLEY & LARDNER LLP

5

Deficit Reduction Act (“DRA”) of 2005

- Sections 6001, 6002, and 6003 of DRA made significant changes to Medicaid Drug Rebate Program
- Changes include:
  - Revised definition of AMP and expanded us of AMP
  - Establishing new formula for calculation of FULs
  - Requiring rebates for certain physician-administered drugs
  - Clarifying rebate liability for authorized generic drugs

FOLEY
FOLEY & LARDNER LLP

6

DRA of 2005

- Goals of AMP and FUL provisions:
  - Encourage States to pay more appropriately for estimated acquisition costs of generic drugs
    - In part result of 2004 GAO and OIG reports that Medicaid payments to pharmacies were much higher than what pharmacies were actually paying for generic drugs
    - States overpaid for drugs because using commercial drug pricing guides as basis for setting State reimbursement levels
    - It is estimated that the DRA provisions will save States and Federal government $8.4 billion in Medicaid funding over next 5 years

FOLEY
FOLEY & LARDNER LLP

DRA of 2005

- Promote transparency
  - Manufacturers will have to report AMPs monthly and data will be published on CMS website
  - States will have access to information in determining their methods for setting reimbursement rates

Final AMP Rule

- The Centers for Medicare & Medicaid Services (CMS) issued final AMP rule on July 17, 2007 (the "Final Rule")

  72 Fed. Reg. 39142

- Unless otherwise specified, changes became effective October 1, 2007
- CMS requested additional comments regarding AMP and FUL outlier provisions with comments due on January 14, 2008

9

Determination of AMP

- Social Security Act definition:
  - "AMP is defined as "the average price received by the manufacturer for the drug in the United States from wholesalers for drugs distributed to the retail pharmacy class of trade"

FOLEY
FOLEY & LARDNER LLP

10

Determination of AMP

- Final Rule guidance:
  - Definition of Manufacturer: CMS adopts a definition of "manufacturer" based on definition used by Medicare Part B program in average sales price (ASP) regulations
    - Entity is manufacturer only if it "possesses legal title to the national drug code (NDC) for a covered drug or biological product"
    - Two exceptions:
      - With respect to authorized generics, term "manufacturer" also includes original holder of new drug application
      - With respect to drugs subject to private labeling arrangements, term includes manufacturing entities that do not possess legal title to NDC

FOLEY
FOLEY & LARDNER LLP

11

Determination of AMP

- Retail Pharmacy Class of Trade:
  - Includes sales to entities that dispense drugs to general public, including "any independent pharmacy, chain pharmacy, mail order pharmacy, or other outlet that purchases drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public"
- Excludes sales to institutional long-term care pharmacies

FOLEY
FOLEY & LARDNER LLP

12

Determination of AMP

- What is included in AMP?
  - Sales to wholesalers, except for sales that can be identified with adequate documentation as being subsequently sold to any excluded entities
  - Sales to retail pharmacies
  - Sales to specialty pharmacies
  - Sales to mail-order pharmacies
  - Sales to pharmacy benefit managers (PBMs) for mail order pharmacy purchases
  - Sales to physicians

FOLEY
FOLEY & LARDNER LLP

Determination of AMP

- Sales to outpatient facilities, such as clinics, surgical centers, ambulatory care centers, dialysis centers, and mental health centers
- Sales to home infusion providers
- Sales to home health care providers
- Direct and indirect sales to hospitals, where drug is used in outpatient pharmacy, except sales that cannot be identified with adequate documentation as being used in outpatient pharmacy
- Sales directly to patients

FOLEY
FOLEY & LARDNER LLP

Determination of AMP

- Sales to other manufacturers who act as wholesalers and do not repackage/relabel under purchaser's NDC, including private labeling agreements
- Sales at nominal prices (less than 10% of AMP) to any entity except covered 340B entity, intermediate care facility for mentally retarded, or State-owned or operated nursing facility
- Rebates, discounts, or other price concessions associated with sales listed above
- Sales of drugs reimbursed by third-party payers, including Medicare Part D Program

FOLEY
FOLEY & LARDNER LLP

Determination of AMP

- What is not included in AMP?
  - Any prices on or after October 1, 1992, to Indian Health Service, Department of Veterans Affairs, State homes receiving funds under 38 U.S.C. § 1741, Department of Defense, Public Health Service, or covered entity described in section 1927(a)(5)(B) of Social Security Act
  - Any prices charged under Federal Supply Schedule of General Services Administration
  - Any depot prices (including TRICARE) and single award contract prices, as defined by Secretary, of any agency of federal government
  - Direct and indirect sales to hospitals, where drug is used in inpatient setting or in outpatient pharmacy for outpatient use where sales cannot be identified with adequate documentation

FOLEY
FOLEY & LARDNER LLP

Determination of AMP

- Sales to HMOs that purchase or take possession of drugs
- Sales to long-term care facilities, including nursing facility pharmacies, contract pharmacies for nursing facility where sales can be identified with adequate documentation, and other entities where drugs are dispensed through nursing facility pharmacy, such as assisted living facilities
- Sales to hospices (inpatient and outpatient)
- Sales to veterinarians
- Sales to prisons
- Sales to outside 50 States and District of Columbia.
- Sales to State, county, and municipal entities
- Sales to patient assistance programs
- Sales to wholesalers where drug is distributed to non-retail pharmacy class of trade

FOLEY
FOLEY & LARDNER LLP

17

Determination of AMP

- Sales to wholesalers or distributors where drug is relabeled under wholesalers' or distributors' NDC
- Rebates, discounts, or other price concessions associated with sales listed above
- Manufacturer coupons redeemed by consumer, agent, pharmacy, or another entity acting on behalf of manufacturer, but only to extent that full value of coupon is passed to consumer and pharmacy, agent, or other entity does not receive any price concession
- Manufacturer vouchers
- Manufacturer-sponsored drug discount card programs
- Free goods, not contingent upon any purchase requirement
- Bona fide service fees

FOLEY
FOLEY & LARDNER LLP

18

Determination of AMP

- Customary prompt pay discounts extended to wholesalers
- Returned or replaced goods when accepted or replaced in good faith
- Rebates, discounts, rebates, or other price concessions to PBMs, except for mail order pharmacy's purchases
- Rebates, discounts, or other price concessions to third-party payers, including Medicare Part D Program
- Rebates under national rebate agreement or a CMS-authorized State supplemental rebate agreement paid to State Medicaid agencies

FOLEY
FOLEY & LARDNER LLP

19

Determination of AMP

- Sales Versus Rebates
  - Rebates and other price concessions paid to government programs, such as Medicaid, SCHIP, and Medicare Part D, excluded from AMP because programs do not purchase drugs directly but instead reimburse for drugs purchased from entities in distribution chain, which will usually be in retail pharmacy class of trade
  - But sales made through retail class of trade and reimbursed by these programs included in AMP

FOLEY
FOLEY & LARDNER LLP

20

Determination of AMP

- Manufacturer Coupons and Vouchers for Free Products
  - Excluded from AMP if:
    - Coupon is not contingent on any purchase requirement
    - Manufacturer establishes coupon's benefit amount without negotiation with third party
    - Entire amount of coupon's value is made available to patient without opportunity for third party to reduce benefit amount or take portion of it and
    - Pharmacy collects no additional payment other than benefit amount and bona fide service fee

FOLEY
FOLEY & LARDNER LLP

21

Determination of AMP

- Patient Assistance Programs
  - Patient assistance programs excluded from AMP if:
    - Focused on extending free products or financial assistance not contingent on any purchase requirement to low-income individuals
    - Manufacturer establishes subsidy amount without negotiation with third party
    - Entire amount of free product or assistance is made available to patient without opportunity for third party to reduce benefit amount or take portion of it and
    - Pharmacy collects no additional payment other than benefit amount and bona fide service fee

FOLEY
FOLEY & LARDNER LLP

22

Determination of AMP

- Returned Goods
  - Returned goods excluded from AMP provided manufacturer acts in good faith
  - Good faith means product is returned in accordance with pre-existing manufacturer policies that comply with customary acceptable business practices and applicable laws and regulations

FOLEY
FOLEY & LARDNER LLP

23

Determination of AMP

- Lagged Price Concessions
  - Final Rule defines lagged price concessions as discounts or rebates that are realized after sale of drug, except for customary prompt pay discounts, but are not limited to discounts or rebates offered to wholesalers
  - Manufacturers must use 12-month rolling average of lagged price concessions when calculating AMP

FOLEY
FOLEY & LARDNER LLP

24

Determination of Best Price

- DRA did not specifically require CMS to clarify requirements for determination of Best Price
- However, Final Rule contains certain revisions and clarifications on Best Price

FOLEY
FOLEY & LARDNER LLP

25

Determination of Best Price

- Social Security Act definition:
  - Best Price is "the lowest price available from the manufacturer during the rebate period to any entity in the United States in any pricing structure (including capitated payments) in the same quarter for which AMP is computed"

FOLEY
FOLEY & LARDNER LLP

26

Determination of Best Price

- Manufacturer Coupons and Vouchers for Free Products
  - Manufacturer coupons and vouchers for free products excluded from Best Price provided full value of coupon is passed to consumer and receiving pharmacy or other entity does not receive any price concession
  - Final Rule does not state whether additional criteria for excluding manufacturer coupons from AMP also apply to Best Price

FOLEY
FOLEY & LARDNER LLP

27

Determination of Best Price

- PBM Price Concessions
  - Rebates, discounts, or other price concessions to PBMs included in Best Price determination
  - Exception for purchases made through PBM mail-order pharmacies or "such rebates, discounts or other price concessions . . . designed to adjust prices at the retailer or provider level"

FOLEY
FOLEY & LARDNER LLP

28

Determination of Best Price

- Patient Assistance Programs
  - Goods provided free of charge under manufacturer's patient assistance program excluded from Best Price

FOLEY
FOLEY & LARDNER LLP

29

Determination of Best Price

- Nominal Prices
  - Sales made at nominal prices (less than 10% of AMP) traditionally excluded from Best Price
  - DRA limited nominal price exclusion to nominal price sales to only certain entities and safety net providers (*e.g.*, 340B covered entities, intermediate care facilities for mentally retarded, and State-owned or -operated nursing facilities)
  - CMS also expressed concern that manufacturers will use nominal price exclusion as marketing tool which "is not within the spirit and letter of the law"

FOLEY
FOLEY & LARDNER LLP

30

Other Issues for AMP and Best Price

- Customary Prompt Pay Discounts:
  - DRA revised definition of AMP to exclude customary prompt pay discounts to wholesalers
  - Final Rule establishes that non-routine discounts used for purposes other than ensuring payment within specified timeframe, such as marketing, sales, promotional strategies, special package discounts, incentives, and performance-based discounts, not customary included in AMP
  - Prompt pay discounts must be earned according to their terms (and not automatically granted despite timing of payment) to be excluded from AMP

FOLEY
FOLEY & LARDNER LLP

31

Other Issues for AMP and Best Price

- Authorized Generics:
  - Final Rule defines term "authorized generic" as "any drug sold, licensed, or marketed under a new drug application approved by the FDA under section 505(c); and marketed, sold, or distributed under a different product code, labeler code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the listed drug"
  - Manufacturer must include price at which it sells authorized generic to secondary manufacturer in Best Price calculation. But prices charged by secondary manufacturer to customers do not affect primary manufacturer's AMP or Best Price

FOLEY
FOLEY & LARDNER LLP

32

Other Issues for AMP and Best Price

- Direct Patient Sales:
  - Direct sales are those for which manufacturer exerts control over distribution of drug through exclusive wholesaler/distributor or pharmacy
  - Outpatient drugs sold to patients through direct programs, such as specialty drug distribution arrangements where manufacturer retains ownership of drug but pays third party for storage, delivery, and billing of drug, included in AMP because distributor is acting as wholesaler and therefore transaction is through an entity within retail pharmacy class of trade
  - Sales directly to patients also included in Best Price, except to extent sales specifically excluded by statute

FOLEY
FOLEY & LARDNER LLP

33

Other Issues for AMP and Best Price

- Bundled Sales:
  - Final Rule requires Best Price be adjusted for any bundled sale
  - "Bundled sale" is arrangement under which rebate, discount, or other price concession is conditioned upon purchase of same drug or drugs of different types or upon some other performance requirement (*e.g.*, achievement of market share, inclusion or tier placement on a formulary), or where resulting price concessions are greater than those that would have been available had bundled drugs been purchased separately or outside bundled arrangement
  - Manufacturers required to allocate discounts proportionately to dollar value of units of each drug sold under bundled arrangement

FOLEY
FOLEY & LARDNER LLP

34

Other Issues for AMP and Best Price

- Bona Fide Service Fees:
  - Final Rule requires all fees, except bona fide service fees, be included in calculation of AMP and Best Price
  - Final Rule adopts in Medicaid rebate context same definition of "bona fide service fees" (and accompanying interpretive guidance) as CMS adopted for purposes of determining ASP
  - Bona fide service fees means "a fee paid by a manufacturer to an entity that represents fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that a manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that is not passed in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug"
  - Final Rule does not specifically define "fair market value" except that it is determined "consistent with generally recognized standards"

FOLEY
FOLEY & LARDNER LLP

35

Reporting Requirements

- Base Date AMP:
  - Manufacturers have option to revise product's base date AMP based on definition of AMP in Final Rule
  - Option may be exercised on a product-by-product basis. Revised base date AMP must be submitted to CMS within the first four full calendar quarters following publication of Final Rule (through quarter ended September 2008)

FOLEY
FOLEY & LARDNER LLP

36

Reporting Requirements

- Quarterly and Monthly Reporting:
  - Manufacturers must report AMP to CMS on monthly basis
  - Manufacturers must also submit quarterly AMP and Best Price reports and dollar volume of customary prompt pay discounts and nominal price sales
  - Quarterly AMP must be calculated as a weighted average of three component monthly AMPs

FOLEY
FOLEY & LARDNER LLP

37

Reporting Requirements

- Restatements:
  - Manufacturers must restate quarterly AMP and Best Price figures for up to 12 quarters from quarter in which data were due
  - Manufacturers must report revisions to customary prompt pay discounts and nominal prices over same 12-month period
  - Manufacturers must revise monthly AMPs for up to 36 months from month in which data were due

FOLEY
FOLEY & LARDNER LLP

38

Reporting Requirements

- Certifications:
  - All reports and restatements must be certified by manufacturer CEO or CFO, individual who has authority equivalent to CEO or CFO, or individual to whom CEO or CFO has directly delegated certification authority
  - False certification subject to Medicaid Drug Rebate Program penalties
    - Civil money penalty not to exceed $100,00 for each item of false information. Other penalties may apply.

FOLEY
FOLEY & LARDNER LLP

39

Reporting Requirements

- Publication of AMP Data:
  - DRA removed confidentiality protection for AMP data as of January 1, 2007
  - CMS will begin publishing AMP data when it finds the data "sufficiently complete and accurate"
  - Temporarily delayed

FOLEY
FOLEY & LARDNER LLP

40

FULs

- FUL is maximum Federal government will pay to States in federal financial participation ("FFP") for generics (multi-source drugs) dispensed through State Medicaid programs
- DRA requires FUL to be set at 250% of lowest AMP for among a drug's therapeutically equivalent versions (currently set at 150% of published price)
- FUL applies to all drug formulations, including those not proven to be therapeutically equivalent (B-rated)
- Approximately 600 drugs subject to new FULs

FOLEY
FOLEY & LARDNER LLP

41

FULs

- CMS will not use lowest AMP to establish FUL for particular multiple-source drug group if that AMP is an outlier
- Means less than 40% of next highest unless FUL group includes only a brand name product and its first generic competitor
- CMS accepted additional comments on proposed "outlier AMP" formula through January 14, 2008

FOLEY
FOLEY & LARDNER LLP

42

National Association of Chain Drugs and National Community of Pharmacists Association Lawsuit

- On November 7, lawsuit filed challenging FULs and publication of AMP data
- On December 14, U.S. District Court for the District of Columbia issued Preliminary Injunction enjoining CMS from implementing Final Rule to extent affects Medicaid reimbursement rates for retail pharmacies and from publicly posting AMP data and disclosing to States
- CMS may continue to require manufacturers to make AMP and Best Price calculations for rebate purposes

FOLEY
FOLEY & LARDNER LLP

43

National Association of Chain Drugs and National Community of Pharmacists Association Lawsuit

- CMS will not challenge Injunction and has until March 31 to produce administrative documents on Final Rule
- Court found associations likely to succeed on merits of claim that Final Rule violates APA and pharmacies likely to suffer "irreparable harm"

FOLEY
FOLEY & LARDNER LLP

44

Pending Legislation

- Saving our Community Pharmacies Act of 2007 (H.R. 3140)
  - Uses pharmacy retail acquisition cost instead of Medicaid AMPs to set FULs
- Fair Medicaid Drug Payment Act of 2007 (S. 1951)
  - FULs to be based on 300% of weighted average AMP and eliminates public posting of AMP data

FOLEY
FOLEY & LARDNER LLP

45

Physician-Administered Drugs

- DRA requires States to collect rebates on certain physician-administered drugs for FFP to be available for these drugs
- "Physician-administered drugs" are "covered outpatient drugs . . . that are typically furnished incident to a physician's service, . . . usually injectable or intravenous drugs administered by a medical professional in a physician's office or other outpatient clinical setting"

FOLEY
FOLEY & LARDNER LLP

46

Physician-Administered Drugs

- Final Rule establishes that FFP is available for physician-administered drugs only when States require providers to submit claims for these drugs using NDC numbers
- For single-source drugs, providers required to submit claims beginning January 1, 2007
- For 20 multiple-source drugs identified by CMS as having highest value under Medicaid Program, providers required to submit claims beginning January 1, 2008

FOLEY
FOLEY & LARDNER LLP

47

Dispensing Fees

- States may also require manufacturers to pay pharmacies reasonable dispensing fee
- Fee is one that:
  - Incurred at point of sale and pays for expenses other than ingredient cost each time drug is dispensed
  - Includes only pharmacy costs associated with ensuring that drug is dispensed to Medicaid beneficiary and
  - Does not include administrative costs incurred by State

FOLEY
FOLEY & LARDNER LLP

48

Future Issues

- Fate of FUL Changes??
- States
  - May continue to set reimbursement as choose – only at or above 250% of AMP – as long as reimbursement does not exceed FUL
  - May choose to use AMP and/or Retail Survey Price. May continue to use AMP or WAC
    - 2007 OIG Report found most States undecided about using AMP

      See States' Use of New Drug Pricing Data in the Medicaid Programs, OIG Report OEI-03-06-00490 (April 2007)

FOLEY
FOLEY & LARDNER LLP

Future Issues

- Manufacturers
  - Financial, operational, and compliance challenges
  - Pricing strategies
    - AMP transparency
    - Increased rebate payments
- Other Payers
  - May choose to use AMP
  - Part D Plans

FOLEY
FOLEY & LARDNER LLP

AMP/FUL Timeline

December 19, 2005	Deficit Reduction Act (DRA) passed by Congress, containing language requiring reimbursement for generic drugs in the Medicaid program to be based on Average Manufacturer Price (AMP)
February 8, 2006	President Bush signs DRA
May 30, 2006	HHS Office of the Inspector General (OIG) reports to CMS that existing guidelines for calculating AMP are not clear or comprehensive and that manufacturer calculations of AMP are inconsistent
December 22, 2006	CMS publishes proposed AMP regulation
December 22, 2006	U.S. Government Accountability Office (GAO) reports to Rep. Joe Barton (R-TX) that AMP-based Federal Upper Limits (FULs) could mean generic reimbursement on average 36 percent below pharmacy's average acquisition cost (on a sample of 77 drugs)
February 20, 2007	Comment period ends for proposed regulations. More than 1,000 comments are filed
June 2007	HHS OIG reports that FULs would be below average pharmacy acquisition costs for 19 of 25 drugs sampled. Twelve of the 19 drugs had average pharmacy acquisition costs that would be more than double the new reimbursement limit

FOLEY
FOLEY & LARDNER LLP

AMP/FUL Timeline

July 17, 2007	Final regulation published. Extended comment period provided until January 2, 2008, on AMP and FUL outlier provisions
July 24, 2007	Rep. Nancy E. Boyda (D-KS) introduces H.R. 3140 to amend the Social Security Act to ensure and foster continued beneficiary access to generic drugs under the Medicaid program by setting pharmacy reimbursement based on retail acquisition cost (RAC)
August 2, 2007	Sen. Max Baucus (D-MT) introduces S. 1951 to amend the Social Security Act to ensure that individuals eligible for medical assistance under the Medicaid program continue to have access to prescription drugs
September 27, 2007	Rep. Frank Pallone (D-NJ) introduces H.R. 3700, the companion bill to S. 1951
October 1, 2007	AMP regulation takes effect
October 1 – December 30, 2007	First Quarterly AMP reporting period under new regulation
November 2007 – January 2008	CMS expected to publish AMPs, FULs on agency website for first time

Source: National Association of Chain Drug Stores

FOLEY
FOLEY & LARDNER LLP

Selected Resources

- CMS Medicaid Prescription Drug website. Available at http://www.cms.hhs.gov/DeficitReductionAct/39_MedicaidPrescriptionDrugs.asp
- CMS Questions and Answers on Medicaid prescription drug provisions of DRA (September 28, 2007). Available at http://www.cms.hhs.gov/DeficitReductionAct/Downloads/DRAPolicyInquires.pdf
- Sections 6001, 6002, and 60003 of DRA. Available at http://www.cms.hhs.gov/DeficitReductionAct/Downloads/Sections6001,6002,and6003ofthe DRA.pdf

FOLEY
FOLEY & LARDNER LLP

Questions and Answers

Contact Information

Lena Robins
Foley & Lardner LLP
Suite 500
3000 K Street, NW
Washington, D.C. 20007-5101
Tel: 202.295.4790
Fax: 202.672.5399
lrobins@foley.com