Mini Summit X: Government Pricing and Contracting

Introduction, Panel Discussion, and Q&A

Pharmaceutical Regulatory and Compliance Congress
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Agenda

- Business-embedded GP compliance
- Medicaid Drug Rebate Program ("MDRP") Final Rule – Key Issues
- Public Health Service 340B Program
- Service Fee Analysis/Compliance

Marcy Imada

Business-Embedded GP Compliance

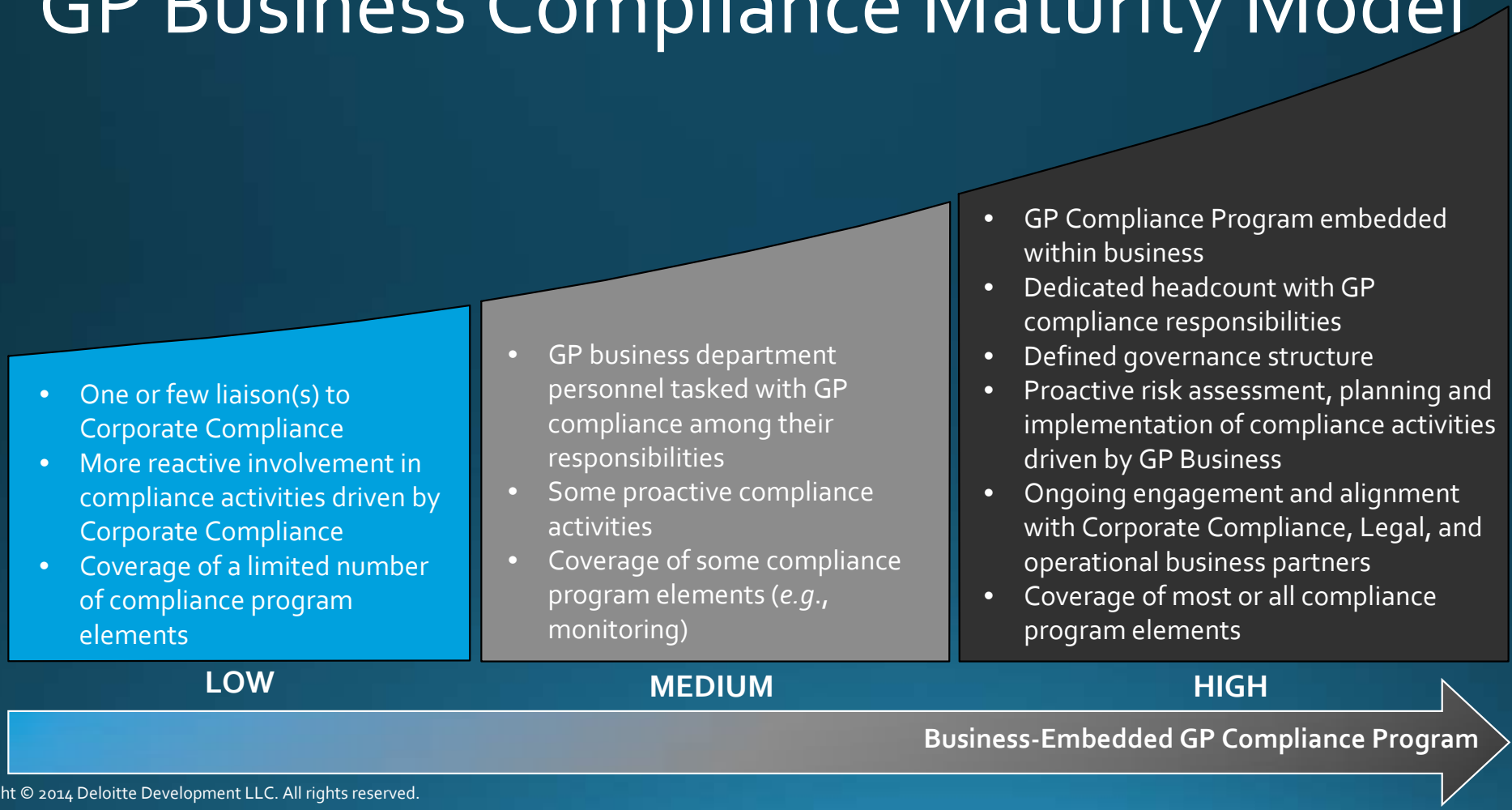
GP Landscape

Significant compliance, financial, operational, and reputational risk

- Complex requirements to ensure access to government program patients
- Onerous business operations involved
- Legislative, regulatory, and sub-regulatory changes impacting:
  - Government rebates and discounts
  - Manufacturer methodologies, systems, and processes
- Enforcement activities by regulators
- Increased strategic commercial pricing and contracting pressures

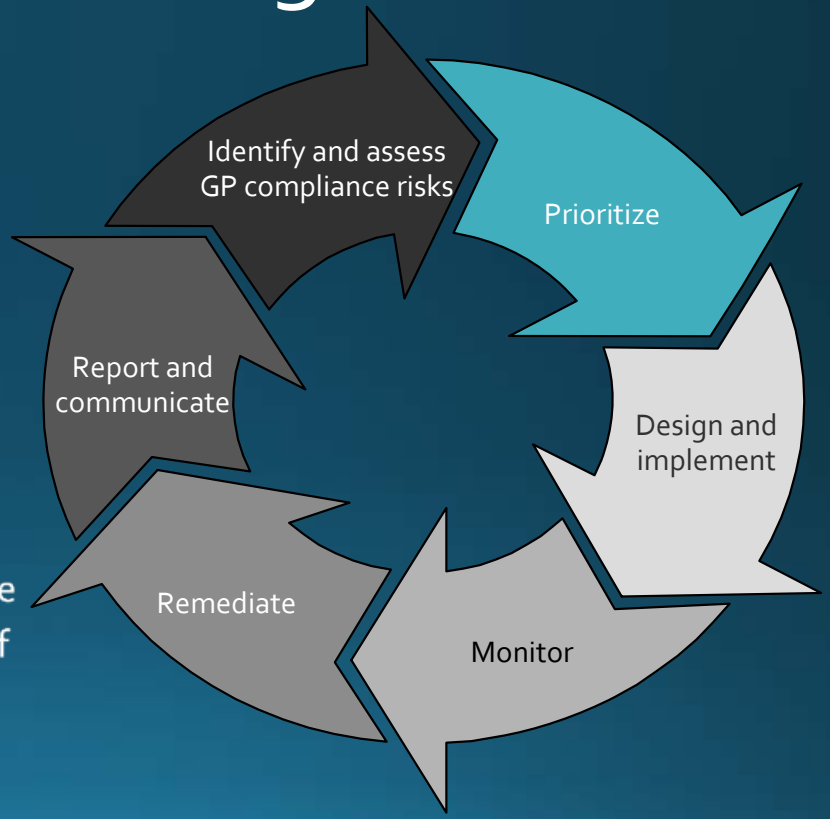
GP risk mitigation can be enhanced through greater engagement between GP Business and Corporate Compliance as well as GP compliance activities carried out by the business

GP Business Compliance Maturity Model



Leading Practices for an Effective Business-Embedded GP Compliance Program

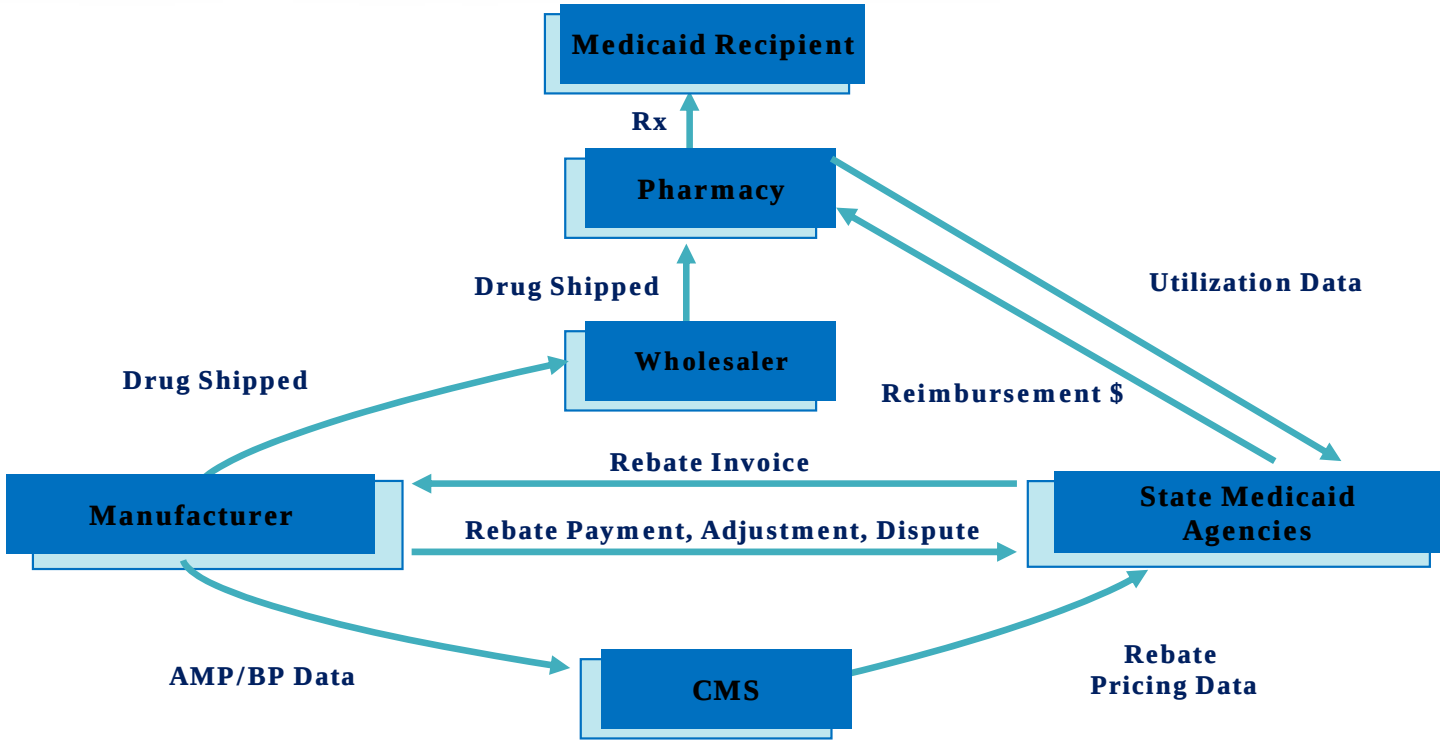
- Strong relationships and alignment between GP Compliance, CCO/Corporate Compliance and Legal for consistency, efficiency, and effectiveness
- Empowerment of GP Compliance personnel and dotted line reporting to CCO
- Sufficient resources with GP technical and compliance knowledge and experience
- Up-front involvement in commercial strategy, contracting, and pricing decisions
- Annual GP risk assessment, policy, and procedure review and compliance training
- Ongoing GP monitoring and reporting to Corporate Compliance
- Ongoing engagement with, communications to, and training of operational business partners
- Periodic compliance effectiveness assessment by independent party to support ongoing enhancement of the compliance program



Katherine Buckley

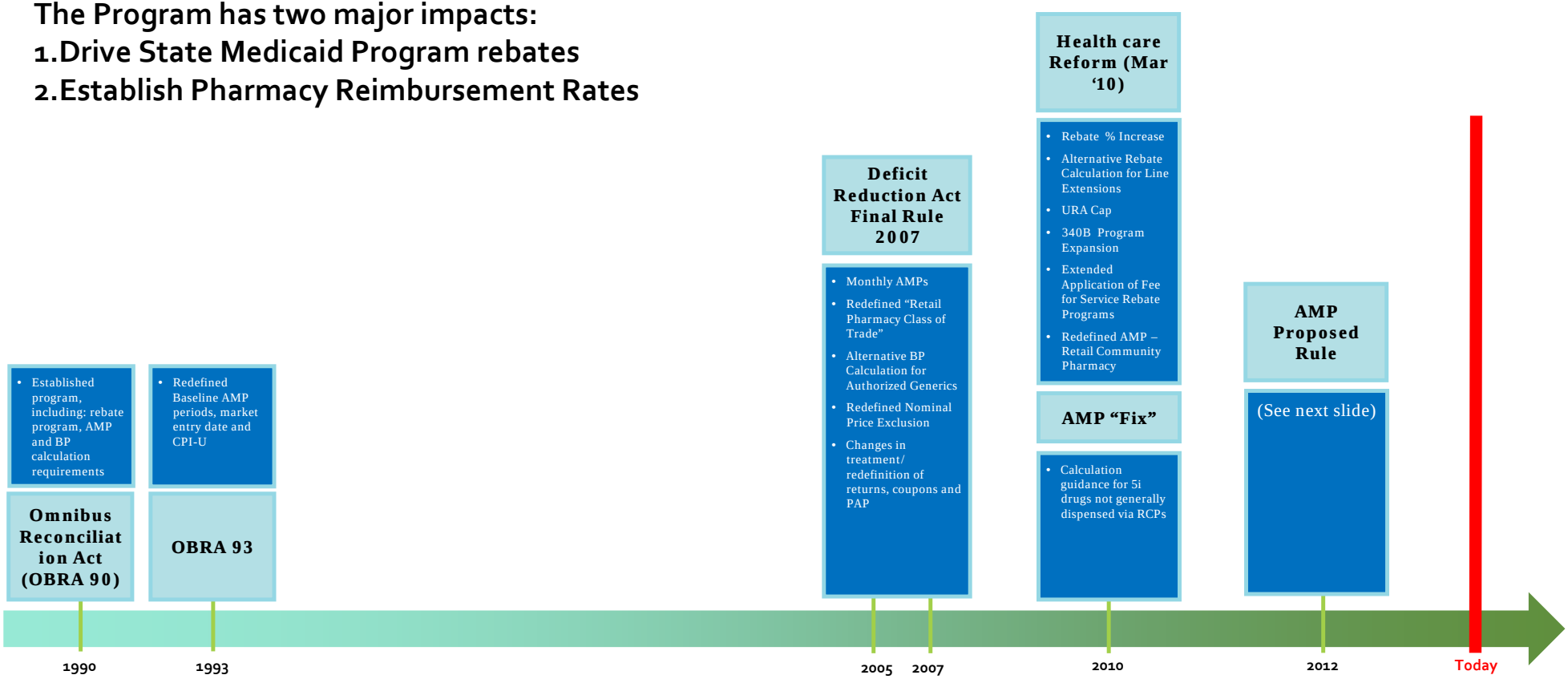
MDRP Final Rule – Key Issues

Medicaid Drug Rebate Program



Medicaid Drug Rebate Program – 25 Year History

The Program has two major impacts:
1. **Drive State Medicaid Program rebates**
2. **Establish Pharmacy Reimbursement Rates**

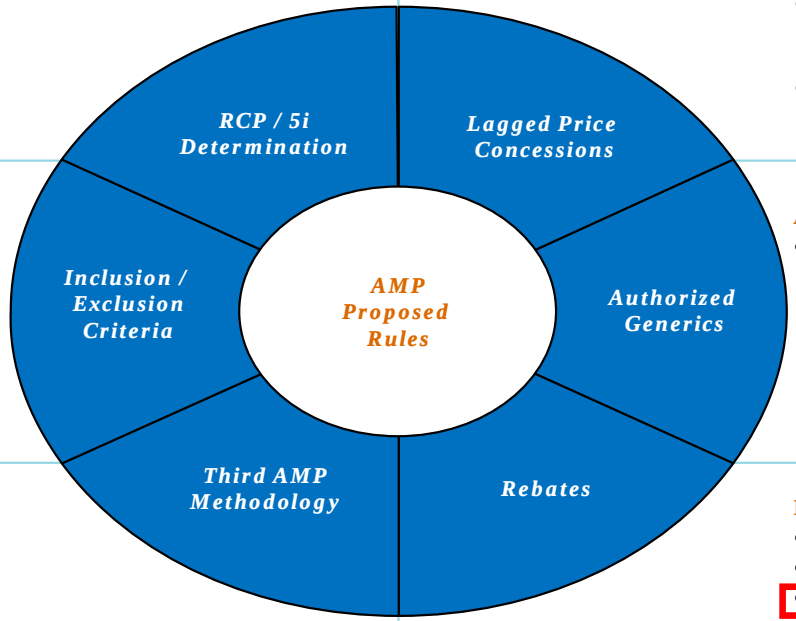


MDRP Proposed Rule – Impacted Methodology Consider

RCP / 5i Determination
- Routes of administration
- Not Generally Dispensed

Inclusion / Exclusion Criteria
- Default Rule
- US Territories
- BP 340b exclusions
- PPD to "Wholesalers"
- RCP Definition
- Nominal Price
- Bundle definition
- Fair Market Value

Third AMP Methodology
- Instances where the drug does not fit the 5i definition and is also not generally dispensed through the RCP channel



Lagged Price Concessions
- Discounts, rebates that may not be available during the rebate reporting period
- ASP Smoothing methodology

Authorized Generics
- Primary manufacturer inclusion of AG sales to the secondary manufacture in its AMP calculation

Medicaid Rebates
- Revisions to base date AMP
- Ability to maintain two base AMPs
- Line Extensions / Oral Solid Dose

Policy | Process | Controls | Technology

MDRP Proposed Rule – Considerations

- Timing?
  - Published within 90 days of the agency sending the rule to OMB
  - No earlier than January 2015
  - Implementation timeline – DRA Final Rule published July '07; effective Oct '07
- Preparation / Setting the context for Leadership
  - Methodology decisions – engaging legal, business & GP
  - Systems – implementation timeline
  - Processes – redesigning supporting business processes to provide new "data" to GP

Miree Lee

Public Health Service 340B Program

Overview of the 340B Program

- Section 340B of the Public Health Service Act
- Participation is required if participating in the MDRP
- Managed by OPA of the HRSA
- Manufacturers must:
  1. Calculate quarterly 340B ceiling prices for covered outpatient drugs
  2. Make available covered outpatient drugs to "covered entities"
- Types of Covered Entities include:
  - DSH Hospitals
  - Children's Hospitals
  - Freestanding Cancer Hospitals and other hospital types
  - Various types of federal grantees and designees

Orphan Drug Rule

- PPACA, Orphan Drugs, and New Covered Entity Types
- Legal Challenges
  - July 2013 HRSA Rule
    - 340B and non-orphan indication
  - October 2013 PhRMA filed suit
  - May 2014 Court invalidated the HRSA rule
  - July 2014 HRSA issued "interpretative rule"; PhRMA asked the court to strike down
  - August 2014 Court denied PhRMA's request
  - October 2014 PhRMA Filed a new lawsuit
- HRSA Letters of "Non-compliance" to Manufacturers

Covered Entities and Contract Pharmacies

- In-house dispensation vs. contract pharmacy
- More than 15,000 contract pharmacy locations with 35,000+ contract pharmacy arrangements with 340B entities
- Manufacturer challenges and concerns:
  - Bill to vs. ship to
  - Contract pharmacy replenishment model
  - GAO: "Increased use of the 340B program by contract pharmacies and hospitals may result in a greater risk of drug diversion…"

Duplicate Discounts

- Covered entities must have system in place to prevent duplicate discounts (Medicaid rebate and 340B discount on same drug)
- Manufacturer Concerns:
  - OIG: "Contract pharmacy arrangements create complications in preventing diversion [and]…duplicate discounts."
  - Managed Medicaid rebate utilization and 340B dispensaries

Other 340B Compliance Considerations

- Non-discrimination and "must sell" provision
  - May 1994 guideline in Federal Register and May 2012 guidance
- Penny pricing and allocation
  - November 2011 guidance
- Audits
  - HRSA
    - As of September 2014, HRSA has published audit findings for 82 entities
  - Manufacturer
    - Duplicate discounts
    - Diversion

Avril McKean Dieser and Elizabeth Lindquist

Service Fee Analysis/Compliance

Analysis of Service Fees

- An important part of compliant and accurate government price reporting is distinguishing between
  - Legitimate fees for service that may be omitted from the prices reported, and
  - Actual or constructive price concessions characterized by customers or intermediaries as "service fees" or "administrative fees"

Definition of *Bona Fide* Service Fees

- CMS' Definition of *Bona Fide* Service Fees
  - The fee paid must be for a *bona fide* (something of value), itemized service that is actually performed on behalf of the manufacturer;
  - The manufacturer would otherwise perform or contract for the service in the absence of the service arrangement;
  - The fee represents fair market value for the services rendered; and
  - The fee is not passed on, in whole, or in part, to a client or customer of any entity.

Definition of *Bona Fide* Service Fees

- Affordable Care Act ("ACA") § 2503(a)(2)(B)(i)(II)
  - "*Bona fide* service fees paid by manufacturers to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs)" are excluded from AMP.

Definition of *Bona Fide* Service Fees

- ACA Proposed Rule – Proposed § 414.802
  - *Bona fide service fee* means a fee paid by a manufacturer to **wholesalers or retail community pharmacies**, that represents fair market value of a *bona fide*, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement and that is not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug. **The fee includes, but is not limited to, distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative service agreements and patient care programs (such as medication compliance programs and patient education programs).”**

Reach of the BFSF Test

- Not all service fees are subject to the BFSF test in the first place
- While the regulation defines the fees payable to any "entity" as subject to the test, this is clearly not the case
- Must have a **logical nexus** with the price
- Generally fair to say that only fees paid to entities in the chain of distribution or payment are subject to the test

Price Reporting Risk

- The obvious risk is that your company (or worse, an outside investigator) will determine that you either *failed to apply* or *misapplied* the BFSF test
- Medicaid rebate liability, potential Part B liability, potential False Claims Act liability, potential liability for the individual who certified
- Vigilance, rigorous internal analysis and prompt correction/self-reporting are key

Enforcement Risk

- Prosecutors have said that they will not hesitate to look beyond the "four corners" of a service agreement to determine the true nature of the fees
- That means e-mails, other contemporaneous communications, interviews with negotiators, even sworn testimony

Recommendations

- Review existing arrangements
- Catalog itemized services
- Evaluate for need, FMV, and retention
- Document process and conclusions
- Consider need for recalculation/resubmission
- Not all fees are or need be *bona fide*, but this analysis must be undertaken
- Establish policies and procedures for early review and analysis of proposed service fees
- Educate managed markets and other service fee contracting teams about government pricing impact for current and future reference

Questions?