16th Annual Pharmaceutical Regulatory and Compliance Congress

Government Price Reporting for Compliance Officers

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October 21, 2015

KING & SPALDING

Agenda

- Introduction to Government Price Reporting
- Compliance Best Practices
- Medicaid and 340B Change on the Horizon
- Other Areas That Deserve Your Attention

Introduction to Government Price Reporting

- What is government price reporting?
  - As a condition of participation in potentially enormous government markets, manufacturers assume price reporting obligations
  - Determining government discounts, purchase prices, reimbursement amounts or manufacturer-supplied rebates with reference to domestic commercial sales
  - Almost all pharmaceuticals and biologics
  - Significant federal and state monthly, quarterly and annual reporting obligations; infrastructure required
  - Not price or WAC setting, but assessing the government liability impact of commercial pricing decisions
  - Intersection of law, business and policy

Introduction to Government Price Reporting

- Relevant Government Programs
  - Medicaid Drug Rebate Program
    - Average Manufacturer Price
    - Best Price
    - Unit Rebate Amount
  - Medicare Part B
    - Average Sales Price
  - VA/FSS/TRICARE
    - Non-Federal Average Manufacturer Price
    - Tracking Customer Price
  - 340B Drug Discount Program
    - Ceiling Price

Introduction to Government Price Reporting

- High risk area
  - Exclusion from government program participation
  - Civil lawsuits
  - High dollar Medicaid rebate implications
  - Subject to increasing scrutiny, particularly as federal programs expand
  - Customer price sensitivity to reimbursement fluctuations
  - Commercial implications of complaint strategies
  - Criminal prosecution
- Particular risk for certifying officer

Introduction to Government Price Reporting

- Available price reporting authority:
  - Statutes
  - Regulations
  - Medicaid Rebate, VA and 340B Agreements
  - Sub-Regulatory guidance, *e.g.:*
    - Medicaid Manufacturer Releases
    - 340B Policy Releases
    - Part B FAQs
  - OIG opinions
  - Individual communications with regulators
  - Reasonable assumptions
  - *Very* little judicial precedent

Introduction to Government Price Reporting

- Principles when there is contradictory or no authority on point
  - Accuracy
  - Financial impact on government health programs
  - Consistency
- Options when there is contradictory or no authority on point
  - Look to industry practice
  - Maintain/disclose assumptions
  - Make a request for guidance (direct? blinded?)

Compliance Best Practices

- Create and maintain thoughtful policies and procedures
  - Their very creation will require in-depth self-assessment of approaches and risks
  - The P&Ps are your first line of defense in the event of an investigation or inquiry
  - Maintain logs or updates to indicate changes in approaches over time
- Audit and monitor
  - Regular checks on policies, systems, procedures will identify weaknesses/concerns long before they come to the attention of regulators
  - In-house audit and outside firms with specialized knowledge

Compliance Best Practices

- Champion out of the ordinary compliance initiatives
  - Service and administrative fee review and evaluation
  - CoT review and update
  - Policy review and update
  - Bundle identification and allocation
  - Comment drafting and submission
  - Patient assistance program review and improvement
  - Data integrity

Compliance Best Practices

- Become educated about the basics of GP
  - No need to become an expert
  - But don't be afraid to put yourself in a position to issue spot
- Support staffing the GP function and legal personnel
  - Talent in GP is difficult to find and almost impossible to create outside of the context of a sophisticated GP operation
  - Investment in these people will pay dividends
- Support GP systems infrastructure and IT

Medicaid and 340B Change on the Horizon

- Medicaid AMP Final Rule likely to be published in the next few weeks/month
  - Proposed Rule pending since 2012
  - Very significant program changes likely
  - Many have already begun implementation efforts
  - MDRP issues in play are too voluminous to list here (*e.g.*, 5i AMP, line extensions, territories, bundle definition, SPs = RCPs?, "original" NDA)
  - May see a short turnaround effective date
  - Legal challenges to elements of the Final Rule?

Medicaid and 340B Change on the Horizon

- 340B Final Rule pending
  - Calculation of Ceiling Prices and Manufacturer Civil Monetary Penalties
  - Comment period closed August 17
- 340B Proposed "Mega" Guidance Released
  - Comments due October 27
  - Broad set of HRSA interpretive guidance on many aspects of the 340B Program
- 340B Orphan Drug Ruling October 14
  - HRSA's overreach on 256b(e) rejected by USDC
  - Immediate effects for manufacturers of orphan-designated drugs
  - Broader questions about final agency action and agencies' right to expand on legislative language

Other Areas That Deserve Your Attention

- Service fee evaluations
- Bundle identification and allocation
- Discounting and the AKS
- New rule/guidance implementations
- Restatements
- 340B refunds to/from covered entities
- Adherence to VA contract terms
- Marketing on the spread
- Determinations of when a GP issue rises to the level of a "reportable event"

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John Shakow is a nationally-recognized expert in all aspects of drug pricing and price reporting. He has counseled pharmaceutical and biotechnology clients on their rights and obligations under the Medicaid, Medicare, Federal Supply Schedule, 340B and TRICARE programs for almost twenty years. John regularly advises manufacturers on the spectrum of regulatory, commercial and litigation matters relating to pricing and government payor programs. He has extensive experience helping clients resolve commercial, strategic, organizational and other legal challenges while maintaining the integrity of their government pricing compliance efforts.

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