Preparing for Government Intervention in Drug Pricing

24th Annual Pharmaceutical and Medical Device Ethics and Compliance Congress

October 2023

GOODWIN

CCC

ankura

Agenda

1. Introduction
2. Legislative Landscape
3. Preparing for Government Intervention
4. The Role of the Compliance Office

Section 1

Introduction

Speakers

Matthew E. Wetzel, JD

Partner
Goodwin Procter LLP

Matt Wetzel provides strategic counseling to pharmaceutical, biotech, medical technology, and diagnostic companies on a host of complex health laws and regulations, including federal and state fraud and abuse laws, Medicare and other coverage and payor requirements, patient privacy obligations, and transparency requirements, among other areas. Matt leads Goodwin Procter's Late-Stage Drug Development and MedTech practices and is the co-founder of the Goodwin Rare Disease Initiative, a hub for patient stakeholders, therapeutic and medical product developers, investors, and policy experts and providing educational, pro bono, and networking opportunities in the rare disease space. Prior to joining Goodwin, Matt served as Chief Compliance Officer of GRAIL; Deputy General Counsel of AdvaMed; and held an executive legal and compliance role at a multinational medical device maker. Matt also serves on the Board of Directors of the American Health Law Association.

Chris Coburn, MS

Principal Business Consultant
Chris Coburn Consulting, LLC

Chris Coburn works closely with pharmaceutical manufacturers in areas related to the management of government programs, including policy review, methodology development, policy and procedure documentation, systems implementation, and class of trade and related commercial systems. He supports manufacturers as they work with the federal government in self reports, restatements, and investigative activity. He has also worked closely with compliance and audit departments to develop monitoring and audit plans and in conducting wholesaler audits, vendor audits, and internal audits related to government programs. Chris specializes in helping businesses evaluate, assess, and prioritize risks, and helps them put practical and manageable compliance programs in place.

Speakers

Julie DeLong, CFA, CVA

Senior Managing Director
Ankura Consulting Group, LLC

Julie DeLong leads the Life Sciences Valuation sector at Ankura, advising biotechnology, pharmaceutical and medical device companies on the valuation issues they face. She routinely consults with life sciences clients to provide compliance guidance and supportable fair market value analyses in connection with the complex relationships underlying payments to and from customers. She provides fair market value assistance in the context of bona fide service fee assessments, arrangements with healthcare professionals, mergers and acquisitions, and litigation.

Disclaimer

The opinions expressed by the participants during this session are their own individual opinions and not those of the companies (or the clients) for which they work.

Objectives

The significant growth of Federally funded health care programs has brought increased scrutiny at the Federal and State levels. Legislative and regulatory efforts to control drug pricing – whether via the longstanding Medicaid Drug Rebate Program or the more recent Inflation Reduction Act's drug price negotiation program – add to the burden that compliance officers face. The role of the **Compliance Office** is evolving to provide objective and independent oversight for a manufacturer's policies in the area, as well as to support strategic decision making on Federal healthcare programs, and government pricing operations.

In this session we will lay the groundwork on why it is important to involve the Compliance Office in complying with government pricing requirements and discuss the role of the Compliance Office in establishing oversight and coordination of stakeholders across finance, contracting, market access, legal, etc.

Section 2

Legislative Landscape

Legislative Landscape

Participation in Federal healthcare programs offers manufacturers many benefits but requires compliance with complex and changing regulations.

- **Pharmaceutical manufacturers can significantly expand their reach through participation in Federally funded programs:**
  - Medicaid: 85.6 million participants
  - Medicare Part D: 51.6 million participants
  - 340B: greater than $100 billion (in WAC dollars)
  - VA: annual budget of approximately $68 billion with more than 9 million enrolled veterans
- **As the "Government Market" has dramatically increased, the focus on Compliance, Transparency in Pricing, and investigative scrutiny has also increased**
  - There has also been an increase in legislative action at the state and federal level, including many Congressional actions looking at pricing behaviors (i.e., 340B, Price Increases).
- **Each program is administered by a Federal Agency that promulgates regulations and guidance**
  - Regulations define monthly and quarterly statutory price reporting requirements.
  - The regulations continue to evolve, are very complex, and often subjective. Manufacturers have to develop calculation methodologies and develop "reasonable assumptions."
  - The calculations are driven by commercial activity (direct sales, indirect sales, rebates), so the decisions made by the commercial group directly impact the government's price.
- **The mandate of the OIG is to "protect the integrity of the programs"**
  - Published Recommendations for pharmaceutical manufacturers in 2003, which included defining the key risk area of The Medicaid Program integrity.
  - Where CMS and other agencies publish guidance, the OIG, and the DOJ provide compliance oversight and enforcement.
  - Under the OIG's annual work plan they have the mandate and authority to audit manufacturers.
  - The OIG is very focused now in payments and interactions with third parties, and how payments can impact the statutory price reporting, and hence the government's price.
  - The OIG can apply both the False Claims Act and the Anti-Kickback Statute; they often overlap in ways many in the organization may not understand (i.e., BFSF and business need).

Legislative Landscape

In the daily news are examples of the evolving regulations:

Inflation Reduction Act

- Drug price negotiation program
  - *Primary vs. Secondary Manufacturer*
  - *Price calculations*
  - *Detailed information required to CMS*
  - *Compliance with MFP Requirements – or face excise tax / penalties*
- Inflation-Based Rebates
  - *Inflation calculations*
  - *Process to verify and review demands for rebates*
- Redesign of Part D shifting coverage from the government to manufacturers and payers
  - *10-20% Discount*

CMS Proposed Changes to the Medicaid Drug Rebate Program Rule

- The proposed rule will require manufacturers to aggregate – or “stack” – price concessions in calculating best price
- Drug Price Verification Survey requirements

Section 3

Preparing for Government Intervention

What does it look like to be prepared?

The manufacturer will need to:

- Determine what “Compliance” is for your company in an evolving and sub-regulatory environment, where the rules are vague, and the risks are high.
- Evaluate current regulations and other authoritative guidance and apply it to the business, contracting and pricing to develop calculation methodologies and document reasonable assumptions.
- Demonstrate an appropriate level of due diligence to make objective reasonable assumptions, and review these with management, as well as legal counsel where appropriate.
- Consistently apply the calculation methodologies.
- Have robust policy and procedure documentation.
- Periodically perform independent assessments or audits to ensure that the calculations are accurate, and any potential mistakes can be proactively corrected with the various agencies.
- Don’t be afraid to be transparent, ask agencies when appropriate, or state assumptions. And document your communications.

Key Areas of Compliance and Audit Focus

Area	Description
Bona Fide Service Fee Evaluation	Evaluate the agreements in place with third parties to determine that an appropriate level of due diligence has been performed to determine treatment of the fees in the statutory pricing calculations, and how decisions are made on whether a payment is included or excluded
Pricing Committee	Evaluate the process for determining price increases and the approval of agreements. Ensure that there is appropriate evaluation by the experienced functions to understand the impact across all Government Pricing, Transparency Reporting and now the IRA.
Class of Trade	Determine the class of trade schema, the process of assigning COT, and the accuracy of COT in the customer master
Calculation Methodologies	Determine if the calculation methodologies are current with guidance, reasonable assumptions are well documents, and appropriate due diligence and/or legal review is performed on key areas
System Testing	Determine if the calculation methodologies are accurately configured in the system performing the calculations (often involves a parallel calculation)
Transactional Testing	Sample transactional data for correct treatment in the system according to the methodologies
Bundling	Are there any agreements in place that are a potential bundled arrangement, if so, how are they being allocated
Prompt Payment	Are Prompt Payments being treated accurately in the calculations
Coupon/PAP programs	Are coupon programs and PAP programs appropriately included/excluded
Product Master in DDR and FDA	Is the CMS DDR Product Master accurate, and does it align the FDA database
340B Validation	Have 340B transactions been accurately identified and excluded in the calculations
Product Acquisition	Are products treated accurately in Product Acquisition transition

Section 4

The Role of the Compliance Office

The Role of the Compliance Office

OIG compliance guidance highlights the importance of including government price reporting in the overall compliance program.

"…of all the potential risk areas, the OIG has identified three major potential risk areas for pharmaceutical manufactures: (1) Integrity of data used by state and federal governments to establish payment…."

"Given the importance of importance of the Medicaid Rebate Program, as well as other programs that rely of Medicaid Rebate Program benchmarks (such as the 340B Program), manufacturers should pay particular attention to ensuring that they are calculating Average Price and Best Price accurately and they are paying appropriate rebate amounts for their drugs.

In sum, pharmaceutical manufacturers are responsible for ensuring the integrity of data they generate that is used for government reimbursement purposes."

The Role of the Compliance Office

OIG compliance guidance recommends manufacturers implement seven elements for an effective compliance program:

1. Implementing written policies and procedures
2. Designating a compliance officer and compliance committee
3. Conducting effective training and education
4. Developing effective lines of communication
5. Conducting internal monitoring and auditing
6. Enforcing standards through well-publicized disciplinary guidelines
7. Responding promptly to detected problems and undertaking corrective action

The seven elements have been applied to CIAs arising from price reporting allegations

Seven Elements and Two Enforcement Actions

OIG Compliance Guidance's 7 Elements of an Effective Compliance Program	Mylan 2017 CIA:	Sandoz 2021 CIA:
	In 2017, Mylan entered into a CIA following alleged violations of the False Claims Act.	In 2021, Sandoz entered into a CIA following a DPA for generic drug price fixing.
Written policies and procedures	Requires written policies and procedures on the operation of the compliance program.	Requires written policies and procedures on the operation of the compliance program.
Designated compliance officer and compliance committee	Must maintain a compliance officer over the term of the CIA and appoint a Compliance Committee consisting of senior executives in relevant departments such as government pricing and contracting, human resources, audit, and operations.	Must maintain a compliance officer over the term of the CIA and appoint a Compliance Committee consisting of senior executives in relevant departments such as sales, marketing, legal, medical affairs, regulatory, HR, audit, finance, pricing, and operations.
Effective training/education	Training on the CIA requirements for owners, employees and contractors, as well as requirements of the Federal health care programs. Additional training for those involved in government pricing functions.	Annual training on the CIA requirements for owners, employees and contractors. Additional training for those involved in pricing and contracting functions on Federal health care program requirements.
Effective lines of communication	Requires a disclosure program where individuals can report to the Compliance Officer any identified issues with respect to Federal health care programs.	Requires a disclosure program where individuals can report to the Compliance Officer any identified issues with respect to Federal health care programs.
Internal monitoring/auditing	Annual risk assessment and internal review process to identify and address risks associates with government reimbursed products.	Establish an internal monitoring program to ensure pricing and contracting decisions are make in compliance with Federal health care program requirements. Results from internal monitoring reported to Compliance Officer.
Well-publicized disciplinary guidelines	(Not explicitly addressed)	(Not explicitly addressed)
Prompt response to and corrective action for problems	Investigate all issues disclosed and implement corrective action.	Investigate all issues disclosed and implement corrective action.

Performing a robust assessment of bona fide service fees is an important part of government price calculations

Qualitative Prongs

Itemized Service

- The level of detail in describing the service varies by contract, type of service, vendor, etc.

Actually Performed

- Often overlooked, but important.

On Behalf of the Manufacturer

- Factors to consider:
  - Does the vendor have an independent need to perform the service (e.g., by law)?
  - Who is driving the need for the service?
  - Is the service considered a core function of the vendor's business that it would perform in the absence of a fee?

The Manufacturer Would Otherwise Perform

- Speaks to the legitimate business need.

Not Passed On

- The preamble to the 2016 Final Rule provides that the manufacturer may presume a fee is not passed through by the recipient in the absence of evidence or notice to the contrary.

Quantitative Prong

Fair Market Value

- Assessed for each of the detailed services.

Potential Overlapping AKS Prong

Business Value

- Consider the business objective and whether a payment could be perceived as promoting prescribing behavior.

The CMS Bona Fide Service Fees Evaluation

An example of the overlap between Compliance, Legal, Finance and Commercial

- Compliance
  - Overall oversight of the process and documentation of the rational used.
  - Identify and contract with an experienced firm with solid fair market value credentials.
  - Oversees a consistent approach towards all key areas of fair market value, including the CMS four part test, arrangements with healthcare professionals, PAP administration, etc.
  - Evaluate potential AKS impacts, outside of the BFSF evaluation.
- Legal
  - Considers whether the evaluation of BFSF demonstrate effective due diligence.
  - Reviews what method of fair market value was employed and why, and what data was available (CMS does not define fair market value, but requires the analysis).
  - Maintain privilege as appropriate.
  - Considers whether there are other potential kickback concerns outside of the four part test, as in the business intent of the payment, and is it possibly inducing prescribing behavior.
- Commercial/Sales & Marketing
  - Actual knowledge of the customer and the agreement.
- Finance
  - Providing much of the data used for the analysis.
  - Final signoff on the methodology, as the certifier.
- Contract Operations
  - Must accurately capture and treat each payment in the various calculations.

Why is a Pricing Committee so important, and how should it function?

An example of the overlap between Compliance, Legal, Finance and Commercial

- Demonstrate independent and objective evaluation of potential Commercial arrangements and price increases
- Know the potential impacts of third-party arrangements and price increases
  - Best Price, Medicaid AMP and URA and CPI-U penalties (especially with the URA cap going away)
  - ASP customers being “under water” due to the 6-month lag
  - 340B Penny Pricing
  - VA/FSS impacts and inflation penalties
  - New IRA impacts on Medicare Part D CPI-U penalties
- Make sure that the pricing functions will know where the data is and what it will mean
- Document that the company is performing consistent due diligence and following policy, that all appropriate functions can be informed, and the decision made is best for the organization

Compliance Officer Concerns

- Internal company policies / regulations / agency guidance followed?
- Integrity of data collected, stored, and used to generate required reporting?
- Accuracy of reporting?
- Certifications / sub-certifications from senior management?
- Good data from third parties?
- Assumptions documentation?
- Government inquiries and disputes?
- New and evolving legal requirements?
- Complying with requirements under commercial and government agreements?

Matthew E. Wetzel, JD
Partner
Goodwin Procter LLP

+1.202.346.4208
mwetzel@goodwinlaw.com

Chris Coburn, MS
Principal Business Consultant
Chris Coburn Consulting, LLC

+1.207.841.1353
cccgprx@gmail.com

Julie DeLong, CFA, CV
Senior Managing Director
Ankura Consulting Group, LLC

+1.404.602.5021
julie.delong@ankura.com