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FEATURE

Back to Basics: Compliance Oversight of Government Pricing Programs

Where We Are Now and Where We Are Headed

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Summary: GPP compliance is an increasingly significant focus area for life science companies. However, although compliance functions are essential in guiding their organizations, many professionals struggle to appreciate GPP complexities and how best to effectuate that role. This article discusses those complexities and the role of compliance.

After more than 25 years working in the life sciences industry as a Government Pricing Program ("GPP") consultant, I see increasing awareness among compliance officers of the importance of effective compliance for these programs. Specifically, they are concerned that "they don't know what they don't know," so they turn to Helio and me to perform independent GPP compliance audits or assessments. This article explores why the role of the compliance function is essential to GPP compliance and some areas that life science compliance professionals should focus on.

Background

At the outset, GPP compliance has always been under the purview of in-house compliance functions. For example, in 2005, King Pharmaceuticals entered into a Corporate Integrity Agreement ("CIA") to resolve allegations of government pricing and federal False Claims Act ("FCA") violations.[2] At the time, it was one of the first major GPP-related agreements.

However, King's compliance department was intimately involved in the case from the beginning. In fact, after the whistleblower's initial complaint, the U.S. Department of Health and Human Services Office of Inspector General ("HHS-OIG") approached the company's compliance department. As a result, the compliance department had a crucial role in overseeing a four-year process to evaluate King's historical reporting for Medicaid and other government programs. Compliance also was involved in helping to negotiate the CIA's terms. King's experience is not unique, and many life science company compliance officers involved with CIAs have shared similar experiences.

As outlined in the CIA's preamble, King was required to continue operating its compliance program, which it voluntarily implemented before the CIA was finalized.[3] That program essentially mirrors the HHS-OIG's guidance on how pharmaceutical manufacturers should implement the Federal Sentencing Guidelines elements of an effective compliance program.[4]

Moreover, while the U.S. Department of Justice ("DOJ") eventually issued a press release about the case's resolution, indicating that the DOJ had not found intentional wrongdoing, the HHS-OIG essentially concluded that King failed to maintain appropriate processes and controls to ensure compliance with GPP requirements.[5] Thus, it became the compliance officer's responsibility under the CIA to ensure that the appropriate controls and oversight were implemented such that King could demonstrate that it had established a sustainable and meaningfully compliant GPP. King is only one example of CIAs and other government settlements involving government pricing.

Continued Focus on Government Pricing Programs

The HHS-OIG has a long history of focusing on GPP compliance. Ensuring the integrity of federal healthcare

programs (i.e., fighting fraud, waste, and abuse) is a fundamental reason for highlighting GPP compliance as an essential risk area. The HHS-OIG stated as much in the 2003 Guidance and again in the General Compliance Guidance recently issued in November 2023.[6]

Moreover, the HHS-OIG's mission is "to provide objective oversight to promote the economy, efficiency, effectiveness, and integrity of HHS programs."[7] The Agency fulfills its mission primarily through audit and investigative activity. Therefore, as federal healthcare programs have grown, so has the level of scrutiny on the total amount the government spends on these programs and the prices paid for products under these programs.

Government Impact on Pharmaceutical Spending

For some context, in 2022, the total overall spending on pharmaceutical products in the U.S. exceeded $574 billion.[8] A significant percentage of this flows through government payors and providers. Consequently, more than half of all Americans see some drug benefit under one of the following programs:

- Medicaid: over 90 million participants
- Medicare Part D: 65 million participants
- 340B: greater than $100 billion (in WAC dollars)
- Veterans' Affairs (VA): annual budget of approximately $68 billion with more than 9 million enrolled veterans.[9]

Both in terms of dollar amounts and participant impact, it is self-evident why the government is concerned about fraud, waste, and abuse, and specifically, drug pricing under the various government programs.

FCA as the Primary Enforcement Tool

The federal False Claims Act ("FCA") is the government's primary enforcement tool for GPPs. Initially enacted in 1863 to address unscrupulous military contractors supplying the Union army with shoddy goods, the FCA, also known as Lincoln's law, provides a mechanism for the government to recover civil penalties for false or fraudulent claims presented to the government for payment or using a false record or statement in connection with such a claim.[10] While the government ultimately must establish that a manufacturer knowingly made the payment requests, that is not required to commence an investigation.[11] As emphasized in the King situation, manufacturers must have effective controls and processes to ensure accurate statutory price reporting.

In the past, the government's FCA focus was on the prices charged for products. This was certainly true during my military experience with defense procurement. However, with the continued growth of government spending on pharmaceutical products, the focus has evolved into the broader context of government pricing.

The theory is simple. By participating in GPPs, drug manufacturers gain significant market access in the U.S. because of the substantial amount of pharmaceutical spending covered by government payors and providers. In exchange for this access, these manufacturers have monthly and quarterly reporting obligations to the federal government that essentially establish the "government price" based on requirements defined by government regulations and operationalized by each manufacturer in calculation methodologies. These calculation methodologies, in essence, adapt the government requirements to the manufacturer's business and commercial practices. If the manufacturers' inaccurate price reports result in federal healthcare programs paying more for drugs than they should, this potentially becomes an FCA issue.

While the scrutiny on the integrity of price reporting is high, the regulations and guidance on what manufacturers must do for their price reporting are vague. Thus, the rules are subject to various interpretations and can be challenging to apply to specific business scenarios (Table 1).

GPP Compliance

Unlike manufacturing compliance, where the U.S. Food and Drug Administration ("FDA") evaluates if drugs meet specific manufacturing requirements, manufacturers must develop individual methodologies and approaches to complete the required price reports for GPPs. For example, the Centers for Medicare and Medicaid Services ("CMS") used the term "reasonable assumptions" more than 85 times in the most recent Average Manufacturer Price ("AMP") regulations.[12] Thus, manufacturers must make reasonable assumptions about their approach and interpretation of guidance in lieu of following specific mandated guidance.

TABLE 1: *Snapshot of Government Programs and Requirements*

Program	Population	Operational Details
Medicaid (and Medicaid Managed Care Organization MMCO coverage)	• State-administered program providing outpatient-based drug benefits to the financially needy (all ages). • Serves over 85 million Americans	• Manufacturers calculate and report Monthly Average Manufacturing Price ("AMP"), and Quarterly AMP and Best Price ("BP"). • Manufacturers pay quarterly rebates to the states, the rebates are based upon the Unit Rebate Amount ("URA"), calculated from the reported AMP and BP.
Medicare D (optional participation by the Manufacturer)	• Outpatient-based prescription drug benefit for the elderly. • Serves 51.6 million, expected to increase to 80 million by 2030.	• Manufacturers participate in plans, providing rebates based on utilization. • Manufacturers currently also pay 70% during the coverage gap (subject to change under the Inflation Reduction Act).
Medicare B	• Reimbursement to physicians for drugs administered to Medicare patients in the physician's office.	• Reimbursement to physicians is typically equal to 106% of volume-weighted Average Sales Prices ("ASPs") within the payment code.
340B Drug Discount Program	• Provides covered outpatient drugs at reduced pricing to eligible 340B covered entities	• Manufacturer inputs the Quarterly 340B/Public Health Service ("PHS") price into 340B Office of Pharmacy Affairs Information System ("OPAIS"). • Eligible entities purchase from wholesalers at the 340B price (Manufacturer receives a chargeback).
VA/Federal Supply Schedule ("FSS")	• Mechanism for the federal government to purchase drugs at discounted prices	• Manufacturer calculates and reports Quarterly and Annual (Non-Federal Average Manufacturer Price ("NonFAMP") and Annual Federal Ceiling Price ("FCP"). • Eligible entities purchase from wholesalers at the FSS or FCP price (Manufacturer receives a chargeback).
TRICARE Retail Pharmacy Program ("TRRx")	• A program that provides outpatient pharmacy services to TRICARE beneficiaries.	• Drugs dispensed by the TRRx are subject FCP limitations. • Manufacturers pay quarterly TRICARE rebates

The lack of precision emphasizes the need for compliance functions to ensure manufacturers can show effective due diligence, supporting clear and objective pricing determinations in their calculation methodologies. Doing so requires that manufacturers, with the support of their compliance functions, demonstrate that they have:

- Evaluated current regulations and other authoritative guidance and applied it to the business, contracting and pricing to develop calculation methodologies, including documenting reasonable assumptions.
- Conducted an appropriate level of due diligence to make objectively reasonable assumptions and reviewed these assumptions with management and legal counsel where appropriate.
- Consistently applied calculation methodologies.
- Established robust GPP policies and procedures.
- Periodically performed independent assessments or audits to ensure that the calculations are accurate and any potential mistakes can be proactively corrected with the various agencies.

Compliance departments are not expected to be GPP experts. However, they should have an essential oversight role connecting various organizational stakeholders and ensuring effective and independent due diligence is performed, documented, and applied.

Furthermore, because the various GPP price points are interdependent, always taking an approach that favors the government concerning pricing and reimbursement (i.e., a conservative approach) can create unintended negative consequences. Bona Fide Service Fee ("BFSF") determinations of customer payments are a case in point.

Excluding a payment arrangement under a BFSF determination could increase the ASP by reducing the number of discounts on gross sales. However, it would also raise Medicaid AMP, the URA, and the 340B price, as fewer reductions would keep AMP and URA higher. Although increasing the URA may favor the government by generating larger rebate amounts to the states, it also increases ASP, potentially increasing the government's reimbursement costs for ASP products and increasing VA FSS and 340B prices.

As the BFSF example illustrates, pricing decisions must be made independently and objectively from reasonable assumptions, not the potential impact of specific approaches. Consequently, compliance officers should consider the essential focus areas below when operationalizing GPP compliance.

Staying Abreast of Current Regulatory Requirements & Developments

Given the complexity of GPP compliance and the potential penalties for missteps, manufacturers must maintain visibility on changes as regulations and guidance evolve. For example, the recent passage and ongoing implementation of the Inflation Reduction Act ("IRA") is bringing fundamental changes to ASP and Medicare Part B. Therefore, beyond maintaining a line of sight on these changes, compliance plays a crucial role in helping organizations understand the potential impact of those regulatory requirements on their business and operations.

Effective BFSF and Fair Market Value ("FMV") Determinations

CMS has published guidance on determining how each agreement and payment will be treated for BSFS purposes.[13] Commonly referred to as "the four-part test," a fee is a BFSF if the fee:

1. Represents fair market value,
2. The service is a bona fide, itemized service performed on the manufacturer's behalf,
3. The service is not something that the manufacturer would perform (or contract for) in the absence of the service arrangement, and
4. The fee is not passed on, in whole or in part, to a client or customer of the entity.[14]

Although the provisions are detailed, CMS has not defined what constitutes fair market value, leaving manufacturers to define it based on their reasonable assumptions.[15] Given the complexity of performing BFSF/FMV analyses and their importance, it is commonplace that these evaluations are undertaken by the compliance function with the assistance of specialized firms, such as Helio.

Evaluating Potential Anti-Kickback Statute Risk

The Anti-Kickback Statue ("AKS") establishes criminal and civil liability for "knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person … to refer an individual to a person for the furnishing … of any item or service" that is reimbursable under a federal health care program.[16] In 2010, Congress amended the criminal penalties section of the AKS, clarifying the connection between kickbacks and false claims.[17] Specifically, the amendment stated, "a claim that includes items or services ***resulting from*** a violation of this section [the AKS] constitutes a false or fraudulent claim for purposes" of the FCA.[18]

Therefore, even if a manufacturer undertakes a thorough BFSF review and religiously follows the CMS guidance, the FMV analysis may not completely insulate the manufacturer from AKS violations.[19] For example, indirect AKS risk can arise when evaluating the true business need and the value related to specific payment arrangements. Thus, compliance can play a critical role in evaluating potential AKS risks.

Robust GPP Policies and Procedures

As outlined by the Federal Sentencing Guidelines and the OIG's Compliance Program Guidance, robust compliance policies and procedures (i.e., written standards) are essential to an effective compliance program. They also improve business efficiency by establishing consistent, repeatable processes for employees, eliminating the need to "reinvent the wheel" when engaging in specific activities. Therefore, GPP written standards that guide day-to-day operations are crucial. Compliance can play a significant role in developing these standards, evaluating their application, and keeping them current.

GPP Calculation Methodologies

As part of any GPP written standards, organizations must maintain precise and current pricing methodologies. Methodologies must be documented and traceable from the source data through the algorithms, including sorting and filtering, generating the calculations. They also must clearly outline any reasonable assumptions. Finally, the methodologies must address complex situations such as bundling and stacking (e.g., rebates, discounts, or price concessions conditioned on additional purchase requirements). As noted previously, compliance can ensure that the business and the lawyers review these methodologies and assumptions where appropriate.

Pricing Committees

As the BFSF example illustrates, holistically evaluating the potential impact of price increases, decreases, and contracting is extremely challenging. For example, organizations must understand that potential inflation penalties can dramatically increase the Medicaid Rebate and reduce the 340B price (sometimes as little as a penny).

Therefore, adapting the Compliance Committee model recommended by the HHS-OIG,[20] companies should establish a pricing committee comprised of compliance and other relevant GPP company stakeholders. Companies can include the pricing committee's duties as part of the overall Compliance Committee, create a subcommittee of the larger body, or maintain an independent committee. However, regardless of the organizational design, the pricing committee should be involved in evaluations and mitigating GPP compliance risks, including developing detailed work plans as appropriate. Moreover, we recommend that the compliance officer chairs the committee, which is consistent with their role.

Independent GPP Compliance Evaluations

Continuous improvement is another essential hallmark of effective compliance programs. Compliance programs are not static but must evolve as laws, regulations, and guidance change.[21] Therefore, manufacturers should conduct periodic independent assessments of GPP compliance. It doesn't matter how big or small the company is, whether it manufactures branded, generic, 100 drugs or one, GPP Compliance is on the government's radar, and it has to be on the company's.

Since compliance departments are not expected to be GPP experts, companies should utilize the services of an experienced third party to conduct an independent and objective review, including evaluating whether the company has implemented any recommended enhancements. Moreover, since many manufacturers outsource their GPP operations to vendors, the review should encompass their operations and practices because the company is ultimately responsible for certifying the activities conducted on their behalf. For example, we have observed issues with these vendors' Class of Trade ("COT") assignments, including a lack of transparency, insufficient documentation, and significant errors.

A key component of conducting these assessments is that manufacturers can identify and voluntarily self-disclose and remediate discovered gaps and errors to the appropriate regulatory authorities. Thus, companies should understand the established processes for making such disclosures, including their benefits and limitations.[22]

Conclusion

As recent events demonstrate, GPP compliance is increasingly on the radar of regulatory agencies. It also is appropriately on the radar of life science compliance professionals. However, because the area is exceedingly convoluted and complex, compliance departments should proceed cautiously and seek appropriate expert assistance to avoid potentially costly missteps.

References

1 Mr. Colburn is an experienced GPP consultant who provides GPP advisory services with Helio Health Group. Helio Health Group LLC is a life sciences professional services company providing consulting, technology-enabled services, and AI Solutions.

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3 *See id.* at 1-2.

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11 "Knowingly" also includes submitting claims in deliberate ignorance or reckless disregard of the truth.

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17 *See* 42 U.S.C. §1320a-7b(g).

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