



7 Strategies for Scaling Government Pricing Compliance



Foreword



Are you effectively navigating the complex landscape of government pricing compliance in the pharmaceutical industry? What risks are you unknowingly exposed to, and how can you mitigate them to ensure your company's growth and reputation?

With more than 100 million people enrolled in Medicare and Medicaid, the US government is the largest payer in the country. To scale and expand your access to these patients, you will have to navigate the labyrinth of government pricing protocols. A single misstep can lead to hefty financial and legal penalties, severely impacting your bottom line and risking irreparable damage to your brand reputation. It's a scenario no company can afford.

In this eBook, we'll share seven pivotal strategies to not only meet these unique compliance challenges but also use them as stepping stones for scaling your operations effectively and ensuring your pharmaceutical business is well-positioned for growth in a regulated environment.

Warm regards,

Sarah McClure

Vice President, Knowledge Management
RLDatix Life Sciences



The Anatomy of Government Pricing Compliance

Navigating government pricing in the pharmaceutical industry is a complex endeavor. It demands a deep understanding of various components that directly affect both pricing strategies and your ability to stay compliant.

These include:

- Calculation of government discounts or rebates
- Adherence to best price requirements
- Price reporting for covered outpatient drugs
- State and Federal compliance obligations
- Regular monitoring and updating of compliance policies
- Maintaining accurate and comprehensive records
- Training and educating staff
- Internal auditing and compliance assessments
- Effective data management and analysis
- Establishing a liaison with government agencies
- Responding to industry and regulatory changes
- Handling of government inquiries and audits
- Collaboration with legal and regulatory advisors
- Implementation of technology solutions for compliance

Government Pricing Glossary



Understanding the definitions and components of government pricing is a first step for anyone dealing with government pricing compliance. Each component plays a significant role in how drugs are priced and reimbursed in the U.S. healthcare system, directly impacting a company's revenue and compliance strategies.

Here are some definitions to be familiar with:

340B Drug Pricing Program: This program provides discounts to healthcare organizations that serve uninsured or low-income patients. Eligible organizations can purchase outpatient drugs at significantly reduced prices. It is also known as the Public Health Service (PHS) program.

Average Manufacturer Price (AMP): The average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade for the retail/standard AMP calculation. The 5i AMP is calculated using additional classes of trade. The use of the retail/standard or 5i AMP methodology should be determined each month by employing the not generally dispensed 70/30 formula. Both AMP calculations are used for Medicaid drug rebate purposes. AMP determines the rebate amount pharmaceutical companies owe to state Medicaid agencies. It is also used to establish the 340B/PHS price, making it a critical financial figure in government pricing.

Average Sales Price (ASP): The net quarterly average sales price of a drug, calculated by dividing revenue from a drug by the number of units sold. This calculation includes all discounts and rebates that are eligible for Best Price. ASP is used primarily in Medicare Part B to set the reimbursement rates for drugs administered in a physician's office or hospital outpatient department.

Best Price (BP): The lowest commercially available price from the manufacturer during a quarter within the United States. BP is used in calculating Medicaid rebates and ensures that Medicaid is offered prices comparable to the most favorable prices in the market.

Contractual Adjustments: Refers to negotiated discounts or price reductions between manufacturers and purchasers, often impacting final pricing decisions.

Group Purchasing Organizations (GPOs): These entities negotiate prices on behalf of healthcare providers, impacting the overall pricing structure within the pharmaceutical industry.

Manufacturer's Rebates and Discounts: Incentives offered by manufacturers to purchasers, which can affect the net price of pharmaceutical products.

Medicaid Drug Rebate Program: This program requires drug manufacturers to provide discounts to state Medicaid programs for each unit of covered medication dispensed to Medicaid patients.

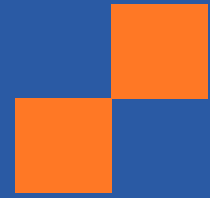
Medicare Part B Coverage: Covers drugs that are typically not self-administered, such as those given in a doctor's office.

Penny Pricing: This rule reduces a drug's ceiling price to one cent per unit for the 340B/PHS price. It is usually triggered when a drug's price increases faster than inflation, ensuring manufacturers provide substantial discounts to keep costs low for 340B/PHS patients.

Veterans Health Care Act: This act includes provisions for pharmaceutical pricing agreements and discounts for federal agencies, including the Department of Veterans Affairs.

Note: Programs like the Medicaid Drug Rebate Program, Medicare Part B, the 340B Drug Pricing Program, and the Veterans Health Care Act have unique rules and implications. You will want to become familiar with each program to ensure comprehensive compliance

Medications Reporting Requirements



Knowing what qualifies as a covered outpatient drug is also critical. Understanding National Drug Codes (NDCs), FDA approvals, and exclusions is crucial for ensuring compliance. Here's a breakdown of the drugs you must report on.

Covered Outpatient Drugs include:

- Any prescribed or over-the-counter drug that possesses an NDC
- Includes only drugs approved for safety and effectiveness as a prescription drug by the FDA
- Drugs sold in the US as an outpatient product
- Is a biological product other than a vaccine that may only be dispensed upon a prescription and is licensed under the Public Health Service Act (PHSA) and is produced at an establishment licensed under the PHSA to produce such product; or
- Insulin, certified under section 506 of the FFDCFA

Covered Outpatient Drugs do NOT include:

- A covered outpatient drug does not include any drug, biological product, or insulin provided as part of or incident to and in the same setting as any of the following services and for which payment may be made as part of that service instead of as a direct reimbursement for the drug:
 - Inpatient Services;
 - Hospice Services;
 - Dental Services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs;
 - Physician services;
 - Outpatient hospital services;
 - Nursing facility and services provided by an intermediate care facility for individuals with intellectual disabilities;
 - Other laboratory and x-ray services; or
 - Renal dialysis.
- Any drug, prescription or over-the-counter (OTC) for which the FDA does not require an NDC number
- Any drug for which a manufacturer has not submitted to CMS evidence to demonstrate that the drug satisfied the criteria
- Any drug or biological used for a medical indication that is not medically accepted
- Over-the-counter products that are not drugs

Your Compliance Toolbox

What are the activities and processes you will need to put into place to manage government pricing practices and policies adequately? Here's a list of the processes and tools you will need to put into place to manage government pricing compliance successfully:

Product Review Process:

Be sure you are conducting regular audits to ensure that your product information is aligned with what you submit to both the FDA and CMS (Medicare and Medicaid). Monitor and manage regularly to ensure there are no discrepancies. Reviews should include product attributes such as the unit of measure (UOM), unit per package size (UPPS), product market date, baseline CPI, and baseline AMP — all of which impact government pricing calculations. Ensure you are reporting on inner package sizes that have an NDC. Evaluate and review acquired products to verify compliance and determine federal program liability.

Class of Trade (COT) Management:

Review customer databases and their assigned classes of trade (COT) on an ongoing basis to ensure you are maintaining the correct COT for customers. COT inclusions and exclusions impact the government pricing calculations so ensure you are maintaining the COT methodology accurately.

Reconciliation Process:

You will also want to reconcile transactional data used in the government pricing calculations against your accounting system to identify and address any variances. Every month, once the accounting system has closed for the month, you will want to reconcile your transactional data, including direct sales, direct sales adjustments, chargebacks, and rebates. Then, document that reconciliation to verify you have utilized all the relevant transactions in the government pricing calculations — and document variances and the reasons for them.

340B Entity Review & Validation:

Reviewing all 340B entity purchases will help ensure you don't have revenue leakage or unintentionally set a new, lower best price. You will also want to be sure all entities are actually eligible for the 340B price and validate that wholesalers are providing accurate information. (Tools such as our RLDatix Life Sciences 340B Validation Tool make this easy.)

A Revenue Management System (RMS):

All of the above becomes simpler if you are using a Revenue Management System, such as RLDatix Life Sciences' RMS solution. By automating commercialization and compliance processes, you can reduce errors, save time, and ensure accuracy for Best Price reporting, calculation of AMP, verification of Medicaid inflation rebates, maximizing ROI, and more. A revenue management system also ensures data accuracy and establishes audit trails to save you problems down the road.

A Great Revenue Management System Will Include Features Such As:



Chargeback Processing Tool (Chargeback Payer): to help with validation, reconciliation, disputes, payment, and notification.

Rebate Calculation Tool (Rebate Payer): to manage commercial rebate and incentive-based contracts, including calculations based on direct and indirect sales, net sales, utilization, and more.

COT Assignment Tool: to manage customer COTs and assign COTs to new customers.

Government Pricing: a transparent solution to calculate, analyze, and maintain your government pricing calculations including, AMP, ASP, URA, PHS, BP, and NFAMP.

Gross-to-Net functions: to aid in calculating current and future accrual reserve figures — including channel inventory and forecasting.

Medicaid Payer: to manage disputes, adjustments, payments, and compliance with states.

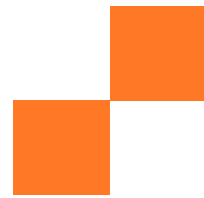
Medicare Gap D Payer: to manage the Coverage Gap Discount Program rebates, and let you automatically load, validate, and pay invoices submitted by the TPA at the summary and detail level.

340B Validation Tool: to review and maintain 340B/PHS purchaser transactions and customer databases which will aid in limiting revenue leakage and ensure a new, lower best price has not been established.

State Price Transparency Reporting: to manage state price and new product reporting requirements and ensure compliance.

Advanced Reporting and Analytics: to leverage your commercial and government contract and transactional information to assist in managing revenue, compliance, financial reporting, sales analysis, commercial strategy development, and ensure compliant commercialization.

7 Strategies for Managing Government Pricing Compliance



Here are seven strategies we consider fundamental best practices for managing government pricing (GP).

01

Implement Quarterly and Monthly GP Checklists: Implementing checklists for monthly and quarterly tasks is essential for staying on top of government pricing (GP) compliance. These checklists should cover all the necessary steps for Medicaid and Medicare pricing compliance. They act as a guide to ensure all required actions are taken consistently and thoroughly.

02

Establish Written Policies and Procedures: Develop detailed Standard Operating Procedures (SOPs) and policies that clearly outline the processes for monthly and quarterly compliance activities. These documents should assign specific responsibilities and be regularly updated to reflect changes in employees or internal processes as well as regulatory changes. They should be living documents, accessed and reviewed regularly, and should reference the checklists mentioned above.

03

Boost Employee Compliance Awareness: Foster a culture of compliance within the organization. This involves educating all employees, not just those in the compliance team, about the importance of compliance and their role in it. Regular training and updates can help maintain a high level of awareness and understanding across the company.

04

Open Up Intercompany Communication: Encourage open communication between different teams, such as the Compliance Committee, pricing committee, and sales team. Breaking down silos and facilitating dialogue among these groups ensures a unified approach to compliance and better understanding across departments.

05

Conduct Internal Audits Regularly: Conduct internal audits regularly to review and verify compliance processes. By auditing your own procedures quarterly or annually, you can identify and address issues proactively rather than waiting for external audits.

06

Enforce Your Standards: Maintain consistency in applying and enforcing compliance standards. This includes documenting the steps taken during monthly and quarterly processes. Any discrepancies or variances should be thoroughly documented and included with the relevant calculations.

07

Respond to Detected Problems and Take Corrective Action Promptly: When issues are identified, either through internal audits or routine checks, it's crucial to respond quickly and effectively. Implement corrective actions as soon as possible to rectify any non-compliance issues and document these actions for future reference and learning.



Maximize Your Pharmaceutical Compliance and Growth with RLDatix Life Sciences Revenue Management

By understanding and implementing these best practices, your organization can not only avoid the pitfalls of non-compliance and hefty civil monetary penalties but also position itself to better support continued growth and operational efficiency.

Ready to explore these strategies in more depth and discover how RLDatix Life Sciences Revenue Management platform and professional services can help transform your compliance journey into a strategic asset?



Our collective mission is to
empower our customers to
overcome challenges and drive
better results for
compliant commercialization.

Contact Us

100 Southgate Parkway, Suite 101
Morristown, NJ 07960

info@rldatixlifesciences.com
www.RLDatixLifeSciences.com