

ANNUAL GOVERNMENT PRICING COMPLIANCE CHECKLIST

At least once a year, you should focus on strategic planning for compliance, ensuring your organization not only maintains compliance but also aligns its compliance strategies with growth objectives. What does that look like? Check out our Annual Compliance Process Checklist below!



Review the Regulatory Landscape:

Analyze changes in the regulatory landscape and assess their impact on compliance strategies.



Evaluate your Compliance Program:

Review the effectiveness of the existing compliance program and identify areas for improvement.



Assess your Technology and Solution:

Evaluate your current technology solutions for compliance (e.g., RMS) and if they are not meeting the mark, consider upgrades or new solutions to enhance efficiency.



Refresh Employee Training and Awareness Program:

Revisit and update training materials and programs to reflect the latest compliance standards and best practices.



Enhance Intercompany Communication:

Plan for improved communication channels between your compliance, pricing, and sales teams to ensure a cohesive approach.



Assess Progress against your Long-term Compliance and Growth Strategy:

Develop and update your long-term strategies to integrate compliance as a key component of the company's growth and expansion plans.



Use this annual checklist to stay ahead of compliance and keep your organization on track as you scale. To follow best practices, you'll want to implement a comprehensive Revenue Management System, such as the RLDatix Life Sciences Revenue Management solution to help you stay aligned with your strategy and avoid unintended violations.

By automating the commercialization and compliance processes, you can reduce errors, save time, and mitigate risk. RLDatix Life Sciences Revenue Management platform is a state-of-the-art solution that automates and simplifies compliance, turning a daunting task into a strategic advantage for your business.

Looking for more tips on turning compliance into your competitive edge?

Download our full eBook, [7 Strategies for Scaling Government Pricing Compliance](#).

MONTHLY GOVERNMENT PRICING COMPLIANCE CHECKLIST

Trying to streamline the daunting task of government pricing compliance into a manageable monthly process? Here's a handy Monthly Compliance Process Checklist that can help keep you organized.



- Review and Update Product Information:**
Ensure all product attributes (UOM, UPPS, product market entry date, baseline AMP, baseline CPI, and drug category) are current and aligned with FDA and CMS submissions.
- Verify Class of Trade (COT) assignments:**
Confirm the accuracy of customer COT assignments and update as necessary.
- Reconcile Data:**
Reconcile transactional data with your accounting system, documenting any variances and reasons for those variances, prior to calculating.
- Review 340B Pricing Compliance and Validate 340B Entity Eligibility:**
Ensure new products have an estimated PHS price published and validate 340B eligibility on all 340B/PHS purchases.
- Conduct Government Pricing Variance Analysis**
Complete monthly calculations for AMP and conduct variance analysis of AMP fluctuations to ensure accuracy and readiness for reporting.
- Assemble Compliance Documentation:**
Update compliance documentation with the month's activities, reasonable assumptions, variances, and any corrective actions taken.



This checklist can help you manage the mountain of tasks required to maintain compliance — but to ensure that no detail is overlooked in the pursuit of operational excellence, you'll want to implement a transparent and auditable Revenue Management System, such as the RLDatix Life Sciences Revenue Management solution.

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QUARTERLY GOVERNMENT PRICING COMPLIANCE CHECKLIST

Government pricing requires quarterly review and oversight to ensure compliance and avoid fines or penalties. But where do you start? Here's a handy Quarterly Compliance Process Checklist that can help keep you organized.



Review Quarterly GP Calculations:

Review and conduct variance analysis of the quarterly government pricing calculations to understand how your commercialization strategy impacts your government liability.



Conduct an Internal Audit of Compliance Practices:

Conduct an internal audit focusing on adherence to SOPs, correct COT assignments, and accurate government pricing calculations.



Update Training and Education:

Review and update training programs for staff on compliance and regulatory changes.



Review Policies and Procedures:

Examine and update written SOPs and compliance policies to reflect any regulatory updates or internal changes.



Develop a Corrective Action Plan:

Identify any compliance issues or gaps and develop a plan for corrective action.



Documentation and Record-Keeping:

Ensure all compliance activities and outcomes from the quarter are fully documented and stored for future reference.



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This checklist is a great sanity check for quarterly compliance, but if you want to monitor your compliance on a regular basis, it's best to rely on a comprehensive, proven Revenue Management System, like RLDatix Life Sciences' Revenue Management — along with professional services to lighten the load.

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