



# GOVERNMENT PRICING: POLICY AND PROCESS ALIGNMENT

## Constant Change Demands Constant Realignment

Government Pricing (GP) administration for programs such as Medicaid, Medicare, and Veteran’s Affairs has grown to be one of the most complex operations in the pharmaceutical industry. Pharmaceutical manufacturers are challenged with interpreting an expanding set of frequently changing and often ambiguous legislative language and regulatory requirements. Often manufacturers’ policy and work process documentation simply repeats the government’s legal language without clear reference to internal business terminology. In addition, the programs have been in existence for over twenty years, increasing the possibility that methods and documentation have gradually become outdated. Policies and processes that have often been in place for years are gradually diverging, and actual work behavior may differ from Standard Operating Procedure (SOP) documentation.

What is missing in many organizations is a clear translation of general regulatory terms into company-specific language that effectively maps the regulatory concepts to business practices. It is in the best interest of all corporate stakeholders, including the organization, management and its employees, to ensure that procedures and documentation are consistent and current to minimize legal and regulatory risk.

## Providing a Clear Roadmap for Government Pricing Improvement

Paragon Solutions is helping pharmaceutical companies efficiently and effectively meet government pricing program demands in a challenging regulatory environment through:

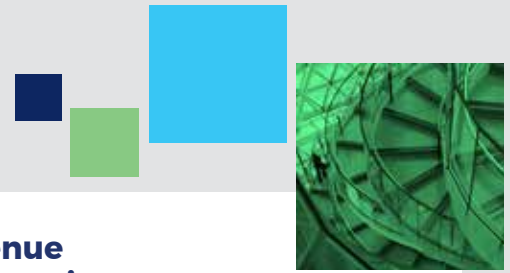
- Policy Evaluations – Are written approved policies complete?
- Refinement of operational definitions to clarify policy – Do policies clearly translate to company’s unique internal terminology?
- Alignment of SOPs and behaviors – Are process documents complete and up to date?
- Optimization of data management and systems – Do data elements match the documented policies and procedures?

Each of these approaches, when implemented, leads to more than just improved compliance with regulations, decreased audit/risk and overall improvement in operations. Some of the businesses we have helped have also reduced operational costs or erroneous government rebate payments to save tens of millions of dollars. Firms that have implemented these improvements are also more responsive to the steady stream of future legislative changes.

Paragon’s Government Pricing evaluation provides a comprehensive review of all aspects of the process using methodology that augments the usual internal audits to produce a complete diagnostic and clear roadmap for improvements.

### Paragon Solutions Addresses the Full Breadth of Government Policy Needs

Component	Function	Objective
Organization	Governance	Roles, Responsibilities, Controls and Oversight
Policy	Government Pricing	Legislative and Regulatory Interpretation Documentation and Support
SOPs	Documentation	Completeness, Alignment with Policy, Clarity
Processes	Work Processes	Alignment with SOPs, Accuracy, Efficiencies
Operations	Data Management	Source Data, Mapping, Validation
Technology	System Implementation	Alignment with Operations and Policy, Gap Analysis, Data Integrity



## Assessing the Alignment Between Policy and Process

A Paragon evaluation of GP Policy and Processes is designed to:

- Evaluate all levels of documentation from policy through to data sources
- Evaluate for consistency, compliance, clarity
- Identify gaps and revise documentation as needed
- Enhance operational definitions and linkages between the components
- Assess how well actual processing reflects documentation
- Realign the workflows and corporate documentation
- Update materials for changes in business practices and regulatory guidance
- Confirm the translation of source system data definitions up through technical, operational and policy documents

Paragon's assessment can help organizations achieve the following benefits:

- Updated and improved documentation
- Clear alignments between regulations and daily work processes
- Certainty of compliance and process improvements
- Improved information and analytic capabilities
- Costs savings

## Paragon's Revenue Management Practice

Paragon's Revenue Management practice provides innovative expertise and proven methodologies to address priorities in the managed markets contracting, government pricing, policy and compliance functions. We provide solutions for the following areas:

- Industry best practice operating procedures from strategic roadmap development through design and implementation
- Ensuring government policy and pricing team operational execution alignment within the current solution platform to address current and future legislative edicts
- Initiating customer-driven services to enhance contracting operations and enable account team excellence
- Technology solution implementations providing program/project management, analysis, development, qualification and delivery for SaaS based solutions

**Historically, there have been six major pieces of federal legislation that have dramatically changed the Medicaid reimbursement requirements for pharmaceutical companies.**

## About Paragon Solutions

Paragon Solutions is an advisory consulting and systems integration firm that specializes in enterprise information management to help clients leverage information assets for better business results. The company does this through its industry practices, solution accelerators and specialized technology competencies that help clients achieve operational efficiency, business scalability and regulatory compliance. Paragon works with businesses that are focused in a few key industries—communications, financial services, healthcare, insurance and life sciences. The industry-focused practices work with Paragon's competency groups to address today's client concerns in Process Optimization, Information Management and Information Insight.

For more information, visit Paragon at [www.consultparagon.com](http://www.consultparagon.com), or call 1.800.462.5582.

## Paragon Client Roster

- **abbvle**
- **AstraZeneca**
- **Bausch & Lomb**
- **Bayer**
- **Bristol-Myers Squibb**
- **Celgene**
- **CSL Behring**
- **Daiichi-Sankyo**
- **GSK**
- **Lilly**
- **MedImmune**
- **Merck**
- **Novo Nordisk**
- **Otsuka**
- **Roche**
- **Shire**
- **Chiltern**
- **inVentiv Health**
- **Worldwide Clinical Trials**
- **Regeneron**