



## Government Price Reporting: A Window into Your Business Processes

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*This story takes place in an average US Pharmaceutical firm. Michael Goddard could be the director of the Government Pricing group of any US based Pharmaceutical firm. His story is not dependant on annual revenues, product lines, IT software or the firm's internal or outsourced business process strategy.*

Michael Goddard leads the company's Government Pricing (GP) department. He assumed his current position last year, and just a few months ago he reported to the board of directors on the successful implementation of a multi-million dollar state-of-the-art government pricing system. At the time, Michael had the full support of the board, and they were pleased to know that he had used a leading law firm to help him develop all the policies for his GP reporting.

But now, Michael is waiting outside his company's boardroom to discuss serious errors in government reporting and the organization's resulting financial liability.

As he waits, Michael reviews the implementation project and the steps he and his team took to ensure success. They:

- Created a steering committee comprised of business and IT management
- Established a project management office
- Tightly controlled the project timeline and costs
- Brought together a Quality Assurance team to ensure the accuracy of each calculation
- Generated several hundred test cases accompanied by controlled test data
- Received approval and verification from IT and business users on all test results

"What more could have been done?" Michael wondered.

### What Went Wrong?

Many companies assume that a competent government pricing function supported by sound policies and procedures and a state-of-the-art GP system will automatically generate accurate government prices. But unfortunately, this is no longer the case. While these elements alone may once have been sufficient, numerous government mandates, complex customer and product inclusion rules, tight response timeframes and high volumes of calculation data have made GP reporting an increasingly difficult task. Today, a GP system is merely one part of a larger solution that must exist in order to ensure accurate government price reporting.

The most serious challenge to accurate government pricing systems comes as a result of the fact that much of the source data and many of the calculations affecting the accuracy of GP functions come from outside the government

### "All or None"

By law, drug manufacturers have to participate in all or none of the government programs.\* Since all the government programs require price reports that are based on the same data sources, a reporting error in one program likely results in an error in the other programs.

*\*The three major government drug programs are Medicaid, Medicare, Federal Procurement (VA)/ 340B/PHS*

pricing group. On a monthly basis, government pricing groups receive calculation transactions whose counts range from tens of thousands to tens of millions. These data volumes can sometimes cause subtle data errors to go undetected for months or years.

Often these errors can be traced back to mistakes related to Best Price (BP) and Average Manufacturer Price (AMP) calculations, which are governed by seemingly simple regulations. The regulations define the calculation and identify calculation inclusion and exclusion rules based on customer type and products. While the regulations themselves may be relatively straightforward, everyday business activities outside the usual control and scope of the government pricing group can and often do violate these regulations. For example, each time a sales order clerk takes an order and incorrectly sets up a customer with the wrong class of trade, or when a customer product return is accepted with missing units or an inaccurate product code (NDC), the government pricing group receives inaccurate calculation data. Using inaccurate data such as this to calculate government pricing places the company at risk for federal non-compliance penalties costing millions of dollars.

That leaves Michael and his team with a serious challenge. How can they manage not only their own function within the organization but also implement strategies that will enable other parts of the company to comply with the appropriate government pricing regulations and to develop processes that will ensure compliance with federal requirements?

**Correcting the Problem – Integration Control Points**

In order to solve Michael’s dilemma, we must first understand that a competent government pricing function is the result of a long term, company wide effort to identify all upstream business processes on which the accuracy of government pricing calculation depends. There are many points along the business process chain, also known as integration control points (ICP), which determine the accuracy of data that will later be utilized to calculate government pricing. These ICPs are the key to generating accurate government pricing calculations.

On average, more than 120 integration control points occur within the daily, weekly and monthly business processes of an average pharmaceutical firm. These integration control points exist in almost every business area within the firm, with several ICP occurrences happening each and every day. The chart below identifies the most common business areas that contain integration control points.

Area	Data Input to GP
Data Management	Customer and Product Masters Data retention Support information
Legal	Terms and conditions
Contract Management	Customer contracts Pricing
Order Management Process	Sales invoices Price overrides
Product Distribution Process	Returns and Other Credits
Sales Operations	Customer discounts
Finance	Rebates, Discounts and Other Fees Paid to Customers
Chargeback Processing	Rejections Eligibility determination

**Step One – Documenting Integration Control Points**

Teams from each of the areas above who work with government pricing-trained individuals should identify and document each of the integration control points in their areas. Special attention should be paid to ICPs that occur in multiple areas such as membership eligibility determination. Identification of each ICP occurrence and the

evaluation of the resulting government pricing impact is the first step toward ensuring the accuracy of government pricing data. It's important to remember that not every execution of an ICP will result in an impact on government pricing nor can all negative financial impacts be prevented or reversed. Identification of ICPs is a continuous process as business environments evolve, political pressures and mandates continue and customer requirements are in flux. As federal requirements and the organization itself change, new integration control points will pop up in the business landscape.

**Hitting Two Birds  
with One Stone**

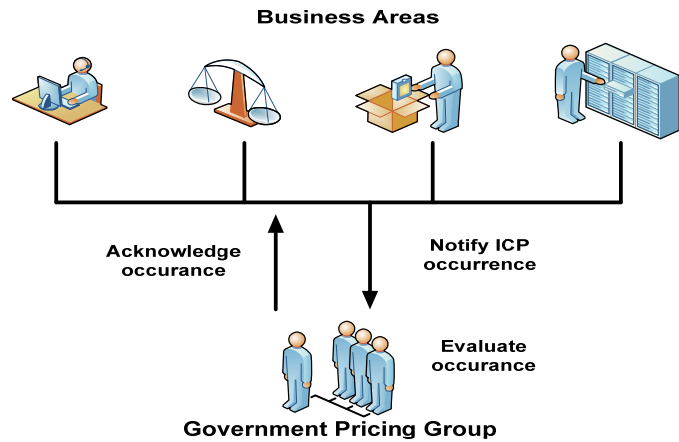
Use the Sarbanes Oxley 404 internal control certification process to evaluate the appropriate controls for integration points.

**Step Two – Building Controls**

Once all ICPs are identified, the next step is to create a strong control infrastructure incorporating both manual and automated controls. These controls will ensure that your company will be in compliance with all federal regulations, thereby avoiding the multi-million dollar fines and negative press that result from non-compliance.

Each of the manual or automated controls should be designed around a three-step principal:

1. Notification of the event
2. Evaluation of the event
3. Acknowledgement of the event



**Step Three – Designing and Implementing Monitoring Tools**

Once the integration control points have been identified and process controls designed, monitoring tools must be developed by each relevant business function group under the oversight of government pricing-trained individuals. Automated monitoring will enforce consistent application of the desired control, which will result in consistent and accurate government reporting. Some examples of automated monitoring tools and processes that provide high value for the dollars invested include:

- Customer validation
  - Class of trade validation
  - External identifier validation
- Product validation
  - Unit of measure conversion
  - Hierarchy validation
- Customer eligibility
  - 340B contract eligibility
- Contract pricing
  - Automated monitoring of the 340 contract pricing
- Data synchronization
  - Non shared support data validation
- System overrides
  - Changes to system generated customer pricing, calculations or rebates

## **Conclusion**

The error that put Michael in front of the board did in fact result from regular business processes outside the control of the government pricing group. The package for the company's bestselling product was redesigned such that each carton held 1,000 dispensing units rather than 100. The unit of measure conversion factor assigned to this product for government pricing calculations purposes was never updated resulting in inaccurate pricing calculations. The error existed for ten months of government submissions before it was discovered and corrected. Unfortunately this mistake cost them hundreds of man hours of recalculation and resubmissions time accompanied by 10's of millions of dollars in penalties.

What would Michael's government pricing project and current work environment be if he had instituted a corporate wide government pricing system in conjunction with teams from IT, finance, and contracting? What if integration control point identification, controls and automated monitoring had been part of the early stages of his government pricing project? Some obvious results for Michael and his group would have included:

- Controls would have existed to provide time to react to negative ICP results. Crisis mode business reactions would have been held to a minimum.
- Processes and procedures would have been in place to identify and reverse the effect of negative financial impact business events prior to any calculation effect.
- Necessary business events that result in a negative financial impact would have been identified and planned for in an orderly fashion.
- Impact analysis during initial customer contracting could have been planned and provided.
- Future government mandated changes and their respective business decisions would have been based on sound, well-documented impact analysis.

Michael also would likely have been able to stay out of the boardroom.

### **Steps to take now**

Identify all upstream business process integration control points (ICPs) within your organization

Whether you are planning for a new system or an update of you current system include the design of controls that address your ICPs

Establish procedures that continuously review and identify new ICPs

Ensure that outside firms that review ICPs have broad pharmaceutical business process knowledge