

Practical Case Study: A Compliance Professional's Playbook for Conducting a Government Price Reporting Assessment

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Agenda

- Introductions
- When to do a Price Reporting Assessment
- Conducting a Price Reporting Assessment
- Six Common Problem Areas in a Complex Reporting Environment
 - Classifications of Customers and Transactions Types
 - Monitoring for Reference Pricing
 - Data Integrity
 - Written Policies and Procedures
 - Inter-Departmental Communications
- Questions

When to do a Price Reporting Assessment

When to do a Price Reporting Assessment

- As Part of Regular Compliance Audit Plan
- Implementation of New Price Reporting Methodology Calculation or Change in Standard Operating Procedures
- New Price Reporting Software/Systems
- When there any reason to question – **Don't Wait Until It is Too Late**

Conducting a Price Reporting Assessment

Conducting a Price Reporting Assessment

- Initial Considerations
 - ✓ Define Scope Carefully
 - Products/Labeler Codes – Consider initial “Sample Size”
 - Timeline
 - Systems
 - Calculations (Medicare, Medicaid, VA, PHS, States)
 - ✓ Establish Budget
 - ✓ Gain Senior Management Buy-In
 - ✓ Vendor Selection
 - ✓ Outside Counsel Involvement
 - ✓ Privilege

Conducting a Price Reporting Assessment, cont'd

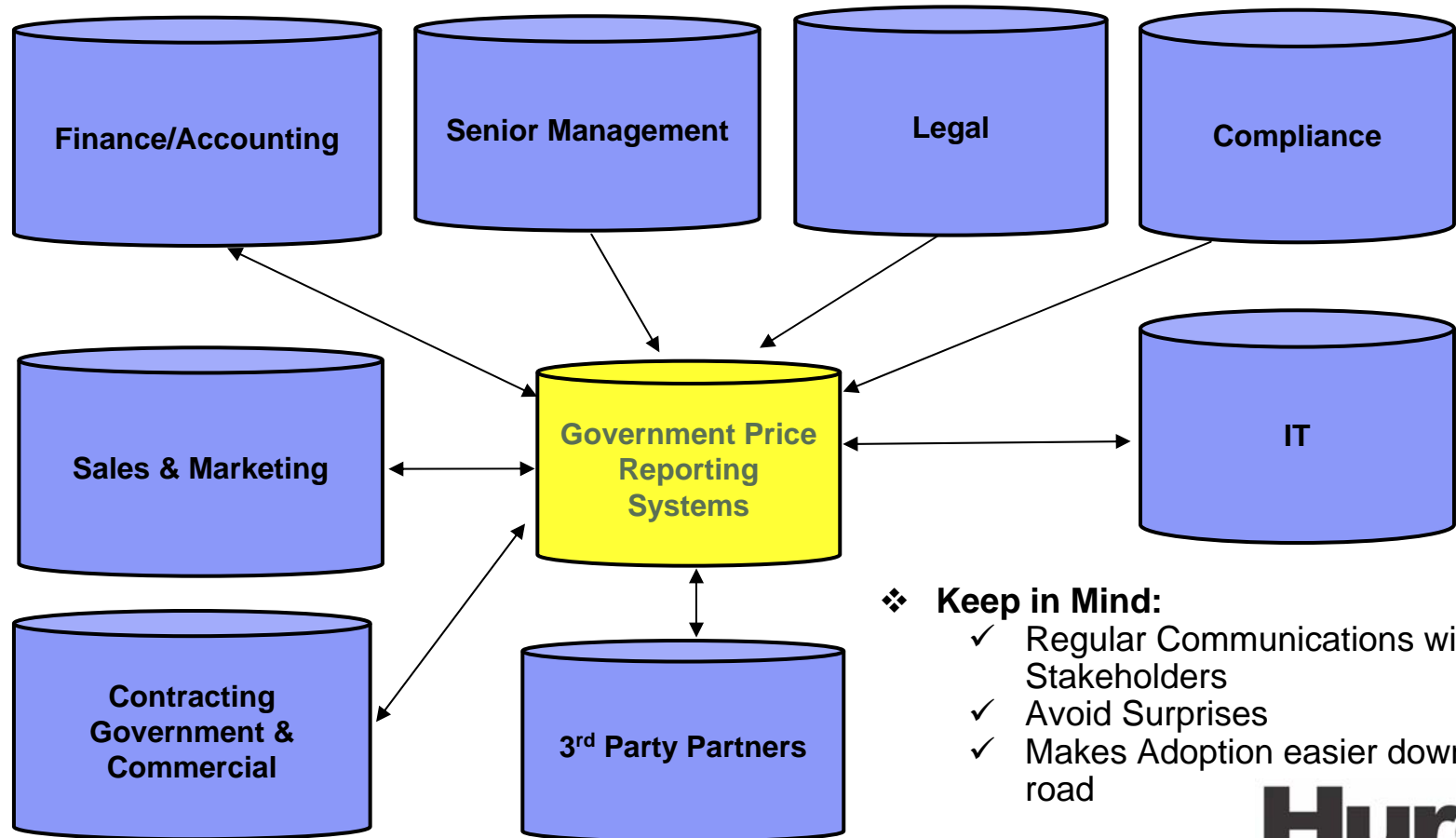
- What to do
 - ✓ Establish Project Plan
 - ✓ Review your company's product line for relevant time period
 - ✓ Review your company's product distribution system; identify all types of customers
 - ✓ Review your company's pricing systems and practices
 - Government price calculations
 - Core transaction systems
 - Customer and transaction classifications
 - Promotional programs (including discounts; rebates and other financial transactions with customers)
 - ✓ Search for off-invoice price concessions
 - ✓ Identify all types of fees, other financial arrangements with customers
 - ✓ Review charitable donations, PAPs, coupons, free goods arrangements

Conducting a Price Reporting Assessment, cont'd

- How to do it
 - ✓ Determine whether to conduct that the review under privilege; if so, be sure to set it up appropriately
 - ✓ Review existing written policies and procedures
 - ✓ Review communications with relevant government agencies
 - ✓ Review selected commercial contracts, such as
 - Wholesaler agreements – includes DSA, IMA, and other service agreements, as well
 - Distributor
 - Pharmacy (including retail chains, mail order, specialty)
 - GPO
 - PBM/MCO
 - Part D
 - Provider agreements
 - Government Entity Contracts (city, county, state, department of corrections, SPAP, ADAP, etc.)
 - ✓ Review VA contract

Conducting a Price Reporting Assessment, cont'd

Identify and interview key stakeholders from relevant areas to gain an understanding and document current practices



❖ Keep in Mind:

- ✓ Regular Communications with Stakeholders
- ✓ Avoid Surprises
- ✓ Makes Adoption easier down the road

Conducting a Price Reporting Assessment, cont'd

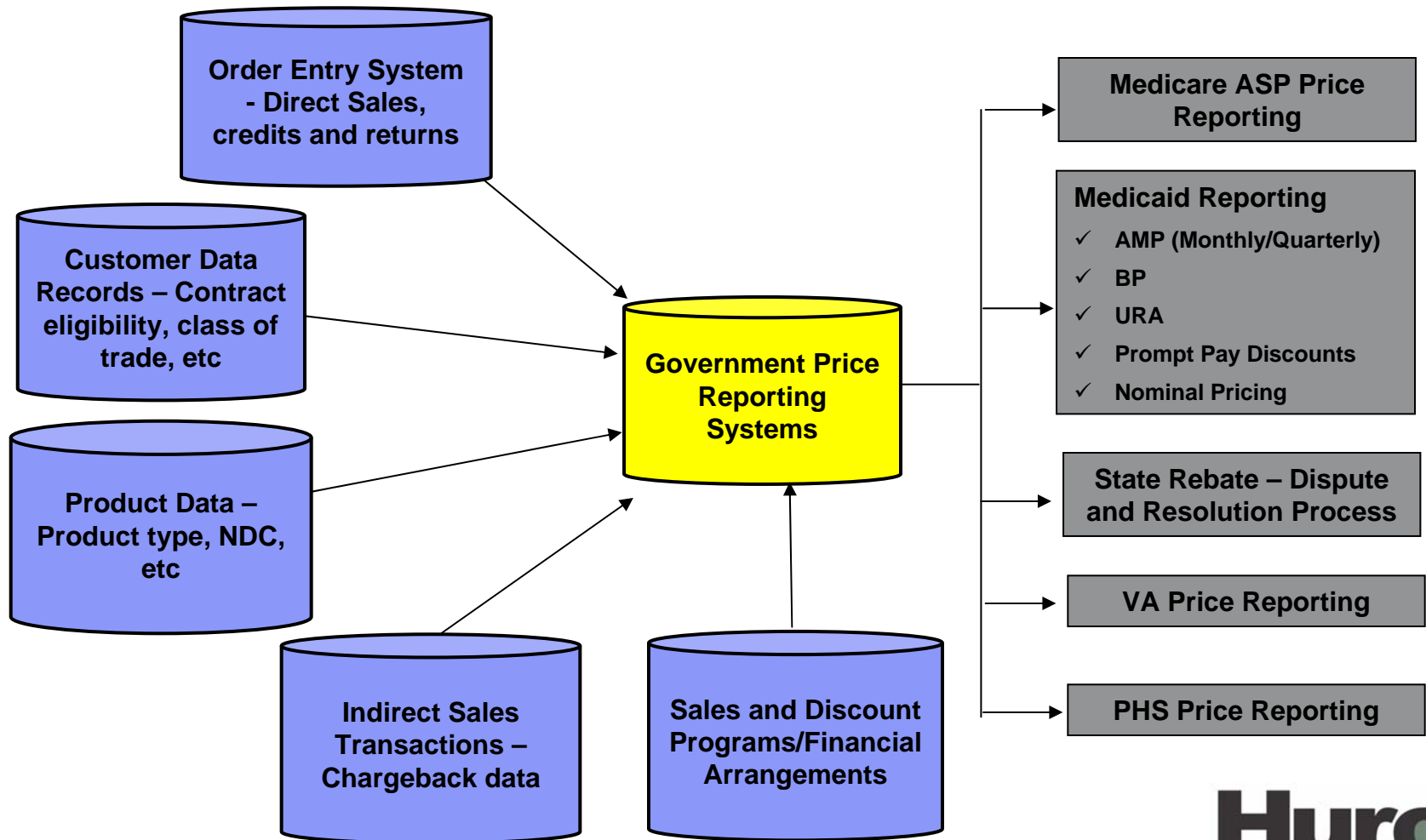
- Communication Plan for Results
 - ✓ Review in Draft with Counsel
 - ✓ Recommended Action Steps; should include
 - Clear Understanding of Issue
 - Effect on Government Price Reporting
 - Effect on Other Business Practices
 - Matter for Consideration
 - Proposed Implementation Plan
 - ✓ Identify Timeline for Implementation
 - ✓ Top down and bottom up buy-in

Conducting a Price Reporting Assessment, cont'd

- Likely outcome of the assessment
 - ✓ Update and revision the written policies and procedures
 - ✓ Provide additional training to implementing personnel
 - ✓ Establish cross-functional pricing committee; increase/improve communication
 - ✓ Enhance controls over promotional activities
 - ✓ Change contracting processes, terms, sign-off, etc.
 - ✓ If necessary, communicate revised methodologies to appropriate government agency
 - ✓ Assess impact of revised methodology effect on previous filings and if necessary, voluntarily re-file with the appropriate government agency

Conducting a Price Reporting Assessment, cont'd

Understanding Government Price Reporting Environment



Six Common Problem Areas in a Complex Reporting Environment

Six Common Problem Areas in a Complex Reporting Environment

- ✓ Each company has its own unique set of issues:
 - Product mix:
 - **ANDA (non-innovator) vs. NDA (sole source/innovator) vs. Authorized Generic**
 - **ASP Eligible Drugs**
 - **VA Covered Drugs**
 - Complexity in market strategy
 - Product distribution scheme
 - Internal control structure
 - System limitations and interfaces
 - Government Price Reporting methodology due to interpretation of legislation and guidance
 - Staffing model
- ✓ The following summarizes some of the common potential troublesome areas all manufacturers should closely consider when reviewing their government price reporting calculations

Six Common Problem Areas in a Complex Reporting Environment, cont'd

Classifications of Customers and Transactions Types

- ✓ Formal written policies and procedures clearly identifying how customers should be classified, as well as how transactions should be assigned for government price reporting purposes
- ✓ Proper training should exist for those responsible for assigning customer class of trades and transactions
- ✓ Risk assessment should be performed to ensure the policies and procedures that are in place are actually being followed
- ✓ How can information be overridden and who has the ability to perform overrides
- ✓ Assess whether appropriate data retention and audit trails exist
- ✓ How are direct & indirect customers classified

Bottom Line – Make Sure Everyone Is Speaking the Same Language

Six Common Problem Areas in a Complex Reporting Environment, cont'd

Classifications of Customers and Transactions Types, cont'd

- ✓ One of the principal parameters of each calculation is what sales are included in the calculation, and what sales are excluded from the calculation
- ✓ Two key characteristics per sale:
 - Customer classification (e.g., wholesaler, retail pharmacy, hospital, 340B entity)
 - Transaction type (e.g., sale, sample, international)
- ✓ Each calculation is partly defined by its own set of includable and excludable sales
- ✓ By examining the characteristics of each sale, the manufacturer determines if the sale is *eligible* or *ineligible* for consideration in the AMP or Best Price calculations
- ✓ This process is known as “filtering”
- ✓ For instance, sales to the federal government, state eligible pharmacy assistance programs, the Public Health Service, state supplemental Medicaid rebates, and inter-company transfers could be determined ineligible for all calculations

Six Common Problem Areas in a Complex Reporting Environment, cont'd

Classifications of Customers and Transactions Types, cont'd

Representative customer class of trade “buckets:”



Retail
Pharmacies



Mail Order
Pharmacies



Wholesalers

Six Common Problem Areas in a Complex Reporting Environment, cont'd

Classifications of Customers and Transactions Types, cont'd

Customer Class of Trade Category	Per CMS Manufacturer Release #29		Per CMS Final Rule	
	Included (Yes)/Exclude (No) in the calculation			
	AMP	Best Price	AMP	Best Price
Wholesalers	Yes ⁽¹⁾	Yes ⁽¹⁾	Yes ⁽¹⁾	Yes ⁽¹⁾
Wholesalers where the drug is relabeled under the wholesalers NDC number	No	No	No	No
Retail Pharmacies	Yes	Yes	Yes	Yes
Mail Order Pharmacies	Yes	Yes	Yes	Yes
Outpatient facilities (Clinics, Surgical Centers, Ambulatory Care, Dialysis Centers, etc)			Yes	Yes
Home Infusion Providers			Yes	Yes
Specialty Pharmacies			Yes	Yes
Home Health Care Providers			Yes	Yes
Physicians			Yes	Yes
Patients			Yes	Yes
Hospital Sales (Unless Adequate Documentation to Ensure Outpatient Use)	No	Yes	No	Yes
Long-term care facilities, nursing facility pharmacies, contract pharmacies	Yes	Yes	No	Yes

(1) - Except sales to wholesalers which can be identified with adequate documentation as being subsequently sold to any of the excluded sales categories

Note: The above should be reviewed in detail with counsel to assess the application of transactions to various customer types are compliant with CMS Final Rule

Six Common Problem Areas in a Complex Reporting Environment, cont'd

Classifications of Customers and Transactions Types, cont'd

Customer Class of Trade Category	Per CMS Manufacturer Release #29		Per CMS Final Rule	
	Included (Yes)/Exclude (No) in the calculation			
	AMP	Best Price	AMP	Best Price
Hospices			No	Yes
Veterinarians			No	Yes
Prisons			No	Yes
Medicare Part D MA-PD and PDP			No	No
Managed Care Organizations (MCOs)/ HMOs	No	Yes	No	Yes
Pharmacy Benefit Managers (Except Mail Order)			No	No
State, County, and Municipal entities			No	Yes
Patient Assistance Programs			No	No
Medicaid Rebates and CMS-authorized State supplemental Rebate			No	No
State Childrens Health Insurance Programs			No	No
Designated State Pharmacy Assistant Programs	No	No	No	No
Entities Covered under the Public Health Service Program	No	No	No	No
Sales at nominal prices (to customers outlined in §447.508 of subpart)			No	No
Depot Prices, Single Award/ TRICARE			No	No
Entities Covered under the Federal Supply Schedule Program	No	No	No	No

(1) - Except sales to wholesalers which can be identified with adequate documentation as being subsequently sold to any of the excluded sales categories

Note: The above should be reviewed in detail with counsel to assess the application of transactions to various customer types are compliant with CMS Final Rule

Six Common Problem Areas in a Complex Reporting Environment, cont'd

Classifications of Customers and Transactions Types, cont'd

Entity Type	Entity Description	Class of Trade System Codes	Business Rules for Applying to Specific Calculation
Document the entity type as described in the system (i.e. Wholesaler, Distributor, Retail Pharmacy, etc.) for both Direct and Indirect Sales Entities	Document a detailed description for each of the entity types. The detail should be clear that any individual with minimal training could correctly assign a customer to an entity type	Document the code within the system that matches the entity type	Document the business rules to be applied to transactions to each entity type. Application should be detailed enough to address the various methodologies (i.e. traditional vs. direct method), as well as elements of a transaction (i.e. direct sales and units, indirect sales and units (chargebacks) and other price concessions (paid rebates/discounts directly vs. through a wholesaler)

Sample

Entity Type	Description	COT Code	Government Price Reporting Calculation Business Rules	
			Sales \$ / Units	Other Price Concessions
Wholesaler	Any entity to which the manufacturer sells, or arranges for the sale of, the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug.	123 or WHOL	Traditional Method Y Direct Method N	Traditional Method Y Direct Method N

Six Common Problem Areas in a Complex Reporting Environment, cont'd

Classifications of Customers and Transactions Types, cont'd

- ✓ Consideration When Understand Your Customer Types
 - How to Determine the customer classification
 - Who has knowledge internally
 - Who owns the process internally when evaluating new customers and monitoring existing customers
 - What is adequate customer classification documentation
 - How to handle conflicting information on indirect customers
 - May require extensive research and painstaking categorization

Six Common Problem Areas in a Complex Reporting Environment, cont'd

Classifications of Customers and Transactions Types, cont'd

Representative transaction type “buckets:”



Donations



International
Sales



340B Contract
Sales

Et cetera...

Six Common Problem Areas in a Complex Reporting Environment, cont'd

Classifications of Customers and Transactions Types, cont'd

- ✓ Out-of-Quarter adjustments can have a substantial impact on reportable amounts
 - Chargebacks
 - Rebates
 - Invoice adjustments (i.e. returns, credit memos, price protection, etc)
- ✓ Formal written policies and procedures clearly identifying how these transactions should be applied for each calculation
- ✓ How these transactions are valued and what is the effect on the government pricing calculations
- ✓ How can information be overridden and who has the ability to perform overrides; and what record is maintained of override
- ✓ Assess whether appropriate data retention and audit trails exist

Six Common Problem Areas in a Complex Reporting Environment, cont'd

Classifications of Customers and Transactions Types, cont'd

- ✓ Improper treatment of off-invoice price concessions has been the basis for many recent lawsuits in the pricing area
- ✓ Manufacturers should have established lines of continuous communication between sales and marketing, finance/accounting, legal, pricing and contracting, information technology and the Government Price Reporting administrators to ensure the following:
 - Timely communication of new promotion programs or alternate contracting/financial arrangements
 - Complex promotion programs are evaluated in the context of Government Pricing regulations and are incorporated into existing Government Pricing models
 - Capabilities and limitations of IT systems are considered. “One-off” contracts or programs that cannot be captured by systems are timely and appropriately considered within the pricing calculations

Six Common Problem Areas in a Complex Reporting Environment, cont'd

Classifications of Customers and Transactions Types, cont'd

Transaction Type	Transaction Type Description	Transaction Type Code	Core Transaction System	General Ledger Account Reconciliation	Application Method	Application to Government Price Reporting Calculation
Document the transaction type as described in the system (i.e. invoice, return, chargeback, rebate, etc.)	Document a detailed description for each of the transaction types. The detail should be clear that any individual with minimal training could correctly assign and identify transaction to a transaction type	Document the code within the system(s) that matches the transaction type	Document the core transaction systems the transaction code types could be found (i.e. order entry system, chargeback system, rebate administration system, manual/excel/access database files, etc.). This information will assist in identifying where in the data process flow the transaction type could be found.	Document the general ledger accounts the transaction code type would be recorded for financial reporting purposes. This information will assist in assessing the completeness of the transactions accumulate for calculation purposes.	Document how the transaction the transaction will be applied to the calculation (i.e. process date, invoice date, allocation methodologies, if applicable). This information will assist in applying transactions in accordance with policy, as well as avoid inconsistency from filing to filing	Document the business rules to be applied to each transaction type. Application should be detailed enough to address the various methodologies (i.e. traditional vs. direct method), as well as elements of a transaction (i.e. direct sales and units, indirect sales and units (chargebacks) and other price concessions (paid rebates/discounts directly vs. through a wholesaler)

Sample

Transaction Type	Transaction Type Description	Transaction Type Code	Core Transaction System	General Ledger Account	Application Method	Application to Government Price Reporting Calculation	
						\$	Units
Finished Goods Invoice	These are regular invoices that are generated during a direct sale to any customer.	100	Order Entry System (provide system and/or program name)	1000 - Sales	Applied based on invoice date	Y	Y

Six Common Problem Areas in a Complex Reporting Environment, cont'd

Monitoring for Reference Pricing

- ✓ Controls need to be in place to monitor and identify price concessions before they are offered to the customer to assess if:
 - A new Best Price is going to be set
 - A new FSS price is going to be set, based on price concessions offered to a VA negotiated Most Favored Customer
- ✓ Controls need to be in place to ensure entities being offered PHS pricing are 340 eligible customers
- ✓ Understand when nominal pricing is being offered and why
- ✓ Monitor and assess if pricing offered at the nominal levels (i.e. 10% and to an appropriate entity) are still eligible for exclusion

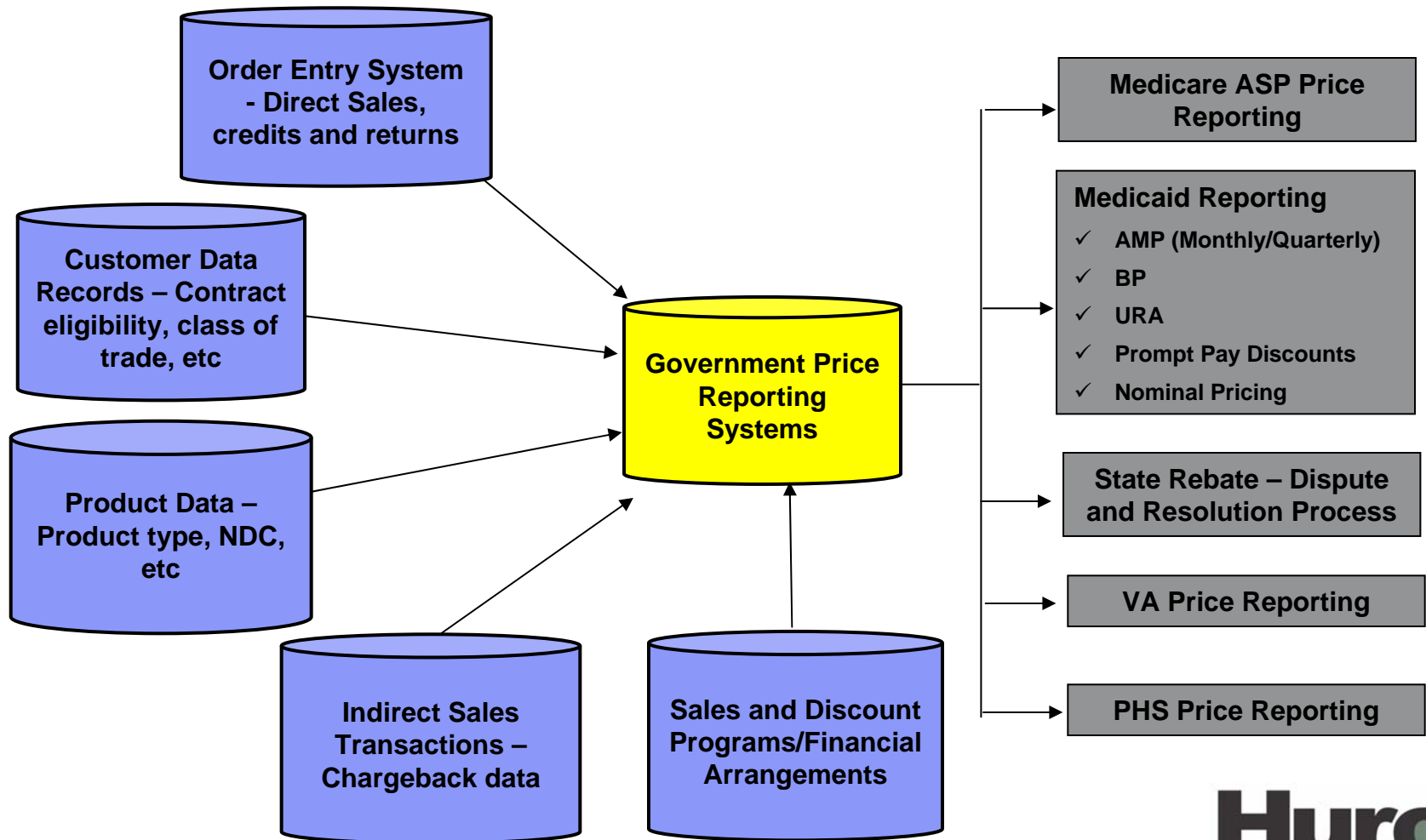
Six Common Problem Areas in a Complex Reporting Environment, cont'd

Data Integrity

- ✓ Manufacturers should understand the data and process flow of all information being interfaced into the government price reporting system. This should include discussion with users and IT personnel to map out the following:
 - All data sources used
 - All transactions included / excluded during the interface, as well as within the Government Pricing system
 - Understanding of system edit checks and reports generated by the interface system, as well as, the Government Pricing system
 - What is being done with each of these reports and errors discovered during the edit checks
- ✓ Manufacturers should develop and maintain well documented policies and procedures around all of the data interfaces, which take into consideration the use of the data when performing the Government Price calculations

Conducting a Price Reporting Assessment, cont'd

Understanding Government Price Reporting Environment



Six Common Problem Areas in a Complex Reporting Environment, cont'd

Data Integrity, cont'd

- ✓ The following outlines questions to be considered when reviewing the data interfaces:
 - What are the data interfaces into the government price reporting system
 - What formal written policies and procedures exist, when were they developed, do address all current systems, and have they been reviewed by counsel and management
 - Has a risk assessment been performed to ensure the policies and procedures that are in place are actually being followed
 - What controls exist around this data within the interfacing systems, as well as, once the data is gathered and implemented in the government price reporting calculations
 - What is being done with the data once it is gathered into the government price reporting system
 - Does proper supervision and training exist
 - How can information be overridden and who has the ability to perform overrides
 - How are transactions being valued and what is the effect on the government pricing calculations
 - When was the system reviewed to evaluate if all relevant customer information and transaction data is being extracted properly
 - Assess whether appropriate data retention and audit trails exist

Six Common Problem Areas in a Complex Reporting Environment, cont'd

Written Policies and Procedures

- ✓ Manufacturers should have a complete set of policies and procedures that provides a detailed understand outlining the following:
 - Outlining the company's calculation methodology;
 - Identify and explain all assumptions;
 - Identify what included / excluded (customers, transactions, contracts, etc);
 - Identify manual vs. automatic procedures;
 - Include controls to ensure the information is accurate;
 - Identifying the appropriate supervision and sign off (consider a sub-certification process)
 - Identifying what procedures are performed to assess the accuracy of the information being used; and
 - Procedures and various reports used to analyze the results of the government price reporting calculations

All policies and procedures should be reviewed and approved by legal (either internal or external counsel) and senior management

Policies and Procedures should be reviewed periodically to address changes in relevant systems and to assess if gaps between what is actually being performed and current legislation and guidance exist

Six Common Problem Areas in a Complex Reporting Environment, cont'd

Inter-Departmental Communications

- ✓ As previously stated, manufacturers should have established lines of continuous communication between sales and marketing, finance, legal, information technology and the Government Price Reporting administrators to ensure the following:
 - Timely communication of new promotion programs
 - Complex and “One-Off” contract or promotional programs are evaluated in the context of Government Pricing regulations and are incorporated into existing Government Pricing models
 - Capabilities, changes and limitations of IT systems are continuously considered for their effect on government price reporting

Questions
