Gross to Net Principles

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Deloitte & Touche LLP
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Overview

• Types of Pricing Adjustments
• Gross-to-net Estimation Process
• Updates on GTN Hot Topics
• Sales Returns and Other Considerations
Key Learning Objectives

• Identify and understand the key types of pricing adjustments on a per class of trade basis and the significant components for each

• Understand best practices undertaken to estimate gross-to-net adjustments

• Identify and understand the key considerations around product sales returns for both steady state products and products approaching loss of exclusivity

• Discuss key considerations around internal controls and how they impact gross-to-net accounting
Polling Question #1

Level Setting – What would you say is your current level of knowledge related to Gross-to-Net accounting

A. Elementary
B. High School Diploma
C. Bachelors Degree
D. PhD
Gross-to-Net Estimation Process

Accounting & Financial Reporting Challenges

Key Forces at Play

Internal Challenges

- **Process**
  - Cumbersome manual analysis, calculation, & reconciliation; Resource Constraints; Timing

- **System Functionality**
  - Disparate Systems Impacting Functionality and Timeliness

- **Governance & Collaboration**
  - Disjointed Business Groups and Functions; Contracting & Pricing Information Sharing

- **Control Environment**
  - Clearly Defined Roles & Responsibilities; Strong vs. Burdensome

External Challenges

- **Increasing Risk**
  - Financial, Compliance, Operational, & Strategic

- **Financial & Operational Pressures**

- **Conservative Approach**
  - Impacting Profitability & Forecasting Capability

- **Audit Compliance**
  - Focus on Management Estimates, Source Data Reliability, Control Environment, SEC Requirements

- **Data Scale & Reliability**
  - Size and Reliability of 3rd Party Data used for Accrual Estimates (Retail Inventory, Utilization, etc.)

- **Competitive Environment**
  - Loss of Exclusivity Implications, Formulary Pressures Increasing Incentives & Discounts

- **Healthcare Regulation**
  - Uncertain and Changing Healthcare Environment (Affordable Care Act)
Types of Pricing Adjustments
Types of Pricing Adjustments

- Managed Care/Medicare Part D/Coverage Gap Rebates
- Medicaid Rebates
- Prime Vendor Chargebacks
- Pharmaceutical Company
- Sales Returns
- Other Pricing Arrangements
Prime Vendor Chargebacks

- Represents difference between the wholesaler’s acquisition cost and the negotiated price with the Prime Vendor
- Prime Vendors can include organizations such as government-run hospitals, clinics and group purchasing organizations
- Chargeback claim is paid to the wholesaler by the pharmaceutical company
- Time period between the date of the original sale of the product and the date that chargeback claim is processed by the pharmaceutical company is generally one month or less in the Life Sciences industry
Managed Care/Medicare Part D Rebates

• Pharmaceutical companies can offer rebates and/or discounts in exchange for certain positioning on a formulary with commercial insurance companies/health plans or increases in market share

• Both Managed Care and Medicare rebates are paid to managed health care organizations by the pharmaceutical company

• Time period between the date of the original sale of the product and the date that the rebate is paid to the commercial insurance company/health plan can approximate a 3 month to 6 month period in the Life Sciences industry

• Lag period is due to the health plans submitting utilization (claim) data to pharmaceutical companies on a quarterly basis

• Utilization data is usually analyzed by management prior to rebate payments being issued to the health plans
Medicare Part D Coverage Gap

- Became effective for calendar years beginning January 1, 2011
- Commonly referred to as the “donut hole”
- Provides for 50% discount on purchase of prescription drugs while the participant is in the Part D Coverage Gap (Donut Hole)
- Specific identification model (point-of-sale model) or spread (effective rate) model may be used
Medicaid Rebates

Pharmaceutical companies generally participate in the Medicaid program whereby discounts and rebates are provided to governmental entities.

Rebates due under the program are paid to the states by the pharmaceutical company.

- The Center for Medicare and Medicaid Services (CMS) has established guidelines for minimum rebates to be paid
- Rebates can also be provided for participation in supplemental programs with the states in exchange for certain formulary status

Time period between the date of the original sale of the product and the date that rebate is paid to the states can approximate a 6 month to 9 month period in the Life Sciences industry.
Financial Statement Presentation

Balance Sheet presentation
• Reserves as a reduction of accounts receivable – generally include chargebacks
• Accrued liabilities generally include:
  o Managed Care, Medicare, Medicaid rebates
  o Sales returns
  o Coupons and other pricing adjustments
• Consideration can be given to the method of reimbursement – the issuance of credit as compared to the issuance of a rebate check

Income Statement presentation
• Generally presented as a gross to net adjustment (adjustment between gross and net sales)
• Fees related to services performed under Inventory Management Agreements are generally reflected as a direct reduction of gross sales
Gross-to-Net Estimation Process
Gross-to-Net Estimation Process

Accounting for Rebates, Chargebacks, and Other Adjustments to the Price Charged for a Product Sale

To recognize revenue upon shipment of a product, an entity must be able to reasonably estimate any potential future adjustments to the price of a product sale that is subject to such adjustment.

Although ASC 605-15 Products does not specifically address the accounting for pricing adjustments such as chargebacks and rebates (it is primarily focused on sales returns), the same conditions must be met for revenue to be recognized, with an emphasis on the following:

- The seller’s price to the buyer is substantially fixed or determinable at the date of sale.
- The amount of future returns (or in this case - chargebacks and rebates) can be reasonably estimated.

The following factors may also be helpful in such an evaluation:

- Existence of product-specific historical information regarding chargebacks and rebates.
- Availability and specificity of customer-specific pricing information.
- Availability of information related to product distribution channels and related business practices regarding product pricing in reseller arrangements (if applicable).
- Availability and specificity of customer inventory levels (arrangements).
Gross-to-Net Estimation Process

Key Terminology

• Class of Trade (Medicaid / Medicare / Chargebacks / Commercial / etc.)
• Factory Sales
• Demand Sales
  • Utilization / Mix
  • Rebate rate / Blended rate
• Pipeline
  • Wholesaler days
  • Retailer days
  • Chargeback processing lag
• “Lag”
  • Medicaid – two to four quarter lag
  • Medicare / Managed Care – one to three quarter lag
  • Chargebacks – one month lag
Gross-to-Net Estimation Process

Income Statement Method (Method used to Record the Reserves)

\[
\text{Beginning Reserve} + \text{Accruals for Reserves} - \text{Payments in Quarter} = \text{Ending Reserve}
\]

- Under this method management performs a rollforward of the reserves by taking the beginning balance and factoring in the accruals that run through the Income Statement and backing out the payments made in the quarter to arrive at the ending reserve
  - The accrual is based on sales multiplied by the established accrual rates (“blended rate”) within the ERP system.

- The end product of that process above will match the General Ledger Balance in ERP system unless there have been adjustments made to the calculated reserve.
Typical GTN Inventory and Claims Flow

Manufacturers

Wholesalers

Hospitals, Etc. (Chargeback Entities)

Demand Sale!

States / PBM / Plans, Etc.

Retailers

Medicaid/MHC/MMA, Etc.

Patient

Chargeback Activity

Factory Sale

Claims Data

Demand Sale!
What a Typical GTN Estimate looks like

### Balance Sheet Approach

<table>
<thead>
<tr>
<th>Demand Estimate</th>
<th>Pipeline Estimate</th>
<th>Liability</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Q1 14</strong></td>
<td><strong>Q1 15 Est. Claims</strong></td>
<td><strong>Total GTN Liability</strong></td>
</tr>
<tr>
<td>Proj Paid</td>
<td>Daily Average</td>
<td></td>
</tr>
<tr>
<td>125 (120)</td>
<td>155</td>
<td>189</td>
</tr>
<tr>
<td></td>
<td>1.7</td>
<td></td>
</tr>
<tr>
<td><strong>Q2 14</strong></td>
<td><strong>Inventory Days</strong></td>
<td></td>
</tr>
<tr>
<td>Proj Paid</td>
<td>Whl Retail Pipeline Reserve</td>
<td></td>
</tr>
<tr>
<td>130 (134)</td>
<td>10</td>
<td>38</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Q3 14</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proj Paid</td>
<td></td>
<td></td>
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<tr>
<td>135 (110)</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Q4 14</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proj Paid</td>
<td></td>
<td></td>
</tr>
<tr>
<td>150 (25)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total O/S Claims</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>151</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Beginning Balance</strong></td>
<td><strong>140</strong></td>
<td><strong>Manufacturers</strong></td>
</tr>
<tr>
<td><strong>Plus: Accruals</strong></td>
<td><strong>160</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Less: Payments</strong></td>
<td>(130)</td>
<td><strong>Factory Sale</strong></td>
</tr>
<tr>
<td><strong>Ending Balance</strong></td>
<td><strong>170</strong></td>
<td><strong>Wholesalers</strong></td>
</tr>
</tbody>
</table>

### Income Statement Method

<table>
<thead>
<tr>
<th>Beginning Balance</th>
<th>Plus: Accruals</th>
<th>Less: Payments</th>
<th>Ending Balance</th>
</tr>
</thead>
<tbody>
<tr>
<td>140</td>
<td>160</td>
<td>(130)</td>
<td>170</td>
</tr>
</tbody>
</table>
Gross-to-Net Estimation Process

Income Statement Method – Calculation of Accrual Rate

- Accrual Rate – This rate is typically based on management’s estimate of product utilization/mix and the respective rebate rate associated with that respective program
- For example in an automated environment, management typically has controls in place to evaluate the accrual rates that are included in the ERP system
Gross-to-Net Estimation Process, con’t.

Income Statement Method – Calculation of Accrual Rate

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What a Typical GTN Estimate looks like

**Balance Sheet Approach**

![Diagram illustrating the balance sheet approach]

**Income Statement Method**

<table>
<thead>
<tr>
<th>Beginning Balance</th>
<th>Plus: Accruals</th>
<th>Less: Payments</th>
<th>Ending Balance</th>
</tr>
</thead>
<tbody>
<tr>
<td>140</td>
<td>160</td>
<td>(130)</td>
<td>170</td>
</tr>
</tbody>
</table>

**Table Example**

<table>
<thead>
<tr>
<th>Q1 14 Proj Paid</th>
<th>Q2 14 Proj Paid</th>
<th>Q3 14 Proj Paid</th>
<th>Q4 14 Proj Paid</th>
<th>Total O/S Claims</th>
</tr>
</thead>
<tbody>
<tr>
<td>125</td>
<td>(120)</td>
<td>130</td>
<td>(134)</td>
<td>135</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>150</td>
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<td></td>
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<td></td>
<td>(25)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>151</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Q1 15 Est. Claims</th>
<th>Daily Average</th>
<th>Inventory Days</th>
<th>Pipeline Reserve</th>
<th>Liability</th>
</tr>
</thead>
<tbody>
<tr>
<td>155</td>
<td>1.7</td>
<td>10</td>
<td>12</td>
<td>38</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>189</td>
</tr>
</tbody>
</table>
RECALL: Typical GTN Inventory and Claims Flow

Where is the current quarter demand??

1. Manufacturers
2. Wholesalers
3. Hospitals, Etc. (Chargeback Entities)
4. States / PBM / Plans, Etc.
5. Medicaid/MHC/MMA, Etc.
6. Retailers

Chargeback Activity:
- Demand Sale!
- Factory Sale

Data Flow:
- Patient
- Claims

Gross-to-Net Adjustments

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Gross-to-Net Estimation Process

Balance Sheet Method (Method used to analyze Recorded Reserves) (excluding Chargebacks)

- Projected Rebates
  - Projected Current Quarter Rebates
  - Unpaid Prior Quarter Rebates

- Pipeline
  - Wholesaler Inventory
  - Retailer Inventory

- Balance Sheet Reserve
Gross-to-Net Estimation Process

Balance Sheet Method (Method used to analyze Recorded Reserves)

**Projected Rebates**

| Projected Current Quarter Rebates | Unpaid Prior Quarter Rebates |

**Projected Current Quarter Rebates** –
- Utilizing the most current data available, an estimate of demand sales is developed by management
- The appropriate rebate rate is then applied to calculate the estimated rebate

**Unpaid Prior Quarter Rebates**
- Based upon actual claims received, management will true-up based on new information their prior quarter rebate estimate as needed
- Estimate of unpaid claims is reflected net of actual processed payments based upon claims received
## Gross-to-Net Estimation Process

**Balance Sheet Method** (Method used to analyze Recorded Reserves)

### Projected Rebates

<table>
<thead>
<tr>
<th></th>
<th>Projected Current Quarter Rebates</th>
<th>Unpaid Prior Quarter Rebates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Projected</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paid</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q1 14</td>
<td>125</td>
<td>(120)</td>
</tr>
<tr>
<td>Q2 14</td>
<td>130</td>
<td>(134)</td>
</tr>
<tr>
<td>Q3 14</td>
<td>135</td>
<td>(110)</td>
</tr>
<tr>
<td>Q4 14</td>
<td>150</td>
<td>(25)</td>
</tr>
</tbody>
</table>

**Demand Estimate**

<table>
<thead>
<tr>
<th>Proj</th>
<th>Paid</th>
<th>Proj</th>
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<th>Proj</th>
<th>Paid</th>
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</table>

Assume Current Q is Q4 14

Changes in estimates to demand, pricing, or other components identified in the current quarter should be considered for their impact to previous quarters.
Management Changes in Estimates

There is a significant amount of management judgment and estimation required by companies in developing their gross-to-net accruals.

This is largely due to the varying lag times between time of factory sale and when the company receives a rebate claim:
- Medicaid – approximately two to four quarters
- Medicare & Managed Care – approximately one to two quarters
- Chargebacks – approximately one month

Upon receipt of the actual claim submission, management may determine that sufficient actual data is present representing a change to their original estimate.
Example Life Cycle Events Impacting Demand Forecasting

Below are additional examples of life cycle events that can impact management’s demand forecasting:

- **Events likely to decrease demand forecasts**
  - Product Loss of Exclusivity

- **Events likely to increase demand forecasts**
  - Declines in competitor landscape (less efficacious)

- **Events that can increase and/or decrease demand**
  - New Competitor launch or change to Competitor pricing strategy
  - New or changes to laws, regulations, or communications from state agencies
  - Formulary changes
Gross-to-Net Estimation Process

Balance Sheet Method (Method used to analyze Recorded Reserves)

<table>
<thead>
<tr>
<th>Projected Rebates</th>
</tr>
</thead>
<tbody>
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<td>Projected Current Quarter Rebates</td>
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Relevant Data

- Product sales data (factory sales and demand sales)
- Actual invoiced claims received from health plans (Managed Care / Medicare) or from State Medicaid programs
Gross-to-Net Estimation Process

Balance Sheet Method (Method used to analyze Recorded Reserves)

Projected Rebates

| Projected Current Quarter Rebates | Unpaid Prior Quarter Rebates |

Points of Focus for Audit Procedures:

• Testing internal controls over the projection process
• Test the completeness and accuracy of data utilized by management in developing their estimate
• Perform procedures to understand management’s projection process (walkthrough procedures, understand and test inputs, reperform calculation)
  • Gain and understating of changes to legislature impacting how rebates are calculated
  • Test changes in estimates to previously estimated rebates
    • What data changed from the previous estimate
    • What triggered management to record the adjustment (i.e. new data, sufficient trend, etc.)
What a Typical GTN Estimate looks like

Balance Sheet Approach

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<td>Daily Average Whl</td>
<td>Total GTN</td>
</tr>
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<td>Inventory Days Retail</td>
<td></td>
</tr>
<tr>
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Gross-to-Net Estimation Process

Balance Sheet Method (Method used to analyze Recorded Reserves)

There are several ways to calculate the pipeline, however the below is a suggested Best Practice performed on a per class of trade basis

\[
\text{Pipeline Component} = \frac{\text{Wholesaler Inventory Days}}{\text{Retailer Inventory Days}} \times \text{Average Daily Claim Payments} = \frac{\text{Total Inventory Days}}{\text{Total Inventory Days}}
\]
RECALL: Typical GTN Inventory and Claims Flow

Why is the pipeline important?

Manufacturers → Wholesalers
Factory Sale

Wholesalers → Hospitals, Etc. (Chargeback Entities)
Demand Sale!

Hospitals, Etc. (Chargeback Entities) → Medicaid/MHC/MMA, Etc.
Chargeback Activity

States / PBM / Plans, Etc. → Retailers
Claims Data

Retailers → Patient
Demand Sale!

Patient