RETAIL TO SPECIALTY: HOW LEGISLATIVE & REGULATORY ISSUES AFFECT DRUG REIMBURSEMENT

By Ron Lanton III, Esq.
President
True North Political Solutions
INTRODUCTION

- Introduction to how this information will be presented
- Discover what is happening in the specialty drug market Learn how payers are reimbursing pharmacies that are expanding to serve specialty patients
- Become familiar with the necessary accreditation
- Learn suggestions about what disease states to start with
- Understand the current state and federal policies surrounding specialty medications
- Discussion of difference between retail and specialty
Specialty Pharmacy is Estimated to Increase

Pharmacy Sales

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2021 (Projected)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialty</td>
<td>30%</td>
<td>42%</td>
</tr>
<tr>
<td>Retail/Other</td>
<td>70%</td>
<td>58%</td>
</tr>
</tbody>
</table>

Pharmacy Revenue (Billions)

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2021 (Projected)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialty Sales</td>
<td>$115</td>
<td>$240</td>
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</tbody>
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OVERVIEW OF PART B

What is Part B?

- Medicare Part B is part of the fee for service Medicare and covers outpatient services, preventative care, ambulatory services and durable medical equipment
- Patients can enroll in either Part B or Medicare Advantage Program
- Not enrolling in Part B when first eligible will incur a premium penalty
- Unlike Part A, Part B requires a premium
Medicare Part A and/or B Enrollment (Monthly Average) in Millions

- **Aged**
  - 2015: 46.7
  - 2016: 48.2
  - 2017*: 48.7

- **Disabled**
  - 2015: 8.9
  - 2016: 8.8
  - 2017*: 9

*Projected/Preliminary

Information obtained from: https://www.cms.gov/fastfacts/
Medicare Individuals Served by Service Type (2015) in Millions

- Part B (33.8 Million) Total
  - Physician/DME: 33.3
  - Outpatient: 25.3
  - Home Health: 2

Medicare Payments by Service Type (2015) in Billions

- Part B ($178 Billion) Total
  - Physician/DME: 36% ($64.4 Billion)
  - Outpatient: 58% ($102 Billion)
  - Home Health: 6%
OVERVIEW OF PART B

- What is covered?
- Limited prescription coverage
- Drugs that the patient would usually not give to themselves. Either they are doctor administered or through home infusion
WHAT MEDICATION DOES MEDICARE PART B COVER?

- Drug used with an item of durable medical equipment (DME)
- Some Antigens
- Injectable Osteoporosis Drugs
- Erythropoisis-Stimulating Agents (used from end-stage Renal Disease)
- Blood Clotting Factors
- Injectable & Infused Drugs
- Oral End-Stage Renal Disease Drugs
- Parenteral and enteral nutrition (such as feeding tube)
- Intravenous Immune Globulin provided at home
- Shot Vaccinations (such as Flu shots, Pneumococcal shots, & Hep shots)
- Transplant drugs
- Oral cancer drugs
- Oral anti-nausea drugs
- Self-administered drugs in hospital outpatient settings

Information obtained from: https://www.medicare.gov/coverage/prescription-drugs-outpatient.html
OVERVIEW OF PART B

Costs?

- The current Medicare Part B premium is $134
- For individuals with Social Security Benefits the average premium is $109
- The deductible is $183 per year and the copay is 20% once the deductible is met
- Premiums have increased steadily over the years at an average rate of 8%
Medicare Part B Payments in 2015 (Millions)

- Physician/Other Suppliers: $69,199
- DME: $6,502
- Home Health Agency: $43,574
- Laboratory: $11,491
- Other Intermediary: $8,534
- Managed Care: $92,934
- Other Carrier: $21,184
- Outpatient Hospital: $19,459

MEDICARE PART B PREMIUMS
INCREASING AN AVERAGE OF 7.7% PER YEAR

OVERVIEW OF PART B

- ASP and how it works
- Medicare Prescription Drug, Improvement and Modernization Act of 2003
- ASP relies on manufacturer sales data to set pricing and the data must be reported to CMS on a quarterly basis
- Rebates and discounts are used in the ASP calculation
- Lowered reimbursement when first enacted
OVERVIEW OF PART B

- Home infusion changes
- Congress exempted DME drugs from the ASP calculation
- Medicare Home Infusion Site of Care Act
- Home Infusion drugs are calculated with the same ASP methodology
- The service payment will start in 2021
MEDICARE PAYMENT AND DOLLARS SPENT BY PAYOR CATEGORY FOR EACH THERAPY CATEGORY EXTRAPOLATED TO NHIA MEMBERSHIP (730 SITES) IN MILLIONS (ROUNDED)

Information obtained from: https://2010 NHIA Provider Survey • Comprehensive Aggregate Analysis Report
POTENTIAL REIMBURSEMENT CHANGES

OIG recommendations

1. Least Costly Alternative
2. ASP Inflation Limit
3. Lower dispensing and supply fees
POTENTIAL REIMBURSEMENT CHANGES

MedPAC- Medicare Payment Advisory Committee

- WAC + 3 instead of ASP
- ASP inflation rebate
- Consolidated billing codes
- Create a Drug Value Program as an alternative to ASP payment system
- Reduce ASP add-on so that physicians will enroll in Drug Value Program
DIR FEES

- CMS recent report
- Higher use of DIR fees
- CMS acknowledged they lower premiums
- DIR Federal Legislation
- Sponsors
- Where is the bill now?
MANUFACTURER POLICY

- PhRMA, increasing lobbying efforts
- PhRMA vs. ICER & PCMA
- Manufacturer Pricing Transparency
  - Allergan Pledge to keep price increases at single digits
  - Abbvie and Novo follows Allergan
  - Merck
  - JNJ
MANUFACTURER POLICY

- Campaign for more drug price transparency
- Investor campaign asking for price transparency
- Interfaith Center on Corporate Responsibility
- Wanted companies to show evidence as to why prices increased
- The campaign was blocked by manufacturers
PAYOR POLICY

- Pathways: Emerging cost-containment protocols by payers
- Pathways may incentivize doctors to prescribe a specific treatment protocol for patients with a particular diagnosis based on available evidence
- Goal is to reduce costs
- May result in different pathway protocols by each insurer
PAYOR POLICY

- Value Based Contracts
- These are contracts in which insurers pay for drugs based on their effectiveness
- Novartis Contract with Cigna and Aetna
- Amgen contract could be new model for Part B drugs
- Value based contracts are used to control high drug prices
- Drug Tiering
NEW TREATMENTS TO KNOW ABOUT

- Immunotherapy and Gene Therapy
- Newest FDA approvals
- Biosimilars
- Amgen v. Sandoz
- State substitution laws
- How should retailers get involved?
- HIV, Hep. C, RA, Immunology
ACRREDITATION ORGANIZATIONS

- Accreditation Commission for Health Care (ACHC)
  - Pharmacy Compounding Accreditation Board (PCAB) - a service of ACHC
- LegitScript
- Utilization Review Accreditation Commission (URAC)
RECOMMENDATIONS ON WHAT TO DO NEXT FROM A BUSINESS PERSPECTIVE

- MedPAC should be monitored
- Watch the policies being implemented by HHS Secretary Tom Price; he could affect pricing with demos or direct changes via regulations
- Watch Congress and state legislatures for relevant information
- Monitor the payer and manufacturer communities for pricing policies.
- Advocate to your policymakers about your business
CONTACT INFORMATION

Ron Lanton III, Esq.
President
True North Political Solutions
Email: ronlanton3@truenorthps.com
Phone: 202-969-5466
Twitter: TrueNorth_PS