Innovative Contracting Solutions in a Changing Healthcare Landscape

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Profile and background of Trinity Partners, LLC

Founded in 1996, Trinity Partners has over 100 employees that specialize in the life sciences industry.

Trinity provides a range of strategy consulting services that run the gamut from strategic to tactical in nature, drawing on best-in-class capabilities in primary market research and advanced analytics.

Our clients are among the most successful firms in the industry.

Trinity has worked with 6 of the top 12 global pharmaceutical companies, 12 of the top 20 specialty and biopharma companies and 6 leading consumer and medical products companies.

We strive for partnership with our clients, and hold ourselves accountable for their success.
Key Questions for Today

Contracting and Reimbursement – 2015 Issues

How has the rising cost of healthcare lead to a greater integration of risk and increased risk-bearing as a means to control costs?

How have ACOs and other risk integrating structures fared to date? What contracting models can help risk-sharing models become opportunities?

How does medical benefit products contracting with providers evolve and which contract analytics can help optimize new contracts or amendments?

How can advanced analytics of your payer environment help reduce costs and waste in pharmacy product access contracts with MCOs and PBMs?
Why pricing and contracting matter – Facilities are sensitive

Because of reimbursement arbitrage associated with the generic availability of ondansetron (Zofran), Aloxi for CINV lost >30% of sales and didn’t rebound fully for 18 months

Aloxi U.S. Net Sales ($M)

November 22, 2006 – Teva launches generic injectable Zofran

Accounts switch to ondansetron (being temporarily reimbursed as Zofran) → >$100MM in Lost Aloxi Revenue

Source: EvaluatePharma
Agenda

Part 1: The Evolving US Healthcare Landscape

- The New Norm
  *The shift to bundled contracting, accountable care, and performance-based payment*

- The ACO Model: Does it Work?
  *ACO partnerships and the financial drivers of the ACO model for manufacturers*

Part 2: Parsing the Complexities of Contracting & Reimbursement

*Essential considerations & tools for success*

- Medical Benefit Products

- Pharmacy Benefit Products

Key Learnings and Q&A
The runaway cost of healthcare is unsustainable

Healthcare in the US is expensive and inefficient, and the government is pursuing innovative strategies to curb costs while maintaining quality of care.

The US spent 17.4% of GDP on healthcare in 2012. The UK spent just 9.4%.

If this trend continues, healthcare expenditure can break 20% by 2020. This is 4x the national spending on Education in 2010.

What Worries Payers?

Payer research highlighted ACA and escalating expenditures among their top concerns.

Payers rated ACA as a significant cause of concern.

2/3 of payers interviewed report that the ACA has already had a major impact on their plan.

Payers are ready to support products with adequate health economic and outcomes data to warrant use.

Source: Trinity Partners Research: Demystifying the U.S. Payer Mindset and Expectations, May 2014
Mounting Costs of Drug Therapies and Providing Care

Cost of therapies and system financial pressures continue to mount and garner increased attention

The Washington Post
Cancer clinics turning away thousands of Medicare patients. Blame the sequester

Orphan Therapies to hit 19% of all drug expenditures by 2020

Gene Therapy first €1MM+ Price Tag

The Wall Street Journal.
Launch of 2 IPF products $90k+

How can pharma and biotech get in front of the trends in the industry that have payers and providers so worried about sustainability?
Health Systems are Becoming More Organized

The New Customer Structure

A changing market and new care priorities are driving a shift in customer structure.

Providers:
- ASCs
- Medical Groups
- Hospitals
- Community Clinics
- IDNs

Payer & Provider:
- IDNs
- Medical Groups
- ACOs
- Federal

Payers:
- MCOs
- Medicare
- Medicaid
- PBMs
- *owned by payer or containing payer

Supply Chain:
- Hospital GPOs
- Clinic GPOs
- Distributors
Health Systems are Becoming More Organized

The New Customer Structure

A changing market and new care priorities are driving a shift in customer structure

- Providers
  - ASCs (No payer)
  - Medical Groups (No payer)
  - Hospitals
  - Community Clinics

- Payers
  - MCOs
  - Medicare
  - Medicaid
  - PBMs

- Payer & Provider
  - IDNs*
  - Medical Groups* (CMS or commercial)
  - ACOs
  - Federal (VA, DoD)

- Supply Chain
  - Hospital GPOs
  - Clinic GPOs
  - Distributors

*owned by payer or containing payer
Changes in Structure Look to Share Risk for Total Care

Trinity surveyed 76 respondents across 26 Integrated Delivery Networks (IDNs)

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<thead>
<tr>
<th>Category</th>
<th>No risk</th>
<th>Some risk</th>
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<tr>
<td>Medical Risk</td>
<td>Physician Compensation tied to Quality of Care</td>
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<td>ACO Penetration</td>
<td>Pharmacy Risk (Payer Owned)</td>
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<td>Capitation Penetration</td>
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<td>EMR Utilization</td>
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- Trinity identified **7 organizational characteristics** that were redefining how IDNs approached delivery of health care
- A key driving force in change has been **how risk can been shared by organizations**

Source: Trinity Partners Research
What are Pharma and Biotech Opportunities?

As organizations move to accepting greater risk, manufacturers can use health economic and outcomes data to drive increased use of novel products with strong supporting evidence.
Medicare Shared Savings Program Shows Promise

Preliminary analysis of the Medicare Shared Savings Program (MSSP) ACOs indicate over half of the participants that began in 2012 and 2013 have reduced spending.

Preliminary Results for MSSP ACOs Joining in 2012 and 2013

- Costs same or higher than benchmark: 102 (46%)
- Cut costs, no sharing: 66 (30%)
- Cut costs, shared savings: 52 (24%)

6 ACOs failed to report satisfactory quality metrics hence lost savings; 1 ACO went significantly over-budget and shared losses.

Over $700M savings generated to date

More than $300M paid out to ACOs so far

Sources: Centers for Medicare & Medicaid Services; Early evidence on Medicare ACOs and next steps for the Medicare ACO program. *Health Affairs.*
The Evolution Towards Outcome-based Contracting

As organizations move to absorbing more risk, manufacturers can use health economic and outcomes data along with shared risk to drive usage of novel products or to maintain access and preference.

The Manufacturer’s Contracting Continuum

- **Traditional Contracts**
- **Health Econ / Outcomes-Based**
- **Shared Risk**
- **Product “Guarantee”**

**Example Shared Risk Contract Design**

- **Launch**
  - 12% Discount
- **Month 12+**
  - 4% Discount
  - 12% Discount
  - 16% Discount

**New Challenges:**
- What measures?
- Who evaluates data?
- Who arbitrates?

- Outcome / Cost Reductions Fully Achieved
- Outcome / Cost Reductions Partially Achieved
- Outcome / Cost Reductions NOT Achieved
Health Systems are Becoming More Organized

A changing market and new care priorities are driving a shift in customer structure.
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Key Learnings and Q&A
**“Traditional” Contracting Considerations – In a New Light**

Strategic contracting and reimbursement decision-making varies widely between medical and pharmacy benefit products.

### Medical Benefit Products

“Buy and bill” contracts supported by comprehensive evaluation of holistic metrics from multiple perspectives

**360 Degree Contracting**

- Manufacturer’s Bottom Line
- Clinical Profile
- Effective Contracting
- Government Pricing
- Customer’s Bottom Line

### Pharmacy Benefit Products

Acquiring and understanding contract performance data and evaluating payers’ ability to actually control in order to be armed for managed care negotiations.

**Payer Indexing & Context-Dependent Contract Optimization**
360 Degree View of Medical Benefit Product Contracting

The scope and degree of provider contracts depending greatly on the therapeutic space and clinical value and/or interchanability.

Buy-and-Bill Contracting 2006-2014

- Implied contract concessions (calculated as ASP / WAC)
  - Oncology Therapeutics (5-10%)
  - Oncology Supportive Care (20-50%)
  - Other Products (20-35%)

Implied Discount (ASP/WAC) – Onc Therapeutics

Implied Discount (ASP/WAC) – Onc Supportive Care

Implied Discount (ASP/WAC) – Other Products

Sources: EvaluatePharma, RedBook, CHS

Range: Core oncology supportive care

Range: Core oncology supportive care
360 Degree View of Medical Benefit Product Contracting

Downstream impacts of price increases include government pricing (and penalties), price protection, and potentially additional rebates or incentives to offset demand sensitivities to price or cost-recovery.

Understand Impact of Contracting on Net Revenue

- **A price increase is not always what it seems**
  Widening Gross-to-Net mean less-than-expected incremental net revenue

- **Contracting should enable product use for contract sensitive providers**
  Although price/contract parity is critical, no discount dollar should go to waste in supporting demand

**Tools for Success**

- Contract Design Research & Incentive Testing
- Comprehensive GTN Modeling
360 Degree View of Medical Benefit Product Contracting

Effective forecasting of government pricing calculations is critical to understanding the impact of any pricing or contracting decision on the bottom line.

Understand Impact of Price Changes on Government Pricing

- **Government pricing calculations are complex**
  
  ...but may have a large impact on bottom line if ignored (ASP, AMP, Non-FAMP, etc.)

- **Price increases may have a disproportionate impact on government business**
  E.g. CPI-U penalty for 340B customers & Medicaid volume; best price considerations

**Tools for Success**

**Government Pricing Impact Assessment & Forecasting**

- **Clinical Profile**
- **Effective Contracting**
- **Manufacturer’s Bottom Line**
- **Customer’s Bottom Line**
- **Government Pricing**

![Graph showing government pricing impact assessment and forecasting](image-url)
360 Degree View of Medical Benefit Product Contracting

The “customer” for medical benefit drugs may be a specialty pharmacy, GPO, or the provider: for buy-and-bill drugs in this setting, reimbursement may become disconnected from actual acquisition cost.

Know Your Customer

- Increasing scrutiny on practice economics
  ... as reimbursement limits tighten, pressure on providers goes up

- Consider contract mechanisms that protect accounts from going “underwater” for any patient
  E.g. price protection, ASP-based pricing

Net Cost Recovery Analysis

**Tools for Success**
**Know Your Product**

- Pricing & contracting decision-making must account for competitive environment
  
  *Clinical profile is, of course, the primary driver of business for any product*

- ...But ineffective contracting/pricing can doom even the best drugs

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**Tools for Success**

**Price Sensitivity Research**

*Will an effective net price differences impact Demand? If so, how much?*

**Product Positioning Work**

*Including contract/price elements*
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Key Learnings and Q&A
MCO / PBM Contracting Key Questions?

Which MCOs are effectively operationalizing plan controls they put in place for your category?

Are you getting an adequate return for your contract $ for preferred status or for limited formulary coverage?

What is the right rebate to offer relative to the achievable share gain for preferred status?
Contract Optimization for Pharmacy Benefit Products

For pharmacy benefit products, *access*, and therefore MCO contracting, is often a critical driver of success in meeting demand targets.

**MCO Impact**

- **MCO contracting should be context-dependent**
  All payers are not created equal: contracting should account for relative influence on potential patient volume

- **How well does payer execution of design controls impact the class? Specific Products?**

- **Weight influence by covered lives for the target indication**

**MCO Incentives**

- **Offer contracts that help secure preferred status**
  Although clinical profile and market/payer context will often preclude a drug from preferred status, contracting may give a product the “nudge” it needs

- **…But understand your breakeven rebate for the additional share you may achieve?**
Contract Optimization for Pharmacy Benefit Products

Tools such as payer indexing & context-dependent contract optimization will provide important support for contracting & pricing decisions.

**Payer Index Tools – Evaluating the Payer Landscape**

- **Share vs Discount Index: Cross Payer View**
  - Share Over-Performing Discount
  - Share Under-Performing Discount

- **Stack-ranked Payers by Control Impact**
  - (spread of preferred / disadvantaged products vs their national averages)

- **Ineffective Controls**
- **Effective Controls**
Contract Optimization for Pharmacy Benefit Products

Tools such as payer indexing & context-dependent contract optimization will provide important support for contracting & pricing decisions.

Payer Index Tools – Evaluating Efficacy of Controls

Performance by Plan Degree of Control

Performance by Relative Formulary Position
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Key Learnings and Q&A
Key Learnings

- The ACO model and risk-based contracts are here to stay and will almost certainly become more prevalent in coming months and years.

- Novel analytics behind provider-based contracting requires a thorough assessment of the product, manufacturer objectives and financials, and provider-level impacts.

- All payers are not created equal – each has a unique ability to execute on controls and to do so with varying degrees of success. Having these insights can help reduce or eliminate contract waste.

Questions?
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