

Pharmacy Benefit News

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Commentary: The Math Must Work

In insurance, the law of large numbers is critical. Essentially, a large number of individuals must be insured to make sure that everyone pays in, while a smaller percentage of individuals take out. The individuals who take out require therapy or interventions. Similarly, for physician providers, the sicker patients must be balanced by the patients who are healthy. For example, in physician practices, "healthy patients" cost about \$1600/person/year. On the other hand, patients who have major illnesses or injuries cost about \$60,000/person/year, and patients at the end-of-life have variable costs. In between, patients with one chronic illness cost about \$6000/year, and those individuals with two conditions cost about \$12,000/year. As a result, the average patient in a waiting room costs about \$8000/year.

If the health care team is accountable for care, as in the Affordable Care Act, then the team needs a preponderance of "healthy" individuals to cover the sicker patients. If everyone is given the opportunity to purchase care at lower prices, as in the American Healthcare Act, then healthier individuals must purchase insurance or the math will not work.

Pro Pharma has designed and managed pharmacy risk for employers that uses a "virtual waiting room" model to bulk up the number of individuals with healthy and sick patients. The challenge of the model is demographics and geography. If the population of patients is composed of poor and elderly, then access to care drives the population to higher use, and more expensive care. Clearly, different subspecialties of medicine are necessary to treat healthy, co-morbid, major illness, and end-of-life patients.

The model including the law of large numbers for coverage, a virtual waiting room to lower cost of care, and technology to spread the cost of access to care are all critical. For the math to work, we must find solutions that include demographics, access to medical subspecialties, affordability, medical malpractice reform, and regulatory protections to address multiple problems at once. Also, for the math to work, we must solve multiple problems at the same time. This is a free market solution as well as a population management problem. Politics must pay attention to the math or all solutions will fail.

Reference: Modern Healthcare, 11/14/16, pg. 35

Analytics at Work: A Real World Example

Audit This!

Problem: A Client Health Plan had several audits of PBM claim adjudication performed in the past on different PBMs. Some were done to recapture funds, and some to check compliance with the PBM contract and benefits. Rather than dwell on financial reimbursement, which had previously been time consuming and did not achieve expected compensation, the goal was to develop corrective action plans for the PBM that would achieve the desired results. What had not been clearly addressed in the prior audits, was an objective, measurable benchmark of the Plan's performance and what to do about it. The Plan asked Pro Pharma to perform a digital analysis of all claims, validate efficiency,

Methodology: Pro Pharma enlisted ProData Analytics to perform a fully digital analysis of 100% of claims for the most recent two year period. All eligibility, benefits, pricing, comparison to benchmarks, and clinical compliance outcomes were evaluated. Variances from contract, benchmarks, State/Federal compliance regulations, and Pharmacy Quality Alliance (PQA) metrics were quantified.

Outcomes: The digital analyses made the audit and analyses more efficient and less costly. Contract and benefit compliance were evaluated and variances with corrective action plans were developed. Benchmarks provided measurable variance from both regional and national trends on a pricing, and PMPM (Per Member Per Month) as well as PUPM (Per Utilizer Per Month) basis. These variances identified the drivers of trend (cost, utilization, new entrants) and specifically what actions were necessary to reverse or reduce these metrics.

A separate compliance audit was identified as State and Federal guidelines varied in some cases from actual performance. These variances would signal a compliance notification for the Plan such that corrective action plans preempted any notification. This finding saved the Plan from unforeseen notifications and State applied financial consequences.

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Commentary: Specialty Rx Challenges All Treatment Effectiveness, Risk and Affordability

Specialty Rx approvals slowed in 2016, but the expectation is that approvals in 2017 will be much greater. Manufacturers are targeting cancer, autoimmune diseases such as rheumatoid arthritis and multiple sclerosis, blood products, hepatitis C and rare diseases. Only Hepatitis C experienced a slowing probably due to coverage of known viral carriers.

The introduction of biosimilars to place downward pressure on cost has not been a major driver yet. Will the new treatments provide greater effectiveness and lower risk? This is yet unknown. However, the current emphasis on “noninferiority trials” do nothing to prove that new products are better, only that they are probably no better.

So, what can we expect for 2017? The table below provides an indication of what is coming.

Ref: Diplomat Clinical Services, Drugstorenews.com, March 2017

Commentary: Value-Based Care Seems to Have Legs

Value-Based Care, also known as Integrated Coordinated Care, is a complex issue that seems to have staying power regardless of the national health care system. Under the Affordable Care Act there was an expansion in access to care and how providers are paid. Under the American Healthcare Act there is an emphasis on access and affordability. However, the cost of care has been rising, especially the cost of Specialty Rx.

At the same time, provider reimbursements have decreased while there is an urgent need for IT infrastructure without the capital to purchase, install, implement, and maintain these architectures. Part of the rising overall cost of care is medical malpractice insurance which requires review and re-evaluation. Couple these problems with a shortage of nurses, physicians and pharmacists, and the cost of staffing increases.

These drivers -- namely, rising cost of Specialty Rx, provider reimbursements, IT infrastructure, and a shortage of professionals -- are already being addressed to a degree:

- Biosimilars are one method to lower Specialty Rx cost, although they are currently providing 10-15% discounts. Further competition in each therapeutic category, including innovations from international sources, should lead to competition to lower cost. A competitive marketplace will require more innovative financing options to ensure affordability.
- IT infrastructure will require investment. Part of this is already provided by the federal government, presuming that the investment capital is not cut by future federal budgets. Mobile apps will also provide information directly from patients to speed care and allow for more timely adjustment in therapy.

2017 expected specialty approvals†

EXPECTED FDA DECISION DATE	DRUG	TARGET INDICATION	MANUFACTURER
Q1 2017			
Feb. 24	Revlimid (lenalidomide)	Multiple myeloma, maintenance therapy after stem-cell transplant (expanded indication) / Oral	Celgene
Feb. 28	Tecovistat ethyl	Carcinoid syndrome / Oral	Lexicon
March 28	Ocrelizumab	Multiple sclerosis / IV	Roche
March 29	Dupilumab	Atopic dermatitis / SubQ	Sanofi, Regeneron
March 30	Abelaparnide	Osteoporosis / SubQ	Radius
Early 2017*	SB-2 (infliximab)	Remicade biosimilar / IV	Samsung Bioepis
Early 2017*	NO-CP / NK0989	Hemophilia B / IV	Necesa
Early 2017*	Tisimor (pembrolizumab), Makinist (trametinib)	Non-small cell lung cancer, BRAF+ (expanded indication) / Oral	Novartis
Early 2017*	TLE-400 (etanercept + lornoxicam + tenofovir disoproxil fumarate)	HIV (new combination) / Oral	Mylan
Q2 2017			
Early-mid 2017*	Midostaurin	Acute myeloid leukemia and aggressive systemic mastocytosis	Novartis
Early-mid 2017*	Ribociclib	Breast cancer / Oral	Aster, Novartis
April 2017	Berictinib	Rheumatoid arthritis / Oral	Eli Lilly, Incyte
April 3	Dolutegravir	Huntington's disease / Oral	Teva
April 11	Valbenazine	Tardive dyskinesia / Oral	Mitsubishi Tanabe, Neurocrine
April 24	Praluent (alirocumab)	Hypercholesterolemia / SubQ (once monthly dose)	Sanofi, Regeneron
April 27	Cerliponase alfa	Batten Disease / IV	Blomarin
April 29	Brigatinib	Non-small cell lung cancer / Oral	Ariad
June 9	Pegfilgrastim (CIS-1701)	Neulasta biosimilar / SubQ	Cohesus
June 30	Bimegestinib	Melanoma / Oral	Amyx
June 30	Ecdanone	Amniotrophic lateral sclerosis / IV	Mitsubishi Tanabe
June 30	Niraparib	Ovarian cancer / Oral	Janssen, Tesaro
Mid-2017*	Hazgarda (C1 esterase inhibitor, human)	Hereditary angioedema / SubQ (new formulation)	Cal Behring
Mid-2017*	Nitisinone	Hereditary tyrosinemia (new formulation) / Oral	Cyclo
Mid-2017*	Bertysia (belimumab)	Lupus / SubQ (new formulation)	GlaxoSmithKline
Mid-2017*	Isozumab	HIV / IV	Takeda
Mid-2017*	Stivarga (regorafenib)	Hepatocellular carcinoma (expanded indication) / Oral	Bayer
Mid-2017	Academia (ocicizumab)	Giant cell arteritis (expanded indication) / SubQ	Genentech
Mid-2017	Relacor (epoetin alfa)	Epreon and Procrit biosimilar / SubQ	Hospira, Pfizer
Mid-2017	Sarilumab	Rheumatoid arthritis / SubQ	Sanofi, Regeneron

† As of press time * Formulated
Source: Biopart Clinical Services

must be addressed to ensure that tests and procedures are not done to protect professionals.

- The shortage of professionals may already be addressed with the expansion of medical, nursing and pharmacy schools. Triaging care to mid-level practitioners (i.e., nurse practitioners, physician assistants, and clinical pharmacists) will also relieve the stress on primary care. Tele-medicine options will also provide medical subspecialists in areas where these specialties are unavailable.

Value-Based Care places an emphasis on effectiveness and affordability. This is a rational approach to evaluating new agents, but it is predicated on prevention and other, non-drug, solutions. While political arguments drive to payment of care, they miss the point. The costs are rising regardless. Prior solutions have been bipartisan, experiments that are regularly changed to improve outcomes, and emphasize the underlying drivers of care. Value is dynamic. Our health care systems must also be dynamic and target more than one solution, or nothing will work.

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- Eligibility Audit
- Audit of Claims for Validity, Pricing, AWP, etc.
- Rule-Based Benefit Simulation of Benefit Design
- Financial Drivers of the Benefit
- Questionable/Abuse Audits
- Reconciliation
- Medicare Modernization Act (MMA) / Part D

Rebate Analysis

- Baseline Audit of Rebate Claims
- Benefit Design Scenarios vs. Impact on Rebate/ Net Cost Optimization
- Net Cost vs. Rebate Optimization Modeling
- PBM / Manufacturer Contract Review (if available and applicable)
- Drug Utilization Review Audits
- Coordination of Benefits

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