Pharmacy Benefit News

Issue # 313| October 5th, 2017

Watch the Latest Episode of Professor Speaks!

Special Edition

This special issue of the Pharmacy Benefit News (PBN) is a compilation of our prior articles about the Affordable Care Act (ACA). Based on the multiple bills in Congress to repeal the ACA,we felt that fundamental principles should be addressed in this discussion. Our position is not to support or condemn, but rather to present factual information upon which to base further, and future, discussions. The information is collected from messages from prior PBNs and Facebook Live discussions. All hyperlinks are provided to find supporting discussions. In a world that is debating truth as differentiated from fiction, we hope that this information provides some clarity and understanding to complex and multifaceted problems.

Three Years Later, Where Are We Now with Accountable Care Organizations?

In a report published on August 29, 2017, the Office of Inspector General (OIG) concluded that Accountable Care Organizations (ACOs) saved about $1 billion for the Centers for Medicare & Medicaid Services (CMS) while providing high-quality care. ACOs are established as a part of the CMS's shared-saving program initiative under the Affordable Care Act (ACA). This initiative – which accounted for $168 billion in Medicare expenditure over the past three years – focused on paying providers based on value rather than volume.

The report analyzes CMS data from 428 ACOs over the first three years of the program. About 82% of ACOs improve the quality of care based on CMS's 33 individual quality measures. ACOs also outperform the traditional fee-for-service providers on 81% of the quality measures. In term of cost, 282 of the 428 ACOs (67%) reduced spending for at least one of the first three years. The remaining 146 ACOs exceeded their spending, compared to their benchmarks, for all three years. Notably, ACOs that generate savings have higher benchmarks on average.

Commentary:
ACOs are groups of providers and hospitals who come together to coordinate care for Medicare patients with two major goals: provide quality care and decrease health care spending. When an ACO achieves both goals, the CMS will share a portion of the saving with the organization. The goal for healthcare spending is set based on each ACO's historical benchmark. In terms of quality, there are four major domains established by the CMS: patient/caregiver experience, patient safety/care coordination, preventive health, and at-risk population.

This report shows that ACOs are improving quality of care as compared to the fee-for-service models. The cost-saving aspect of the shared-saving program is not universal. The net $1 billion in saving is only a small fraction of the $168 billion investment in the program. Moreover, using

Indeed, the ACO model is still not the perfect model for value-based payment nor it is the “silver bullet” for solving our increasing healthcare spending problem. However, the ACO model is a step in the right direction. The OIG report proves that, with the right incentives, the US healthcare system is capable of spending less while also delivering quality care.

Reference:
1. Office of Inspector General, Department of Health and Human Services. “Medicare Shared Savings Program Accountable Care Organizations Have Shown Potential for Reducing Spending and Improving Quality.” Office of Inspector General - US Department of Health & Human Services, Office of Inspector General, 29 Aug. 2017, oig.hhs.gov/oei/reports/oei-02-15-00450.asp

Commentary: Politicians Need to Know

As politicians argue how best to design health care for the US population, changes in Medicare and Medicaid are active targets for change. Yet, it is important that they understand the numbers. Twenty percent of people on Medicare (about 11 million beneficiaries) also receive Medicaid assistance. These are often referred to as “duals”.
Who are the major Medicare-Medicaid (Medi-Medi) recipients? Forty percent are less than 65 years old with significant disabilities. Two-thirds of Medicaid spending is for long-term care services. Two-thirds of nursing home residents are Medi-Medi and are women. Finally, federal and state Medicaid spending was almost $147 billion in 2011 according to the Kaiser Family Foundation

Source: KFF

The Medi-Medi patients are a large subset of the patients covered under the Affordable Care Act (ACA). There is also over 100 million people with pre-existing conditions. These populations add to the use of Emergency Medicine, acute care hospitals and other expensive “primary” care sites.
As we argue about how to support these patients, they were are significant concern, because they either are without insurance or paid high fees. Access has always been available. Approximately two-thirds of the insured population paid for some insurance even if it was not adequate.
The others had access but couldn’t afford it. The Medi-Medi and pre-existing illness patients are the most expensive. Do we choose access that they already have, or find some ways to pay for their care?

Healthcare Trends Have No Roadblocks

The fate of the American Health Care Bill (AHCA) is in flux, though there are three immutable trends in the US healthcare system that won’t change. The first trend is demographic: The US population is continuing to age. Second, technology has become a pervasive element across the health care system, with a major impact on diagnosis, treatment and communications. Third, discoveries in the life sciences that enhance the quality and extend the length of life will continue to flow from research laboratories.
As a result, businesses that help patients to understand, access and use the healthcare system; that allow older patients to receive high-quality care while remaining in place; and that expand the capabilities and reach of electronic health records and digital health applications will benefit. Regardless of how the Health Care Bill evolves, tremendous opportunities will remain in these areas for consumers, medical providers, healthcare payers, and investors to shape and improve the health care system.

Citation: Karpay, F. B. (2017, May 25). 3 Health Care Trends That Don't Hinge on the ACA. Retrieved June 12, 2017, from https://hbr.org/2017/05/3-health-care-trends-that-dont-hinge-on-the-aca

Commentary: The expansion of portable digital health tools along with electronic health records, has facilitated smoother transitions of care, easier access to patient files, and a reduction of paper trails. Along with moving into the digital era, it will be easier to see trends and track certain disease states, which can adjust certain screening guidelines and potential treatments. Providing easy electronic access to health records and tracking milestones in health, can lead to a reduction in healthcare costs and a better understanding of the roadmap of burdening disease states. Particularly with an aging population at hand. Improving outcomes and compliance can be two areas of benefit for the expansion of technology in health.

Commentary: Who Is a Diabetic?

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

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

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	Telotristat ethyl	Carcinoid syndrome/Oral	Lexicon
March 28	Ocrelizumab	Multiple sclerosis/IV	Roche
March 29	Dupilumab	Atopic dermatitis/SubQ	Sanofi, Regeneron
March 30	Abaloparatide	Osteoporosis/SubQ	Radius
Early 2017*	SB-2 (infliximab)	Remicade biosimilar/IV	Samsung Bioepis
Early 2017*	N9-GP / NN7999	Hemophilia B/IV	Nexus
Early 2017*	Tafinlar (dabrafenib), Mekinist (trametinib)	Non-small cell lung cancer, BRAF+ (expanded indication) / Oral	Novartis
Early 2017*	TLE-400 (efavirenz + lamivudine + 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	Astex, Novartis
April 2017	Baricitinib	Rheumatoid arthritis/Oral	Eli Lilly, Incyte
April 3	Deutetrabenazine	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	Biomarin
April 29	Brigatinib	Non-small cell lung cancer/Oral	Ariad
June 9	Pegfilgrastim (CHS-1701)	Neulasta biosimilar / SubQ	Coherus
June 30	Binimetinib	Melanoma/Oral	Array
June 30	Edaravone	Amyotrophic lateral sclerosis/IV	Mitsubishi Tanabe
June 30	Niraparib	Ovarian cancer/Oral	Janssen, Tesaro
Mid-2017*	Haegarda (C1 esterase inhibitor, human)	Hereditary angioedema/SubQ (new formulation)	Csl Behring
Mid-2017*	Nitisinone	Hereditary tyrosinemia (new formulation)/Oral	Cycle
Mid-2017*	Benlysta (belimumab)	Lupus/SubQ (new formulation)	Glaxosmithkline
Mid-2017*	Ixekizumab	HN/IV	Talmed
Mid-2017*	Stivarga (regorafenib)	Hepatocellular carcinoma (expanded indication)/Oral	Bayer
Mid-2017	Actemra (tocilizumab)	Giant cell arteritis (expanded indication)/SubQ	Genentech
Mid-2017	Retacrit (epoetin alfa)	Epogen and Procrit biosimilar/SubQ	Hospira, Pfizer
Mid-2017	Sarilumab	Rheumatoid arthritis/SubQ	Sanofi, Regeneron

† As of press time * Estimated
Source: Diplomat Clinical Services

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

Commentary: Is Selling Health Insurance Across State Lines a Promising Idea?

Twenty-one (21%) of insurance enrollees in states participating in the federal marketplace have only one participating insurer, but 79% of enrollees do have more than one choice.

Access is a problem. Five (5) states have legislation to allow or explore out-of-state sales of health insurance – Wyoming, Kentucky, Georgia, Maine and Rhode Island. Twenty-one (21) states have introduction legislation in the last decade to allow for sales across state lines. Yet, zero (0) insurers have sold out-of-state insurance.

The total number of health insurers that consumers can access across all of www.healthcare.gov is 167 in 2017. But, the average

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.
- Medical malpractice insurance is a legislative problem that 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.

is three (3) using www.healthcare.gov.

When questioned, only 11% of voters believe that they should only be allowed to buy insurance in their state. Seventy-seven (77%) of voters think they should be able to buy insurance across state lines.

Then, why has there been so little uptake in selling insurance across state lines? The National Association of Insurance Commissioners (NAIC) indicates that there is zero (0) evidence that selling health insurance across state lines increases affordability and availability.

Mandated benefits are not the problem. The NAIC indicates that mandated benefits contribute about 5% to health care premiums.

Is the problem that there is no evidence, or that the experiment of selling health insurance across state lines has not been tried, or that there is no state motivation? As with all experiments, this one may have to be tried to further identify if access and savings are validated. Alternatively, a trial for a few years could be initiated to see if the five states allowing out-of-state sales actually do produce improved access and savings. Can the politics support such an experiment? Time will tell.

Commentary: Is Comparison Shopping in Health Care Easy to Do?

Utilizing a market approach to purchasing health care in the US is a goal for all most plans in that it ensures competition for access, services and cost. However, comparison shopping is still not that easy. Forty-three (43) states still do not have a mandatory regulation for access to health care price information. Yet, 59% of consumers surveyed in 2014 chose a less expensive plan when

Commentary: What Are the Correct Wellness Priorities?

Congress wants to encourage employee wellness programs, though the privacy of individual health care information is a stumbling block. As a benchmark, 81% of employers with 200 or more employees offered wellness programs and 46% offered reduced insurance costs for participating. The result is about 46.8

healthcare comparative information, but only 21% of consumers were able to compare prices when there were multiple providers.

The drive for less costly solutions is motivated by an average $4290 health care bill for every household in 2014. Add to that a growing average deductible of $1478 per individual in 2016. The future is no better. Inpatient services experienced a consumer price increase of 195% between 1997 and 2016. In the same time, outpatient services increased 200%.

Cost matters! If the market-place solution is supposed to be viable, then State rules and regulations as well as provider transparency is crucial. If the provider community cannot make these prices available, then the States and Federal government must act!

Source: US Bureau of Labor Statistics, Modern Healthcare, 4/17/17

total wellness market in 2016 was $7.8 billion.

Only 19% of employers in 2015 required a health risk assessment, and only 13% offered disease management. Yet, 87% of workers in wellness programs were focused on lifestyle management. The payback? The RAND Corp estimates that there is a $3.80 to every $1 spent on wellness with disease management, and $0.50 payback for every $1 spent on wellness targeted to lifestyle management.

Clearly, disease management has a better payback than lifestyle changes. Wellness programs focused on both disease and lifestyle management would be ideal.

Source: Modern Healthcare, 3/20/17

Commentary: Rx Spending Growth In 2016

US drug spend in 2016 grew at 4.8% to $323b. This was less than ½ of the rate in the prior two years when off-invoice discounts and rebates are factored into the calculation. Fewer than ½ as many new drugs were launched than in 2014-2015 which contributed to the decline. The decline in new patients treated for Hepatitis C was also a factor.

The total use of prescriptions grew 3.3% over 2015, despite the reduced growth in 2016 and amounted to 6.1b in prescriptions dispensed. Net prices (including rebates and other manufacturer price breaks) increased an average of 3.5% in 2016 vs. 2.5% in 2015. Half of the total spending growth in 2016 was due to new medications for cancer, auto-immune diseases, HIV, multiple sclerosis, and diabetes.

What about the future? There are over 2,300 late stage novel products including more than 600 cancer treatments. As a result, net total spending is predicted to increase 2% to 5% through 2021. Total spend is expected to reach $375b to $405b. These predictions are based on net spend including rebates and other discounts that do not show up in point-of-sale payments. Be careful how you interpret the information.

Source: QuintilesIMS

Co-Pays vs. Cost - Who Pays?

According to a recent Bloomberg report, several lawsuits are being filed against the major US pharmacy chains, CVS and Walgreens, for charging copays higher than the actual cost of the medication, while prohibiting the pharmacies from disclosing the lower cost alternative to consumers. The lawsuits stated that the difference in price is often pocketed by the Pharmacy Benefit Manager (PBM). Several other similar cases had been filed against UnitedHealth Group Inc., Cigna Corp., and Humana Inc.

Commentary:
Copayment, as a cost-sharing mechanism, was initially designed to manage consumer's utilization rather than as a profit mechanism for any parties involved. The issue here is transparency of drug pricing at the point-of-sale. With a lack of transparency, it is difficult for consumers to know the actual drug cost. Some benefits are designed such that the pharmacy can collect the whole copay regardless of the cost of the drug. Other benefit designs require patients to pay only up to the cost of the drug. Yet, how are Plans able to determine if patients are paying the correct copay?

Audits determine if copays are allocated correctly. However, on an ongoing basis, there should be a method to determine if a problem is happening. Pro Pharma and its subsidiary ProData looked at this problem and offer the following advice. We performed an analysis to search for instances in which consumer's copayments are higher than the cash price of the drug. Since there are several prices it was necessary to decide

Customary (U&C), or paid amounts are not a costs as they include dispensing fees and potential profits for the pharmacy. The actual cost should be the Ingredient Cost which is usually an AWP minus a discount. Therefore, when analyzing for drug cost consider the Ingredient Cost and compare to the Copay.

Source: Feeley, Jef, and Jared S Hopkins. “CVS Health Is Sued Over 'Clawbacks' of Prescription Drug Co-Pays.” Bloomberg.com, Bloomberg, 8 Aug. 2017, www.bloomberg.com/news/articles/2017-08-08/cvs-health-is-sued-over-clawbacks-of-prescription-drug-co-pays.

PRO PHARMA
PHARMACEUTICAL CONSULTANTS, INC.

PSQ

Patient Specific Queries™

Pro Pharma analyses all pharmacy and medical data monthy for compelling clinical edits. These reports identify categories of edits as effectiveness problems, elevated risk concerns, and opportunities for improving utilization or cost savings. There are over one-hundred reports, but some of the most compelling are: compliance problems, duplicate therapy, medications discouraged for age or gender, dosing concerns, polypharmacy, coordination of care, and drug-induced disease. Each clinical report is prioritized on a 10 point scale so that problems can be prioritized for management purposes.

Reports can be viewed in total by prescriber and/or patient. They can also be evaluated by category. The results of reports identified for all prescribers and patients are trended over time to identify performance improvements.

PSQs Provide Answers to:

- *What are the high priority risks to my population?*
- *Who is responsible for managing these risks?*
- *How have the risk changed over time?*

PSQs are also included in the Quality Management Program™ that identifies and drives drives quality improvements down to the patient level for appropriate management.

CONTACT US

P.O. Box 280130
Northridge, CA 91328-0130
(888) 701 - 5438
info@propharmaconsultants.com

WWW.PROPHARMACONSULTANTS.COM

New Episodes Wednesdays at 12:00pm (PDT)
Live on Facebook, Twitter and YouTube

Pro Pharma Pharmaceutical Consultants, Inc. has assisted payers and providers for over 31 years to maintain quality while controlling costs.

Pro Pharma Pharmaceutical Consultants, Inc.

P.O. Box 280130
Northridge, CA 91328-0130
(888) 701-5438 | www.propharmaconsultants.com

.
.
.
.
.