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Rx newsletter

In this issue

Market trends:

The No Surprises Act and Prescription Drug Transparency

Pharmacy 101:

Picking the pricing model that works for your plan!

Disease spotlight:

A new option for treating presbyopia

Clinical spotlight:

Medication Adherence Programs

Pipeline:

Pending drug approvals
Brands losing patent

Market trends

The No Surprises Act and Prescription Drug Transparency

What is the No Surprises Act?

The No Surprises Act (NSA) is part of the Consolidated Appropriations Act (CAA) and was signed into law December of 2020. These laws are structured to provide insight and protection to consumers against prescription drug and healthcare spending.

The NSA grants consumers federal protections against unexpected medical bills, prohibits balance-billing for certain out-of-network care, and changes billing and reimbursement processes, while the overall CAA requires federal agencies to issue rules of cost transparency regarding healthcare and prescription coverage.

The No Surprises Act (NSA) transparency requirements

Among the many different transparency requirements, the NSA specifically affects employer-provided health coverage for:

- Health care and prescription drug spending reporting (see prescription drug data collection below for more information).
- An advance explanation of benefits (EOB) requirement.
- ID card disclosure requirements for medical and Rx.[1]

The insurance carriers and PBM's will have most of the required reporting data and are able to fulfill the reporting on behalf of group health plans. It would be a good idea to contractually delegate reporting to insurance carriers.

Prescription Drug Data Collection (RxDC) of CAA

We know that spending on prescription drugs is rising faster than total spending on health care services. To understand these increases, the government is looking to know more about the inner workings of prescription drug costs.

The CAA is requiring information to be submitted on the following topics:

- Spending on health care services, including prescription drugs.
- The prescription drugs that account for the majority of employer and patient cost.
- Prescription medications that are prescribed at a frequency greater rate than others.
- Prescription drug rebates from manufacturers.
- Costs and premiums allocated to patient spending.[2]

The government is looking to accumulate this data by both insurance companies and employer-based health plans to help call out key indicators and increases in prescription drug and health care spending and to understand how prescription drug rebates impact insurance premiums and out-of-pocket costs.

The deadline for submission is December 27, 2022 and requires a calendar year of reporting for both 2020 and 2021. Having the data in calendar year form will allow for more effective trend comparison and cleaner data. Findings will be published about prescription drug pricing trends and how prescription drug rebates impact patient out of pocket costs. The release date is yet to be determined, but they will be released on the Department of Labor or Department of Treasury's website.

Sources:

1. *No Surprises Act: Prescription Drug and Health Care Spending Transparency Rule: Marshmma.com accessed, Aug 31 2022. https://www.marshmma.com/us/insights/details/no-surprises-act-prescription-drug-and-health-care-spending-transparency-rule.html*
2. *Prescription Drug Data Collection (RxDC): CMS.gov accessed Aug 31, 2022. https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/Prescription-Drug-Data-Collection*

Pharmacy 101

Pricing Models - Refresher

Picking the pricing model that works for your plan!

Plan Sponsors have options when it comes to PBM pricing models. Based on market interest, each PBM offering will vary and include different options that fits each plan sponsor the best.

Traditional

A traditional PBM contract is when the PBM uses sources hidden within the contracts to create revenue. These PBMs may receive revenue from spread pricing, which is the difference between what the PBMs pays the pharmacy filling the claims and what the PBM bills the plan sponsor. They will also retain a portion of the manufacturer rebates that are generated when a client's members are filling rebate eligible drugs.

- Over 90% of self-funded, carved-out plans are in the traditional pricing arrangement.
- Typically, this arrangement does not have an administrative fee as the PBM generates revenue through spread.
- Can produce high savings for the plan, while also providing contract guarantees.
- Little to no transparency on how much the PBM is making and how they are making it.

Transparent / Pass-Through

A true transparent or pass-through model may vary by PBM but will always pass-through 100% of discounts and rebates to the plan sponsor. The PBMs revenue is derived from either a per script fee, per member fee, or a per month fee.

- While currently only a small portion of the self-funded, carved-out plans are in this pricing model, it has continued to gain traction over the past few years.
- PBM is very transparent about all potential revenue.

Variations of Traditional & Transparent models

- *NADAC:* National Average Drug Acquisition Cost. This model typically falls into the transparent/pass-through model.
    - Fully transparent, with free access to all NADAC drug pricing posted on Medicaid.gov.
    - Plan Sponsor is always charged the same amount that is reimbursed to the pharmacy.
    - 99% of prescription medications have a NADAC price. If there is no NADAC price available, a second layer of pricing based off of AWP is put in place to capture and process the claim. These are typically specialty medications.
    - Only source of revenue for the PBM is the administration fee.
- *Low Net Cost:* This model can be either traditional or transparent/pass-through.
    - In a traditional model, a low net cost model typically means a PBM is applying a brand over generic strategy in order to capture highly rebated medications. The cost of the brand minus the value of the rebate makes the brand more affordable than the generic.
    - In a transparent model, low net cost typically means the PBM is making clinical decisions on which drugs to exclude within a specific drug class. High cost, low value medications are normally excluded from the formulary.

Disease Spotlight

Vision Enhancement Drugs

New FDA-approved eyedrops could improve close-up vision and replace reading glasses for millions of Americans.

A new eyedrop medicine, called Vuity, was approved by the FDA in October to treat presbyopia in adults. Presbyopia affects approximately 1.8 billion individuals worldwide and approximately 128 million Americans. Presbyopia is age-related and impacts the eye's ability to focus on close-up objects. It is a refractive error in the eye and occurs because the lens, the inner part of the eye that helps the eye focus, stops focusing on light correctly in the retina.[1] Presbyopia is part of the normal aging process and there is no way to stop or reverse presbyopia. However, it can be corrected through glasses, contact lenses, or eye surgery.[1] Now, presbyopia can be treated with eye drops (Vuity).

Vuity

What is Vuity and how does it work?

Vuity is an old medication used in a new way. The active drug in Vuity, pilocarpine, has been used to treat high pressure inside the eye caused by glaucoma and other eye diseases. However, Vuity is the first drug to utilize it to improve vision. Vuity works by using the eye's natural ability to reduce pupil size. Reducing pupil sized expands the depth of focus which allows a person to focus at different ranges naturally. By using once-daily drops of Vuity, patients have experienced enhanced close-up vision in as little as 15 minutes. One drop in each eye provides sharper vision for six to ten hours. The drops work best for ages 40-55 and are less effective after age 65. The medication is available by prescription only. A 30-day supply of the drug will cost about $80 and is not currently covered by insurance.

Two Phase III clinical trials led to the FDA-approval of Vuity. Across GEMINI 1 and GEMINI 2 studies, there were 750 participants diagnosed with presbyopia aged 40 to 55 years old. Participants were randomized across both studies to be given either the placebo or Vuity. Patients treated with Vuity during the trials were able to read three or more lines on a reading chart 3 hours after receiving Vuity on day 30 of the trial without having their distance vision impacted in comparison to the placebo. No life threatening or serious adverse events were noticed in any of the participants.[2]

Vuity may be the only eyedrop for treatment of presbyopia on the market today, but competitors are coming up close behind. Eyenovia revealed that its drug device combination, MicroLine, is in the works for helping presbyopia patients. The product uses the company's Optejet dispenser to deliver small doses of pilocarpine. The Optejet dispenser is a point of differentiation between Vuity drops and Eyenovia's MicroLine.

Sources:

1. *Kierstan Boyd. "What is Presbyopia?", available at https://www.aao.org/eye-health/diseases/what-is-presbyopia, accessed 8 September 2022.*
2. *Joseph M. Coney. "Vuity", available at https://eyewiki.aao.org/Vuity, accessed 8 September 2022.*

Clinical Spotlight

Medication Adherence Programs

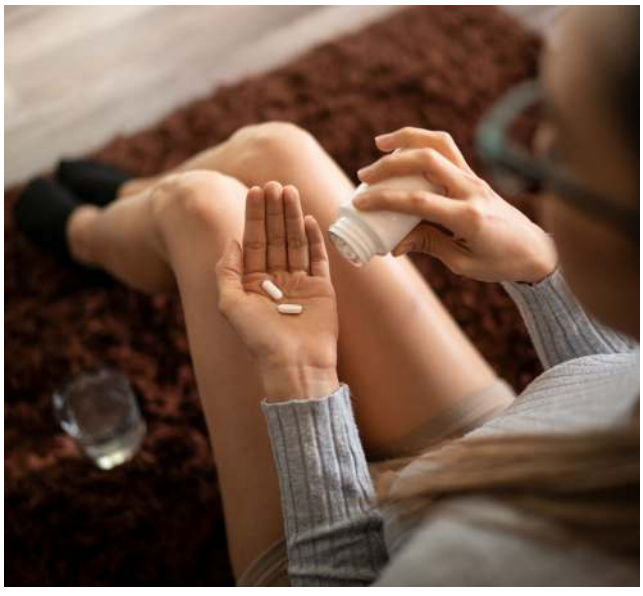
According to the WHO, 50% of patients with chronic illness do not take medications as prescribed.[1]

In the current healthcare landscape of the United States, there are enormous barriers to achieving consistent positive outcomes for patients. One of the simplest ways to achieve positive outcomes is medication adherence.

Adherence vs. New Therapeutics

In their 2003 report, the World Health Organization (WHO) quoted Haynes et al stating "increasing ... adherence ... may have a far great impact ... than any improvement in specific medical treatments."[1]

When the question of improving patient outcomes for any disease is discussed, the first response is typically centered around a need for new and improved therapeutics. Unfortunately, the proverbial low hanging fruit is often forgotten. Patients are often failing to adhere to their prescribed medication regiments. The immediate reaction from some is to blame patients, assuming medication nonadherence must be lack of personal reasonability. While this black and white perspective may simplify the conversation, it overlooks the realities of medication adherence and the relationship between employers and patients in modern healthcare.



Medication nonadherence arises from a variety of factors which can be loosely categorized as patient-related factors, physician-related factors, and health system related factors.

- *Patient-related factors range from a lack of understanding of their illness, mental illness, lack of family support system, to suboptimal medical literacy.[2]*
- *Physician-related factors range from the utilization of overly complex drug regiments, failing to explain the medication, to inadequacy considering the financial burden to the patient.[2]*
- *Health System-related factors range from prohibitive drug costs, lack of primary care access, to clinicians not having adequate time to dedicate to individual patients.[2]*

Employer Intervention and Impact

While physician related factors are mostly out of the control of employers, patient and health system factors are areas where employers can make enormous strides. Employer sponsored interventions such as medication adherence programs either offered through health insurers, PBMs, or ancillary vendors can have real tangible impacts on patient adherence.

Health system related factors is likely where employers can have the most impact. With the majority of Americans receiving their prescription drug coverage through their employer, affordability of most drugs falls to employers. By ensuring access to affordable drugs, broad pharmacy networks, and patient medical literacy programs employers can do what is best for the health of their employees and their families, but also control medical trend and spend.

Sources:

1. *Sabaté E, ed. Adherence to Long-Term Therapies: Evidence for Action. Geneva, Switzerland: World Health Organization; 2003.*
2. *"Medication Adherence: WHO Cares?" Brown, M.D. & Bussell, M.D., accessed September 7th, 2022, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3068890/#R3*

Pipeline

Pending drug approvals

Drug name	Manufacturer	Indication/use	Expected FDA decision date
ublituximab	TG Therapeutics	MS (relapsing)	9/28/2022
futibatinib	Otsuka	Cholangiocarcinoma	9/30/2022
olipudase alfa	Sanofi	Niemann-Pick disease	10/3/2022
apomorphine infusion pump	Supernus	Parkinson's disease	10/7/2022
cipaglucosidase alfa	Amicus	Pompe disease	10/29/2022
aflibercept (biosimilar to Regeneron's Eylea)	Viatris/Janssen	DME; Diabetic retinopathy; Macular edema following RVO; Wet AMD	10/31/2022
etranacogene dezaparvovec	CSL Behring	Hemophilia B	November 2022
sparsentan	Travere/Bristol-Myers Squibb	Immunoglobulin A (IgA) nephropathy (IgAN)	11/17/2022
mirvetuximab soravtansine	Immunogen	Ovarian cancer	11/28/2022
Omaveloxolone	Reata/Abbvie	Friedreich's ataxia (FA)	11/30/2022
adalimumab 100 mg/mL (biosimilar to Abbvie's Humira)	Alvotech	RA; AS; PSO; PsA; JIA; CD; UC	December 2022
Adagrasib	Mirati	NSCLC	12/14/2022
trastuzumab (biosimilar to Genentech's Herceptin)	Novartis	Breast cancer; Gastric/ gastroesophageal cancer	12/20/2022
lecanemab	Eisai/Biogen	Alzheimer's disease (early)	1/6/2023

Brands losing patent

While these drugs are nearing the end of their patent term, the release of generics may be delayed due to litigation or exclusivities.

Brand name	Generic name	Indication/use	Date generic available
Oravig	miconazole	Antifungal	September 2022
Yondelis	trabectedin	Liposarcoma/ leiomyosarcoma	October 2022
Lumason	sulfur hexafluoride lipid-type a microspheres	Ultrasound of the liver	November 2022
Xerese	acyclovir; hydrocortisone	Herpes labialis	November 2022
Xofigo	radium ra-223 dichloride	Castration-resistant prostate cancer	November 2022
Goprelto	cocaine hydrochloride	Nasal solution local anesthesia	December 2022
Giapreza	angiotensin ii acetate	Hypotension; shock	December 2022

For more information about Rx and other solutions from MMA, visit www.mmaeast.com, or contact your local representative.

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