Q4, October 2020

Market Access

Quarterly Advisor

IQVIA

Market Access: The New Normal

We have surpassed the 6 month milestone of the COVID-19 pandemic, with cases once again on the rise in much of the country. The associated challenges we face as a nation, industry, business, and as individuals are many as we head into what will most certainly be a hotly contested presidential election, punctuated by vitriolic rhetoric from both sides. Now more than ever, the uncertainty of the last few months, coupled with a cloudy (at best) horizon looming over the next 6-12 months, underscores the need to be forward thinking with regard to addressing current and anticipated challenges.

Here at IQVIA, we have been building a Market Access Center of Excellence over the past few years with an eye to the future. We are enhancing customer and IQVIA data, building new solutions, addressing emerging client concerns and challenges, and actively producing materials to help guide the industry through the pandemic. In this quarter's newsletter, we will look at new proposals from The Centers for Medicare and Medicaid Services (CMS) around accumulator adjusters and best price implications; review a recent COVID-19 webinar that identifies emerging trends to watch; and, discuss the demand and margin challenges of the Big Squeeze – challenges being exacerbated by declines in patient visits and shifts in payer channel mix away from the Commercial book of business.

— Luke Greenwalt, Vice President, Market Access Center of Excellence

Battling the Big Squeeze

HOW UNDERSTANDING DEMAND AND MARGIN CAN IMPROVE BRAND PERFORMANCE

At the time IQVIA's white paper, "Battling the Big Squeeze," was in the final stages of editing, news of COVID-19 was just emerging. Since that time, the impact of the pandemic on our daily lives has been, at least in the short-term, significant to say the least. With the resulting increase in social distancing, there also has been an impact on nearly every aspect of the pharmaceutical industry.

Brands everywhere are under pressure as both demand and margin challenges converge. Symptoms of the "Big Squeeze" can be seen in cut budgets, restricted and/or misallocated sales resources, incorrect financial accruals, investment uncertainty, and more missed forecasts than can easily be counted. Manufacturers across the industry – large and small – struggle to diagnose and adjust to market and margin dynamics in time to be effective in developing and implementing mitigation strategies.

Just a few of the end results are the year-over-year continued downward pressure on net sales, the turnover of brand and market access teams, the cutting of Selling, General and Administrative Expenses (SG&A) expenses, the inability to invest and innovate, and the kicking of the proverbial can down the road by burdening future launches with unrealistic sales expectations.

The life sciences industry is under more pressure today than at any time in its history. In this IQVIA white paper, we look at several demand and margin factors that impact brand performance, as well as strategies and tactics that manufacturers can explore to help battle the "Big Squeeze."

View Recent IQVIA Webinars On Demand

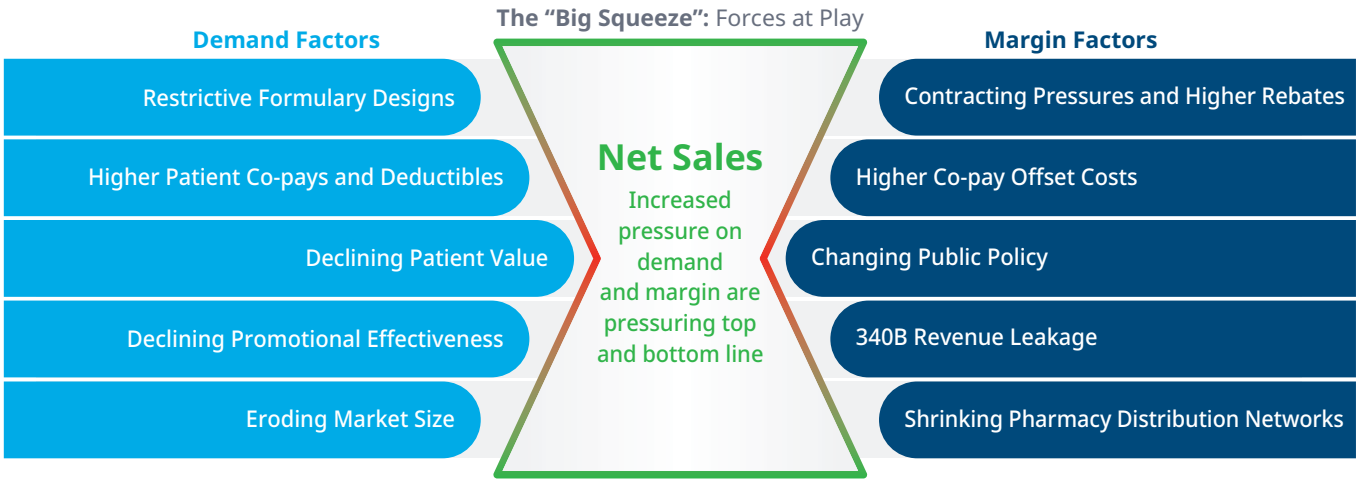
NOW AND NEXT: A COVID-19 ACCESS AND PATIENT ENGAGEMENT UPDATE

Many trusted voices in the industry – including IQVIA – are releasing their own reports, updates, and estimates of the impact of COVID-19 on our businesses and clients. In this webinar, we bring many of these assessments together and lay the groundwork for pharma's response to these uncertain times. (Click here to access the webinar)

WEBINAR SERIES: MONITORING THE IMPACT OF COVID-19 ON THE U.S. PHARMACEUTICAL MARKET

Healthcare stakeholders around the world are working with governments to address the COVID-19 outbreak, from supporting the development of vaccines to planning for medicines supply chain challenges.

View this webinar to gain an understanding of the global impacts of COVID-19 as well as evaluations of the impacts on Copay/Affordability, Payer Dynamics, and Gross to Net, Demand, and HCP Practice Dynamics. (Click here to access the webinar)



COVID-19: Payer Channel Shift

The pandemic has had enormous adverse impact on U.S. unemployment figures. With more people out of work, the market has experienced a substantial increase in patient enrollment in Health Insurance Exchanges (HIX). Likewise, recently there hasn't been much movement in claims to reflect what is seemingly happening to the economy. So, why is then and what do these trends mean for manufacturers?

Lag in Claim Shift

- **COBRA** (https://www.dol.gov/general/topic/health-plans/cobra) allows displaced workers to maintain their existing insurance temporarily until they find new jobs. COBRA isn't always a good option for people, as it puts the full premium burden, at the unsubsidized rate, on the employee that just lost their job, but it does provide some continuity. Subsidies to offset COBRA have been approved by the federal government. The deadline to enroll in and pay premiums for COBRA was extended at the beginning of COVID-19. The Federal Government is looking into extending it even further.
- **Some employers have extended coverage for furloughed and laid off workers.** Although, as COVID-19 restrictions continue and there is no expectation of a "return to normal" anytime soon, employers may not be able to continue paying for coverage for these non-active employees.
- Though not a perfect analogy, the Recession of 2007 wasn't really reflected in Medicaid enrollment until 2008 and 2009. Moreover, **losing employment alone is not enough to qualify for Medicaid**, meaning some patients would still have to buy into HIX, COBRA, or Medicaid (Fig. 1)
- Uncertainty around when people will be able to return to/find work could play into patients' enrollment into HIX or Medicaid. Also, **job loss is disproportionately impacting workers that didn't have employer-sponsored insurance in the first place** (Fig. 2)

Patient Claims

- **Patient stockpiling and prescriber sampling** may ensure that patients with high need and high risk are accommodated temporarily to weather their unemployment
- Uninsured patients may not fill prescriptions if the costs are prohibitive to them, even with the availability of discount programs.

MEDICAID AND BEST PRICE

It is commonly known that rebates for pharmacy transactions are highest in Medicaid. These claims are, at minimum, subjected to a statutory rebate of ~28%. However, this rebate must also reflect the "best price" made available in other contracts, meaning the Medicaid rebate would be increased to reflect rebates given elsewhere. For example, if Sovaldi has given a 60% rebate to Caremark, Medicaid will get that, too. Moreover, brands are penalized for price increases. So, with many brands, particularly older, established brands, Medicaid provides "penny pricing." This means that manufacturers earn a penny on their Medicaid transactions because the rebates and price penalties are so high. So, **if a meaningful volume of claims move to Medicaid and that is reflected in a brand's channel mix, the margin will surely go down for manufacturers.**

MEDICARE AND PATIENT ACCESS

In the face of unemployment, patients may choose or be urged to retire and enroll in Medicare. **A shift to Medicare includes a fair amount of margin pressure between rebates and coverage gap liabilities. This could be further exacerbated on the top line if patient access is challenged due to higher cost-sharing and no copay card use.**

Fig. 1: Unemployment and Enrollment Trend

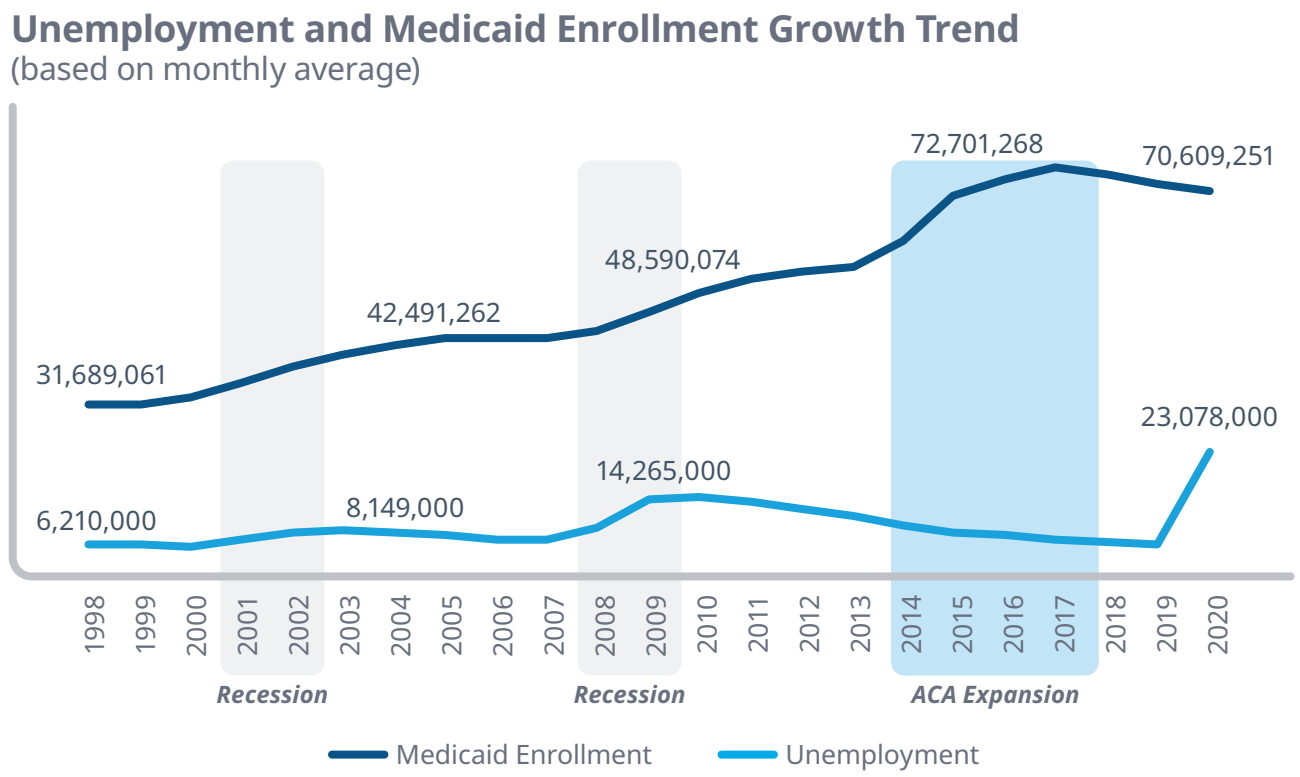
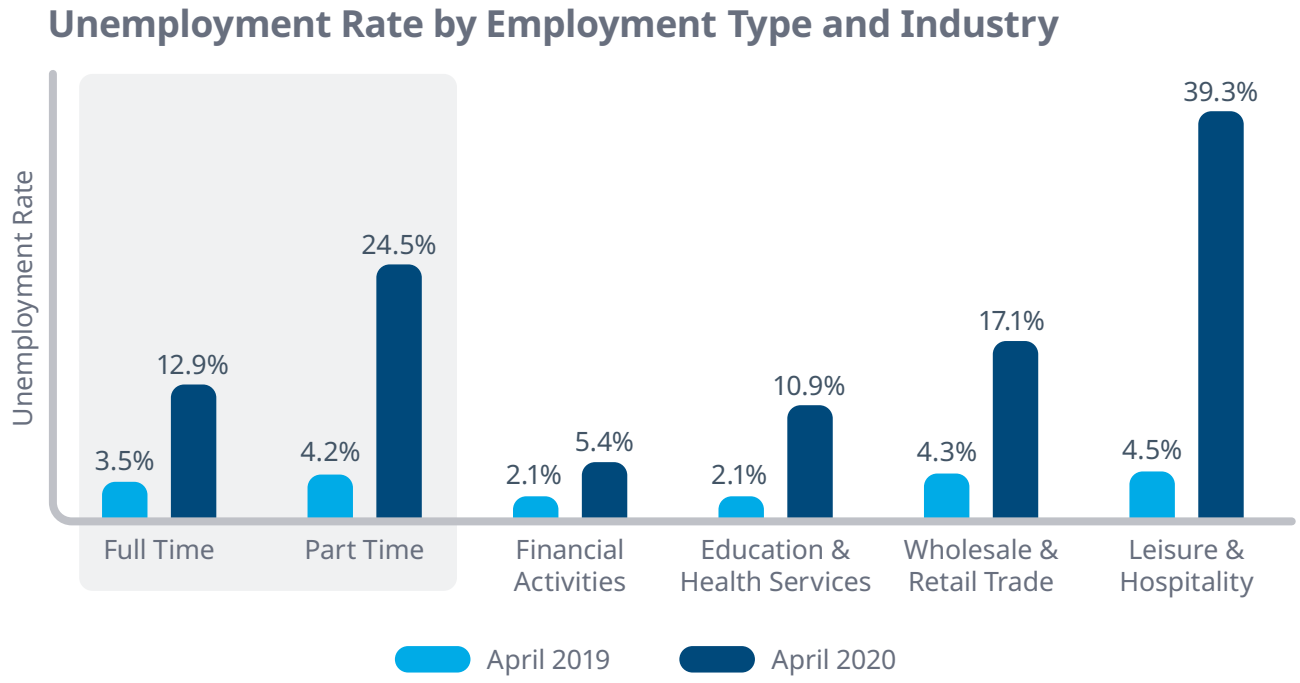


Fig. 2: Unemployment by Industry/Job Type



PATIENT SUPPORT PROGRAMS

Patients with no insurance or less generous coverage in the Health Exchanges could create a **much greater need for manufacturer support.** In fact, **some manufacturers are offering temporary coverage** (which effectively works like a bridge program) that, if not managed correctly, could create tremendous costs for brands. The intention of these programs is to temporarily continue providing access for patients as they navigate unemployment and loss of coverage. However, the level of uncertainty makes this potentially risky for manufacturers. What if patients don't return to coverage for several months? A year? Longer? What if patients return to coverage, but they enroll in Medicaid where the brand has penny pricing? What if most of the patients paid for the program without utilizing their insurance coverage before COVID-19?

GEOGRAPHIC VARIATION

Unemployment rates, Medicaid Expansion enrollments, and other demographics tell us that not all geographies are created equal. Manufacturers will need to incorporate a geographic view in their forecasting, pull-through, and contracting decisions.

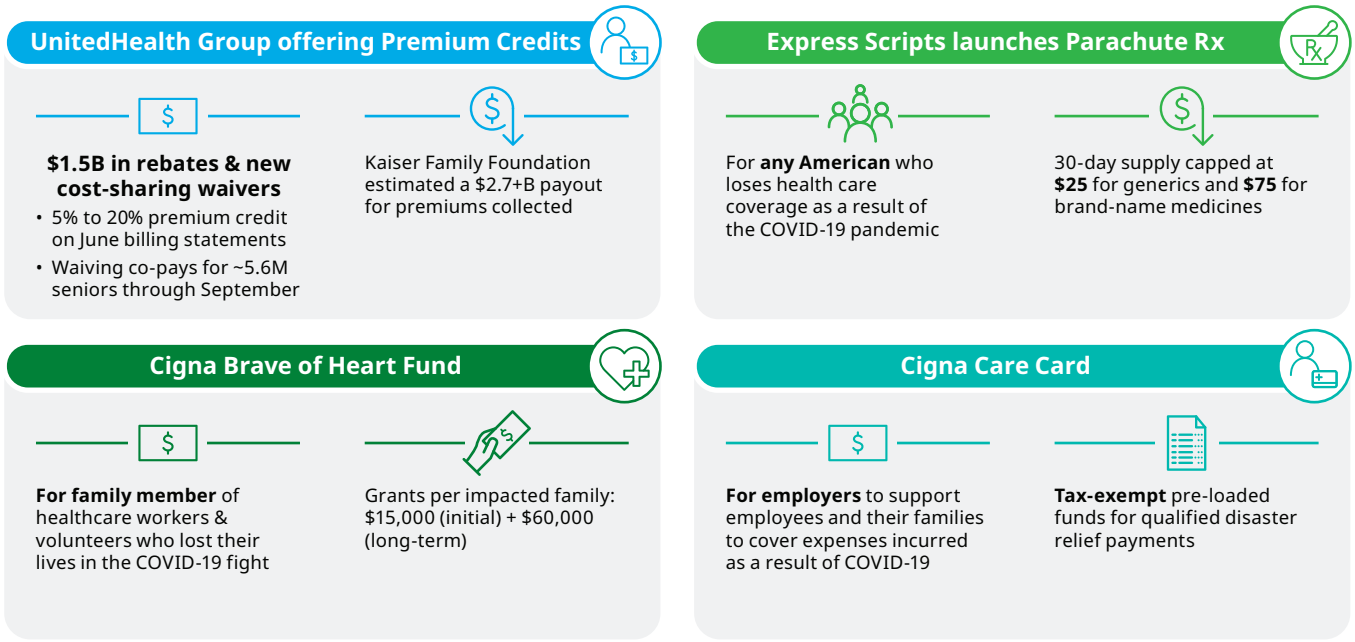
EMERGING OPPORTUNITIES FOR DISCOUNT CARDS?

Commercial services such as GoodRx and Inside Rx are establishing their programs as viable options for patients that have lost insurance (Fig. 3). In the case of ESI's Parachute Rx, patients are moved to the PBM's discount program (Inside Rx) where discounted medicines are available for <= $25 in generics and <= $75 for SELECT brands. **Brands that partner with discount programs have an opportunity to pass discounts directly to patients that may be between or without insurance.** Moreover, they may avoid the potential margin challenges that channel shift or support programs might create.

These programs make money and work by collecting fees. If you're GoodRx, for instance, you share these fees with a PBM. If you're a PBM, you are saddled with the entire fee. This is yet another way that PBMs' diversified business practices will likely boost their resilience during an economic downturn like we are currently experiencing. Historically, these programs have appealed to insured patients who wish to avoid deductibles or high copays on generics.

Based on the ever-shifting payer landscape, IQVIA is poised to help our manufacturers understand their risk

Fig. 3: PBM-Affiliated Discount Programs



and increase patient adherence. Through the use of IQVIA's many data assets, top notch consulting services and market access gross-to-net analytics we are helping manufacturers stay one step ahead in the ever-evolving healthcare continuum. For more information, contact Marcella Vokey, Associate Director, Thought Leadership & Innovation Market Access Strategy Consulting at marcella.vokey@iqvia.com.

Future Public Policy: CMS-Proposed Medicaid Rules

A proposed rule issued on June 19, 2020 by CMS is elevating the conversation about Pharmacy Benefit Manager (PBM) accumulator tactics and their impact on manufacturer copay programs to new levels. The proposed revisions to regulations include new context with accumulator programs and the calculation of best price/Average Manufacturer Price (AMP) and *"…provide instruction to manufacturers on how to consider the implementation of such programs when determining best price and AMP for purposes of the Medicaid Drug Rebate Program (MDRP)."*[1] This instruction effectively increases the burden on manufacturers to ensure that **all** copay program payments benefit patients and not plan issuers. When proof cannot be established (as is the case with unencumbered accumulator programs), the calculation of Best Price/AMP is negatively impacted.

An important statement in the proposed rule highlights CMS' perspective on the impact of the proposed rule revisions to manufacturers: *"We believe manufacturers have the ability to establish coverage criteria around their manufacturer assistance programs to ensure the benefit goes exclusively to the consumer or patient."*[1] In most pharmacy transactions sent to secondary payers or copay programs there is no delineation of patient out-of-pocket amounts owed (i.e. copay, coinsurance and deductible). Without this delineation and enforcement of its inclusion, manufacturers have a very difficult task of detecting accumulator activities on a patient-by-patient basis. Further, secondary prescription claims lack precise information regarding the primary insurance plan which could help with mapping transactions to accumulator plans. Sophisticated algorithms are required to identify accumulator activity for subsequent action.

CMS' final rule for 2021 Patient Protection and Affordable Care Act (PPACA) Notice of Benefit and Payment Parameters published on May 14th stated in context with accumulator programs that *"…we encourage issuers and group health plans to consider the flexibility to exclude these amounts [manufacturer support] … from the annual limitation on cost sharing…."*[1] It is improbable that the outcome on this proposal will do much to lessen the burden on manufacturers given CMS' established perspective.

There are options for addressing accumulator tactics and for helping to ensure that patients receive their intended benefits, including the intelligent use of debit accounts. When designing and deploying an approach, it is critically important to consider the concept of 'tortious interference' and to ensure that the approach taken applies uniform practices without creating cohorts of patients within the copay program. If debit or credit accounts are used as an approach for a secondary source of funds, it is important that continuous and full transparency of funds disposition is in place. All copay funding belongs to the manufacturer and should not be subjected to hidden vendor fees or strategies to keep unspent funds.

1 Centers for Medicare and Medicaid Services proposed rule changes in August 2020

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