Q1, March 2021

Market Access

Quarterly Advisor

IQVIA

Market Access: Looking forward

I cannot remember the closing of a year when I was so glad to turn the page on New Year's Eve as this past one. We saw more world-changing and market-shaping events in 2020 than any year in recent memory. As we now stride through 2021 and look beyond, we will once again find a "new normal". What that will look like is still being shaped, but what we can say for certain is that market access challenges will continue to impact healthcare for the foreseeable future. This year, IQVIA will focus on Patients, Payers, Policy, and Pressure as key trends to watch. Stay tuned for future thought leadership, webinars, newsletters, blogs, whitepapers, and more. We have a lot of activity planned to not only keep you informed on the latest trends, but more importantly, on what to do about them.

— Luke Greenwalt, Vice President
Market Access Center of Excellence

The importance of patient services in the midst of a pandemic: Anticipated 2021 trends

Last year, the COVID-19 pandemic had major effects on the healthcare market and the pharmaceutical sector, and was associated with considerable impacts. As we start the new year, it is important to look back on 2020 and catalogue what we learned about the pandemic's impact on patient services. What did not change is that patients remain our primary focus, and our guiding principles continue be centered around supporting patients so they can access and adhere to the therapies they need to improve health outcomes. We are optimistic that some of the impacts of the pandemic will be short-term, but realize that others will linger and become part of our "new normal" whenever that emerges.

2020 was a year of both disruption and resilience within the pharmaceutical industry. Some of the noteworthy trends that emerged were

- Patients replacing face-to-face office visit with telehealth visits
- Decreases in diagnostic testing to support the diagnosis of new conditions
- Increasing number of patients showing no prescription activity compared to 2019
- The trends indicate that consumers were rationalizing care, physicians were spending less time with patients due to revised office safety protocols, and new-to-brand prescriptions decreased. IQVIA data recently showed that there were nearly 1 billion missed diagnoses in 202, ranging from simple lab diagnostics to oncology diagnoses.

The COVID-19 pandemic altered traditional healthcare pathways for patients, forcing new routes and entry points for patient support services in some cases. It is more important than ever that brands evaluate whether they are offering the right mix of patient support services to their patients. Many of the industry's traditional tactics remain valid, but new support models and contingency plans have emerged as best in class. Patient landscapes have been re-shaped with new barriers so new or revised avenues of support may be necessary for patients who did not need the support in the past. Since the start of the COVID-19 pandemic, care gaps have made it essential to ensure patient access to medicines and provide expanded support offerings throughout the patient treatment journey.

IQVIA's Market Access Center of Excellence has expanded its offerings in the patient services space through the recent acquisition of AllCare Plus Pharmacy, LLC.

2020 in Review *A year of disruption and resilience*

ACCESS

- ↓ **56%** In-person rep details
- ↓ **920M** Missed patient diagnosis visits
- ↓ **3.2%** Newly diagnosed cancer patients

ENGAGEMENT

- ↑ **3,048%** Increase in telehealth visits
- ↓ **21%** Elective procedures
- ↑ **291%** Remote details

ECONOMICS

- ↓ **3%** YTD TRx vs. 2019
- ↓ **86.5M** New to brand Rxs lost
- **6.9%** Unemployment rate as of Oct. 2020

IQVIA can now provide reimbursement and access support (traditional HUB services) along with non-commercial dispensing services to support Patient Assistance, Bridge, Starter, Quick Start, or other manufacturer-sponsored free drug programs. The acquisition of AllCare Plus is thus, even more relevant in today's COVID-19 pandemic environment, and offers relevant and essential services for pharmaceutical manufacturers.

AllCare's focus is to ensure patients always have access to the care they deserve, making the treatment of difficult conditions as simple, safe, and effective as possible. The acquisition was a natural fit for both organizations and compliments the already existing portfolio of commercial and patient engagement services that IQVIA offers. IQVIA is now in a position to offer comprehensive patient services to our customers.

As 2021 kicks off, we will continue to trend the disturbances and shifts relevant to our Market Access customers. We are focused on working with existing and new customers to ensure our patient support services are well-rounded healthcare destinations for patients and the healthcare providers that support them. The COVID-19 pandemic is forcing us to look at things differently and do more contingency planning than prior to the pandemic.

Evaluating and revising patient support program strategies is now more important than ever due to the changing needs of our key stakeholder – the patient. Entering this new world order, IQVIA is leveraging its backbone of advanced analytics and reporting capabilities to ensure our clients are as prepared as possible. The business intelligence that we provide from our versatile technology platforms allows us to mine the data that can help our clients make informed business decisions. During this time of change and uncertainty, our tools, knowledge, and consultative approach allow us to support deliberate and well-informed decision making.

Pharmaceutical manufacturers need data-proven solutions and consultation to effectively navigate through these unprecedented times. If patients cannot access the therapies they need and remain on therapy to experience improved outcomes, then the healthcare system has failed. These trends and obstacles will continue to evolve, and so must we.

IQVIA is committed to empowering our pharmaceutical manufacturers with comprehensive, agile patient support solutions adapted for the current landscape and powered by the use of data and intelligence to ensure we are making smarter decisions together.

CMS Final Rule: What does this mean for manufacturers?

Prior to the end of the year, The Centers for Medicare & Medicaid Services (CMS) released a Final Rule covering various manufacturer price reporting changes under the Medicaid Drug Rebate Program. This follows the Proposed Rule from June 2020 and incorporates many of its components. Of primary interest is that the effective dates of key provisions of the Final Rule are set for January 2022 and January 2023, giving manufacturers a bit more time to prepare. The time will fly by as it always does however, so manufacturers should be reviewing the key components covered in the Final Rule, and evaluate the financial and operational impacts on their business.

Key Components of CMS Final Rule (December 21, 2020)

COMPONENT	DESCRIPTION	RISK TO MANUFACTURER	NEXT STEPS
PBM Accumulator Programs *Effective 1/1/23*	Requirements on manufacturers to identify accumulator programs impacting their patient savings programs, and then incorporating such transactions into AMP and Best Price	- Manufacturer may set a new Best Price if an accumulator program is in place on a patient assistance transaction - Manufacturer is required to "ensure" that patient assistance benefited the patient and not the payer, even when visibility to the accumulator is limited	- Review ways to ensure accumulator programs do not impact patient assistance programs by speaking with vendors such as IQVIA-PAAS - Make preparations for Q1-2023 start date to ensure compliance - Forecast the impact on Medicaid rebates and PHS Ceiling Price if a new Best Price is triggered by the existence of an accumulator program
Value-Based Pricing (VBP) Arrangements *Effective 1/1/22*	CMS defines VBP arrangements and then describes an approach for manufacturers to report multiple Best Prices in VBP situations	- Non-compliant Medicaid Best Price reporting if VBP arrangements are in place - Expansion of operational tracking requirements - May need to offer states the VBP terms offered commercially	- Evaluate VBP strategies with expert legal counsel to ensure compliant tracking and reporting approach is designed and established for 2022
Line Extensions *Effective 1/1/22*	Expanded definition of products that could qualify as line extensions	- If manufacturer products are deemed to be a line extension, there may be increased Medicaid rebate exposure and lower PHS prices	- Evaluate products to confirm if they are a "new formulation" of a drug. New formulations could include a change in dosage form, strength, route of administration, or ingredients; as opposed to simply being an extended release version of a product which was a traditional definition of a line extension. - If line extensions exist, evaluate Medicaid and PHS financial exposure which would begin in Q1 2022
Authorized Generics (AG) *Effective 10/1/19*	Confirmed AMP calculation treatment for AG transactions	- This component was issued via legislation and sub-regulatory guidance in September 2019 and now the regulations are codified for consistency - If manufacturer has not been following these AG rules since Q4-2019 there could be compliance concerns	- Confirm compliance has been in place if any AG products are in manufacturer portfolio
Medicaid Supplemental Programs & Medicaid MCOs *Effective 1/1/22*	CMS clarified that Medicaid MCO plans doing their own supplemental rebate agreements with manufacturers may be subject to Best Price	- If manufacturer has created supplemental rebate agreements with Medicaid MCOs, and pays the MCO directly, it may now set a new Best Price - Could result in higher rebates and lower PHS ceiling price	- Evaluate all supplemental agreements and properly categorize them - Verify if the state is paid the supplemental rebate or the MCO - If impacted, confirm how rebate transactions will be incorporated into AMP and BP operationally

Revenue management insights for manufacturers

Revenue Management (RM) operations within our industry is increasingly becoming a strategic imperative for executives to minimize revenue leakage while reducing ongoing operating costs. In a world of frequent biopharma mergers and increasing investor pressure to reduce operating cost, the optimal size and structure to manage contract operations effectively is a moving target. Whether you're setting up a new department or adjusting an existing one, meeting these shifting expectations is a challenge. There is typically no single way to determine your company's unique best fit – one that balances management expectations with budget constraints and resource capacity.

When tasked with reorganizing their contract operations department, managers typically do so with no supporting framework to help create a business case that effectively evaluates options and benchmarks. The process remains more art than science.

When approached with the question of organizational sizing, executives typically deal with the following business questions:

- What size should my contract operations team be? (contracting, rebates, chargebacks, government pricing, Medicaid, IT support, etc.)
- Is my current team under- or over-staffed?
- How does the size, structure, and skillset of my team compare with industry peers?
- What are the key gaps compared to peers and internal requirements?
- If there is a need for additional resources, how do I build a stronger business case to support incremental funding requests?

IQVIA Global Pricing and Contracting (GPC) helps clients address the sizing question from multiple perspectives to not only balance budget constraints, resource utilization, and compliance risk, but also to prevent resource burnout. To enable that, we recommend a three-step methodology:

- Use multiple approaches to evaluate current structure and gather data points for go-forward size and structure
- Reconcile recommendations from different approaches
- Finalize and build your supporting case

To learn more about evaluating your contract operations department for optimal sizing and structure, please contact Neelabh Saxena, Practice Lead, Global Pricing & Contracting, at Neelabh.Saxena@iqvia.com

---

Advisory Services

- Landscape Assessments
- Contract Strategy Development
- Operational Transformations including Process Improvement and Harmonization
- Policy and Procedure Development
- Vendor Assessments
- Road Maps and Business Case
- Program Governance/PMO
- Emerging Technologies (RPA)

System Implementations

- Revenue Management (Model N, Flex)
- CLM and CPQ (Apttus, Model N)
- Gross to Net (BPI, Breakaway, Integrichain)
- Global Tender Management
- Custom Reporting and Analytics

Outsourcing & Support

- Staff Augmentation
- Government Pricing Calculations
- State Transparency Reporting

Choosing the optimal solution for addressing the negative impact of accumulators

On December 21, 2020, CMS published a new rule on Medicaid Drug Utilization Review (MDUR) which included specific language regarding accumulator plans and their potential effect in the calculation of best price and Average Manufacturer Price. Essentially the rule establishes pharmaceutical manufacturer responsibility for ensuring that all co-pay program funds benefit patients even when payer accumulator tactics are present. The topic is complex and adds to existing concern and frustration with the negative effects that accumulator plans have on patient affordability and gross-to-net.

While the enforcement of the rule is not currently scheduled to begin until January 1, 2023, it is important for pharmaceutical manufacturers to begin establishing a response plan that includes the deployment of countermeasures that combat the negative effects of accumulators. The choice of the most optimal countermeasure(s) is a challenging one and needs to take into consideration many variables to help ensure effectiveness and positive impact. IQVIA's Patient Services team has spent nearly three years working with 33 of its brand program clients to build a playbook consisting of best practices that delve into four main areas of consideration.

1. INTERNAL STAKEHOLDER ALIGNMENT

While various internal pharmaceutical manufacturer stakeholders may bring to the table a common agreement and understanding that accumulators should be mitigated, there may not be uniform agreement regarding the approach. In particular, the question regarding whether a solution should target the subset of patients affected by accumulators or be more generalized is very important. The concept of tortious interference is one that has surfaced often in conversations among the more conservative internal stakeholder viewpoints.

In IQVIA's experience, the solution that has achieved success across all 33 of our accumulator solution brand clients is one that provides a uniform approach across all transactions versus one that targets accumulator patients specifically. An accumulator solution is by nature disruptive to traditional co-pay program dynamics. In light of this, another important solution concept to which internal manufacturer stakeholders must align is a clear, unimpeachable 'Program Intent' or reason for a change in co-pay program behavior. Program intent establishes and influences the external stakeholder communication component of an accumulator solution, and helps ensure cooperation and pull-through. IQVIA's Patient Services team has achieved consistent success with its customers by integrating communications strategies around transaction validity and fraud prevention.

2. PAYMENT BIFURCATION

From the perspective of the payer/PBM/pharmacy entities that drive accumulator activities, the ability to disallow the application of manufacturer co-pay program funds to patient deductibles heavily leverages the use of standard, electronic prescription claims data. U.S.-based pharmacies use a specific transaction standard that is governed by the National Council of Prescription Drug Programs (NCPDP) to transact with all payers, including co-pay program administrators. The ability to collate primary insurance claim data and outcomes together with secondary claim payments allows full visibility into the total amounts collected on behalf of the patient. As a result, the ability to determine which funds may be collected but not applied to patient balances is simple.

The most prevalent solution technique for breaking the chain of accumulator data tracking and helping patients offset their deductibles involves splitting payments into more than one channel. The most common secondary channel of cash paid is the use of debit accounts and they can take many forms: physical, virtual, single-use, reloadable, etc. But having a secondary channel is not enough. It's critical for an effective accumulator solution to leverage real-time, in-house prescription claims processing together with immediate electronic integration to achieve coverage for all patient use cases. The most optimal

solution will consider amounts paid in other channel(s) and load a precise amount onto the debit channel for immediate use. As we'll see further on, it's equally critical that in-house co-pay prescription claims processing considers the prevalence of claims reversals and manages the availability of cash through the secondary channel appropriately.

3. PATIENT ENGAGEMENT

While nearly all co-pay programs require patients to attest to their eligibility to participate (i.e. commercially insured, U.S. resident, etc.) not all copay programs go farther with required enrollment data capture including contact information and preferred communication channels. This can influence both the ability and desire for the pharmaceutical manufacturer to ask their co-pay program participants to play a role more complex than presenting their activated co-pay card to the pharmacy.

There are generally four accumulator solution models available, and three of them require the patients to do something specific in addition to providing their co-pay card ID to the pharmacy. One model requires no extra patient involvement, but is most effective in specific situations. Chances are, however, that patients will need to be approached to add steps to their involvement in order to receive maximum program benefits. An accumulator solution choice will be affected by many factors including: manufacturer communications expectations, the availability of patient communication channel data, approved messaging content, messaging timeliness, and Program Intent (as discussed earlier). The most optimal accumulator solution will leverage advanced technology to leverage available channels, in order to deliver triggered, real-time communications in the most simple, yet impactful way.

4. STRONG FINANCIAL CONTROLS AND FUNDS TRANSPARENCY

The final area that the most optimal accumulator solution will address is maximum control over co-pay program funding throughout the delivery process, with full and transparent accounting for how and where funds were used. Traditional co-pay spend generally takes the form of payments made directly to the pharmacies that transact with the program, but as discussed under Payment Bifurcation, the addition of a debit channel for delivering secondary sources of cash brings more complexity. The best accumulator solutions will first and foremost be designed in such a way as to ensure that all cash belongs to the manufacturer at all times until spent. Funds ownership is a key component to establishing the ability to retrieve cash from debit accounts when co-pay claims are reversed and when funds go unspent (whether through partial spend or aging). Make sure that you ask careful and thorough questions about funds ownership, and inquire about the availability of funds reporting that takes into consideration both the direct payments to pharmacies and the payments delivered through debit accounts.

It's also important to engage as many technical controls as possible for verifying that the funds spent from debit accounts are used by the right party. Traditional controls such as Merchant Category Code (MCC) restrictions help but they don't go far enough. An optimal solution will be able to associate the location of where the funds are used to the pharmacy that submitted the original co-pay prescription claim, without the need to visit each location and perform unnecessary registration steps.

Accumulator plans are a significant, negative inhibitor to co-pay program success, and they undermine both patients' ability to remain persistent and manufacturers' gross-to-net. CMS has added another layer of concern by placing responsibility on manufacturers to ensure that all co-pay program funding benefit patients despite the presence of these accumulator plans. While the deadline for addressing accumulators in context with the MDUR is set for January 1, 2023, it is important for manufacturers to begin planning their strategy for mitigating the issue. The choice of an accumulator solution is complex and not all solutions are created equally. Ask tough questions of solution providers, and determine their ability to design a custom fit based upon your business needs, their technological capabilities, their strong financial controls, and funds transparency.

Special thanks to Luke Greenwalt, Kevin Curran, Neelabh Saxena, Jake Keenan, Heather Gagnier, and the rest of the team for their contributions to this publication.

CONTACT US
One IMS Drive,
Plymouth Meeting
PA 19462 USA
+1 513 404 1313
scott.brzygot@iqvia.com
iqvia.com