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Growing pressures keeping the heat on healthcare

By Luke Greenwalt, *Vice President, IQVIA Market Access Center of Excellence*

Healthcare markets are getting more complex and the speed of change is accelerating. The compounding effect is to create more uncertainty and a wider range of scenarios that could play out over the next few years than the industry has ever seen.

For example, launches of new innovative, but high-cost, treatments will continue to surge and place pressure on the entire system to control costs; biosimilars are beginning to gain traction ahead of an important year in 2023; revenue leakage throughout the system continues to grow due to 340B, and stakeholders advance ways to impact payment; health equity disparities exposed during COVID lockdowns fuel public discourse; healthcare reform is heating up as budget reconciliation forces potential public policy changes; accumulator adjuster and copay maximizers impact patients, potentially best price, and balloon budgets; and more.

Over the course of the last four years, the IQVIA Market Access Center of Excellence has been engaged in helping clients understand, plan, and navigate the challenges with our innovative, industry-leading solutions. If you are facing a market access, launch, revenue, or patient service challenge, we likely have a solution you can leverage. We are here to help.

340B drug discount program growth drivers

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The 340B Drug Discount Program ("340B Program") has grown into a considerable market force, exacerbating the margin pressures that manufacturers already face in the United States. By the end of 2020, 340B Program sales made up 13% ($80B) of total U.S. pharmaceutical sales and grew four times faster than the overall pharmaceutical market (Growth of the 340B Program Accelerates in 2020). Understanding the drivers behind this growth is critical for stakeholders that must plan for and strategize around the program's trajectory.

IQVIA's Market Access Center of Excellence continues to track 340B prevalence and impact across the industry. Through data and advanced analytics, the insights derived play a key role informing policymakers, providers, and payers alike as they make changes to the policies and implementation of this important program.

GROWING 340B PARTICIPATION

Beneath the growth of 340B sales volume is an increase in the number of participating 340B entities, which are reported by the 340B Program administrator, Health Resources & Services Administration (HRSA). Between 2010 and 2020, the number of participating covered entities grew by 50%, from 3,600 unique covered entities to more than 5,000. However, the number of sites – provider locations affiliated with these entities – grew seven times over within the same period. This pattern of growth among individual sites from a comparatively steady number of unique entities reflects the increasing eligibility and interest of participation, rather than the expansion of covered entities themselves.

Even more, contract pharmacies outpaced entity and site growth, becoming the largest driver of 340B Program

expansion. In 2010, there were fewer unique contract pharmacy locations than there were unique entities. By 2020, the number of contract pharmacies increased nearly 15 times, and today there are more than 28,000 contract pharmacies participating in the 340B Program.

EXPANDING PROVIDER-PHARMACY RELATIONSHIPS

Contracts between participating pharmacies and covered entities, referred to as "relationships" by HRSA, grew faster still than the number of unique entities, sites, and pharmacies. Not only are more pharmacies participating in 340B, but they are affiliating with an increasing number of contracted sites, further saturating their footprints with 340B eligibility. Large pharmacy chains have been driving a bulk of the growth in entity-pharmacy relationships since 2010, increasing more than 16 times over and facilitating the rapid expansion of 340B. Entire networks of pharmacies - with broad geographic reach - are able to come online through the use of a single contract negotiation. This is unique to the nature of these large chains.

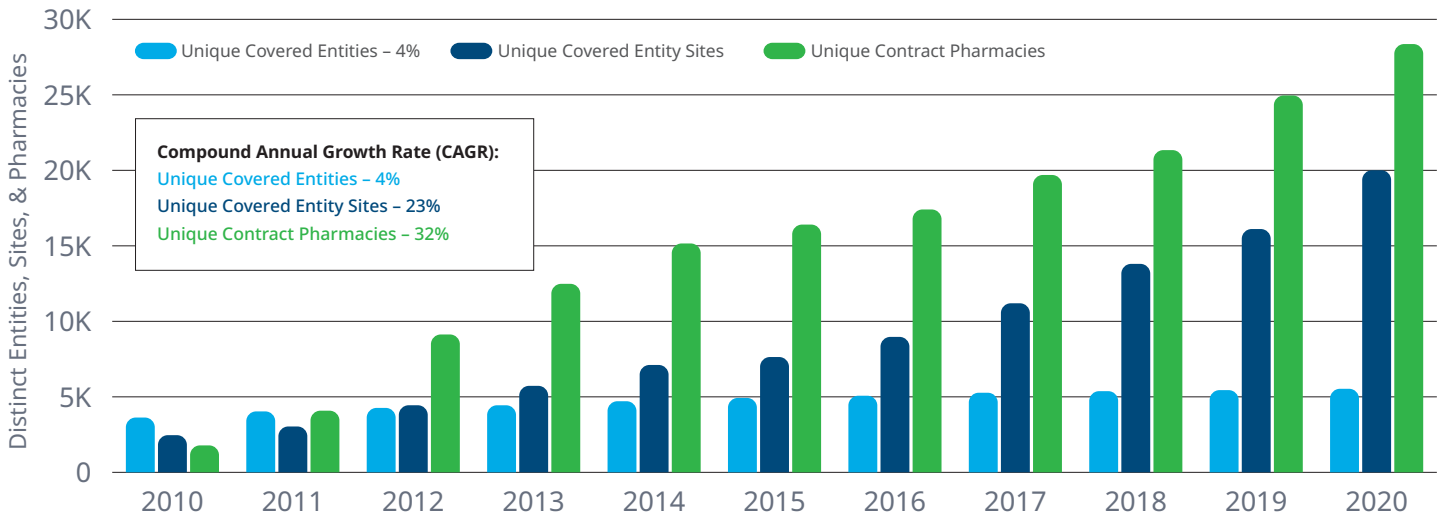
Specialty and mail order pharmacies, another rapidly growing segment, were not a growth driver for 340B until 2016, when the number of covered entity relationships began to increase, growing more than 60% on average every year - triple the rate of large chain contracts (20%). As part of their business model, mail order and specialty pharmacies can be located hundreds and thousands of miles away from their contracted covered entity and the patients filling prescriptions, thus removing geographic barriers as a factor preventing 340B program participation. Furthermore, the narrowing of pharmacy distribution for specialty products by the large pharmacy benefits managers (PBMs) have also served to push more volume through vertically integrated models.

GEOGRAPHIC REACH

As 340B participation and networks expand, so too has the program's geographic reach. In the last five years, the proportion of U.S. zip codes with a contract pharmacy grew from 39% to 68%, expanding beyond the coasts and into rural and middle America over this period.

Mail order and specialty pharmacies decouple distance and 340B accessibility, enabling any patients of a covered entity to potentially fill 340B prescriptions remotely. These pharmacies, by nature, are not always proximal to their contracted entities. As the number of specialty/

Figure 1 - Number of distinct entities, sites, and pharmacies in 340B



Unique Covered Entities are pulled as a distinct list of a combination of Medicare Provider Number or Grant Number (covered entities have one or the other based on their facility type). Unique Covered Entity Sites are based on a distinct list of the 340B IDs in HRSA, which roll up to the Unique Covered Entities. Unique Contract Pharmacies are based on a distinct list of Pharmacy IDs in HRSA.

Source: HRSA Office of Pharmacy Affairs (OPAIS) 340B

mail relationships increase and more of these pharmacies participate in 340B, the average distance between pharmacies and entities also has increased. This, in turn, has enabled out-of-state distances between entity sites and chain/mail pharmacies to exceed 1,000 miles in 2020. In-state chain and independent pharmacies have also formed relationships with covered entities at greater distances since 2015 when, on average, they were 15 miles from their entity sites. In 2020, this increased to an average of 23 miles. As more contract pharmacies begin participating in a wider radius around a covered entity, a broader portion of the patient population will be able to fill 340B prescriptions at the pharmacy.

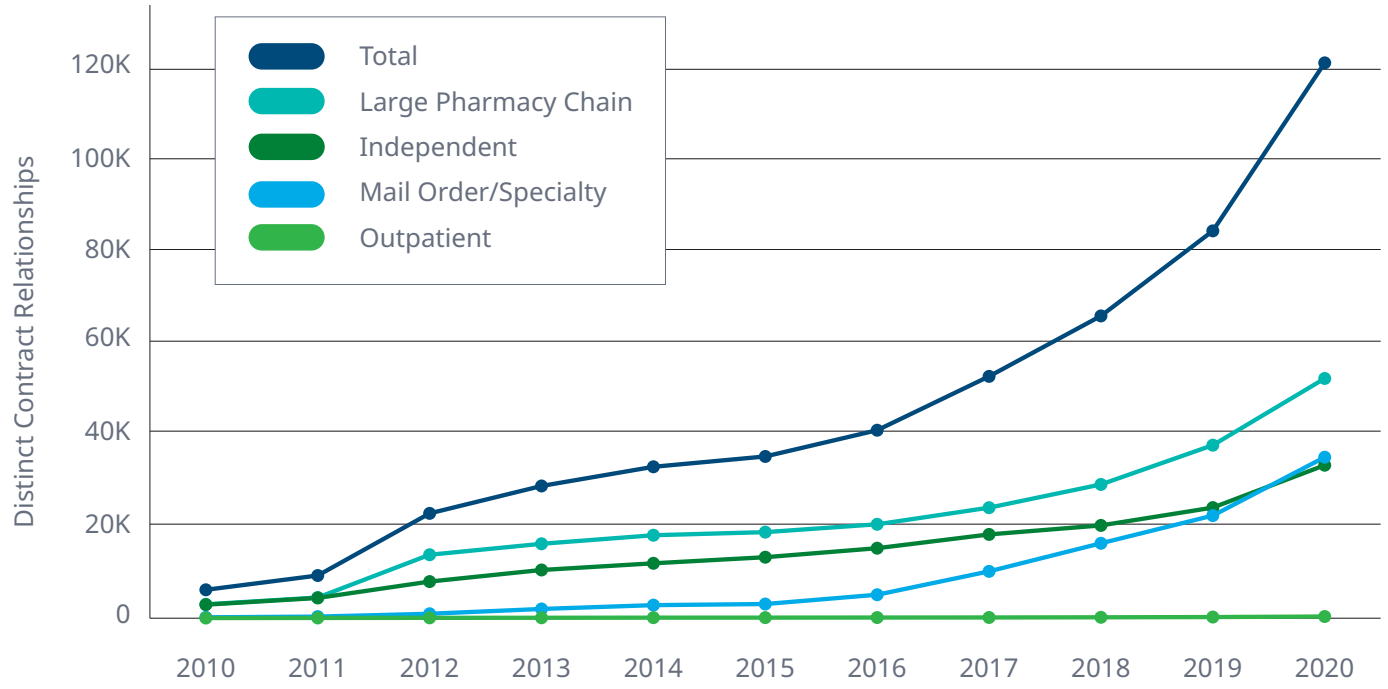
THE PATH FORWARD

As 340B expansion continues, more providers and patients will have access to the program. Yet, in addition to better reaching underserved communities, this expansion raises the stakes for those who must ensure 340B discounts reach the intended population. The breadth and depth of the 340B Program presents unseen challenges — in the form of duplicate discounts, diversion, etc. — for manufacturers, many of whom are investing in capabilities to address them. These tactics include operational processes such as identifying duplicate discounts, distribution concentration, and legal petitions.

Mitigation tactics aside, brands with high rebates and 340B exposure must account for this rapidly increasing gross-to-net line item in their forecasting and planning. However, 340B does not exist in a vacuum. It is, rather, one element of the larger market access ecosystem that should be considered alongside rebates, discount cards, etc. Recent policy examples highlight the web of discounts and interdependencies affecting 340B and margin. The Centers for Medicare & Medicaid Services' (CMS) recent change to best price calculations will include accumulator buy-downs, and thus, could increase the top-line discounts as well as the hidden costs of 340B participation for manufacturers. President Biden's American Rescue Plan Act (ARPA) removes the cap on Medicaid rebates so that manufacturer discounts could exceed 100% in Medicaid. Though "penny pricing" would still apply in 340B, that is a rule that could change to mirror Medicaid's standard.

Neither policy would take effect until 2023 and 2024, respectively, but they demonstrate the program's

Figure 2 - Distinct contract relationships by pharmacy type



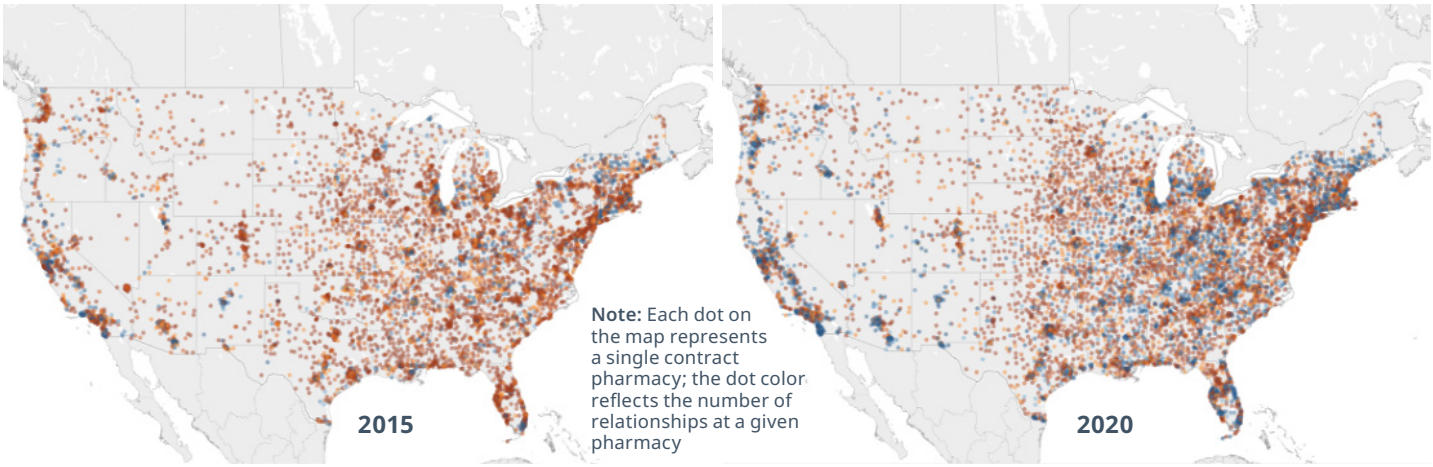
Unique CE-CP Contract Relationships are based on a distinct list of the Contract IDs in HRSA, broken out by the pharmacy type, which is based on name matching and in- vs out-of-state status of a pharmacy relative to its contracted covered entity.

Source: HRSA Office of Pharmacy Affairs (OPAIS) 340B

susceptibility to policy changes. One way to prepare for these new margin pressures is to understand the demand-side drivers of the 340B volume and incorporate these insights into forecasting and strategic planning decision making processes. When companies account for the individual growth drivers such as entity and pharmacy expansion, manufacturers will be better positioned for the uncertainty ahead.

Acknowledgements: The authors of this blog would like to thank Diane Weisbrod, Rory Martin, Steve Krikorian, and IQVIA's Contract Performance Solutions team for their support.

Figure 3 - Map of contract pharmacies and number of relationships



Contract Pharmacies are based on a distinct list of Pharmacy IDs in HRSA for 2015 and 2020. Each contract pharmacy's count of contract relationships in 2015 and 2020 is based on the number of distinct Contract IDs listed for that Pharmacy ID in each year.

Source: HRSA Office of Pharmacy Affairs (OPAIS) 340B

Controlling cancer care: The emergence of formulary exclusions in oncology

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Formulary exclusions were once rare among cancer medicines. This was, in part, driven by the lack of brand and generic alternatives within a specific tumor type and oncology's protected class status. As more oncology treatments with similar clinical profiles have launched, formulary exclusions are becoming increasingly common. Because payer control in anti-cancer medicines is less precedented than in other therapy areas, manufacturers could be unprepared for the ways in which exclusions can influence physician treatment preference, patient access, and support program demand.

RISING USE OF EXCLUSIONS IN ONCOLOGY

Every year, major pharmacy benefit managers (PBMs) and national insurers publish their formularies — annual lists of excluded products and their preferred alternatives. These formularies are one way in which industry stakeholders can measure and track which therapeutic areas face payer control by way of formulary blocks.

Among the six commercial U.S. payers[1] regularly evaluated, the first formulary exclusions against cancer treatments emerged in 2017 when the brands had a generic alternative. As generic and biosimilar versions of existing treatments

continued to become available, so came more exclusions. In time, continued development in oncology created more treatment options and competition, facilitating the expansion of formulary blocks into tumor types without generic/biosimilar options.

As of 2021, twelve tumor types across all modes of administration (oral, intravenous, subcutaneous, and infused) have at least one exclusion. As new treatment development continues, payers will have even greater willingness to grant select brands preferred access and block others. In fact, even smaller tumor type markets are showing an increase in control. Open access in oncology is no longer a safe assumption.

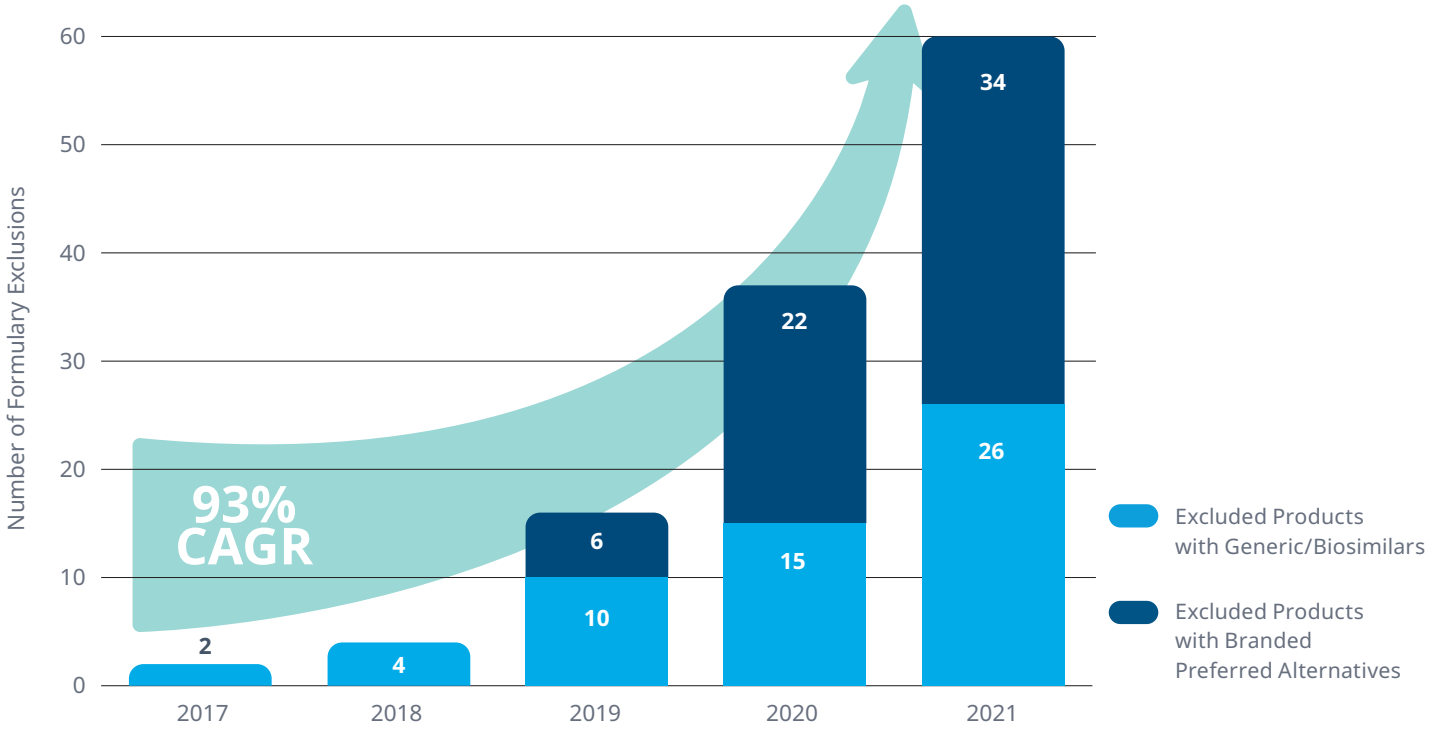
IMPACT OF ONCOLOGY FORMULARY EXCLUSIONS

For years, brands in traditional retail therapies have analyzed payer ability by measuring the effect of control – particularly formulary exclusions – on new patient behavior and prescription demand. Yet, this approach is still novel to many in the oncology space.

An oral metastatic breast cancer medication had been excluded from a payer's national formulary in 2020. While the brand had been restricted by prior authorizations and step therapies at this payer before the exclusion was implemented, most restrictions shifted to coverage blocks after the formulary change. In all other commercial payers, new patient approval rates for the excluded brand remained stable once the formulary exclusion was implemented.

It is likely that payer control of oncology products will continue to grow. Current oncology exclusions are driven by payers, including the negotiated prices and therapeutic equivalence of the brands they contract with. It remains to be seen how the Institute for Clinical and Economic Review (ICER) evaluations of anti-cancer drugs, as well as guidelines from the National Comprehensive Cancer Network (NCCN), may further encourage payers to utilize formulary exclusions. Additionally, continued vertical integration within the healthcare industry may spur organizations to focus on overall cost effectiveness and vertical integration between PBMs and payers that further facilitate control.

Figure 1 - Number of national formulary exclusions (Top National Payers, Commercial Insurance, Oncology)



Note: Top National Payers include Aetna, CVS Caremark, Cigna, Express Scripts (the PBM subsidiary of Cigna), OptumRx (the PBM subsidiary of UnitedHealthcare), and Prime Therapeutics. **Source:** Published national formularies, US Market Access Strategy Consulting analysis, IQVIA

[1]Aetna, CVS Caremark, Cigna, Express Scripts (the PBM subsidiary of Cigna), OptumRx (the PBM subsidiary of UnitedHealthcare), and Prime Therapeutics have consistently published their national formularies and also maintain historical records of their lists, facilitating the trend analysis of this paper.

Figure 2 - Impact of formulary exclusion on therapy initiation (Oral Metastatic Breast Cancer Brand, Commercial, 2019-2020)

Note: Analysis is limited to new-to-brand prescriptions (NBRx) only. A 30-day look-forward period is applied after new attempts to account for rejection durability. Baseline period precedes January 2020 exclusion: Q1 2019 through Q3 2019. Implementation period follows January 2020 exclusion: Q1 2020 through Q2 2020. PA = Prior Authorization. Step = Step Therapy Restriction. **Source:** IQVIA LAAD Pharmacy Data, US Market Access Strategy Consulting Analysis, IQVIA

Contract compliance reviews – How to mitigate delays

By Becky Barnhart, *Audit Services Associate Director, Contract Performance Services, IQVIA*
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The manufacturer rebate process is rapidly evolving and changing as mergers and acquisitions of Pharmacy Benefit Managers (PBMs), consolidations of Managed Care Organizations (MCOs), expansion of the control of retail and mail order pharmacy companies, and reorganizations within manufacturers continue to make front page headlines. More recently, several PBMs have created separate business units to manage all commercial rebate agreements under a single entity, or group purchasing organization (GPO).

To clarify the myriad scenarios and provide assurance that rebate agreements are being uniformly met, many manufacturers perform rebate compliance reviews (also referred to as "Audits"). Most often these reviews are done in conjunction with the manufacturers' internal Sarbanes Oxley requirements. Compliance reviews may also be undertaken because of mergers, identified problems such as 340B compliance, concerns over trading partner practices, or due to an agreement dispute. The primary goal of the contract compliance review is to provide a level of

assurance that trading partners are adhering to the specific provisions of the rebate agreement. Given the financial scope of rebates and the detailed formulary and benefit provisions associated with most rebate agreements and governmental requirements, it is industry best practice to review trading partner compliance on a periodic basis.

TIMING CONSIDERATIONS

Five years ago, a rebate compliance review averaged a time span of 4-6 months from the notification to the delivery of final results to the manufacturer. While some audits are still completed in this timeframe, the average span is now 9-12 months, with some trading partners averaging close to a year or more for completion.

What are the factors that are extending the timeline, and how can manufacturers mitigate delays?

IQVIA is seeing more frequently that trading partners will stall progress after notification and refuse to move toward negotiating scope because there are disputes, or outstanding invoice amounts not paid. At times, we have found the manufacturer is not always aware of the disputes that exist at the time of notification. We recommend manufacturers investigate the status of the reconciled invoices prior to notification for the relevant review period to ensure unpaid invoice amounts and disputes are resolved with the trading partner.

Non-disclosure agreements (NDAs) can also cause lengthy delays in the audit process, often taking months to execute before the manufacturer is even allowed to provide the auditor with access to the agreement and data files and move the audit forward.

Another issue that has affected audit timelines are audit restrictions, protocols, and timing delays. Some trading partners have issues with retrieving requested documents due to data storage or archiving issues, despite audit language in the agreement that clearly states records will be maintained for three or more years. Others may fail to provide documentation due to clients that have terminated and no longer submit utilization through that trading partner. Unresolved trading partner disputes also shrink the window of data availability.

Other time-related restrictions include the establishment by the trading partner of strict timelines under which the audit must be conducted, and an overall deadline for recovery of manufacturer overpayments (for example, any recoupment must be made within 18 months from the date the utilization was invoiced or within one year of the audit onsite).

Finally, some trading partners have regular blackout periods which must be worked around for compliance review activity, so knowing the timing of blackouts and notifying early is essential to ensuring adherence to any expected time frames.

What's causing delays?

DISPUTES

Many trading partners will not move forward with an audit if there are an outstanding disputes or unpaid invoice amounts

NDA DELAYS

Non-Disclosure Agreements can take months to execute and must be complete before the Manufacturer is allowed to provide auditor access to agreement and data files for the audit to move forward

RESTRICTIONS AND PROTOCOLS

Issues retrieving files past a certain date due to storage and archiving

Some trading partners no longer have access to terminated clients

May place restrictions on the time the Manufacturer has for recoupment

BLACKOUT PERIODS

Many trading partners have regular black out periods in which they will not conduct any compliance reviews

SCOPE LIMITATIONS

Limiting the scope to certain clients and formularies

Requirements to use national CPA firms

Increases in the requests to "approve" the final compliance report prior to manufacturer receipt

SCOPE LIMITATIONS

Another common area of discussion relates to the scope and the number of formulary documents and/or claim samples permitted for review. With the number of consolidations, mergers, and acquisitions, the number of plan IDs, claims, and formularies included in each invoice period has dramatically increased for some trading partners. This means that any negotiated scope must consider the products under review and the number of clients and formularies invoiced during the period. The scope must cover and allow for the review of an acceptable percentage and confidence level of the invoiced dollar amounts for those products under review.

Likewise, there has been an uptick in aggressive trading partner agreement audit clause deflection in the form of vague statements regarding "audit protocols" without defining or providing explanations of the limitations contained within those protocols. Some trading partners are also attempting to require the use of national CPA firms. Compliance reviews of rebate agreements are not, in fact, "audits" in the true sense of the term, and do not involve attestations or require CPA involvement, as they do not involve financial analysis. These firms tend to specialize in financial audits and are typically generalists that lack the depth of industry knowledge, skills, and expertise necessary for rebate compliance reviews. Again, it is important the manufacturer understand and modify the audit clause to provide for their needs.

One emerging issue noted more frequently is the trading partner requests to "approve" the compliance review report in its entirety prior to manufacturer receipt. This can be an issue because the report includes the dollar impact of the findings. While it is certainly appropriate to share findings with the trading partner and allow the opportunity to provide management response and resolve findings, the dollar impact for findings is more problematic. The report is a document paid for and owned by the manufacturer; the audit firm is acting as an agent in a fiduciary capacity with obligations to the manufacturer. It is the manufacturer's right to consider the findings, in light of their scope, including financial impact, and to determine whether to pursue recoupment, or just modify agreement terms moving forward.

Putting a financial value on findings before the manufacturer has an opportunity to review and choose how to act on those findings could potentially have an adverse effect on the relationship with the trading partner. The dollar value of exclusions and findings may be used to help a manufacturer understand the financial impact of an issue, and may not necessarily relate to the manufacturer's plans to recoup the findings. Findings may be utilized by the manufacturer on a prospective relationship basis to identify areas requiring changes in the amount of the rebate (either higher or lower discount percentages), and corrections and/or changes to other areas of the agreement.

Trading partners must be able to provide the necessary documentation to ensure a satisfactory level of confidence to the manufacturer that they are in compliance with agreement terms. Delays, limitations, and restrictions by the trading partners extend the length of time to complete the review and shorten the manufacturer's time to appropriately act on findings.

If you are searching for a partner to assist you in managing the ever-changing compliance review landscape, IQVIA's Audit Services team can help. For more information, contact Scott Brzygot at scott.brzygot@iqvia.com.

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