Wednesday, December 9, 2015

With 2015 coming to a close, we wanted to provide a recap of the major updates impacting the pharmacy industry and what pharmaceutical manufacturers, pharmacy benefit managers (“PBMs”), and pharmacies might expect in 2016. This past year saw significant changes in the pharmacy industry. From multiple high-profile mergers changing the PBM landscape, to the recent controversy over drug pricing, the pharmacy industry was in the national spotlight for much of 2015. Meanwhile, federal and state enforcement continued to focus on pharmaceutical manufacturers, PBMs, and pharmacies. We also saw the first biosimilar approval in 2015, significant updates to the 340B program, an increased focus on value-based purchasing, and additional state legislation focusing on PBMs.

Industry Consolidation - Changing PBM and Payor Landscape

There was a significant wave of merger activity in the PBM and payor industry in 2015, with pharmacy chains acquiring PBMs and long term pharmacies, as well as mergers among some of the largest payors. This consolidation has reshaped the traditional PBM industry paradigms with a move away from stand alone PBMs to payor and provider affiliated PBMs. This consolidation and alignment with payors and providers has been driven by a need to increase negotiating power and create economies of scale in the face of rising drug costs and fewer drug discount opportunities. In addition, PBMs and payors are looking to adapt to new forms of payment encourage by the Affordable Care Act. The Affordable Care Act has spurred CMS and private payors to focus on value-based purchasing and pricing. Entities with integrated payor and provider operations (including expanded access to data critical for analytics) may be in a better position to save costs and compete in the market.

Moving into 2016, it is unclear if this merger frenzy will continue and if we will see additional consolidation among some of the stand-alone PBMs. Nonetheless, this increased merger activity may lead to more competitive pricing and negotiating power among PBMs, as well as a new focus on the use of contract terms with performance based results.

National Debate Over Drug Prices

Controversy around drug pricing came to a head in 2015. The debate surrounding drug pricing is not new and much of the buildup occurred in 2014, when drug spending increased 12% over the previous year. This increase was due, in part, by dramatic generic drug inflation and the cost of new Hepatitis C treatments. Further fueling the drug pricing debate were reports of pharmaceutical manufacturers increasing the price of their drugs by 200% to sometimes 5,000%.

The political response to this issue has been notable. Senator Bernie Sanders proposed legislation which, among other provisions, would authorize the Secretary of Health and Human Services (HHS) to negotiate drug prices with pharmaceutical companies. The House Democrats also implemented an Affordable Drug Pricing Task Force to review drug pricing. At the same time, State Attorney Generals, including the Massachusetts and New York...
Attorney General’s Office, are issuing subpoenas requesting documentation related to pricing decisions. And, multiple states have considered legislating “pricing transparency” and requiring drug manufacturers to disclose information such as research, development and marketing costs for their drugs. And just last month HHS held a forum bringing industry stakeholders together to explore ways to address rising prescription drug costs.

The focus on drug pricing will likely continue into 2016 with continued scrutiny by Congress and rhetoric among presidential candidates. While it is unlikely that this debate will lead to new federal legislation in the Republican majority Congress, the current scrutiny may result in drug manufacturers self-regulating price increases going forward. For PBM’s, this debate may offer an opportunity given their role in managing drug costs and assisting employers and payors with population health strategies. It may also lead to more pressures from the pharmacy lobby for PBM’s to disclose their rebate agreements with manufacturers and/or to share savings from those rebate agreements. As for the impact on pharmacies, the drug pricing controversies have lead to recent disclosures by pharmaceutical manufacturers of certain captive pharmacy arrangements. In light of these disclosures, PBM’s are taking a closer look at these arrangements to determine if they frustrate payor formularies and potentially increase system costs. Pharmacies should expect even greater oversight from PBM’s in the coming year as a result these pricing issues.

2015 Enforcement Trends

Pharmaceutical manufacturers, PBMs, and pharmacies continued to be a focus of enforcement activity in 2015. This year saw multiple settlements by drug manufacturers to resolve allegations that they paid kickbacks to PBMs and pharmacies. In early 2015, AstraZeneca paid $7.9 million to settle allegations it provided kickbacks to a PBM to maintain Nexium’s formulary status. In October 2015, Novartis paid $390 million to settle allegations that it paid kickbacks to PBMs and pharmacies to increase the prescribing of certain drugs. These settlements highlight the Department of Justice’s continued focus on the relationships among pharmaceutical manufacturers, pharmacies, and PBMs.

Enforcement also focused on the use of copayment cards by pharmacies. Kmart paid $1.4 million to settle allegations brought in a false claims act qui tam alleging that it (i) improperly permitted beneficiaries of federal health programs to redeem drug manufacturer coupons and (ii) offered customers discounts on gasoline purchases at participating gas stations in order to incentivize beneficiaries of federal health programs to use Kmart pharmacies. It is important to note that, like the Kmart case, more and more false claims cases are being litigated by qui tam relators after the government declines to intervene.

Pharmacy implementation of discounted pricing and the failure to use such reduced price as the “usual and customary” price in Medicaid and Medicare Part D claims was also a focus this year. Only days into 2015, we blogged about a qui tam based on usual and customary billing allegations surviving a Motion to Dismiss in U.S. ex rel. Doe et al. v. Houchens Industries, Inc. Although this case subsequently settled and was dismissed, we continue to believe that “usual and customary” billing for drug products will be fodder for qui tam filings.

We anticipate pharmaceutical manufacturers, PBMs, and pharmacies will continue to be a focus of federal and state enforcement and, with release of the “Yates Memo” in September 2015, the Government will focus on individual accountability as part of its investigations and enforcement.

Breakthrough Year for Biosimilars

In 2015, the Food and Drug Administration (“FDA”) approved the first biosimilar, which is now on the market. CMS also took initial steps to provide guidance on Medicare Part B, Medicare Part D, and Medicaid reimbursement of biosimilars. States have begun regulating in this space but, the recent influx of state legislation on biologics and biosimilars may actually hinder rather than advance the use of biosimilars.

340B Drug Discount Program - Challenges Continued in 2015

This year turned out to be another tough year for the 340B Program. The Program had an uphill battle after 2014, in which a U.S. District court ruled that HRSA lacks regulatory authority to promulgate regulations expanding access to 340B discounts for so-called orphan drugs. As part of that fallout, the Health Resource and Services Administration (“HRSA”) pulled an expected mega-reg on the Program. Following the ruling, HRSA reissued its intended orphan drug rule as a statutory interpretation. PhRMA promptly filed a new lawsuit seeking to enjoin any implementation or enforcement of HRSA’s statutory “interpretation” as beyond its authority.

In 2015, HRSA released its Proposed Mega-Guidance (“Proposed Guidance”) to replace its pulled mega-rule. This guidance is intended to clarify expectations and provide guidance on key issues in the 340B Program; however it adds additional requirements on covered entities making it difficult for them to provide drugs to the un- and underinsured. The success achieved in releasing the Proposed Guidance may have been short-lived. Shortly after
its release, the DC District Court invalidated the orphan drug “interpretive” rule. The Court’s reasoning may well provide fodder for challenges to the Proposed Guidance if and when it is finalized.

The Program faced an additional blow in November 2015, when the OIG issued a report on Medicare Part B payments for 340B drugs finding (i) nearly 1/5 of Medicare Part B drug expenditures in 2013 went towards purchasing 340B drugs, much of those purchases involving cancer drugs; (ii) in the aggregate Medicare Part B and its beneficiaries spent $3.5 billion for 340B drug purchases in 2013; and (iii) those Medicare Part B payments exceeded 340B ceiling prices by an average of 58% — meaning that in the absence of subceiling agreements, covered entities potentially reaped approximately $1.3 billion in profits on the purchase of those drugs. OIG went on to propose three different Medicare Part B payment scenarios for 340B drugs.

Between this OIG report and the DC District Court’s framework to invalidate the Proposed Guidance, HRSA may be limited in its ability to update the program without Congressional action.

**Increasing State Regulation**

Throughout 2015, states continued their focus on regulating the PBM industry, with a specific focus on regulating transparency in drug pricing. Numerous states enacted new legislation strengthening current or enacting new MAC transparency laws. Further, states are increasingly regulating PBM operations. Examples of these regulations include (i) requiring PBMs to use and receive electronic prior authorizations (“ePA”), (ii) dictating what a PBM can audit during pharmacy audits, including how much notice must be provided, and the appeal processes that must be provided; and (iii) limiting cost-sharing for specialty tiers. Compliance with these state regulations is typically delegated to state division of insurance that may not fully understand the PBM industry.

**Value-Based Pricing and Purchasing**

As discussed above, the industry continued to discuss and move towards value-based pricing and purchasing. CMS is increasingly focusing on promoting value-based purchasing arrangements. In its 2016 Call Letter, CMS indicated it would be reaching out to Medicare Advantage plans on their implementation of value-based contracting to achieve these goals. Based on this input, CMS will also ask plans this year to share data regarding their adoption of alternative payment models. Most recently, in November 2015, CMS released a letter to State Medicaid Directors and drug manufacturers seeking to learn about “value-based” pricing arrangements that may make drugs, and specifically certain Hepatitis C drugs, more affordable for states.

Although payors are still hesitant to fully embrace value-based purchasing, with the increase in merger activity, payors will likely be more receptive to such arrangements in the coming year. PBMs have an opportunity to lead the way in this area with value- and outcomes-based drug pricing arrangements with pharmaceutical manufacturers. This is especially true in integrated models, where the PBMs now have access to both the patient’s medical and pharmacy data.

Overall, this past year saw significant changes in the pharmacy industry through consolidation, regulation, controversies, and payment reform. 2016 is poised to be another noteworthy and likely challenging year for PBMs, pharmacies, and pharmaceutical manufacturers.

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