Unintended Public Law Intent Has Private Sector Employer Plan Impacts

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The use of employer commercial insurance plans has continued to grow as the economy is still emerging from the COVID-19 pandemic. Importantly, employer self-insured or self-funded plans have remained strong through the past 5 years, resulting in about 60% covered lives in these programs.[1]

Clinical pathways are an established resource for insurance underwriting and actuarial assessments for the financial risk of clinical care. The utilization of pathways has been most visible in cancer care and select high-cost conditions where case management is key for effective risk mitigation for plan sponsors.

For decades, innovative therapy cost solutions have been introduced in private and public sector plans. The 340B program continues to be mired in controversy as hospitals or health-systems, employer insurance plans, and retail pharmacies remain at odds. The 340B program was intended to reduce patient care costs while avoiding over-regulation through government legislation. However, the economic reality of ever-increasing cost shifting to provide care access onto commercial plan costs while not necessarily improving population access or improved quality of care nationally, has prevented the program from reaching its intended goal.

The 340B program aimed to give discounts to disproportionate share health care provider organizations/hospitals (DSH) or safety net institutions (federally qualified health centers or FQHCs, and hospitals), while balancing Medicaid discounts that effectively created a manufacturer best market price floor. The savings difference on product cost could be utilized by the DSH entity to offset patient bad debt and safety net operational losses.

Over the last 30 years, the expansion of 340B sales has set new revenue records for DSH entities as they were able to profit from their commercial insured populations while purchasing below any other plan, except for Medicaid. Cancer centers—where clinical pathways were in heavy use—became important revenue centers akin to surgical specialties like orthopedics. Medical billing for drug therapies continues to be a business and political battleground over the best solution forward.

In the previous issue of the *Journal of Clinical Pathways*, Sheryl Riley, RN, OCN, CMCN, and F. Randy Vogenberg, PhD, FASHP, identified pathways for novel therapies, and case management expansion was mentioned as a driver for greater use of clinical pathways and by a wider variety of users.[2] Immunologic therapies along with cell and gene therapies (CAGT) that typically have million- to multimillion-dollar catastrophic claim costs to plans, are positioned to grow in number and approved conditions. This expansion would likely result in greater use of clinical pathways as seen previously in cancer care to aid in risk management of such cases.

Employer Concerns of Risk Trends

The current set of market incentive structures have impacted pricing by manufacturers and therefore costs to plans. This is evident in pharmacy benefit plans and the ever-increasing medical benefit claim costs, despite utilization and case management systems. The 340B program is just one example of unintended impacts across sectors.

Tax implications for manufacturers further incentivizes adverse pricing due to accounting or tax code issues around cost basis vs selling price. These additional unintended impacts of 340B legislation also need to be addressed.

Some good news is that efforts are underway to provide improved tracking and reporting of all entities involved in 340B transactions. To date, it has been difficult to clearly follow the money trail due to opaque contracts combined with multi-entity contracts that can be at cross purposes. Now the program is so large that change in financial oversight is coming.

Complicating matters further, however, for commercial employer plans, care providers, and plan members, is the growing use of alternative funding programs (AFPs). Promoted by brokers, advisors, and others, AFPs unknowingly create financial perils for employer plan sponsors along with provider networks and their patients, particularly in the pharmacy benefit.

In an article titled "Caught in the Middle: The Negative Impact Alternative Funding Programs are Having on Specialty Providers and Health Systems," Matthew Kupferberg, Esq, discusses the challenges with AFPs:

> AFPs earn profits by keeping a portion of the "savings" that the Plan realizes—ie, a portion of the money collected from the patient assistance programs (PAP) as a fee. They are therefore incentivized to work with the Plans to drive "savings" on these drugs. In some AFP models, if a patient is denied coverage under the available alternate funding sources, the AFP or the Plan may issue an

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> "override" to allow the patient to receive coverage as if the drug was covered all along…Meanwhile, the PAP refuses to cover these claims because it has concluded that the patient has insurance, even though the Plan won't cover the drug because it is subject to a coverage exclusion.[3]

This pattern not only impacts the beneficiary, but also presents challenges to the commercial plan sponsor, including negative member experiences, potential loss of specialty rebate arrangements, increased administrative fees, and litigation exposure. Plan sponsors should also consider compliance risks, such as US Health Insurance Portability and Accountability Act compliance, tax implications, and income discrimination associated with AFPs.

Conclusion

Clinical pathways are directly and indirectly linked to the employer plan risk mitigation strategy that plays out as care coverage language impacting members and providers. Beyond cancer care, pathways are increasingly routinely utilized in community-based care settings as out-of-hospital care has shifted post-pandemic. That shift has also leveraged the purchasing of drug therapies through 340B entities that grew through vertical integration over the past few decades.

While specific ideals were intended originally, various unintended impacts of the 340B program have negatively impacted health care costs for commercial employer plans. This can further impact providers and plan members (patients) as employer plans seek to exclude specific drugs and conditions or better manage the coverage provision in their insurance plan.

The future of 340B and other similar legislation must reduce negative and unintended impacts in an ever-changing care system. Changing a health care market that resorts to emotional short-term approach toward a thoughtful, collaborative, and truly patient-centric outcome-based solution that align with employer plan goals can be a powerful system beneficial to all concerned.

Reader questions, feedback, and suggestions are always welcome and can be directed to JCPEditors@hmpglobal.com. ◆

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