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Outlooks and Lessons Learned From Outcomes-Based Agreements

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Outcomes-based risk sharing contracts will continue to become more common as health plans, providers, and drug manufacturers realize the benefits of these arrangements, according to speakers at a session of the Academy of Managed Care Pharmacy 2017 Nexus meeting, being held in Dallas, Texas.

Josh J. Carlson, PhD, MPH, an associate professor at the University of Washington, provided the academic underpinnings for the idea, while John Fox, MD, MHA, vice president and associate chief medical officer of Priority Health, offered the health plan and clinician perspective.

Performance-based risk sharing arrangements go by many names—managed entry, market access, patient access schemes, and more—but they all share a common thread of basing coverage or reimbursement decisions on future outcomes, not on existing research or data, Carlson said. These outcomes range from health measures to financial and utilization results, and can be assessed at the patient or population level.

The main drivers encouraging the rapid uptake of these types of arrangements include the rising costs of healthcare and continued uncertainty about the efficacy of new drugs. While they are used across the world, particularly in Italy, which operates a nationwide registry with data tracking, they are also a good fit for the unique US healthcare market in which there is no government mechanism forcing drug manufacturers and payers to align their interests.

According to Carlson, linking drug performance to prices addresses several concerns held by both entities. For instance, plans may desire additional data supporting a drug's efficacy, but generating more evidence is costly and delays entry into the market, so manufacturers are able to provide a guarantee for certain outcomes linked to reimbursement so the drug can reach patients sooner. Additionally, the mechanism allows for price discounts without changing list prices.

One outcomes-based arrangement in the news recently, Carlson mentioned, has been that between Novartis and CMS for the new genetic therapy for treating cancer, Kymriah. He perceives it as a sign of the changing times that public payers are getting involved, and predicts that "if CMS has a mechanism around this, I think that's going to expand the interest in the US."

Still, some barriers exist to the implementation of risk-based payment contracts, even if the idea is gaining steam. Carlson mentioned study findings published in the September 2015 issue of *The American Journal of Managed Care*® in which he and his co-authors determined that the majority of stakeholders they had

interviewed were at least cautiously to mildly optimistic about the potential of risk-sharing arrangements, but predicted challenges with their execution due to the US' fragmented payer system and currently limited data infrastructure.

Essentially, Carlson said, "the juice has to be worth the squeeze" in order to gain buy-in from all participants, but he perceives the adoption of outcomes-based arrangements to be in line with the broader trends in healthcare moving towards value.

That message was echoed by Fox, who explained that as the healthcare system shifts, both payers and providers are seeking partners who will share mutual accountability for outcomes and costs, and this idea of accountability is now extending to the drug manufacturers who produce the drugs used by patients.

"What do payers want?" Fox asked the audience, showing a photo of a Monopoly board with some spaces replaced by skin. "Skin in the game!"

In other words, both parties must hold each other accountable for relevant outcomes that patients themselves would be willing to pay for. These outcomes should be timely and should be evaluated in patients who are representative of the larger patient population. However, Fox said, agreeing on the clinical outcomes is relatively easy: coming to terms on the contract itself is more difficult.

He illustrated examples of how outcomes-based agreements have been leveraged not only for drugs, but for diagnostic tests, medical devices, and gene therapies. He then polled the audience on whether, as payers, they would agree to contract scenarios based on whether the outcome was clinically meaningful and easily measured and whether the level of financial risk assumed was reasonable. For instance, one would not want to enter into an agreement where the manufacturer agrees to rebate 1% of spend if patients do not achieve the specified goal.

Still, Fox emphasized the importance of all stakeholders coming to the table with positive intentions to work towards a common goal. "It's hard to shake hands with a clenched fist," he said.