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Uptake of Outcomes-Based Deals Is Hindered by Multiple Factors

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As drug prices continue to escalate and new agents enter the market at higher and higher prices, plan sponsors have shown increasing interest in performance-based or outcomes-based drug purchasing arrangements with manufacturers. But uptake of such deals in the U.S. has been limited, most likely due to challenges such as the costs of gathering data and inadequate infrastructure to measure patient outcomes, suggested two panelists at the Academy of Managed Care Pharmacy (AMCP) Nexus 2015 conference, held Oct. 26-29 in Orlando.

According to a University of Washington (UW) database tracking performance-based risk-sharing agreements between drugmakers and payers from 1995 to 2015, roughly 30 out of 292 total arrangements worldwide represent RSAs in the U.S. Although the database may not be comprehensive, most of the deals in the U.S. were conducted in Medicare rather than the private sector, observed Louis Garrison, Jr., Ph.D., a professor in the UW School of Pharmacy, who spoke at the AMCP panel, "Making Sense of Risk-Sharing and Managed Entry Agreements."

RSAs between drug manufacturers and plan sponsors can take on many names, from performance-based risk-sharing arrangements and pay-for-performance programs to managed entry agreements and coverage with evidence development. But in all, coverage and/or reimbursement levels are based on real-world performance or utilization of products and devices, with both sides sharing in the risk.

Both Garrison and co-presenter Zoltán Kaló, Ph.D., professor of health economics at Eötvös Loránd University in Budapest, Hungary, explained that such arrangements are borne out of the "pervasiveness of uncertainty" that goes along with the entry of a new drug. There is, among other things, uncertainty about efficacy, effectiveness in the real world, unknown safety risks, and cost-effectiveness, they observed.

Gathering Post-Launch Data Is Costly

"When the payer is negotiating price or use conditions at launch, they run the risk of making a bad buy, where the incremental health benefits aren't worth the money," said Garrison. The payer is free to collect post-launch data to determine whether the drug they're paying for is actually worth the price, but it's expensive to do and "we don't see a lot of that in the U.S., particularly in the private sector." Moreover, there's no incentive for manufacturers to collect such data unless it's in their competitive interest, he suggested.

When measuring the value of an obesity treatment, for example, he said payers can track a drug's performance by following changes in body mass index and markers such as glucose tolerance, cholesterol and blood pressure, etc. But those things are also shown in clinical trials, and the biggest concern — and unknown — to the payer is what they are getting longer term in the form of improved cardiovascular outcomes

or quality of life, for example. “But we don’t have certainty about any of the parameters of that model,” he pointed out. “So when you come to the table to negotiate, you’re trying to say, ‘Well, what’s really the biggest source of my uncertainty and how can I address that through collecting data as part of a risk-sharing agreement?’”

UW in 2013 and 2014 conducted in-depth interviews with 14 payers and manufacturers that identified several key barriers to RSA in the U.S. The results of that survey, published in the September issue of *The American Journal of Managed Care,* included:

- ***Significant additional effort required to establish and execute RSAs,*** as opposed to negotiating rebates and discounts through traditional contracts;
- ***Challenges associated with defining meaningful outcomes*** and measuring relevant real-world outcomes;
- ***Inadequate data infrastructure*** for measuring and monitoring relevant outcomes; and
- ***Implications for Medicaid “best price,”*** since the discount associated with an RSA-covered medicine that does not perform as anticipated by the manufacturer could be perceived as a new best price and made available to all Medicaid purchasers (see brief, p. 8).

As RSAs or managed entry agreements continue to increase abroad, particularly in Italy and Sweden, there has been an observable decrease in the amount of published information on such deals, said Kaló. This may be because of the “free rider” effect, in which payers are referencing other deals to try to negotiate a better price. One unintended consequence of “external price referencing” has been higher income countries referencing prices in lower income countries, which has translated into less funding available for research and development. As a result, many manufacturers have insisted on confidential agreements, and Kaló said he suspects the bulk of deals in countries with high RSA adoption are financially based, meaning reimbursement is linked to more easily measurable data such as sales or utilization.

Garrison suggested that payers are therefore most likely to use outcomes-based RSAs for high-cost disease areas and expensive drugs, that such arrangements should address an agreed-upon certainty and that they should use existing data systems when possible. Since access to clinical data was also cited as a key barrier, value-based delivery models like accountable care organizations and patient-centered medical homes, in which reimbursement is linked with patient outcomes, may become ideal settings for outcomes-based RSAs but aren’t yet mature enough. For now, financial-based RSAs may be the most feasible for private payers.

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