Ready for Risk Sharing? Challenges and Implications for Manufacturers

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KEY POINTS . . .

As risk-sharing for health care delivery gains momentum, the pressure is increasing on manufacturers to factor the risk of non-performance into their product offerings in the United States.

There are multiple ways to structure risk-sharing arrangements that manufacturers need to understand; no one approach is optimal for all products.

There are both challenges and opportunities in risk-sharing agreements.

With spiraling costs and outcomes that consistently lag many other developed nations, the US health care system is in the midst of fundamental change. In response, payers have been exploring ways to restructure payments (and risk) to increase accountability for cost and quality. Thus far, most activity has occurred between payers and providers through such mechanisms as value-based contracts and bundled pricing. Such arrangements obligate providers to manage against agreed-upon quality criteria and pre-set cost targets in return for a share of potential savings and increasingly, financial risk for missing them. Consequently, providers are now increasingly adopting evidence-based care paths to better control their own costs and outcomes.

As pressure for "better outcomes at lower cost" continues to mount, manufacturers must understand that they face a future in which they may be asked—or even required—to take on more of the risks related to the performance and cost of their products. However, before entering into risk-sharing agreements, manufacturers must understand the challenges and implications of these agreements, including considerations for the collection of outcomes data. In addition, manufacturers must be able to accurately assess when these arrangements are beneficial, and when they are not.

payment models by 2020. The task force is a coalition of some of the largest health care systems, insurers, and employer groups. Value-based pricing and bundled payments are not only becoming more common, they are being hailed as a new way to ensure that desired outcomes are achieved within an expected cost range.

As payers and providers transition to value-based payments, manufacturers must realize that they face a future where they might be asked or even required to assume more of the risks related to the performance and cost of their products. Risk-sharing agreements (RSAs) are gaining more attention and becoming part of provider leadership objectives. Reasons payers and providers have expressed interest in engaging in RSAs include:

- ensuring there is focus on the right patient;
- avoiding the risk of product use (and associated cost) in non-responders;
- capturing real-world evidence (RWE);
- demonstrating that the formulary is not 'up for sale'; and
- requiring manufacturers to demonstrate confidence in their product.

It should be noted that risk-sharing is not a new concept; in Europe and other developed markets these types of arrangements have been in existence for many years. And these arrangements are not limited to pharmaceutical products. Medical device manufacturers, like Boston Scientific, Medtronic, Johnson & Johnson, and St. Jude Medical are also beginning to enter into these types of discussions.

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Why Is Risk-Sharing Gaining Attention Now?

In 2015, the US Department of Health and Human Services Secretary Sylvia Burwell announced that by 2018 at least half of all Medicare payments would be based on quality of care or value. On the heels of that announcement came another by the Healthcare Transformation Task Force that also vowed to move at least 75% of their payment arrangements away from fee-for-service payment models and into alternative

The Rationale for Engaging in RSAs

Entering into RSAs requires organizations to give careful consideration to their ultimate

goals for participation. Some of these goals include:

• creating an alternative approach to achieving market access and premium pricing when more traditional routes prove unsuccessful;
• enabling movement into the market ahead of competitors;
• developing additional insights into particular patient populations; and
• building deeper relationships with key payers and providers.

However, RSAs are complex agreements that take considerable time to develop. Many organizations find that one of the key first steps is gaining internal alignment on the goals the organization is trying to achieve. Similarly, manufacturers must define who will be involved in the approval process and at which stages go/no-go decisions will be made. Sometimes organizations are approached with an opportunity and start working on bringing it to fruition, without first gaining internal agreement that the effort is justifiable. This results in unnecessary expenditure of time and resources. It can also damage the customer relationship.

Another consideration for manufacturers is the type and level of risk they are willing to take on. Internal discussions should focus on defining the specific therapeutic areas and products where an RSA might be advantageous; how much risk they are willing to entertain; how they'll be able to measure success; as well as criteria for identifying a good partner. Exploring these topics in advance of customer conversations will help manufacturers to ensure the potential benefits of entering into an RSA are significant enough to justify the necessary effort and risks.

RSAs Can Take Many Forms

There are numerous ways to structure risk-based agreements and these vary based upon the amount of risk assumed by each party. The risk proposed in the agreement can be upside, downside, or a combination. The most common of these arrangements are finance-based and outcomes-based agreements.

Historically, finance-based arrangements have been more common than outcomes-based approaches. Finance-based arrangements involve setting caps or limits on the amount of spend per product or patient. Outcomes-based arrangements involve establishing a measurement that must be achieved before additional payment is made or a rebate is offered. Determining what to measure and how has been an ongoing challenge in creating these types of agreements; however, they are not uncommon. Since 1997, over 120 outcomes-based arrangements have been in place across the globe with about 10% to 15% of them in the US. The small volume is an indication of the challenge of establishing these arrangements, but there are benefits as well. More specifically, outcome-based agreements present an opportunity to engage in good faith collaborative efforts with provider and payer stakeholders to facilitate improvement in the standard of care in the therapeutic areas where manufacturers have products to bring to the table.

Challenges of RSAs

One of the biggest challenges of RSAs is determining how to structure these types of arrangements. Organizations must be clear about the mutual goals they are trying to achieve, and if a finance-based or outcomes-based model is better. For outcomes-based agreements, it is critical to ensure that the measures to be tracked are objective, clearly defined, reproducible, and difficult to manipulate. In addition, consideration must be given to how the outcomes will be captured. The extent to which current tracking mechanisms can be used will help minimize partner objections for moving forward.

Opportunities in RSAs

Although RSAs carry risk, they also create opportunities for companies. One of the greatest opportunities is the ability to develop a deeper relationship with a partner. Through discussions, manufacturers have an ability to gain greater insight into the partner's operations and goals, and ultimately generate greater alignment. These insights can enable a stronger working relationship that will be helpful in the future.

Outcomes-based agreements also provide the opportunity to develop data about a particular population. These insights might enable the partners to create further product differentiation. To the extent a manufacturer can learn about how well its product works with a particular subpopulation, it can leverage that information in future negotiations with other partners. Similarly, providers can use the insights to demonstrate better quality care for their specific population—something that is becoming more critical in the rapidly consolidating marketplace.

A Promising Future

Risk-sharing is an old concept that is gaining new attention as providers struggle to meet growing demands for better outcomes at lower costs. Payers have made clear their intention to share risk with providers, and providers will increasingly look to manufacturers to do the same with them. Those organizations that spend time determining how and when these arrangements might be beneficial will be best positioned to respond to providers. Many manufacturers are taking the time to evaluate the pros and cons—are you? ■

Additional information:
The preceding article was based on the issues panel of the same name held at the ISPOR 20th Annual International Meeting, May 16-20, 2015, Philadelphia, PA, USA.

To view this presentation from this meeting, please visit the 20th Annual Meeting Released Presentations page at: http://www.ispor.org/Event/ReleasedPresentations/2015Philadelphia#issuepanelpresentations

This topic will be presented at the ISPOR 21st Annual International Meeting in Washington, DC, USA,as a short course, "Risk-Sharing/Performance-Based Arrangements for Drugs and Other Medical Products," and also during Workshop 2: "Risk-Sharing Agreements for Manufacturers and Commercial Payers in the United States: How Can Theory Help Practice? Design And Aligning Incentives Are Key." See pages 30-31 for further meeting details.