Measures of success: How value-based pricing may change the pharmaceutical industry

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Adoption of value-based pricing, where drug prices are linked to real-world outcomes rather than on a per-pill or per-treatment basis, will have a profound impact on the pharmaceutical industry. And with the Centers for Medicare and Medicaid Services indicating that they are ready to test new pricing models, the shift toward value-based arrangements has already begun.

Alice Valder Curran, Partner and Head of Hogan Lovells' Government Regulatory practice group; and Bob Spurr, Head of Patient Solutions and Access at Novartis Oncology, say that two key areas of value-based pricing — collecting drug performance data and meeting CMS's current pricing requirements — raise particularly challenging operational and legal questions, especially in a regulatory environment that's attempting to operate under the status quo.

Challenge: Delivering the right data

There is no single definition of what a value-based pricing arrangement is, but what unifies the approach is the linkage of a drug's price to the health outcomes of the patients who use it. That means any manufacturer and customer (e.g. a payer or health plan) who engages in such an arrangement must be able to gather the necessary data that measure the drug's performance. Selecting the right data, and collecting it in a way that doesn't infringe on the rights of patients is highly complex.

"If you want to contract with a health plan and agree that your drug's price will vary based on how well it works in your population, you're going to need patient data," Valder Curran says. "But how do you define what those data are? [They] are going to depend on what the plan can gather. In the real world, as opposed to the clinical trial setting, those data might not be as precisely defined as the package insert for that product as approved by the FDA."

"The spectrum of data you could have for a patient is also incredibly protected, as is appropriate, by federal and state law," adds Spurr. "Oftentimes when we're trying to build contracts with our customers, they may be unable to identify, collect and then aggregate data to measure the necessary outcomes. That creates another layer of difficulty in ensuring that we're making the right pricing decisions."

Solution: Start early

Spurr and Valder Curran say that substantiating metrics for success and deciding how data will be measured at the outset of creating a new pricing arrangement is essential to avoiding regulatory barriers later on.

"First we ask: 'What are the right metrics to select and how will those metrics and those data points we're collecting implicate themselves in an actual contract?'" says Spurr. "In the development of new products, we ensure there's information and data that we can integrate into the package insert before we approach our negotiations with the FDA. Having those endpoints built into the product early on has great utility in the value-based schema."

Challenge: CMS pricing standards

Valder Curran says that meeting CMS's current standard for pricing price reporting — which requires "per-unit" price reporting — represents another major hurdle in establishing a value-based arrangement.

"Health care providers and manufacturers may be willing to go to alternative units of measure for pricing a product, such as pricing a drug month-to-month or as a course of therapy, regardless of the amount of drug product each patient may require. But [manufacturers] are required to force an alternative pricing arrangement into a per unit price when reporting to the government," she says. "That affects the price the government pays and the discount manufacturers must pay to programs like Medicaid. It's a square-peg, round hole problem, with very real financial risk."

Solution: Ask the right questions with the right partner

Every value-based contract is different. The terms vary based on the type of product (oral versus injectable), customer (retail, pharmacy, physician/hospital, or plan), and the outcomes measurement. If the arrangement does not readily translate into the pricing metrics CMS requires, Valder Curran recommends approaching regulators early on to discuss the details and to formalize how the company intends to reflect the arrangement in its data.

"[The government] wants to learn about these arrangements as much as we want to talk about them," says Valder Curran. "[In our work] with Novartis, we've approached the regulators directly on this issue, and they welcomed it. They took our input and gave us feedback that confirmed our government pricing approach. They want these arrangements to work in the marketplace, so long as the government gets its appropriate price too."

But Spurr says that manufacturers who are navigating the privacy and data challenges inherent in value-based pricing should collaborate closely with their legal team throughout the process.

"What you learn when you start to interface with the government is they also see [value based pricing] as very innovative and forward-looking," he says. "But if you don't come prepared with

the right questions to help guide decisions that you're about to make, it's a waste of time. A legal team with deep experience in this area can really help manufacturers understand the regulations, and interpret those regulations to benefit the outcomes we're trying to achieve on behalf of both patients and providers."

"Close collaboration is the only way to make these new arrangements work for everyone."

Watch the video to learn more about the operational and legal implications of value-based pricing arrangements.

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