

Payers face challenges in paying for the value of prescription medicines because regulatory barriers impede open communication by manufacturers, predictability regarding the biopharmaceutical pipeline and innovative contracting. Value-driven payment for prescription medicines can promote efficiency and affordability by ensuring that more patients receive the best treatment for them, the first time around. We need to remove the hurdles making it difficult for innovative, sensible payer/manufacturer arrangements to emerge.

SOLUTION

#1

Improve Predictability for Payers and Diffusion of Evidence

In recent years, payers have expressed a need for greater predictability and certainty regarding the biopharmaceutical pipeline as they often set premiums and formularies 18 months in advance. Yet outdated Food and Drug Administration (FDA) regulations chill manufacturer/payer discussions. Further, once a medicine is approved, current rules can also prevent timely dissemination of important safety, value or efficacy information about a product when the information is not already included in the product's labeling.

Example #1: Under current policy, manufacturers are constrained in sharing safety and efficacy information about medicines in development with payers, health systems and health care professionals. Until a medicine is approved, there is no safe harbor to share proactively such important information as data on expected indications and the expected effect on the patient population. The ability to share this information earlier would give payers a better sense of potential costs and help them set premiums accordingly.

Solution: The FDA should update its regulations to allow manufacturers to share appropriate, scientifically sound information with payers pre-approval to reduce uncertainty and improve payer ability to set premiums.

Example #2: Under current FDA policy, manufacturers conducting research and publishing peer-reviewed studies showing a medicine can help reduce hospital admissions may not proactively share this information, even with payers or providers at financial risk for hospital readmissions. They may be unable to proactively share results of a clinical trial showing a medicine dramatically reduces prevalence of another disease even where the trial was required by the FDA. And current FDA guidance does not allow companies to share peer-reviewed medical literature if the data are not reflected in the labeling and the study is authored by the company – even if FDA relies on the study in its approval decision. As a result, important medical findings may not be widely recognized, or changes in treatment could be delayed by several years while new data are added to the labeling.

Solution: The FDA should update its regulations to allow manufacturers to proactively share truthful, non-misleading information on clinical and economic outcomes with payers and providers after approval.



SOLUTION
#2

Address Regulatory and Legal Uncertainty Around Value-Based Payment Arrangements

As we move toward value-driven health care, the limits of regulations developed for a fee-for-service world become clear. Biopharmaceutical companies are exploring a wide range of innovative partnerships with private payers and providers that recognize improvements in care and better outcomes for patients. But significant regulatory and legal uncertainty is slowing the development of sensible new business models.

Example: Despite extensive research demonstrating that improved adherence reduces medical spending for chronic diseases, broadly written laws designed to prevent fraud in Medicare and Medicaid also may preclude certain adherence support arrangements designed to help patients.

Further, biopharmaceutical manufacturers must adhere to a complex set of government price-reporting rules for calculating Average Sales Price in Medicare Part B and Best Price in Medicaid. These highly technical price-reporting rules were not established with new approaches to contracting in mind (such as indication-based pricing or outcomes-based arrangements). While the price-reporting rules do permit manufacturers to make reasonable assumptions, ambiguity about how to capture innovative pricing methods in an Average Sales Price or Best Price framework can create significant uncertainty for manufacturers and payers.

Solution: The Department of Health and Human Services should update regulations or guidance to allow new business models in the private market to evolve, including clarification of fraud laws to support better use of medicines through patient adherence programs; and address any outstanding questions related to price reporting as requested by manufacturers. Changes to regulations or new guidance should be developed through notice and comment.

SOLUTION
#3

Improve Patient-Centered Decision Support and Value Frameworks

We face a pressing need to develop rigorous, scientifically sound decision-support tools and definitions of value that reflect the full range of stakeholder perspectives. Sound, well-structured tools for value assessment can help us move beyond silos to a more holistic perspective on value that is central to long-term solutions and patient needs. Better information can help empower informed patient-physician decision-making and make sure patients have a say in the direction of their care.

Example: Organizations, such as the American Society for Clinical Oncology (ASCO) and National Comprehensive Cancer Network (NCCN) have recognized the need for new value frameworks to support patient-physician decision-making, and highlight the importance of accommodating patient differences within these frameworks. But other frameworks, such as the one developed by the Institute for Clinical and Economic Review (ICER), move in the opposite direction by focusing on payers' short-term budget needs and failing to adequately account for individual differences among patients with a one-size-fits-all standard.

Solution: We need to focus on delivering the right medicine, to the right patient, at the right time. Value frameworks and assessments should be developed through an open and transparent process; include meaningful input from patients and providers; support patient differences and preferences; and deliver reliable and relevant information to inform health care decision-making. These tools should be used in ways that help physicians and patients decide which treatment options fit an individual best, and not in ways that replace personalized treatment decisions.