Provider Payment Reforms Present Opportunities and Challenges for the Drug and Device Industries

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Fee-for-service payment for physicians and hospitals has permitted socially desirable drug and device innovation as well as socially undesirable patterns of technology assessment, purchasing, and use. New forms of payment will transform the demand side of the market, and the drug and device industries will be challenged to reformulate their strategies and processes. Emerging responses include a new understanding of the hospital as customer; greater emphasis on documenting outcomes relevant to providers; and reduction in the costs of innovative products and the clinical services that rely on them.

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Fragmented organization and fee-for-service payment for physicians and hospitals inadvertently have benefitted the drug and device industries by permitting rapid product diffusion and generous reimbursement. The resulting cycle of high revenues and margins, continued investments in research, and further product development has benefitted patients with serious medical conditions and established the United States as the global leader in biomedical innovation.

But the medical technology sector faces the risk that contemporary policy and market interest in bundled payment and other payment initiatives will discourage the adoption of cost-increasing new products and squeeze the flow of revenues vital to the engine of innovation. The health care technology sector has been given the opportunity to reformulate its product development, pricing, and sales processes in the context of an increasingly integrated and sophisticated provider sector.

**Implantable Medical Devices**

Hospitals have been hampered in applying value-based purchasing principles to implantable devices due to a lack of coordination with the surgeons who select products on behalf of their patients. However, market and regulatory pressures increasingly are inducing physicians in device-intensive service lines to see their interests as aligned with those of the hospital and to give up some of their autonomy in favor of cooperation with the facility’s supply-chain strategies.

The strongest form of alignment incentive is joint ownership by the physicians and the hospital of ambulatory surgery and specialty inpatient facilities, since the physicians reap a significant share of all savings. Employment of the physicians by the hospital is a weaker form of alignment, since the physicians’ personal earnings are not directly linked to hospital cost reductions. Formal gain-sharing and informal department re-investment initiatives create a revenue potential for physicians who help the hospital reduce its device and service-line costs, but typically can account for only a small portion of the physicians’ overall earnings.

Leading hospitals maintain technology assessment committees that have taken on some of the functions of pharmacy and therapeutics (P&T) committees historically operated by health insurers. These may include, for example, levels of performance by familiar products such as orthopedic joints and cardiac pacemakers, where price looms large in the assessment of value, and breakthrough products such as minimally invasive heart valves and artificial spine disks, where
clinical performance rather than price is of primary concern.

Hospitals are seeking to move device selection from a series of autonomous choices made by individual physicians to a more conventional supply-chain management process in which the hospital obtains better prices in exchange for guaranteed volume. This latter approach begins with a request-for-proposals or other systematic assessment of products among competing device firms, with the intent of awarding semi-exclusive contracts to a subset of firms that will offer good prices and service guarantees. Negotiation tactics include assigning individual devices to distinct classes and either setting a maximum acceptable price for each class or soliciting bid prices by class. Other options include offering volume in exchange for a significant discount off list prices for the device firm’s entire product portfolio. Some hospitals establish a maximum price as a defined percentage of the reimbursement received for a procedure from Medicare or a private insurer.

**Specialty Pharmaceuticals**

Health plans are experimenting with new payment methods to motivate physicians to adopt evidence-based clinical pathways; favor low-cost drugs unless higher-priced alternatives offer superior performance; monitor patients for toxicity and exacerbations; and, where possible, support the continued viability of community-based practice as an alternative to hospital-based consolidation.

Clinical pathways seek to limit variability of care and achieve predictable levels of quality and costs by specifying a preferred course of treatment for each stage of disease based on a review of the evidence on clinical efficacy, toxicity, and cost. For specialty physician practices, adoption of pathway-based care can be promoted through any of several payment changes, beginning with increases in the professional fee schedule combined with reductions in the drug mark-up, which focuses financial incentives on professional services and away from drug sales. Some health plans, such as Anthem Blue Cross, are experimenting with adding new payment codes for cancer care planning and patient management in order to reimburse the practices for activities that promote patient monitoring and education and thereby
reduce adverse side-effects and hospitalizations from toxic chemotherapy. These higher payments are made under the agreement that the oncology practices will use evidence-based pathways and limit drug markups.

In addition to changes in the fees paid for evaluation and management, health plans can vary the drug mark-up above the average selling price level based on whether the physician practice is conforming to an evidence-based pathway. The percentage mark-up can be higher for low-cost than for high-cost drugs in order to equalize the dollar mark-up. While the mark-up for expensive biologics could be 10% above ASP, for example, the mark-up for inexpensive generic chemotherapies could be 50%. This contrasts with Medicare’s administered pricing system, which pays 6% above ASP for all specialty drugs, discouraging the use of low-cost products.

Episode-of-care payment can be adapted to oncology once rates are titrated to the site and severity of the disease. Some episode payment methods exclude pharmaceuticals, reimbursing specialty drugs separately on an invoice-cost basis without mark-up. Such methods protect the physician practice from the financial risk of new drugs being introduced into the market or the epidemiological risk of attracting sick patients who require the most expensive drugs. United Healthcare developed this approach with large oncology practices in the Midwest in a manner that continued past levels of total reimbursement but disconnected it from drug mark-ups. The intent was to reduce future cost trends that normally would have resulted from percentage mark-ups being applied to newly introduced and premium-priced biopharmaceuticals.

The cost of cancer drugs can also be included in the episode payment, which then must be adjusted by the patient’s cancer indication and stage of disease. For example, the Hill Physicians Medical Group pays contracted oncology practices on an episode basis for lung, breast, and colon cancer, with the payment depending on indication and on where the patient is in the course of treatment. Drug costs typically are high
immediately after initiation of chemotherapy and then decline after the course of care is completed several months later. Cost patterns then may remain low if the patient is in remission or rise again if a new course of care is initiated. These episode payments are supplemented by stop-loss limits, which offer the physician practices additional reimbursement for the care of patients whose costs have exceeded a threshold defined in the episode protocol.

Opportunities for the Medical Technology Industry

On their way to patients and profitability, new drugs and devices must overcome three major hurdles. They must document safety and efficacy to the satisfaction of the Food and Drug Administration; convince insurers they should be covered under the definition of medical necessity; and motivate physicians to prescribe and administer them. Historically, technology firms have focused on the FDA and insurers as the most difficult hurdles, relying on the fee-for-service payment methods to ease discussions with physicians over prescription and with hospitals over acquisition. This era is now drawing to a close.

The new shift in payment methods for physicians and hospitals give providers increasingly strong incentives to care about the cost of the products they use. Changes in provider payment are both cause and consequence of changes in provider organization, including increased scale and scope, improved alignment of financial interests, and enhanced capabilities for assessing technology. These developments challenge conventional methods of designing, pricing, distributing, and selling drugs and devices. As always, challenges to the sector bring opportunities for those firms that can make changes faster and better than their competitors.

Conclusion

For the medical technology sector, these are the worst of times. Contemporary changes in provider payment, organization, and incentives will limit the industry’s ability to obtain the prices and revenues that financed innovation in years past.

But these also are the best of times for the medical technology sector. Distribution will evolve toward account management and partnership relationships with hospitals and large physician practices. Widespread provider use of technology assessment and clinical pathways will reward technology companies that are able to develop truly innovative products, manufacture them in the most efficient manner, and document their clinical and economic value to ever more integrated, sophisticated, and cost-conscious providers.

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