Medtech's Shift to Consumer-Based Billing

In an uncertain reimbursement climate, some device manufacturers are considering new ways of billing to ensure revenue and profitability.

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The medical device industry is facing a number of revenue-related pressures impacting growth and profitability due largely to healthcare reform initiatives, changes in purchasing and supply chain management, and billing and reimbursement issues. To succeed against this backdrop and ensure the greatest opportunity for product adoption, manufacturers must not only demonstrate a device's value proposition in clinical and economic terms, but pursue strategies that optimize their ability to obtain timely reimbursement.

Value-Based Reimbursement Has Redefined Purchasing

Accountable care and value-based reimbursement are causing a significant shift in healthcare, with providers facing mounting pressure to improve the effectiveness and quality of patient care at an optimal cost. As the industry moves toward capitated payments for healthcare services, such as Medicare's Bundled Payments for Care Improvement (BPCI) initiative, whereby hospitals agree to payment arrangements that include financial and outcomes accountability for episodes of care, providers must understand their costs at the patient level to succeed and remain profitable.

With supply chain costs the second-largest and fastest-growing expense behind labor costs, medical devices are targets for cost containment measures. Hospitals and health systems are taking direct responsibility for medical device purchasing decisions with a focus on reducing these costs and the number of manufacturers used. Device manufacturers must demonstrate their ability to provide better outcomes at lower costs, and show superiority to other options.

According to Emergo's 2016 Medical Device Industry Outlook report and survey, startups and smaller medical device manufacturers indicated that with decreasing private physician purchasing influence, they believe that large manufacturers will have more negotiating power with both providers and payers, hindering their ability to compete and introduce new or cutting-edge devices into the marketplace.

Payer Challenges and Barriers to Reimbursement

Following the intensive process of demonstrating clinical utility for approval by FDA, coverage issues and timely third-party payment can be significant impediments to the adoption of many innovative medical devices that can spell success or failure for a medical device company. Reimbursement has a direct impact on device adoption—if providers face difficulty getting paid, they will be less likely to support the new device or therapy.

From the payer's perspective, demonstrating long-term clinical and economic value and real-world effectiveness is necessary to gain coverage and drive utilization. Coverage decisions typically include assessment of whether or not devices are "reasonable and necessary" or meet payer medical necessity criteria. Payers will not cover emerging devices and related procedures they consider investigational or experimental.

As we are seeing in the emerging molecular diagnostics and genetic testing markets, from a billing and claims management perspective, documentation is becoming more and more critical to substantiate payment. Payer requests for additional information to process billing claims is increasing. Several of the most common claim issues and reasons for payment denials include the following:

- Services billed with no medical necessity documentation to support the claim.
- Documentation for a service by a health professional deemed insufficient or inconclusive.
- Services provided to a patient deemed experimental or investigational.
- Claims for services coded incorrectly.
- Not approved by FDA.
- Humanitarian device.

Effective billing and revenue cycle management for medical devices is also impacted by increasing requirements for new data and reporting, new billing codes, and ongoing payer and regulatory updates that will routinely challenge the ability to get reimbursed.

One significant regulation that is being phased in currently is FDA's requirement for a unique device identification (UDI) system

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to improve patient safety, facilitate recalls of devices that malfunction, and improve supply chain efficiency. By 2020, most medical devices will need to include a UDI in human and machine-readable format. CMS and FDA are lobbying for universal health insurance claim forms to include the UDI in order to improve postmarket surveillance and device performance. Claim-based UDIs would also help determine costs and outcomes and help track manufacturer rebates.

Providers without the automated system ability to process medical device claims to 100% reconciliation, coupled with the lack of aggressive and purposeful claims follow-up, may face significant challenges in receiving reimbursement, which may erode the successful adoption of medical devices.

Consumer-Based Billing: An Emerging Strategy

Device manufacturers are seeking better ways to ensure revenue and profitability by optimizing their ability to obtain timely reimbursement. Startups and smaller medical device manufacturers in particular are finding significant opportunity to improve adoption, gain competitive advantage, and enhance revenue through a reimbursement strategy based on direct-to-consumer billing for their devices and wearables once prescribed by a physician versus having the healthcare provider bill for the device.

In-house billing allows manufacturers to maximize unit pricing for their devices, aggressively monitor and appeal third-party claims, and take direct control of revenue cycle performance to ensure a high probability of getting reimbursed. Because ordering physicians no longer have to contend directly with billing and reimbursement issues, they are less encumbered in their selection of a preferred medical device.

Automated billing and revenue cycle systems designed specifically to support medical device claims processing provides a rules-based workflow that requires little staff intervention and easily scales to match company growth. Operational alerts and business analytics provide real-time visibility into revenue performance and profitability.

One medical device company adopting an in-house billing strategy has seen an uptick in reimbursement per unit of 30% or more, with a nearly 50% reduction in claims denials and a four-fold increase in appeals success. Device manufacturers are also seeing much higher payer coverage in general, and growth in contracts compared to medical device companies that do not control their own billing.

A significant advantage of in-house billing is that medical device companies are able to work reimbursements from any rejections and denials in a timely manner (that might otherwise have been lost revenue through traditional provider billing) by using automated processes that help them identify root causes of denials, manage resolutions, and reduce write-offs.

Evaluating new reimbursement strategies is necessary to not only increase revenue and grow market share, but to make the difference between surviving and thriving in this era of healthcare reform and reimbursement uncertainty.

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