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1 Driving Successful Commercial Product Launches

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Introduction

Healthcare is undergoing a radical transformation that is driven by uncontrollable cost increases, higher healthcare needs, increased regulatory scrutiny, as well as a shift in payment systems from a volume of care to value of care. New payment models that shift financial risk from payers to providers are evolving. To succeed in this environment, healthcare providers are focused more than ever on controlling the cost of care, being more efficient and delivering improved patient care. As these shifts in the healthcare system continue, new payment methodologies will continue to evolve that place greater emphasis and rewards on improved patient outcomes and provider efficiencies. A stakeholder's willingness to pay for a medical device will be tied to its impact on patient outcomes, cost-effectiveness and support for quality-based performance metrics.

To thrive and provide commercially ready products in this new environment, medical device manufacturers need to implement a collaborative and comprehensive approach in their product development process (PDP), with customer adoption as the goal. To achieve this result, medical device manufacturers will need to understand and demonstrate how their product improves patient outcomes while increasing efficiencies and value to multiple stakeholders within the healthcare delivery system.

This chapter will provide the reader, especially those responsible for developing and building a regulatory strategy, with a framework to achieve a successful commercial product launch. Regulatory leaders and leaders from other cross-functional departments must recognize that their strategies and tactics should not be viewed from their perspective alone. Instead, they must understand that they are part of a process that has a patient-centered and market adoption end in mind. To thrive in this evolving healthcare environment, a collaborative cross-functional market access approach must be embraced by everyone in the organization.

Commercialization Through Cross-Functional Collaboration with Market Access Mindset

In the past, most medical device manufacturers rarely considered payment, value or the end user of their products in their PDP, or may have only considered some of these at the time of product launch. As medical device manufacturers recognize the complexities of the new marketplace, they also have discovered this previous approach has led to poor commercial results. Increasingly, medical device manufacturers are integrating payment, value and other patient- and customer-focused criteria in their strategies very early in the process. Marketplace adoption of medical devices is increasingly dependent upon a range of stakeholders beyond the physician. These stakeholders include payers, patients, regulators, government policy makers and multiple clinical and economic decision makers within healthcare provider systems. Each of these stakeholders brings a unique set of perspectives on how they expect a medical device to impact quality and cost of care. A medical device manufacturer will need to understand each of these stakeholder perspectives and demonstrate how their device meets the demands of improved quality, lower