

US healthcare reform: How it could impact your business

The US market is the largest and arguably the world's most attractive medical market. But healthcare reforms which were enacted last year will bring about change. Edward Berger* and Robert Keefer** explain the changes which the reforms will bring and assess how they will impact medtech companies looking to enter the US

The Patient Protection and Affordable Care Act (PPACA), a set of healthcare reform measures which were signed into law by President Barack Obama on 23 March 2010, have introduced new elements of uncertainty into the US market. It is now more important than ever for companies to understand the impact these measures will have on healthcare provision and for them to do a careful opportunity assessment before entering the market. The overall medtech market will continue to expand, but companies need to understand how the changes will affect their specific products and markets. They particularly need to evaluate the specific effects on pricing and reimbursement. Even a strong clinical package for regulatory submission is not sufficient to ensure product acceptance unless and until you understand how and when you will get paid; and whether customers, including insurers, will fully value your product advantages.

The PPACA is widely viewed as the most substantial reform of the US healthcare system since the creation of the national Medicare programme in 1965. It drives fundamental changes to the US healthcare financing system and, by extension, equally important changes for enterprises developing and selling medical technology products in the US.

While the PPACA contains dozens of distinct provisions, there are only a few major policy elements that have potential impact on medical products. One of them mandates far-reaching reforms of the private health insurance industry – the source of health insurance for the vast majority of non-indigent US citizens under 65 years of age. PPACA requires that insurers' family policies provide coverage to dependent children up to age 26. Insurers are forbidden to impose lifetime maximum expenditure limits or annual maximum benefits limits. They cannot refuse to offer insurance due to preexisting conditions; and they are required to provide coverage for a defined set of preventive services. New insurance policies, but not existing ones, must meet the standards of one of four benefits packages defined in the Act. Finally, private insurers must limit administrative costs to 15% of premium revenues for large group policies and 20% of premiums for individual and small group policies.

Impact on healthcare costs

These insurance market reforms seem well-designed to provide basic health insurance to those who currently have none. They may have some impact on systemic healthcare costs by encouraging the newly insured to seek care earlier, and in locations with lower costs than the emergency departments of hospitals. But they do nothing to constrain

costs for the great bulk of the population. Indeed, when we focus on the PPACA's goal of reducing the cost of healthcare, what is most striking is the absence of provisions that directly address cost. There are no overt cost controls, and no changes in payment methodologies. There are no spending caps and only minimal reductions in certain Medicare programme payment levels. There are no constraints on utilisation of advanced technologies. In fact there are explicit prohibitions against Medicare's consideration of cost in the determination of coverage for new technologies, as well as against the use of federal comparative effectiveness research findings in Medicare's decisions.

The one PPACA provision that directly addresses the cost of healthcare is the creation of a Medicare Independent Payment Assessment Commission (IPAC). IPAC is charged with the responsibility of recommending Medicare payment policy changes if projected spending increases exceed increases in the consumer price index. If Congress fails to approve either the recommended changes, or equivalent savings, the IPAC recommendations would be implemented. This provision is extraordinarily controversial, and is widely considered among the Act's elements least likely to survive Congressional attacks.

For the most part, the PPACA addresses system-wide healthcare spending control by mandating or facilitating a series of initiatives that are designed to encourage more efficient and effective use of healthcare resources. Most prominent among those initiatives are:

1. Requiring broader adoption and utilisation of electronic medical records (EMRs) and related health information technology (HIT) tools. It is believed that EMRs will allow better coordination of information and care across different providers, reduce wasteful duplication, and assure that treatment decisions have the benefit of a complete and readily accessible medical record;
2. Funding an ambitious comparative effectiveness research (CER) initiative. It is widely believed that physicians need more information about the relative benefits of different therapeutic options, and that clinical decision-making would benefit from research providing head-to-head comparison of alternative therapies. Such research is not usually required for regulatory approval, and is not often done by technology developers. The Act provides funding for such research through government agencies; and
3. Enabling a broader programme of Medicare alternative payment demonstration projects, most specifically and notably trials of so-called "accountable care organisations"

(ACOs) as a model for implementing incentives to control costs while improving quality. ACOs are comprehensive service organisations that would provide all required healthcare services to enrollees for a risk-adjusted fixed per-capita payment amount.

PPACA advocates believe that these three initiatives, over time, will lead to healthcare cost reductions coupled with improved quality outcomes. This is rooted in the belief that more complete and easily accessible information about the patient, coupled with better understanding of what clinical interventions will and will not work under specific circumstances, and care delivered through organisations that will prosper by providing good care efficiently will yield an optimal combination of quality and efficient resource utilisation.

Achievement of the desired results from these initiatives is hardly guaranteed, and will certainly require time. All of the pieces discussed here must fit together, and must do so in a system that relies on voluntary participation to a great degree. The PPACA “works” – ie achieves the cost control and quality improvement goals its advocates seek – if and only if near-universal insurance coverage is accompanied by altered provider incentives and the more efficient use of resources enabled by CER, HIT and ACOs. But it is also important to recognise that the movement toward CER, HIT and ACOs predates the passage of the PPACA, and that repeal of reform – or particular elements of the Act -might slow, but would certainly not stop, that movement.

What is the commercial impact?

The many changes to the US healthcare system from the PPACA will affect the commercial fate of various organisations. The insurance companies that adapt most effectively to the new environment, and to the pressures to increase their medical loss ratios, will flourish. Companies that improve healthcare data access and management are advantaged in the evolving marketplace. Medical technologies and/or therapeutics that improve clinical outcomes will meet a receptive customer base, as will diagnostics that lead to more effective therapy selection for specific patient groups. Those that do so while reducing costs will gain the greatest competitive advantage. Provider organisations that effectively address the structural, managerial and care delivery issues will flourish at the expense of those that do not. And it is a good bet that most of these things would have been true absent healthcare reform, and will remain true regardless of the ongoing political debate about healthcare reform.

In other ways, medical technologies seeking to enter the US market will need to overcome precisely the same hurdles in the near future as in the years before passage of healthcare reform:

1. The requirements for marketing clearance or approval by the FDA are unaffected by the PPACA. The regulatory standard of “safe and effective” remains in place, as does the “substantial equivalence” route-to-market for low-risk devices. As in the past, FDA will not consider product cost in its review process;
2. Healthcare insurance will continue to be highly decentralised, with dozens of private insurance companies offering policies through employer group plans, affinity groups, and individual policies. While the PPACA does

define minimum benefit packages, each insurer will retain the right to make its own coverage policies for specific technologies;

3. While private insurers are not prohibited from considering cost in making coverage decisions, they will continue to be constrained to the degree in which they consider cost by competitive pressures in the decentralized health insurance marketplace;
4. The Medicare programme, the primary insurer for most Americans age 65 or above, will continue to be the largest single health insurer. Medicare’s existing inflexible prospective payment systems and fee schedules for different categories of care (physician services, hospital inpatient services, hospital outpatient services, clinical laboratory, durable medical equipment, etc.) remain intact;
5. Medicare remains legally prohibited from directly considering cost of services in its coverage policy decisions for technologies; and
6. Medicare and private insurers will continue to use indirect methods of incorporating cost into their coverage decision-making. The two principal mechanisms for this indirect consideration of cost are:
 - a. Application of increasingly higher evidentiary standards as the cost of the technology under review rises. As technology cost goes up, insurers require more rigorously structured clinical trials, and larger bodies of clinical evidence of effectiveness; and
 - b. Increasingly refined coverage policies, limiting use of expensive technologies to narrowly defined populations in which they are most effective, or requiring prior trials of less expensive interventions.

In summary, after healthcare reform, just as before, the touchstone for successful introduction of new medical technology into the US market will be the ability to make a compelling and unequivocal demonstration of clinical utility. The technology, be it a diagnostic or a therapeutic, must demonstrate a difference in the clinical care process. Technologies that meet an inadequately addressed clinical need, and are demonstrated to be effective, will continue to be covered and reimbursed in the US system without direct regard for cost. But as technology cost goes up, so too does the evidentiary hurdle that the evolving system applies, and new market entrants must be prepared to overcome that hurdle with a substantial body of empirical data from well-structured and well-conducted clinical trials. Healthcare reform may increase the visibility of this process, but it does not in fact introduce any new dynamics.

The bottom line is that companies wanting to enter the US market with a new and better technology have even more reasons to understand whether the commercial opportunity is large enough to justify the investment. Depending on the product, pricing strategy will continue to be driven by the largest insurer (Medicare) but you need to know how and why all customers will value your product in the US environment.

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