

US healthcare reform – the stakes are high for device manufacturers

By Paul Fearis

Healthcare reform is at the heart of President Obama's domestic change agenda. The political differences that emerged when Bill Clinton first tried to introduce healthcare reform in the 90s are back, this time deeper and seemingly more entrenched. Although defining and implementing a solution to the provision and management of healthcare could take years, there seems to be a general agreement that there will be a shift away from continual advancement in patient care (and treat, treat, treat) towards operational efficiency in healthcare. At Sagentia we believe that this trend will have a discernable impact upon device manufacturers, one which they should approach proactively.

Despite polarised political views, just about everybody agrees that the present healthcare system is unsustainable. There is an ever widening gulf between the spiralling cost of the nation's healthcare and the health of the nation. We are bombarded with statistics that bear this out: in 2007 the US spent approximately \$2.25 trillion on healthcare, double what it spent a decade before. The current cost of US healthcare is 16 per cent of GDP – considerably more than

the 11 per cent commonly associated with western European countries – and it's rising at a faster rate than elsewhere. As recently as 2000, the life expectancy of Americans and Cubans was much the same at 77 years. Yet Cuba spent just \$186 per head of population, 1/25th of that spent in the US.

The scale of the problem in the US, and the lengths to which the Obama administration seems willing to go in search of a solution,

were brought into sharp relief by the recently proposed \$4 billion tax on US medical device manufacturers, many of whom are our clients.

AdvaMed, the trade body representing med-tech companies, while acknowledging that health reform is needed, has unsurprisingly voiced its strong opposition to the tax. It argues that the levy will actually contribute to cost growth, stifle innovation, lead to a contraction of the industry and result in company failures. A counter argument however is that reform may actually result in an expanded pool of patients, which will drive demand for more products, which will obviously benefit device

manufacturers. The truth of the matter is that it is too early to say just yet what the long term impact of reform, however it manifests itself, will be on the med-tech sector.

The current reimbursement model, based upon payment per procedure, provides excellent healthcare for those able to pay and drives technical innovation, but also generates significant operational waste and escalating health insurance bills. These bills are not only costly for employers, but are now preventing a growing section of the US population from accessing regular healthcare as costs escalate beyond affordability for the average family; perhaps struck by unemployment.

Healthcare efficiency is inevitable, but will it mean a backward step for patient care? Efficiencies are already starting to emerge across the healthcare sector. Hospitals are now favouring more efficient equipment, or equipment which can combine procedures into a single process. Less invasive surgical procedures such as laparoscopic surgery – already preferred by patients and the combined growing trend toward patient driven Natural Orifice Transluminal Endoscopic Surgery (NOTES) – are reducing the time spent in hospital, and associated aftercare costs. Ambulatory surgical centres (ASC) – 'walk in, limp out' facilities sited in the community – are starting to swim upstream and take increasingly complex procedures away from the traditional, highly intensive (and expensive) hospital OR where hospitals have traditionally earned their money.

Further complicating the picture is the noted decrease in US surgical graduates, resulting in a growing demand for easier, or less technical (but also more efficient), surgical procedures. Although many Americans remain passionately opposed to 'socialised' medicine (the

so called 'public' option), the drivers for change are now so strong that the current reimbursement model – which actively encourages complex procedures, multiple tests, and many expensive drug and other therapies – is unsustainable.

Our medical device clients are already feeling the impact of a changing healthcare landscape, and they need innovation strategies capable of meeting the new demands that will emerge. This is particularly relevant for those clients manufacturing large items of capital equipment, such as scanners, who face the combined force of reduced hospital capital-equipment budgets, higher utilisation targets, the recession, rising healthcare costs and, at present, falling hospital patient numbers (as a direct result of ASC competition).

With potential future reimbursement models uncertain but almost inevitably tighter, many hospitals question the need to make major purchases unless they can improve efficiency; but if they can also improve patient outcomes (perhaps in less skilled hands) then the purchasing decision may become easier. Although change is inevitable, we

believe new opportunities will emerge, especially as hospitals take on increased responsibility for issues such as hospital borne infections, and post-operative complications such as DVT. There will also be greater emphasis on prophylactic treatments, risk mitigation and improved screening. A more efficient system should lead to more equitable healthcare provision, which should, in turn, encourage patients to present their symptoms earlier, enabling swifter identification, treatment, and management of many conditions.

Now our ultimate goal is to enable our clients to fully understand the changes they face and the new opportunities emerging across a broader spectrum of healthcare provision, and enable them to use their considerable expertise to develop equipment that meets new needs, delivers efficiency, and continues to improve patient outcomes.

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Case study

Sagentia led a product development programme for Prosurge for the FreeHand robotic camera controller. We coordinated the project and developed and maintained the DHF (Design History File), fully supporting the approval process. This is an excellent example of the kind of medical device that will become prevalent in the US as healthcare reform gets underway. The innovative solution has overcome many of the problems associated with hand held endoscopes used in the operating theatre. Controlled directly by the surgeon, FreeHand is inexpensive, simple to use and contributes to a significant increase in surgical efficiency. Having gained FDA approval earlier this year, the device has been adopted by prestigious university hospitals for teaching purposes and by community level hospitals where it has helped counter the lack of suitably qualified assistant surgeons. It has attracted interest across a range of surgical disciplines including gynaecology, urology and general surgery.