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# INTRODUCTION

## Med-tech faces a mix of challenges, opportunities

Medical technology—the immediate past and near future of which is the subject of this book—is variously seen as both the hero and villain in the global battle to improve healthcare while simultaneously reining in its staggering costs. From the perspective of those who develop, produce, and market the vast array of innovative products that exemplify this fascinating industry, such innovation means better patient outcomes. The critics, however, say the cost of such new technology is the reason those costs are sure to keep spiraling. These disparate views fuel a lively debate that casts a shadow over what would otherwise be seen as a very healthy industry.

The market for healthcare products and services, including the medical device and diagnostics segment, has exhibited attractive growth recently, driven by increasing demand for health care worldwide. Growth in the medical device and diagnostics sector, for example, has averaged between 8% and 9% over the past four years, and is projected at 7.2% per year over the next four years, with the global market expected to exceed \$225 billion in 2006.

While challenges are now emerging that could represent barriers to growth in the future, there also are opportunities, particularly in certain segments of the market.

Let's look at it from the perspective of a veteran med-tech executive who sees the integration of technologies as a key to meeting healthcare's challenges.

During a talk at the Georgia Life Sciences Summit held in Atlanta, William Hawkins, president/COO of Medtronic (Minneapolis), made the case for the impact of technological convergence in developing new healthcare products.

Noting that 70% to 80% of all physician visits are associated with chronic disease, with aging Baby Boomers now set to swell those numbers and most living with at least one chronic disease by the time they reach their 60s, Hawkins said disease management “continues to transfer and evolve.” For instance, physicians' approaches to disease management have moved from cutting open their patients and “taking things out” to implanting devices, such as pacemakers, in the body for more effective treatment, he noted.

The merging of devices and drugs—most dramatically in drug-eluting stent technology is one dramatic example of this, but Hawkins also cited the pervasive combination of devices with information technology.

Enabled by powerful new sensor technology, disease will be diagnosed, treated, and monitored with new device systems, he said. Sensor systems such as these will move much healthcare technology and treatment management from “passive” to “active.”

“Imagine a world where a 70-year-old is at home asleep,” he said, and a device not only detects an irregular heartbeat, but “corrects it without the man even waking up.”

Hawkins described the likely development of digital devices capable of transmitting patient data

ahead to a hospital or emergency room before the patient's arrival, greatly speeding treatment.

To some extent, that technology is already available, he noted, citing the CareLink System—Medtronic's remote monitoring systems for implanted devices—as an example.

The Carelink basic service allows a patient to connect his or her implanted device, via standard phone line, "allowing [a] doctor to conduct a routine check-up or review a special situation" no matter where the patient is, according to the company, within certain limits.

For patients implanted with wireless Medtronic devices, the CareLink Network offers Conexus Wireless Telemetry, which offers continual monitoring and check-ups when the patient is asleep. At the time of his talk, Medtronic reported having 80,000 patients on its CareLink system.

In addition to these new sensor systems, Hawkins pointed to signal and computer processing, artificial intelligence, predictive modeling and miniaturization, signal and computer processing, artificial intelligence, predictive modeling and miniaturization as available for future examples of healthcare convergence.

Technology is enabling physicians the ability to get information concerning patients "with an ease that was unthinkable even a few years ago," he said. "Today, we have an unprecedented ability to harvest information from the human body."

Information devices go "beyond two devices sharing information," Hawkins said. In the future, for example, it said it will be possible to go online to check one's own heartbeat and do this as routinely as going online to check a bank balance, Hawkins said.

The advances are not just technology for technology's sake, he said. "While this is a technology-led revolution, it is clearly about people."

## Reining in 'new tech' costs

During a July 2006 forum on the role of markets in medicine, hosted by the Center for American Progress (CAP; Washington), a panel took the "less is more" view represented the conflict between the good that new medical technology does and the bad of essentially uncontrollable healthcare costs. They said that if universal healthcare coverage is adopted by the U.S., it probably will come with a price: abandonment of the indiscriminate use of world-class medical technology.

That is the trade-off described by the panelists who to a person advocated adoption of universal coverage and also agreed that Americans will have to reduce their expectations concerning how much med-tech will be available to them in such a system.

Daniel Callahan, PhD, director of international programs at the Hastings Center (Garrison, New York), framed the healthcare issue of the day as balancing "equity on the one hand with personal choice" on the other. He offered as a model for this balance Europe, with Callahan calling that system not an unmitigated success. "The Europeans are struggling to hang on to universal care," he said, while the U.S. continues to examine the idea.

In his view, universal healthcare systems in Europe are "far superior" to the patchwork system in America, while at the same time acknowledging the need for market mechanisms. The impact of such mechanisms on medical culture, he said, require some compromises, noting parenthetically that healthcare economists are typically more interested in efficiency than ethics.

However, an improved delivery system for Americans promises to come with a price tag, one likely to be very unpopular. "Somewhere between 40% and 50% of healthcare costs can be traced to new tech-

nology or intensive use of existing technology,” Callahan said, arguing that the American appetite for the latest and the greatest is unsustainable. Callahan insisted that Americans would have to be willing to “set some limits on progress” if they obtain universal coverage and that corralling spiraling costs is something that “Europeans need as much as we do.”

Willis Goldbeck, consulting director of global public health policy and government affairs at European pharmaceutical maker UCB (Brussels, Belgium), offered a dim view of prospects for limiting the utilization of medical technology, describing the odds as “somewhat less than zero.” Calling U.S. health-care delivery a “very sloppy system,” he termed it “a medical repair model” rather than a method for reducing illness and disease.

Goldbeck said it is “amazing that we don’t have the government as a collective purchaser” for taxpayer-financed healthcare programs. He insisted that “markets should be looked at not as a system, but as a set of tools.” And he slammed competition in the medical marketplace as invoking winners and losers, hardly conducive to optimal outcomes for healthcare as a whole.

Jeanne Lambrew, a senior fellow at CAP and an associate professor for health policy at George Washington University (Washington) discussed Callahan’s book, titled *Medicine and the Market: Equity v. Choice*. She faulted it as being too pessimistic about universal healthcare put in place in the U.S., saying, “It might be [here] sooner than you think.” But she seconded Callahan’s position that Americans are possessed of a “concept of infinity” where medical intervention is concerned. “We really do have this mind-set” that infirmity can be evaded indefinitely.

Lambrew said she sees two reasons to believe that universal coverage is close on the horizon. “Big business outcry is on the rise,” she said, noting the current distress of the domestic auto industry in financing worker health insurance. And she noted, as a harbinger, Massachusetts Gov. Mitt Romney’s move to impose mandatory universal coverage in his state. “When one can see the political capital [in proposing universal coverage],” she said, “this is no longer the third rail.”

So, will med-tech continue to enjoy relatively favored status—among the consumers of healthcare if not the payers—or does the industry face a “close the door” future? Part of the answer may lie in the way the Centers for Medicare & Medicaid Services (CMS; Baltimore) addresses its reimbursement policies. For years, the medical device industry has been critical of CMS, saying its reimbursement policies have the effect of blocking the uptake of groundbreaking new technologies. CMS always has responded with promises to do better, to be open to evidence-based applications for added reimbursements for these technologies. And new policies for revising IPPS makes the same promise by describing an open door for providing additional reimbursement for new technologies.

To be eligible for additional reimbursement, the new regulations state that a product must be:

- New—meaning less than two to three years old.
- More expensive—that is, it must meet a defined cost threshold in relation to the underlying DRG.
- Must offer a substantial clinical improvement for the Medicare patient population.

Instead of making add-on payments easier to obtain, Dr. Henry Dove, an independent consultant to managed care organizations, hospitals, group practices and health information firms, argued that they will in fact, be more difficult to obtain.

In a conference call on the new CMS regulations sponsored by investment banking firm Harris Nesbitt (New York), Dove, who works for Casemix Consulting, said that while hospitals are likely to try and “pass the buck” on to the device companies, he believes that they will only be able to pass on rough-

ly 5% of the reimbursement impact to the hospital.

Another thing that hospitals may try and do, said Dove is “standardize the medical devices that they try to use.” While this standardization may work in the rural setting, he said hospitals probably “won’t have much very much luck at all in the large urban hospitals or the academic medical centers because there are just too many point of view there and it’s too hard to get the physicians to agree to use only manufacturer A vs. manufacturer B.”

Dove said that one trend that might be seen from hospitals because of these payment changes will be a shift to treating “medical” patients as opposed to “surgical” patients,” which could affect some medical devices since hospitals would be less likely to open new surgical wings. Ultimately, he said the “big battle that is going to be occurring with respect to hospitals is going to be between managed care organizations and hospitals and between hospitals and medical suppliers.” Who is going to win those discussions he said, most likely “depends on the local market.”

### **Pushing for cost-effective technology**

Speaking at the Pay-For-Performance leadership summit in Boston last August, Arnold Milstein, MD, of Mercer Human Resources Consulting (New York), said the No. 1 problem with healthcare in the U.S. today is “rapidly spreading unaffordability,” in large part driven by waste. Bringing with him several years’ experience as a member of the Medicare Payment Advisory Committee (MedPAC), Milstein said “There appears to be an opportunity” to save as much as 50% on the nation’s healthcare tab “without reducing quality of care.” He based his comments on a 2005 study by Rand Corporation (Santa Monica, California) that detailed a variety of metrics of healthcare in the U.S.

“Most of us in this room are in the lucky half” of Americans who can afford fairly comprehensive healthcare coverage, he said. Those who cannot afford any coverage at all are in no enviable state, but the “middle quintile of income” is feeling the greatest pressure for finding affordable care.

The MedPAC commissioner referenced a Dartmouth College (Hanover, New Hampshire) study indicating “a quality-neutral gap” in spending between the lowest-spending regions and all other regions in the U.S. He characterized the difference in spending for these equal outcomes on the order of 30%. Furthermore, he posited little difference in healthcare quality between the “lowest-spending providers and all other providers within the lowest-spending regions,” to which he chalked up a cost differential of 15%, and a gap between the lowest-unit cost care delivery methods and all other methods, crunching out to a difference of 20% to 30%.

He called this lack of difference quality-neutral. “The problem is not lack of conscientiousness” in caring for patients, Milstein said, but rather “a medical miracle-powered shark” that devours resources disproportionately to the benefits delivered. Not only are these medical miracles more expensive, they often are more time-consuming to administer. Thus, he showed numbers indicating that inflation of healthcare expenditures outstripped real GDP growth by 4% in 2003 and will likely outstrip GDP growth by 3% in 2006, the bulk attributable to the latest medical thing.

To stem the tide, society must “rapidly adopt” today’s most cost-effective delivery methods and “perpetually gain efficiency to out-swim the medical miracle shark,” he said. This would have to be accompanied by a transition from “making quality fairly reliable” to “making quality highly reliable.”

The first of these simpler approaches, he said, is transparency. “In the absence of that, nothing else will happen,” Milstein said. Much of the transparency he advocated relates to cost, noting that the differ-

ence in cost between U.S. and overseas providers has fueled the medical tourism that has surfaced.

The second simple rule would be to design health plans that are sensitive to performance and to provider payments. The third would be “faster discovery and uptake of care delivery innovations,” all of which would hopefully be followed by “large annual gains in affordability and quality.”

He quoted Robert Pearl, MD, CEO of Kaiser Permanente Medical Group (Oakland, California), as saying that “medicine . . . is a century behind in applying technology effectively.” Assuming this is the case, adoption of technology will aid society’s efforts to make healthcare more affordable. “It’s up to us to build a system that will capture that 2.5% savings” and keep healthcare affordable long into the future, Milstein said.

## **IT poses opportunities, with difficulty**

Healthcare information technology (IT) is one area of opportunity in the sector, based on applying technology to increase the productivity and efficiency of the healthcare system, creating market growth for IT suppliers while helping to resolve profitability issues for providers. Major challenges exist, however, in creating an environment that provides the proper incentives for adoption, and in implementing information technology that produces true improvements in productivity and efficiency. Additional challenges exist in restructuring healthcare systems worldwide to cope with the conundrum of rising demand for and cost of healthcare services in the face of limited financial resources.

Continued expansion of the market for healthcare IT products, and of the healthcare market overall, is virtually assured by the aging of the U.S. population, growth in the use of technology in healthcare, and patient demands for best available treatment. Total spending on healthcare in the U.S. is projected to increase at 7.2% annually on average from \$2 trillion in 2005, or 16.2% of GDP, to \$4 trillion by 2015, or 20% of GDP, based on current assumptions of spending and economic growth.

Healthcare information technology has often been cited as a tool that has the potential to provide major improvements in efficiency and productivity for healthcare providers. Some experts believe that the widespread implementation of healthcare IT, in the form of electronic medical records (EMRs) and connectivity extending throughout the U.S. healthcare system, could provide a significant reduction in overall cost.

During the March 2006 Health Care Forecast Conference at the University of California Irvine (UCI), Roger Taylor, MD, of the RAND Corporation, presented the results of a study of the costs and benefits of electronic medical record systems that shows benefits are large relative to costs, but that major barriers exist that limit the realization of the potential benefits. Taylor has quantified the productivity improvements achieved in other industries such as the retail and telecom industry, and modeled the impact on healthcare spending that would result if similar improvements were realized in healthcare. For example, the retail industry has realized a 15% annual improvement in productivity from implementing IT, and the telecom industry has realized an annual improvement of 8%.

If the healthcare industry realizes a 15% productivity improvement, Taylor projects that total healthcare spending in 2016 would drop from \$4.2 trillion to about \$3.3 trillion, potentially reducing national healthcare spending from 20% of GDP to about 16%. If a 4% productivity improvement were achieved (half achieved by the telecom industry), total spending would drop to about \$2.3 trillion, reducing spending as a percentage of GDP to 11%, significantly improving the outlook for dealing with the burden of affordability of healthcare in the U.S. economy.

A key factor for widespread adoption of an EMR system, as discussed by Vijay Gurbaxani, PhD, associate dean and professor of information systems at the Paul Merage School of Business at UCI, is establishing standards for the EMR and for connectivity of the EMR system. Standards are particularly important in a fragmented industry such as healthcare. Gurbaxani noted that Kaiser Permanente (Oakland, California) has achieved a high level of adoption of healthcare IT because it has set standards that are followed throughout the organization.

Certain segments of the market, however, will exhibit higher growth than others. Paul Ginsburg, PhD, president of the Center for Studying Health System Change (Washington), said a nationwide survey of the healthcare provider market shows that hospitals are focusing on expansion of profitable specialty services such as cardiovascular therapy, orthopedics, neurosurgery and oncology. Hospitals also are expanding their emergency departments to capture more inpatient volume and focusing their expansion in rapidly growing affluent areas. At the same time, physician groups are expanding ancillary services that can be provided on an outpatient basis such as ambulatory surgery, endoscopy, imaging, and diagnostic testing. Mergers of physician practices also are occurring due to the need to build scale for equipment investment, a trend that is aided by technology advances that permit smaller-scale facilities requiring less capital to be built.

## **U.S. healthcare flunks**

The U.S. healthcare system received a failing grade, and will continue to decline unless some drastic changes are made, according to a report card-style assessment issued by the Commonwealth Fund (New York).

The new report, from the Commonwealth Fund Commission on a High Performance Health System, paints a disturbing picture—that of a healthcare system in the wealthiest country in the world failing to achieve top marks in any single assessed healthcare category. In fact, the report shows that the U.S. healthcare system is falling into the classic underachiever category, especially given the country's current level of investment in healthcare.

The U.S. scored an average of 66 out of a possible 100 across 37 national indicators of health outcomes, quality, access, equity, and efficiency. The scorecard findings show that if the U.S. improved performance in key areas, the nation could save an estimated 100,000 to 150,000 lives and \$50 billion to \$100 billion annually.

The U.S. ranks poorly at the beginning and end of life, according to the report, "Why Not the Best? Results from a National Scorecard on U.S. Health System Performance."

One surprising finding was a score of 69 in the category of "long, healthy, and productive lives." The report found that the U.S. is one-third worse than the best country (France at 75 deaths per 100,000 population) on mortality from conditions "amenable to healthcare"—that is, deaths that could have easily been prevented with timely and effective care. In 1998, the U.S. ranked 15th out of 19 countries on this indicator, with 115 deaths per 100,000 population. If mortality were reduced to the benchmark level, the improvement would translate into 88,000 fewer deaths per year.

The U.S. ranks at the bottom among industrialized countries on healthy life expectancy at birth or age 60, and last out of 23 listed high-income industrialized countries on infant mortality (7 deaths per 1000 live births). This last figure is particularly disturbing for a so-called leading industrialized nation, the authors say.

“What this report tells us is that there are many pockets of excellence in healthcare in this country, but overall we are performing far below our national potential,” said James Mongan, MD, chairman of the 18-member commission and CEO of Partners HealthCare (Boston), a corporation overseeing the affiliation of Brigham and Women’s Hospital, Massachusetts General Hospital, and the North Shore Medical Center. “Our purpose in issuing this scorecard is to bring attention to opportunities to improve, with benchmarks to motivate change.”

Taking a more global view of problems facing healthcare was William Castell, then-chairman of GE Healthcare (Chalfont St. Giles, UK), who said during a speech at the BioWales conference in Cardiff, Wales that a tsunami of chronic disease is poised to undermine many decades of improvements in healthcare. “The western world will become regressive in healthcare because it can’t cope with the bolus of cost,” he told delegates at the conference.

“Healthcare isn’t affordable in any economy,” Castell said, pointing out that it now consumes 17% of gross domestic product in the U.S. Japan, with the world’s oldest population, faces a chronic care burden, while in China 850 million people living in rural areas are yet to see any healthcare benefits flowing from the rapid industrialization of the country.

The speech was a swansong moment for Castell, who retired from GE Healthcare in mid-2006 to become chairman of the Wellcome Trust, the world’s largest medical charity.

While diseases such as HIV and malaria are a significant weight, the true cost challenges to health-care systems come from chronic disease. The challenge of chronic disease is to move from treating the later stages to controlling it earlier on. Novel diagnostics will enable a paradigm of prediction and prevention to take hold, he said.

A good example is breast cancer, where mammograms currently fail to detect a high percentage of tumors, while many recalls and biopsies are negative and late diagnoses leads to higher costs and lower survival.

“In cost terms, the things we have to deal with in a better way are cardiovascular diseases and cancer,” Castell said, as he outlined his vision of how the healthcare marketplace will be transformed by a marriage of “biology, bytes, and broadband.”

The starting point for dealing with the specter of chronic diseases is to view health as an asset, not a cost, or, as Castell put it, “an investment in productivity and wealth creation.”

There is huge complexity involved in moving a patient through the system from first reporting cardiac pain to getting a coronary bypass. Castell called for “interdisciplinary innovation” to promote the adoption of medical technology for early and noninvasive diagnosis of disease, supported by electronic patient records and management systems to make healthcare more cost-effective.

## About the book

This sourcebook’s focus is the kind of innovations touted by those with an interest in the future direction of the medical technology industry, with a requisite look at the outside challenges facing the industry. *Medical Device Daily’s State of the Industry Report 2007* represents the third such collection of information—some 500 pages of it—put together by the staff of the only daily newspaper serving this dynamic industry. It’s an industry that employs about 350,000 persons in the U.S. alone, manufacturing medical devices and diagnostic products valued at in excess of \$85 billion.

In the following chapters, we present overviews of what we judge to be the areas of greatest inter-

est and importance for medical device companies and technology developers as they look to the future. We kick things off with “Where We’re Headed,” which looks to the near- and somewhat longer-term future of the healthcare sector. In “Dealmaking,” we review the most significant merger-and-acquisition activity since the 2005 version of this book, with a primary focus on the first nine months of 2006. “Please Show Me the Money” contains an overview of some of the most significant IPOs, financings, and venture investment funds reported over the past year. “Executive/Legislative Outlook” reflects both what has happened and what is on the horizon for the branches of government that impact the med-tech industry. The activities of the FDA, CMS, Department of Health and Human Services, and a variety of other agencies is the focal point of “Regulatory Outlook,” and the Advanced Medical Technology Association and Medical Device Manufacturers Association are highlighted in “Trade Associations.” A look at the all-important “Legal Landscape” wraps up the Overview section of the book.

Those are followed by the heart of our look at this industry—nearly XXX pages devoted to XXX chapters ranging from “Cardiovascular” to “Emerging Companies.” In these sections, we take a broad look at some of the key companies and developments shaping that particular segment of the med-tech industry. These sections include reports from meetings of some of the key medical societies and associations impacting particular sectors, many of them featuring reports on clinical trials of new technologies. The reports cite both market leaders and emerging companies hoping to make their way onto the radar screen.

Please note that this is not a directory, so we have not tried to identify and include every company and technology in each sector. What we have attempted to do is to make note of sector leaders, while also weaving in promising companies or promising areas of development that we’ll hear more about in the not-too-distant future.

This book is the result of the efforts of the staff that brings you *Medical Device Daily* every business day, along with the weeklies *Diagnostics & Imaging Week* and *Medical Technology & Devices Week*, and our two monthlies, *Biomedical Business & Technology* (formerly *The BBI Newsletter*) and *Cardiovascular Device Update*. I particularly want to acknowledge the work of Managing Editor Don Long, Associate Managing Editor Holland Johnson, Washington Editor Mark McCarty, Staff Writer Karen Young, and freelance production editor Robin S. Mason. Thanks too to our cadre of contributing writers, including Michael Simonsen, Larry Haimovitch, Jeffrey Berg, Arthur Gasch, Diana Tucker, Joseph Kalinowski, Cynthia Drake, and Betty Gasch.

I thank them for their efforts, and you for your continuing interest in *Medical Device Daily* and our other publications covering this most interesting of industries. ■

—Jim Stommen, Executive Editor

# Healthcare IT, budget cuts offer opportunities and challenges

By **MICHAEL SIMONSEN**  
**BB&T Contributing Editor**

IRVINE, California - The market for healthcare products and services, including the medical device and diagnostics segment, has exhibited attractive growth recently, driven by increasing demand for healthcare worldwide. Growth in the medical device and diagnostics sector, for example, has averaged between 8% and 9% over the past four years, and is projected at 7.2% per year over the next four years, with the global market expected to exceed \$225 billion in 2006.

While challenges are now emerging that could represent barriers to growth in the future, there also are opportunities, particularly in certain segments of the market. The opportunities and challenges facing the U.S. healthcare system were the topic of this year's Health Care Forecast Conference, organized here by the Center for Health Care Management and Policy of the Paul Merage School of Business at the University of California Irvine (UCI).

Healthcare information technology (IT) is one area of opportunity, based on applying technology to increase the productivity and efficiency of the healthcare system, creating market growth for IT suppliers while helping to resolve profitability issues for providers. Major challenges exist, however, in creating an environment that provides the proper incentives for adoption and in implementing IT that produces true improvements in productivity and efficiency. Additional challenges exist in restructuring healthcare systems worldwide to cope with the conundrum of rising demand for and cost of healthcare services in the face of limited financial resources.

Key topics covered at the UCI conference included trends in healthcare insurance, economic trends, recent initiatives by the federal government to rein in healthcare cost increases, and challenges faced by healthcare providers, including hospitals and practitioners. The impact of the political climate on trends in the healthcare system also was discussed in depth at the conference, with a consensus that the likelihood of any major new initiatives emerging from the federal government is low, given that 2006 was an election year in Congress. There are also a number of issues related to political scandals that are likely to preoccupy legislators, along with an unusually short legislative schedule.

The lack of action by legislators, however, does not mean that healthcare suppliers and providers will be unaffected by changes in healthcare policy. In particular, cutbacks in Medicare and Medicaid spending scheduled for implementation in 2006 that could have a significant impact on both providers and suppliers. Those cutbacks are being implemented in spite of questions about the legal validity of the legislation on which they are based.

Changes in the structure of healthcare insurance, most importantly in the area of consumer-driven health plans, also are moving forward since they have already been cleared by legislators, but their impact is controversial. Some presenters at the UCI conference also indicated that healthcare providers may be contemplating changes in the structure of their care delivery programs, particularly in the area of disease management.

## IT to transform healthcare?

Healthcare IT has often been cited as a tool that has the potential to provide major improvements in efficiency and productivity for healthcare providers. Some experts believe that the widespread implementation of healthcare IT, in the form of electronic medical records (EMRs) and connectivity extending throughout the U.S. healthcare system, could provide a significant reduction in overall cost.

Roger Taylor, MD, of the RAND Corp. (Mississauga, Ontario, Canada), presented the results of a study of the costs and benefits of electronic medical record systems that shows benefits are large relative to costs, but that major barriers exist that limit the realization of the potential benefits. Taylor has quantified the productivity improvements achieved in other industries, such as in retail and telecom, and modeled the impact on healthcare spending that would result if similar improvements were realized in healthcare. For example, the retail industry has realized a 15% annual improvement in productivity from implementing IT, and the telecom industry has realized an annual improvement of 8%.

If the healthcare industry realizes a 15% productivity improvement, Taylor projects that total healthcare spending in 2016 would drop from \$4.2 trillion to about \$3.3 trillion, potentially reducing national healthcare spending from 20% of GDP to about 16%. If a 4% productivity improvement were achieved (one-half that achieved by the telecom industry), total spending would drop to about \$2.3 trillion, reducing spending as a percentage of GDP to 11%, significantly improving the outlook for dealing with the burden of affordability of healthcare in the U.S. economy.

The RAND study analyzed the potential benefits of implementation of EMRs and EMR systems (EMR-S) throughout the U.S. healthcare system, and barriers to implementing EMR-S. The EMR, which replaces the paper medical record, forms the basis of an EMR system, but the EMR-S adds a number of higher-level functions such as clinical decision support, patient tracking and reminders, personal health records, computerized physician order entry, interface with knowledge banks, care guidelines, and interface with other providers, patients, and regional networks.

At present, an EMR in some form has been implemented in only 20% to 25% of hospitals and 10% to 15% of physicians' offices nationwide. Connectivity of EMRs and higher-level functionality has not yet been implemented to a significant degree outside of certain integrated provider organizations.

The RAND researchers identified three key elements that must be in place in order to realize maximum benefit from EMR system adoption. Those elements formed the base assumptions for the model evaluated in the study. First, widespread adoption (90%) of EMR systems is needed. Second, effective connectivity across providers and with patients is required. Third, improvements in the healthcare system that can be enabled by EMR systems must be implemented, such as team care for chronic disease management, prevention and wellness education and reminders, a focus on improving quality and efficiency, and restructured processes and workflows.

A key factor for widespread adoption of an EMR, as discussed by Vijay Gurbaxani, PhD, associate dean and professor of information systems at the Paul Merage School of Business, UC Irvine, is establishing standards for the EMR and for connectivity of the EMR system. Standards are particularly important in a fragmented industry such as healthcare. Gurbaxani noted that Kaiser Permanente (Oakland, California) has achieved a high level of adoption of healthcare IT because it has set standards that are followed throughout the organization.

The results of the RAND study show that, while there is a substantial cost to implement a nationwide EMR system, the benefits should more than justify the investment. As shown in Table 1, the study esti-

**Table 1**  
**Costs and Savings for Healthcare Information Technology**

Healthcare provider segment	Total cost (15 years)	Total savings (15 years)
Hospitals	\$97.4 billion	\$468.5 billion
Physician offices	\$17.2 billion	\$159.0 billion
Connectivity	\$6.0 billion	- - -
Total	\$120.6 billion	\$627.5 billion

*Source: Roger Taylor, MD RAND Corporation, presented at the 2006 Health Care Forecast Conference, University of California Irvine*

mates the efficiency savings from widespread EMR system adoption at more than \$600 billion over 15 years, vs. a cost for implementation of about \$120 billion, resulting in a five-fold return on investment.

The majority of savings (75%), as well as investment, are attributable to the hospital sector, although the return on investment is higher for physician offices. In addition, a number of safety and health benefits are likely to accrue from EMR system adoption, including fewer errors from illegible handwriting, reduced adverse drug events, better delivery of preventive care and self-care, and better management of chronic diseases.

The value of the health and safety benefits in terms of cost savings for the U.S. healthcare system are estimated at \$162 billion per year, more than doubling the savings from efficiency improvement alone. Improved preventive care, one of the benefits that could result from nationwide EMR adoption, offers an example of the health benefits that could be realized. As shown in Table 2, a large percentage of the population is currently not compliant with disease screening and vaccination programs, resulting in later detection of diseases such as breast and colorectal cancer and more costly treatment as well as a higher death rate. Lack of compliance with vaccination programs also results in more deaths and needs for acute care, leading to higher healthcare costs.

There are, however, a number of barriers to widespread EMR system adoption. These include a dis-

**Table 2**  
**Impact of Preventive Healthcare**

Preventive Measure	Target Population	% of population not now compliant	Cost/year for 100% compliance	Health benefits with 100% compliance
Breast cancer screening	Women 40 and older	30%	\$1.5 billion	50,000 cancers detected early, 4,000 fewer deaths per year
Colorectal cancer screening	50 and older	66%	\$4.0 billion	23,500 fewer deaths
Influenza vaccination	65 and older	37%	\$0.2 billion	7,500 fewer deaths per year
Pneumococcal vaccination	65 and older	47%	~\$0.1 billion	21,000 fewer deaths per year

*Source: Roger Taylor, MD RAND Corporation, presented at the 2006 Health Care Forecast Conference,*

connect between who pays for healthcare IT and who benefits from its adoption, a lack of standard-based EMR systems, lack of connectivity between providers and with patients, lack of market pressure or infrastructure to support performance-based improvements and competition, and a disincentive for sharing of clinical information between unaffiliated organizations since most healthcare provider groups view patients as key competitive assets that must be protected.

Taylor recommends initiatives by government and payors to provide incentives for standards-based EMR adoption, potentially including targeted subsidies to develop regional health information exchange networks, initiatives to reduce the risk of adoption and networking, and a monitoring system to assess adoption patterns and needs. One proposal is a per-encounter payment to physicians who adopt EMRs. He estimates that a \$160 incentive per encounter provided over a three-year period would cost \$2.2 billion but show a benefit/cost ratio of 8.5:1. Similarly, a targeted 80% hospital subsidy for EMR system implementation would cost \$15 billion but show a benefit/cost ratio of 5:1.

Another factor impeding the adoption of EMR systems is the rather poor track record of past investments in healthcare IT. In reality, most IT investments in healthcare have not paid off, at least for those who have made the investment, due largely to the disconnect between who pays and who benefits. Also, as discussed by Andrew Wiesenthal, MD, associate executive director of the Permanente Federation for Clinical Information Support (Oakland, California), 60% of all large healthcare IT projects fail, creating a high-risk setting for healthcare providers or government organizations that are considering such investments. The recent announcement by President George Bush to commit funding of \$61.7 million for the Office of National Coordinator of Health Information Technology and his call to establish a national interoperable electronic health record within 10 years are indicators that government is beginning to play a role in moving healthcare IT forward.

Key suppliers of healthcare IT products include Cerner (Kansas City, Missouri), Misys Healthcare Systems (Raleigh, North Carolina), McKesson (San Francisco), Meditech (Westwood, Massachusetts), EPIC (Verona, Wisconsin), GE Healthcare (Waukesha, Wisconsin) and Siemens Medical Solutions (Malvern, Pennsylvania). As discussed by Chris Brandt of Deloitte Consulting (Los Angeles) at the UCI conference, there has been a considerable amount of consolidation within the healthcare IT vendor segment recently, as exemplified by GE's acquisitions of IDX Systems (Burlington, Vermont) and a number of smaller vendors of healthcare software products. GE has evolved its product line to add clinical information systems to its portfolio, expanding beyond the financial focus characterizing most healthcare IT products originally.

Suppliers who did not add clinical IT lost share in the market as customers increasingly have demanded such capabilities. An issue for transitioning to an integrated nationwide EMR system is that different hospitals and provider groups use different IT vendors, creating difficulties for physicians who need to interface electronically with multiple hospitals, and pointing to the need for industry standards that will help resolve connectivity issues. Some progress is being made, as evidenced by Siemens' announcement in January 2006 of the implementation of a regional electronic health information network linking Northwest Physicians Network (Tacoma, Washington) and St. Luke's Health System (Boise, Idaho), allowing the exchange of clinical health data between different provider groups across significant distances. An indication of the future direction of healthcare IT described by Wiesenthal at the UCI conference is Kaiser Permanente's network, which already has been implemented in most of the Kaiser facilities in the U.S. and will be completed in 2007.

Because of the integrated nature of Kaiser itself, standardization of IT was more readily accomplished than in the entire U.S. healthcare system. As a result, a member in any of the nine states included in the Kaiser organization will by 2007 be able to go online to make appointments, order medications, access lab results, talk with a doctor and access his or her own medical record. The Kaiser system also provides decision support tools and online reminders.

Information can be shared nationwide within the Kaiser network, which includes 8.4 million members and logs 40 million ambulatory patient visits annually. Kaiser initially attempted to develop its own IT network internally, but eventually switched to an external vendor, EPIC, that now is supplying Kaiser's systems nationwide.

The most difficult segment of the healthcare system in which to implement EMRs is the physician's office, due to the large number of independent practices, lack of capital to invest in EMR systems, and lack of time and IT expertise to devote to the task of implementation. As discussed by David Kibbe, MD, director of the Center for Health Information Technology at the American Academy of Family Physicians (AAFP; Washington), there are about 150,000 small medical practices in the U.S., vs. about 5,000 non-federal hospitals.

Based on AAFP statistics, 70% of physicians practice in groups of five or less. The number of patient encounters, and the related need for health information, is about 1 billion per year in the physician's office, at an average patient charge of \$200, vs. about 8 million hospital visits annually at an average charge of \$50,000 per visit. Hospitals spent about 5% of revenues or \$24 billion total in the U.S. in 2004 on IT, while less than 1% or under \$2 billion was spent in the physician office.

Clearly, the current level of IT investment is highly imbalanced compared to the relative amount of healthcare spending in each segment. The situation is beginning to change, however. Kibbe's data on the 95,000 physician members of the AAFP show that the use of electronic health records increased from 10% of practices in 2002 to 30% in 2005. Physicians also perceive IT to be less risky now than in 2003.

The main factors limiting adoption of EHRs in the physician's office include cost and concerns about a decrease in productivity. The average cost for a fully integrated EHR for a physician's office is \$7,232 per physician, according to data presented by Kibbe, although costs vary widely, and can range as high as \$134,750. One possible approach to resolving the cost issue, he said, is for hospitals and insurers to serve as sources for EHR implementation in the physician office, since both would also derive benefit. Regardless of the funding source, there is obviously a large, mostly untapped market for EHR systems in the physician's office.

Another driver of growth in the healthcare IT market, which may become increasingly important in the future as trends such as pay for performance become more prevalent in the healthcare system, is investment in EHRs and clinical information systems as a means to quality improvement.

### **Continued growth in healthcare market**

Continued expansion of the market for healthcare IT products, and of the healthcare market overall, is virtually assured by the aging of the U.S. population, growth in the use of technology in healthcare, and patient demands for best available treatment. Total spending on healthcare in the U.S. is projected to increase at 7.2% annually on average from \$2 trillion in 2005, or 16.2% of GDP, to \$4 trillion by 2015, or 20% of GDP, based on current assumptions of spending and economic growth.

Certain segments of the market, however, will exhibit higher growth than others. For example, as

discussed by Paul Ginsburg, PhD, president of the Center for Studying Health System Change (Washington), a recently conducted nationwide survey of the healthcare provider market shows that hospitals are focusing on expansion of profitable specialty services such as cardiovascular therapy, orthopedics, neurosurgery, and oncology. Hospitals also are expanding their emergency departments to capture more inpatient volume and focusing their expansion in rapidly growing affluent areas.

At the same time, physician groups are expanding ancillary services that can be provided on an outpatient basis such as ambulatory surgery, endoscopy, imaging and diagnostic testing. Mergers of physician practices also are occurring due to the need to build scale for equipment investment, a trend that is aided by technology advances that permit smaller scale facilities requiring less capital to be built.

Another trend noted by Ginsburg is the expanded use of hospitalists who assume responsibility for patient management once they are admitted. That trend tends to cause primary care physicians to lose their connection with the hospital, further fueling the competition between hospitals and physicians.

The broadened competition between hospitals and physicians might be expected to control cost increases, but Ginsburg believes that ways in which the two segments are competing may actually drive up spending and threaten access to care for the less affluent. For example, many service expansions are focused on growing affluent areas, where patients have the ability to pay, while inner-city hospitals are faced with obsolete facilities and limited ability to raise capital for upgrades. There also is a decline in the alignment of specialists with hospitals, creating difficulties for hospitals in maintaining, let alone expanding, services.

Another key trend in the healthcare market is the growing utilization of consumer-driven health plans (CDHPs), a factor that is driving growth in the managed care sector. A number of experts presenting at the UCI conference expressed pessimism regarding the positive impact of CDHPs, and in particular effectiveness of the primary tools of such plans, including Health Savings Accounts (HSAs) and Health Reimbursement Arrangements (HRAs) in limiting growth in healthcare costs. HSAs and HRAs are designed to make patients better consumers of healthcare by providing an incentive to shop for providers who offer the best value, primarily for non-catastrophic illness.

According to Jon Gabel, vice president of the Center for Studying Health System Change, 4% of firms in the U.S. now offer an HRA or HSA, and 26% are likely or very likely to offer a high-deductible plan with an HRA or HSA within the next two years. The plans are more popular with employers and insurers than with employees, as indicated by statistics showing that only 7% of employees choose an HSA if offered both a conventional insurance plan and an HSA plan. A recent survey by America's Health Insurance Plans (Washington) found that 1 million HSA policies had been sold as of March 2005, and more recent data suggests that enrollment could be as high as 3 million, although that figure may include high-deductible health plans without an HSA.

As discussed by Pat Bousliman, a member of the Senate Finance Committee, the experience to date with HSAs is not highly favorable, with only about 12% of all covered workers in HSA-qualified high-deductible health plans. A key issue is the difficulty of shopping for healthcare due to limited access to comparative cost and quality data. The ability of consumers to make well-informed choices about the cost of competing healthcare options is a key requirement that is needed in order for CDHPs to work as intended.

Another negative factor is that health insurance plans with an HSA option tend to attract healthier and higher-income workers, and not necessarily the sicker patients with chronic diseases who account

for the majority of national health expenditures. On a positive note, proponents claim that 33% to 40% of enrollees in HSA plans were previously uninsured, so the plans may be more affordable than conventional insurance for lower-income workers. Nevertheless, the experience with HSAs so far does not indicate that they are the solution to the problem of affordability of healthcare.

### Budget cuts to impact market growth

One of the most important factors expected to affect the healthcare market over the next few years is the Deficit Reduction Act (DRA) enacted in late 2005. The act is designed to produce \$40 billion in net savings for the federal government over five years (FY 2006-2010), and \$99 billion in savings over 10 years. One-third of the five-year savings are generated from reductions in Medicare and Medicaid spending, including a \$6.4 billion reduction in Medicare spending and a \$6.9 billion reduction in Medicaid spending over five years. In addition, the act links payment to performance by requiring hospitals and home health agencies to submit data on quality measures in FY07 or receive a payment reduction of market basket minus 2%.

In January 2007, the act makes imaging services provided in physicians' offices (X-ray, ultrasound, nuclear medicine, MRI, computed tomography and fluoroscopy, but not diagnostic and screening mammography) subject to payment caps, and could have a significant negative impact on the market for diagnostic imaging equipment. Questions have surfaced regarding the validity (and legality) of the DRA because different versions of the bill may have been signed by the House, the Senate and the president, which violates legislative rules and makes the bill illegal.

In spite of the questions surrounding the DRA, the Centers for Medicare & Medicaid Services (CMS; Baltimore) is moving ahead to implement the changes called for in the bill. Cuts in Medicare spending are also proposed in the President's FY 2007 budget that if implemented could have significant impacts on certain segments of the medical device market. Table 3 lists a summary of the proposed Medicare savings in the president's budget. Major cuts are proposed for hospital inpatient spending, phasing out of bad debt payments, knee/hip replacement post-acute care, home healthcare, skilled nursing facilities, and oxygen rental. The cutbacks in knee/hip replacement, home healthcare and oxygen rental, which total \$12.5 billion over five years, could have a significant adverse impact on suppliers in those segments.

Government payors are not likely

**Table 3**  
**Summary of Proposed Medicare Cuts**

Proposal	5-Year savings	% of total savings
Inpatient hospital update	\$6.61 billion	17.5%
Outpatient hospital update	\$1.47 billion	3.9%
Inpatient rehab update	\$1.59 billion	4.2%
Phase out bad debt payments	\$6.18 billion	16.3%
Knee/hip replacement post-acute care	\$2.43 billion	6.4%
Medicare Secondary Payer	\$1.56 billion	4.1%
Home health update	\$3.53 billion	9.3%
SNF update	\$5.11 billion	13.5%
Hospice update	\$0.55 billion	1.5%
Ambulance update	\$0.29 billion	0.8%
Clinical lab competitive bidding	\$1.43 billion	3.8%
Oxygen rental	\$6.55 billion	17.3%
Power wheelchairs	\$0.46 billion	1.2%
Part B premium indexing	\$0.04 billion	0.1%
<b>Total</b>		
(net of premium effect)	\$35.9 billion	100%

*Source: Pat Bousliman, Senate Finance Committee, presented at the 2006 Health Care Forecast Conference, University of California Irvine*

to be alone in targeting cutbacks in reimbursement for healthcare products and services. Private insurers have been much less aggressive in increasing insurance premiums over the past two years, as discussed by Gabel. While increases in health insurance premiums remain well above the overall rate of inflation and the increase in workers' earnings, the rate of increase has dropped by almost one-half, from more than 14% in 2003 to 9.2% in 2005, and a further drop in the rate is anticipated in 2006 to the 7% to 7.5% range, according to Gabel. The declining trend is expected to continue, creating pressure on insurers to cut increases in reimbursement to providers. In part, the rate of increase in insurance premiums has been dropping, however, because insured members have been switching to plans with higher deductibles, and paying more costs out of pocket.

Another issue for payors is that one strategy they have been banking on to control increases in healthcare costs, namely disease management programs, is not proving as effective as hoped. As discussed by James Baumgardner, deputy assistant director for health policy in the Congressional Budget Office, new studies about to be released show that disease management is not paying for itself. While disease management may produce better patient outcomes, it may cost more to get that benefit. CMS also has been targeting disease management as a tool to control costs, and has been conducting demonstration programs in disease management, but one major participant in those programs recently

**Table 4**  
**U.S. Federal Budget Outlook Under Current Policies**

	Total Revenues*	Total Outlays*	Total Deficit or Surplus*	Percent of GDP
<b>Actual 2005</b>	\$2,154	\$2,472	\$-318	-2.6%
<b>2006</b>	\$2,312	\$2,649	\$-337	-2.6%
<b>2007</b>	\$2,461	\$2,732	\$-270	-2.0%
<b>2008</b>	\$2,598	\$2,857	\$-259	-1.8%
<b>2009</b>	\$2,743	\$2,984	\$-241	-1.6%
<b>2010</b>	\$2,883	\$3,105	\$-222	-1.4%
<b>2011</b>	\$3,138	\$3,252	\$-114	0.7%
<b>2012</b>	\$3,378	\$3,340	\$38	+0.2%
<b>2013</b>	\$3,546	\$3,506	\$40	+0.2%
<b>2014</b>	\$3,724	\$3,666	\$57	+0.3%
<b>2015</b>	\$3,912	\$3,839	\$73	+0.4%
<b>2016</b>	\$4,113	\$4,046	\$67	+0.3%
<b>Total— 2007-2016</b>	\$32,496	\$33,328	\$-832	-0.5%

\*Billions of dollars

Source: Congressional Budget Office