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CONTENTS

Features

Commentary
California Slow to Adopt New Plans 3

Strategy
Six Sigma Helps System Improve Care 10

Interview
For Practices Seeking Technology Solutions, Expert Offers Advice 13

Departments

Editorial
Hospitals Struggle When Specialists Depart 2

Management
GAO Calls for Malpractice Study 6

Study Shows Cost-Effectiveness of DMARDs

As more therapeutic options have become available in recent years, many rheumatologists are weighing the value of various therapies when making prescribing decisions. Estimates of the cost-effectiveness of various therapies should include both the cost of treatment and of therapeutic outcomes. Although having such estimates could help rheumatologists make informed decisions about care, such comparative estimates have rarely been calculated and published.

In a study presented in May at the annual meeting of the International Society for Pharmacoeconomics and Outcomes Research in Arlington, Va., researchers estimated the cost-effectiveness of three disease-modifying antirheumatic drugs (DMARDs) used in the treatment of rheumatoid arthritis. The data revealed that leflunomide is a cost-effective treatment option for patients with rheumatoid arthritis in a managed care setting. Managed care decision-makers could consider the information provided in the analysis when selecting drugs to include on their formularies, and rheumatologists could consider the data when selecting therapeutic options for their patients with rheumatoid arthritis.

Costs and Outcomes

For the study, researchers compared the cost-effectiveness of leflunomide, etanercept, and infliximab using medical charges incurred by patients with rheumatoid arthritis and tracked in a large outcomes database. They also used two standard measures of efficacy collected from published clinical trials. The results of the study were presented by Anna O. D'Souza, MS, a doctoral candidate in the department of pharmaceutical systems and policy at West Virginia University in Morgantown.

"For years, methotrexate has been the gold standard for patients with rheumatoid arthritis," D'Souza says. "However, a loss of efficacy of the drug may eventually occur for some patients, while others may fail the therapy due to side effects. Fortunately, patients who cannot continue to tolerate methotrexate therapy or who continue to have active disease despite methotrexate therapy now have a choice of newer therapies, such as leflunomide, infliximab, and etanercept."

In terms of acquisition costs of these alternatives, leflunomide costs less than either infliximab or etanercept. Understanding the relative cost-effectiveness of these drugs can help physicians and patients make informed decisions regarding which treatment to pursue.

Furthermore, focusing on optimal drug treatment is one of the simplest, most effective approaches that managed care organizations can take to improve patient outcomes and cut the costs of care, but those who make decisions about managed care formularies may not notice the high cost or

(Continued on page 8)

EDITORIAL

Hospitals Struggle When Specialists Depart

Should specialists, especially surgeons, be allowed to pull out of general community hospitals in order to establish and refer to their own hospitals and ambulatory surgery centers? There are no easy answers to this troubling question.

Although specialty hospitals represent only 2% of America's 4,900 hospitals, administrators are concerned because specialists are leaving general hospitals to start competing facilities. In doing so, certain specialists—such as cardiovascular and orthopedic surgeons, gastroenterologists, and neurosurgeons—are siphoning profit from hospitals that are already squeezed for revenue. Last year in Pennsylvania, for example, specialty hospitals had a profit margin of 12%, while general hospitals had a margin of barely 2%.

When specialists depart, hospitals find it difficult to serve all patients and provide emergency room services 24 hours a day. These specialists, some administrators believe, are taking with them the care that produces the most revenue and are making it difficult for the hospital to meet both accreditation standards and its obligation to those in the community who do not have health insurance.

Specialists, who think hospitals are inefficient, view this issue differently. Besides being bumped from operating room schedules, they argue, they must work with overstressed or poorly trained nurses, overcome administrative hurdles to get the latest technology, and serve on hospital committees and perform other administrative duties in order to continue in hospital practice.

Concerned about declining reimbursement, many specialists see their colleagues developing specialty hospitals and ambulatory surgery centers. They also know that hospitals collect facilities fees from Medicare and other payers that can be as much as two to three times higher than the surgical fees they collect, while in physician-owned facilities, these fees flow to the physician owners.

In fact, specialty hospitals are often more efficient than general hospitals because physicians repeatedly do the same procedures, allowing doctors to be more productive. They are ideal for relatively healthy patients desiring efficient service by skilled specialists. Specialty hospitals and ambulatory care centers represent what Regina Herzlinger, a business professor at Harvard Business School, calls "focused factories." While focused factories are being developed to fill a need in the health care market, they are undermining the mission of general hospitals, forcing them to care for sicker, underinsured, or uninsured patients with more complex diseases.

Rather than leave it to legislators to solve this problem, hospital administrators and specialists should work together to reach a solution that accommodates both of their needs. Making general hospitals that are more efficient and economically attractive for specialists would perhaps be a good start.

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California Slow to Adopt New Plans

California is unlikely to lead the nation in adopting new forms of consumer-directed health care, says a new report. A state that often leads the nation in health care trends, California is the birthplace of prepaid group health plans, preferred provider organizations, point-of-service plans, and Medicaid HMOs, the report says.

But the report in August from the California HealthCare Foundation (at www.chcf.org) shows that the state has been slow to adopt the consumer-directed health plans. What's more, since so many state residents are enrolled in HMOs, the size of managed health plans in California is a significant stumbling block to the growth of new forms of care, the report says.

In the Golden State, 54% of workers and family members who have employment-based health insurance are enrolled in HMOs, about twice the national average, the report says. Such enrollment has helped to keep the average cost of coverage for single individuals about 7% less than the national average for such coverage, according to the report. In California, therefore, consumer-directed plans must compete against lower cost competitors than such plans compete against in other states.

Serious Consideration

In the report, *Understanding Consumer-Directed Health Care in California*, researchers say managed health plans and traditional insurers view consumer-directed plans either as a threat or an opportunity and are considering them seriously. Health plans that do not currently offer such programs have considered the possibility of doing so, even though large insurers have dominated the market so far. Conversely, employers have been cautious about consumer-directed plans and are seeking reassurance from data-driven evaluations of them. If employers gather evidence that such plans control health care costs effectively, do not lead to adverse selection, and do not negatively affect employee satisfaction or quality of care, then it is likely many employers will purchase consumer-directed products, the report says. Ultimately, the success of all consumer-directed plans will depend on their ability to control increases in medical care expenses, without antagonizing the consumers they purport to benefit, the report's authors point out.

The report was produced for the foundation by Jon Gabel, vice president of the Health Research and Educational Trust of the American Hospital Association in Chicago, and Thomas Rice, a professor of health services at the UCLA School of Public Health. It examines consumer-directed health plans, which link consumers' health coverage choices to the financial consequences of those choices. Consumers in these plans who choose a number of health care providers or other services that result in greater overall expenditures pay more in premiums. Although these types of plans may offer some attractive features for consumers, the impetus for them has come from employers trying to contain health care costs, the report says.

Consumer-directed health plans may help to lead consumers toward physicians and other providers who deliver high-quality care, and they may be instrumental in helping to put more powerful decisionmaking tools into consumers' hands, the report says.

Three Plans

In particular, the report focuses on three specific types of consumer-directed plans: health reimbursement arrangements (HRAs), customized plans, and "design your own" (DYO) products. In examining how the products work, the report provides an overview of consumer-directed health plans in California, the organizations behind them, and the factors likely to influence growth.

In an HRA, an employer sets aside a specified dollar amount in an individual health reimbursement arrangement for each enrolled employee. The employee can submit qualified medical expenses for reimbursement until the allotted amount is exhausted. If the amount is not exhausted in one year, the employee can carry the balance to the following year. HRAs are generally offered in conjunction with an insurance policy that carries a high deductible of $2,000 per year or more. California lags the rest of the nation in HRA enrollment, the report says.

In a customized plan, an employer makes a fixed contribution toward the employee's health insurance premium, and the employee then chooses from

(Continued on page 4)

Health Consumers Want More Health Information

As health care costs rise, consumers are becoming more interested in getting information about the cost of care than they have been in the past, according to a survey released this summer.

The survey showed that cost information was more important to a majority of consumers than information about the quality of care delivered by physicians and other providers, the survey shows. The survey, *The 2003 Consumer-Directed Health Care Survey*, was done by the Dieringer Research Group, in Milwaukee, and the Pareto Health Group, in Westminster, Md.

"We were surprised to find consumers valuing health cost information ahead of provider quality information," says Bob Dieringer, president of the Dieringer Research Group. "This represents a significant change from their historical need and preference for drug and diagnostic information. The finding should send a signal to employers and insurers who feel compelled to simply pass along rising health insurance costs to their employees."

Growing consumer demand for health cost information places a new burden on insurers and employers to make such information more readily available and more understandable than it has been in the past, Dieringer says. In addition, the trend toward providing more flexible insurance plan options will continue to grow in importance as more consumers search for ways to control medical costs whenever and wherever they can, he adds.

While consumer-directed health (CDH) plans should help employees make more informed choices about costs and care, researchers have found a lack of consensus about what constitutes a CDH plan, a factor that appears to contribute to a lack of consumer adoption, Dieringer says. The Dieringer-Pareto survey found that only 9% of insured employees are familiar with CDH plans. By comparison, 20% had heard of defined contribution plans and 33% were aware of health spending accounts. More than 67% of employees were aware of PPO and HMO plans, the research shows.

Some analysts have predicted that CDH plans could capture as much as 15% of the overall health insurance market within five years, Dieringer says. However, the survey findings suggest that demand for components of CDH plans may outpace demand for the actual plans themselves unless the market settles on a successful standard package for CDH plans, he concludes.

—JB

(Continued from page 3)

among an array of health insurance options with different prices. The employee's premium reflects his or her choices and the richness of the benefit package. Nationally, and in California, a number of employers are offering customized plans to their employees, the report says.

Under a DYO product, employees can choose their own set of providers and benefit features, essentially designing their own provider network and specifying the services that will be covered. The employee's premium contribution depends on the choices the employee makes. To date, these plans are not offered in California.

Prospects for Growth

Some 400,000 individuals are enrolled in HRAs nationwide, but only about 20,000 of them are in California, the report says. The report does not estimate how many Americans are enrolled in customized plans nationwide, but says that about 800,000 individuals are enrolled in such plans in California. HRA and DYO plans likely will grow only incrementally, as employers and consumers assess their risks and benefits, the report says.

Consumer-directed plans are unlikely to have a significant effect on the health care market unless they can be seen as controlling health care costs effectively, the report says. Greater enrollment in consumer-directed plans might mean they could influence patterns of care, which would benefit consumers and payers because these plans could help to direct consumers toward physicians and other providers who deliver high-quality care, and they may be instrumental in helping to put more powerful decisionmaking tools into consumers' hands, the report notes. But these capabilities are only beginning to emerge in the marketplace, the report adds.

To be sure, consumer-directed health plans have benefited from the soft labor market and slumping economy in California. On the other hand, few employers relish becoming pioneers in such sensitive areas as employee health benefits. Plans and employers fear becoming the first media horror story—the patient who died because he or she procrastinated about whether to visit the doctor, deterred by a high deductible, when a visit would have identified an early stage of cancer or other life-threatening illness, the report says.

Concerns and Drawbacks

For the report, the researchers interviewed 27 experts and health care industry leaders last fall, including employers and benefit consultants, as well as those who work for health plans in California, state government, and universities. Some respondents believed that employers might be reluctant to offer consumer-directed plans. Employers that do not currently offer coverage might consider doing so if a low-cost consumer-directed product was available, but if the employer offers a plan and then finds that it is more costly than previously believed, it would be difficult to drop the plan and the employer then may feel compelled to remain in a plan that was previously found to be unaffordable, the report says.

Another drawback is that consumer-directed plans could be vulnerable to negative publicity in cases in which a participant failed to seek prompt medical attention after the funds in his or her account were exhausted. If this employee became seriously ill or died, the employer might face media or other public scrutiny.

One area of concern involves adverse selection. Some of the respondents reported that when given a choice, relatively healthy employees would join such plans. And these workers would choose consumer-directed plans because they would be less likely to exceed the employer's contribution to the plan. But if these workers join in large numbers, only older and sicker employees (meaning those whose care is the most costly) would be left in the companies' traditional plans, the report says. Such an enrollment trend could fragment the risk pool, causing plans with a less healthy population to pay higher costs, raise premiums, and drive off still more healthy enrollees, the report notes.

To alleviate the problem of adverse selection, employers could make consumer-directed plans the only choice available. Thus far, however, few employers have chosen to do so, and few experts thought that consumer-directed plans would supplant current insurance offerings, the report says. Employers also could risk-adjust premiums to account for any selection bias, meaning workers with poor health habits would pay more than those with good health habits, but only about 1% of employees nationally are enrolled in risk-adjusted plans, the report says.

—Reported and written by editor Joseph Burns in Falmouth, Mass. More information on physician practice strategies is available on our Web site (see page 16).

Health Costs Rose 13.9%

Employers' health insurance premiums rose 13.9% this year, a larger increase than the one paid by employers last year, and marking the third straight year of double-digit increases, according to the *2003 Annual Employer Health Benefits Survey* by the Kaiser Family Foundation, in Menlo Park, Calif., and the Health Research and Educational Trust (HRET) of the American Hospital Association, in Chicago. The increase was the largest since 1990.

In response to rising health care costs, most employers are asking workers to pay more for their care. Employees with family coverage have paid 50% more (rising from $1,619 to $2,412) than they did three years ago, the foundation says. The typical family health insurance policy costs $9,068; and employers pay 73% and employees pay 27% on average. The average premium for a single employee is $3,383.

Many employers that responded to the survey, and particularly employers with 200 or more workers, said they would increase employee contributions and cost-sharing next year. Very few (10%) said they would reduce eligibility or drop coverage. A small but significant group of employers said that were very likely to offer a high deductible plan in the next year.

The survey was conducted between January and May of 2003 and included 2,808 randomly selected public and private firms ranging in size from three to more than 300,000 employees.

Among responding companies, 62% said they were willing to shop for a different arrangement, and a third (33%) said they would change insurers or plan types. Overall, however, employers do not have a high level of confidence in current cost-control strategies, they said. Employers, particularly larger firms, were interested in high-deductible plans ($1,000 or higher for single coverage). Among companies with 5,000 or more workers, 17% offered such plans this year, and 16% said they were highly likely to add such plans next year.

The most commonly identified approach to controlling costs was disease management, yet fewer than 25% of companies believe it is a very effective approach to controlling costs. Another popular approach to cost control is consumer-directed health plans. Some 14% of employers considered these plans to be very effective, the survey shows.

Employers' frustration with the inability of these approaches to bring down health care costs may be behind their interest in trying new alternatives, such as offering a high deductible plan option to their employees, the researchers say. —JB

GAO Calls for Malpractice Study

The high cost of malpractice insurance in many states affects the ability of physicians to deliver quality care, according to a recent report from the General Accounting Office. In the report, the GAO says Congress should pass a resolution asking the National Association of Insurance Commissioners, in Kansas City, Mo., to collect the data needed to evaluate the frequency, severity, and causes of losses in the medical malpractice insurance business.

The findings on the effects of malpractice rates on quality confirm the results of a 2002 survey of physicians, nurses, and hospital administrators in which the respondents said malpractice litigation had hurt their ability to provide quality care. The survey was done by Harris Interactive, a research firm in Rochester, N.Y. Among other findings, the Harris survey showed that 79% of the physician respondents say they order unnecessary tests because they fear litigation; 74% say they make unnecessary referrals; 51% say they suggest unnecessary biopsies; and 41% say they prescribe antibiotics unnecessarily. The report, *Most Doctors Report Fear of Malpractice Liability Has Harmed Their Ability to Provide Quality Care*, is available on the Web (at www.harrisinteractive.com).

But ordering more tests may also help to cut the number of malpractice suits, according to an article in *The Boston Globe* earlier this year. "Breast-Cancer Screenings Boosted," published in May, concludes that because of fear of malpractice litigation, physicians have been ordering more mammograms, although the article does not provide specific numbers. Two insurers reported that the frequency of lawsuits related to breast cancer fell in Massachusetts by about 50% over the previous two years. In the article, Eric Winer, MD, director of breast oncology at Dana-Faber Cancer Institute in Boston, says primary care physicians are aware that they are open to lawsuits if they fail to order mammograms for women at risk of breast cancer. "It has been a common enough cause of malpractice suits that it has made doctors very, very cautious about leaving no stones unturned with breast cancer," Winer says.

The simple reason rates have increased is that insurers have had losses, says the GAO, the investigative arm of Congress. The GAO qualified its conclusion about the cause of higher rates, however, by saying it lacked adequate data to analyze insurers' losses fully.

Rising Rates

Rising malpractice rates threaten physicians' ability to provide adequate care because a lack of profitability has led some large insurers to stop selling medical malpractice insurance, furthering concerns that physicians will not be able to obtain coverage, the report says. The GAO's report, *Medical Malpractice Insurance: Multiple Factors Have Contributed to Increased Premium Rates*, was issued in June.

Since 1999, medical malpractice premium rates have increased dramatically for physicians in some specialties in a number of states. Among larger insurers in the seven states the GAO analyzed—California, Florida, Minnesota, Mississippi, Nevada, Pennsylvania, and Texas—both the premium rates and the extent to which these rates have increased varied greatly, the report shows. In addition to claim losses, several other factors (including falling investment income and rising reinsurance costs) have contributed to recent increases in premium rates in the sample states, the report says.

The GAO found that losses on medical malpractice claims, which make up the largest part of insurers' costs, appear to be the primary driver of rate increases over time. Although losses for the entire industry have shown a persistent upward trend, insurers' loss experiences have varied dramatically across the sample states, resulting in wide variations in premium rates, according to the report.

Factors other than losses can affect premium rates, exacerbating cycles in the malpractice market, the GAO says. High investment income or adjustments to account for lower than expected losses, for example, may allow insurers to price insurance below the expected cost of paying claims, and to do so legitimately, the GAO points out. The time between premium collection and claims payment, however, means that losses may be increasing while insurers are holding premium rates down, requiring large premium rate increases when the insurer recognizes that its losses have been increasing, the GAO report shows. All these factors can explain some events in the medical malpractice market, the GAO told Congress.

Calls for Reform

Physicians, insurers, and regulators disagree over the causes of increased premiums and what, if anything, should be done about the issue, according to the GAO. "For example,

The GAO found that losses on medical malpractice claims appear to be the primary driver of rate increases over time.

some have argued for tort reform as a means of lowering certain awards in medical malpractice lawsuits and advocate legislative changes at the state level designed to place a cap on such awards," the report says. "Others have argued for medical reforms as a means of reducing the incidence of medical malpractice or for insurance reforms as a way to moderate premium rate increases."

The largest writer of medical malpractice insurance in Florida increased premium rates for general surgeons in Dade County by about 75% between 1999 and last year, the report says. But the largest insurer in Minnesota increased premium rates for the same specialty by only about 2% over the same period. The resulting 2002 annual premium the Florida insurer quoted was $174,300, more than 17 times the $10,140 premium rate the Minnesota insurer quoted, according to the report. In addition, the Florida insurer quoted a rate for general surgeons outside Dade County of $89,000 a year for the same coverage, about 51% of the rate it quoted inside Dade County.

Many factors have contributed to the recent increases in medical malpractice premium rates in the seven states the GAO analyzed. First, since 1998, insurers' losses on medical malpractice claims have increased rapidly in some states. In Mississippi, for example, the amount insurers paid annually on medical malpractice claims, or paid losses, increased by about 142% from 1998 to 2001 after adjusting for inflation.

Second, from 1998 to 2001 medical malpractice insurers had decreased income from investments as interest rates fell on the bonds that generally make up about 80% of insurers' investment portfolios. While almost no medical malpractice insurers experienced net losses on their investment portfolios over this period, a decrease in investment income meant that income from insurance premiums had to cover a larger share of insurers' costs, the report says.

Market Competition

Third, during the 1990s, insurers competed vigorously for medical malpractice business, and several factors (including high investment returns) permitted them to offer prices that did not cover their losses on that business, according to the report. As a result, some companies became insolvent or voluntarily left the market, reducing the downward competitive pressure on premium rates that had existed through the 1990s.

Fourth, beginning in 2001, reinsurance rates for medical malpractice insurance increased more rapidly than they had in the past, raising insurers' overall costs. All of these factors contributed to the movement of the medical malpractice insurance market through hard and soft market cycles in which premium rates fluctuate.

In the hard markets of the mid-1970s and mid-1980s, premium rates rose sharply. But since then, the market has changed considerably as a result of actions insurers, health care providers, and states have taken to address rising premium rates. Beginning in the 1970s and continuing into the 1980s, insurers began selling policies based on claims made rather than occurrence-based policies, enabling insurers to predict losses more accurately each year. Claims-made policies provide coverage for claims that arise from incidents that occur and are reported while the insurance policy is in force; occurrence-based insurance provides coverage for claims that arise from incidents that occur while the policy is in force, even if the policy is not continued. Claims that arise from incidents occurring during the policy period that are reported after the policy's cancellation date are still covered in the future.

Other changes that have occurred in the market make predictions difficult. In the 1970s, for example, physicians began to form mutual nonprofit insurance companies when premium rates rose and some insurers left the market. These companies now comprise a significant portion of the medical malpractice insurance market, the report says. What's more, an increasing number of large hospitals and groups of hospitals or physicians have left the traditional commercial insurance market and have begun to self-insure, saving administrative costs.

Finally, since periods of increasing premium rates during the mid-1970s and mid-1980s, many states enacted laws designed to reduce medical malpractice premium rates, the GAO says. Some of these laws seek to decrease insurers' losses on medical malpractice claims, while others aim to control premium rates. These changes make it difficult to predict how medical malpractice premiums might behave during future market cycles, the GAO says.

—Reported and written by Martin Sipkoff, in Gettysburg, Pa. More information on practice strategies is available on our Web site *(see page 16).*

Between 1999 and last year, the largest medical malpractice insurer in Florida increased premium rates for general surgeons in Dade County by about 75%, while the largest insurer in Minnesota increased premium rates for the same specialty by only about 2%, the report says.

(Continued from page 1)

financial impact of the new biologic DMARDs because these products may be billed under the medical benefit rather than under the pharmacy benefit.

Finally, the cost-effectiveness of the various rheumatoid arthritis drug therapies is particularly important as new treatment protocols call for early, aggressive treatment of the condition with pharmaceutical therapy. Early, aggressive therapy has been shown to control disease activity, slow the rate of joint destruction, alleviate pain, and improve or maintain physical function.

The Value of Therapies

"The purpose of the study was to assess the cost-effectiveness of the three novel DMARDs," says D'Souza. "Cost-effectiveness is particularly important in the managed care setting. Leflunomide can serve as a bridge between methotrexate, which is a very inexpensive therapy, and the biologics, which are very expensive. Also, understanding the relative cost-effectiveness among DMARDs can help inform decisions about which drug to try first."

For the analysis, the researchers used real-world, managed care cost data. "Cost data were provided by the PharMetrics Integrated Outcomes Database, which includes data from 40 health plans with 27 million unique patients," D'Souza notes. PharMetrics Inc. is a health care informatics and outcomes research company in Watertown, Mass. "Having information on costs generated by actual patients with rheumatoid arthritis, rather than estimates or assumptions based on decision modeling, makes our analysis more relevant to payers and providers," she says.

The relative cost-effectiveness of various therapies is an important factor to consider when deciding which drugs to prescribe. "Physicians and payers want to consider the overall value of a drug before prescribing it," D'Souza notes. "Currently, the term 'value' is being used a lot by managed care organizations trying to assess whether a particular drug should be on the formulary. Of course, the most important factors in deciding whether to use a given drug are the clinical outcomes and effectiveness measures. However, given limited resources, issues of affordability come into play as well. Cost-effectiveness can be used as a measure of value, because it represents cost per unit of benefit. If a drug is more effective, we want to know how much we need to pay for that extra benefit."

Efficacy Measures

For the analysis, researchers included patients who were diagnosed with rheumatoid arthritis and who received a new prescription for leflunomide, etanercept, or infliximab between Jan. 1, 1999, and Dec. 31, 2000. Researchers excluded patients who had received a prior prescription for a DMARD other than methotrexate in the 180-day pretreatment period.

While assessing patients' claims for 12 months, the researchers calculated the direct medical charges related to the treatment of rheumatoid arthritis, including pharmacy, inpatient, and outpatient charges.

The analysis revealed that the estimated direct medical charges over the 12-month follow-up period were $8,609, $16,534, and $20,263 for leflunomide, etanercept, and infliximab, respectively. The researchers identified the direct medical costs from the database and found they were driven primarily by pharmacy costs related to the treatment of rheumatoid arthritis.

The researchers used two effectiveness measures. The first, the ACR20, is a composite score representing the percentage of patients who achieve at least a 20% clinical improvement in tender joint count, swollen joint count, and three of five criteria: patient global assessment, physician global assessment, pain, Health Assessment Questionnaire (HAQ) score, and either erythrocyte sedimentation rate or c-reactive protein level.

The second effectiveness measure used was the change in the HAQ Disability Index (HAQ DI), an index of physical function derived from the HAQ, a disease-specific, patient-reported questionnaire. "The HAQ DI is a crucial efficacy measure in rheumatoid arthritis research, as physical function is the most important dimension of health-related quality of life that affects patients with rheumatoid arthritis," D'Souza comments.

Measures of effectiveness were extracted from published literature of randomized, placebo-controlled clinical trials. Twelve-month estimates of ACR20 and mean change in the HAQ DI were used for leflunomide and infliximab; six-month estimates were used for etanercept due to the unavailability of 12-month data from patients who were similar in terms of demographics and disease severity. Base case estimates of ACR20 for leflunomide, etanercept, and infliximab were 52%, 59%, and 42%, respectively, while the change in HAQ DI declined by an average of 0.45, 0.62, and 0.29, respectively.

The cost-effectiveness analysis

(Continued on page 9)

Cost-effectiveness can be a measure of value since it represents cost per unit of benefit, says Anna O. D'Souza, MS, West Virginia University.

“Payers and providers cannot always judge the cost-effectiveness of a drug based on only one outcome measure,” D’Souza says.

(Continued from page 8)

using the cost data and efficacy measures revealed that leflunomide is a cost-effective option for the treatment of rheumatoid arthritis.

Relative Cost Effectiveness

Cost-effectiveness using the ACR20 as an efficacy measure indicated that the average cost-effectiveness ratio (cost/ACR20) was $16,556 for leflunomide, $28,024 for etanercept, and $48,245 for infliximab.

A similar pattern was found in the analysis of cost-effectiveness using the change in HAQ DI: The average cost-effectiveness ratio (cost/change in HAQ DI) was $19,131 for leflunomide, $26,668 for etanercept, and $69,872 for infliximab.

The researchers also calculated incremental cost-effectiveness ratios. “The incremental cost-effectiveness ratio is the difference in cost between two drugs divided by the difference in effectiveness measures for the same two drugs,” D’Souza explains. “That measure basically reveals how much more one would have to pay for the incremental benefit of a drug. For example, etanercept is more costly than leflunomide, but it is also more effective. The analysis indicates how much more the managed care organization would have to pay for etanercept to get that additional benefit.”

The magnitude of the results differs depending on the efficacy measure used, D’Souza emphasizes. The incremental cost-effectiveness ratio for etanercept versus leflunomide was $113,214 using the ACR20 measure and $46,618 using the change in HAQ DI. Both leflunomide and etanercept dominated infliximab, meaning that they were both less costly and more effective.

The sensitivity analysis involved three variables: the cost of the medication, the ACR20 score, and the change in HAQ DI. These analyses did not result in a change in the rank order of the drugs in terms of their cost-effectiveness, and therefore supported leflunomide as a dominant therapy, the researchers report.

The sensitivity analysis indicated that the incremental cost-effectiveness ratio for etanercept versus leflunomide was $39,625 using the ACR20 measure and $28,304 using the change in HAQ DI. The incremental cost-effectiveness ratio for infliximab versus leflunomide was $105,945 using the ACR20 measure and $129,489 using the change in HAQ DI. In other words, these are the costs that a managed care organization would need to incur to get the additional benefit over the preferred agent (in this case, leflunomide).

Formulary Decisions

Just as the magnitude of the results differ depending on the efficacy measure used, the cost-effectiveness ratios also differ depending on the efficacy measure used, D’Souza adds. “Payers and providers cannot always judge the cost-effectiveness of a drug based on only one outcome measure,” she notes. “The use of patient-reported outcomes in addition to clinical measures can provide an additional perspective for administrators deciding which drugs to include on the formulary.”

In fact, managed care organizations typically include multiple drugs on the formulary, despite differences in cost effectiveness, since not all patients respond to all products. “Cost-effectiveness is only one criterion payers and prescribers would use to decide which drugs to allow and to prescribe,” observes D’Souza. “The final decisions about drug use are ultimately in the hands of these decision makers.” Some managed care organizations choose to manage drug utilization through the implementation of step-therapy protocols and copays, which can be designed to take drug cost and effectiveness into account.

The cost-effectiveness analysis revealed that leflunomide clearly dominated infliximab, which was more costly and less effective, but etanercept was more costly and more effective than leflunomide, D’Souza points out. “Leflunomide should clearly be offered on managed care formularies because of its overall cost-effectiveness,” she adds.

Rheumatologists, particularly those who have a large number of managed care patients, would likely be interested in the data on the cost-effectiveness of various therapies because often they have to demonstrate cost-effective prescribing practices, D’Souza believes. “Rheumatologists must ensure the treatment they prescribe is effective, and their first concern will be the clinical benefit for the patient,” she says. “But they may also be interested in cost-effectiveness. They may want to see how their prescribing practices may affect the financial performance of their clinic.

“Often physicians practice in HMO settings in which they are evaluated and reimbursed on their ability to practice in a cost-effective manner, D’Souza says. “These physicians would probably be interested in these findings as well,” she says.

—Reported and written by Deborah J. Neveleff, in North Potomac, Md. More information on physician practice strategies is available on our Web site (see page 16).

Six Sigma Helps System Improve Care

Using the management principles of the Six Sigma quality improvement (QI) process, a health system in Bowling Green, Ky., has reduced patient wait time, improved quality, and saved more than $7 million.

"Physicians understand and appreciate processes that are based on hard data; that's the way doctors think, and that's what Six Sigma is all about," says Jean Cherry, executive vice president at Commonwealth Health Corp. in Bowling Green. CHC has 30 staff physicians and several hundred associated physicians in a network of three hospitals and four urgent care clinics.

The Six Sigma process can have a positive effect on all segments of health care, from the time a patient enters a physician's office to the completion of treatment, Cherry explains. The process also can improve disease management programs for patients with chronic conditions, such as diabetes. "We're still learning how much we can do with this," Cherry admits. "We have more than 180 Six Sigma projects completed or under way." CHC has invested about $900,000 in Six Sigma training, materials, and labor and has saved more than $7 million as a result, company officials say.

Six Sigma Concepts

Most health care organizations begin a Six Sigma initiative with outside consultants who introduce them to the concepts and the potential effects it will have on operations and then train staff to undertake projects, says Keith Butler, MD, a principal with Creative Healthcare Solutions, a firm in Scottsdale, Ariz., that specializes in Six Sigma. Fully trained practitioners are referred to as blackbelts, and those designated to work in supportive roles are greenbelts.

In 1998, CHC hired GE Medical Services to train the first group of executives and managers to become greenbelts. Since then, CHC has developed a team of blackbelts to train other executives and managers. CHC also hired Lisa Douglas to be its Six Sigma corporate champion. A corporate champion is responsible for communicating Six Sigma successes internally and externally, as well as for managing staff acceptance of the strategies, Douglas notes. The champion also runs the program and guides its QI teams in developing projects. The projects are selected based on clinical service lines from suggestions by employees, patients, and physicians.

After a Six Sigma project has demonstrated its effectiveness—through data analysis—review procedures become part of a standard, ongoing protocol. The purpose of the reviews is to make sure that "what gets fixed stays fixed," says Cherry. "At CHC, Six Sigma is both an operational tool and a clinical tool," she says. "It has saved us money and has significantly improved the quality of care we provide. It has also changed the way our employees do their work."

In the first Six Sigma project at CHC, staff addressed radiology processes and cut costs per procedure from $68.13 to $49.55, saving more than $1.65 million annually, Cherry says. Radiology examination results are now distributed to ordering physicians faster than they were distributed earlier, patients receive treatments quicker, and the physical workspace has been redesigned to improve efficiency, she explains. Subsequent training has focused on the care of maternity patients; those with certain pulmonary diagnoses, surgery, admissions, billing, documentation, and charge entries; and human resources.

Staff Training

Awareness training is the first level of exposure to Six Sigma. All employees attend at least eight hours of training in the methodology, and department directors and clinical managers identify employees who will be highly involved in projects. These individuals attend what is called "lite training," an intensive three-day session to familiarize "lite trainees" with Six Sigma methodology.

The next level is greenbelt training, "an action-based learning model whereby a trainee completes a project concurrent with training," Douglas explains. This 13-day course is presented in five phases over six months. Each step of the Six Sigma process is presented, and the trainee applies its principles to an ongoing project. CHC has 120 department directors and managers trained as

The first Six Sigma project involved radiology and cut costs per procedure from $68.13 to $49.55, saving more than $1.65 million annually, says Jean Cherry of Commonwealth Health Corp.

greenbelts, and each is expected to complete a project every nine months. All of CHC's vice presidents, members of the senior management team, and CHC's president and CEO have received greenbelt training, Douglas says.

CHC blackbelts receive intensive training and develop health-care-related training materials for classes, a tool kit for project leaders, and a process simulation to facilitate learning. They also provide all levels of training for employees, and coach and mentor greenbelts and other blackbelts.

Cutting Wait Times

At Women's Health Specialists, a four-physician clinic owned by CHC, Six Sigma was used to help physicians improve care, says clinic office manager Sue Hinton. She used the Six Sigma greenbelt training she received at CHC in 2000 to help reduce patient wait and treatment times to less than an hour.

"Using the methodology, we found ways we could improve by studying each step of the process from the time a patient came through the door until the time the patient left the office," Hinton says. "We started doing paperwork in advance and rescheduling patients who were more than 15 minutes late. In six months, our patient satisfaction level with lengths of appointments went from 70% to 98%, and the 2% remaining consisted almost entirely of patients who had to reschedule because they were late."

CHC identified appointment wait time at the clinic as an important issue because one of the strongest elements of Six Sigma involves listening to customers, Douglas says.

Another Six Sigma project implemented at the women's clinic involved improving gestational diabetes screening for all pregnant patients. This project was selected because gestational diabetes affects 3% to 5% of all pregnant women. Failure to detect this condition can lead to complications for both the mother and the baby; untreated, it can result in high birth weight babies and a greater risk of Cesarean section.

"Women with gestational diabetes are reported to be four times more likely to have hypertension, and newborns of mothers with diabetes are more likely to have hypoglycemia," Douglas explains. "Early diagnosis allows the obstetrician to manage the patient's care appropriately and prevent complications. Because of its impact on mothers and babies, this project was identified as a high priority."

Commitment to Quality

Hinton's evaluation of patient charts revealed that 65% of the clinic's pregnant patients did not have a glucose tolerance test (GTT) completed during the appropriate time. Clinic obstetricians adopted a standard that all pregnant women in their care should be screened for gestational diabetes and that the test should be performed at 28 to 32 weeks of gestation. Using Six Sigma tools and certain methods (such as meetings, repeated chart audits, changes to patient forms, and a restructuring of staff responsibilities), Hinton and her colleagues implemented a system ensuring that 100% of patients got the GTT at the appropriate time, says Hinton.

Six Sigma has led to a cultural shift at CHC, from one that involved fixing problems as they occurred to one that involves a commitment to permanent quality solutions, CHC officials say. All of the physicians in the CHC network have supported Six Sigma from its implementation in 1998, says Raymond Cloutier, MD, the corporation's medical director.

"The rigor of the Six Sigma methodology appealed to me from the beginning, but because improvements coming from Six Sigma are ongoing, and don't disappear over time, Six Sigma is particularly meaningful," Cloutier comments. "As our physicians became more involved, they became more appreciative of the process."

Six Sigma is successful partly because the process uses data to focus on a specific problem and then reexamines the data to decide what works and what doesn't when reducing error rates. "The fundamental objective of Six Sigma is to use data to reveal defects in procedures, then operate within six standard deviations of average performance, and to employ customer-driven measures to establish a target for ideal performance," Butler says. Once that performance is achieved for a specific procedure or protocol, an organization is operating at a level that is defective only 0.0003% of the time, he explains.

The term "Six Sigma" comes from the 18th letter of the Greek alphabet, which is also the statistical symbol for standard deviation. The number six in the name reflects six levels of defects per million opportunities (DPMO). Sigma level one reflects

(Continued on page 12)

Using Six Sigma, staff implemented a system ensuring that 100% of maternity patients got a glucose tolerance test at the appropriate time, says office manager Sue Hinton.

More Groups Using Six Sigma

Six Sigma is a management program that involves analyzing data and procedures and then using the data to reduce medical errors and improve quality of care. It focuses on customer feedback and involves intense staff involvement. More and more health care organizations are using the concept to improve quality of care and control costs.

Developed at Motorola Corp. in the early 1980s, Six Sigma gained notoriety in the 1990s when General Electric began using it to improve quality control and promoted its results through seminars and advertising. Several years ago, GE Medical Systems in Waukesha, Wis., began to train health care professionals in the Six Sigma process. By the middle of this year, GE Medical Systems was conducting Six Sigma training at more than 3,000 health care provider organizations and was adding about a dozen new clients a month, GE Medical Systems says.

"Six Sigma is an approach to making quality better, and it's well suited for health care because it's quantitative and it speaks the doctor's language," says Robert Galvin, MD, GE's director of health care. "There are similarities with other approaches, such as total quality management or continuous quality improvement (CQI), but they examine variation around a mean. With Six Sigma, it's unambiguous; you either have a defect or you don't. Fixation on the control phase also makes it an appropriate quality methodology for health care.

"What Six Sigma seeks to instill in a culture is value, defined as the highest quality care delivered at the most competitive price," Galvin continues. "Six Sigma is nothing more than a way of measuring and driving quality. It doesn't so much transform a practice culture as give it a new language."

"Critics argue that Six Sigma is just another fad or that it represents a return of total quality management and CQI techniques under a new label," says Keith Butler, MD, a principal with Creative Healthcare Solutions, in Scottsdale, Ariz. "In fact, Six Sigma tools work effectively with long-term efforts at quality improvement, but the similarity ends there. By definition, it is a short-term resolution to a long-term problem. It cuts across department lines, is driven by senior management, and has a narrow focus but a significant impact on the organization's profitability."

Charleston Area Medical Center in Charleston, W. Va., has used Six Sigma effectively. CAMC, the state's largest medical center, employs 4,300 workers. Its past efforts to develop a CQI culture stopped short at training, yielding incremental results, which depended on managers who were highly motivated to improve existing conditions, says Butler.

In 2000, CAMC began working with Six Sigma and trained more than 80% of its managers in the principles of Six Sigma in the first year. Each executive sponsored at least one project and 59 employees were trained as blackbelts, foundation team members, or change management coaches. Twenty-seven teams completed first projects. The projects yielded improvements in medication safety, coordination of care, recruitment of new employees, and reductions in denials of payment, as well as helping to cut inventory, Butler says. —MS

(Continued from page 11)

690,000 DPMOs, and sigma level six reflects only 3.4 DPMOs. The goal of any Six Sigma project is to reach sigma six.

A Five-Step Process

"The ultimate goal in any Six Sigma project is to define the characteristics of a defective process by examining one operating system at a time: the emergency department, operating suite, billing office, and so on," Butler explains. The analytical process follows a consistent five-step path: define the problem, often through consumer research; measure the problem; analyze the data; improve the system; and control and sustain the improvements. The define, measure, analyze, improve, and control process is known in Six Sigma terminology as DMAIC.

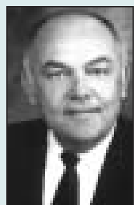
In the Six Sigma process in health care, projects are chosen because they will have an effect on at least one of what are called critical-to-quality characteristics, or CTQs: customer satisfaction; timeliness, speed, and convenience; quality of care or service; or cost, says Douglas. A typical CHC Six Sigma project takes four to seven months to complete.

"Every project is an intense objective study of a particular process, driven by collected data," Douglas says. "Subjective assertions or random recommendations for improvements are not part of the DMAIC process. Greenbelts must prove statistically that a problem exists and that the process has been improved using objective data."

Cherry believes physicians and staff throughout the organization can see the benefits of Six Sigma projects. "Six Sigma was not introduced as an option in which employees could choose to participate," she says. "It became the focal point of a cultural change within the organization."

—Reported and written by Martin Sipkoff, in Gettysburg, Pa. More information on practice strategies is on our Web site (see page 16).

For Practices Seeking Technology Solutions, Expert Offers Advice



***David Koeller** is president and CEO of InteGreat Inc., a health care information technology firm that provides an electronic medical record system, as well as services such as generic systems integration and networking. For this interview, Editor in chief Richard L. Reece, MD, discussed with Koeller how physicians are using technology to improve patient care.*

Q: *Why have physicians and the health care industry in general been slow to adopt electronic solutions that could enhance the efficiency and quality of health care?*

A: One reason is purely technical. Many of the technologies to date have not been user friendly. The good news is that over the last few years we have started to see the development of new technologies—such as the wireless tablet PCs and handwriting recognition software—and certainly the health care industry is beginning to use the Internet for a wide variety of functions. These technologies will dramatically improve adoption rates.

But I believe the major reason for the delay is that the vendors building these products over the last 20 years have totally misunderstood the health care user. Typically, vendors have focused on the 15% of physicians who are trying to lead the charge toward technology adoption. These physicians push advanced technologies when the majority of doctors are simply not ready to accept a revolutionary adoption of information technology into their practices.

Physicians are not a one-size-fits-all type of group. In any practice environment, a certain percentage of physicians are highly computer literate and want all of the functions that vendors have for years been developing in their products. These functions may be great, but ultimately they make the product more complex. At the same time, some physicians will be computer novices or wary of incorporating technology into their practices. Certainly, the majority of physicians are looking for some very simple, easy-to-use tools that will help them alleviate some of their administrative burdens. They are looking for systems that provide technology that supports their needs and processes, not systems that redefine how they must practice medicine.

A third reason for the delay is that the health care information technology industry has a track record of limited success. I have seen studies indicating that less than 10% of the electronic medical record (EMR) systems sold over the last 20 years have been fully implemented. There is significant doubt on the part of physicians and allied health professionals regarding whether any health care organization can implement one of these products successfully. As a vendor, we believe our biggest challenge is to convince the market that there is a product out there that can be implemented broadly, that is affordable, and that will be successful.

Q: *What are the characteristics of a system that physicians should look for when they are considering computerizing their practices?*

A: First, physicians should look for a system that is simple and easy to use. They should look for a system that will take them less than 30 minutes to learn to use effectively. Of course, they will not be able to learn to use every feature in this short time, but they should be able to learn quickly the basic functions that they need to enhance their efficiency.

Second, they should look for a system that will not have an adverse effect on productivity. Today, many studies indicate organizations should expect anywhere from a 10% to 20% loss of productivity during the implementation phase of an EMR. I believe just the opposite. A proper approach to an EMR should have an immediate and positive effect on a physician's productivity. What is important here is both the design of the system and the vendor's implementation philosophy. A system that requires an all-encompassing functionality from day one may require too much training time and affect workflow to such a degree that the

(Continued on page 14)

> **"The majority of physicians are looking for some very simple, easy-to-use tools that will help them alleviate some of their administrative burdens."**

(Continued from page 13)

physician sees fewer patients in the first 6 to 12 months of use. I have heard horror stories in which first-year production dropped as much as 20% after implementation of an EMR.

Third, they should find a system that will be available to them anywhere at any time. Often, Web-based applications, which can be accessed from any computer that has Internet access, can satisfy this need. With the proper security, this type of system can enable the physician to do from any PC whatever he or she can do in the clinic. Such access is critical because physicians cannot be guaranteed that they will have their computer with them when they need to access information.

Finally, physicians want a system that will adapt to the way they practice medicine. Most physicians do not want to have to change their practice patterns in order to use a computer system.

Q: *What types of functions should physicians look for?*

A: Physicians want functions that will enhance their efficiency. They should look for a system that will give them quick access to laboratory, radiology, and transcription reports. They should look for the ability to write electronic prescriptions. Certainly, they should find a system that allows computerized access to a patient's health summary. These are all functions that will enhance quality as well as efficiency.

Ideally, the system should offer a single, unified source of information on each patient. This can be achieved with an interface that links the lab system, the radiology system, their transcription system, and other practice systems so that they can access all data through one single sign-on. A majority of groups already have historical data stored electronically on disparate systems that can be linked in this way. Often, physicians do not access most of the data available to them because they find the systems difficult to use. Furthermore, an interface is important because groups all over the country have major financial investments in their existing systems and want to continue to use them.

Physicians should not focus on all the bells and whistles available in a certain system, even though such functionality may be needed. Rather, they should consider the following more pressing questions: "Will I use this?" "Can I implement it?" "What is the training time?" "Will it have a negative effect on my productivity?" Simple questions such as these are crucial when assessing computer technology purchase decisions, but this is not the way most health care systems are purchased.

This principle is no different in health care than it is for other computer technologies. For example, I have taken advanced classes in Microsoft Excel, Word, and PowerPoint, and yet I probably use only 20% of the capability of these systems. But that 20% is all I need to know. Physicians want systems they can use; they do not want a system that is too time consuming to learn, and they don't need or want a high level of complexity.

Q: *How can information technology make physicians more efficient?*

A: I often hear from doctors that revenue is increasing at a much slower rate than overhead costs are rising. So physicians need to see more patients in a shorter amount of time in order to generate additional revenue. Information technology can alleviate or reduce the administrative burden of medical practice, so that physicians and nurses can find more time to care for patients.

There is not a lot that a physician can or should do to reduce the time spent with each patient. But information technology can enhance the efficiency of the nonpatient care aspects of practice. Physicians may see patients for eight hours a day, but then have to spend four hours catching up on documentation. Computer systems can speed this process because documenting and doing other administrative tasks on paper are simply more time consuming than using electronic systems.

But physicians must also realize that systems enable many processes to occur outside of the medical office. For example, physicians may prefer to handle administrative tasks from home, and they can choose to do so if they have secure access to patient data from their home computer.

Q: *How can such systems enhance the efficiency of the practice staff?*

A: Vendors have typically focused on the actual encounter between the physician and the

When evaluating a system, "physicians should consider the following important questions: 'Will I use this?' 'Can I implement it?' 'What is the training time?' 'Will it have a negative effect on my productivity?' Simple questions such as these are crucial when assessing computer technology purchase decisions."

patient, and that is clearly a critical activity that can be facilitated using computerized information. But there is a tremendous waste of time and money within physician organizations that has nothing to do with the direct physician-patient encounter.

For example, a significant portion of all chart pulls on any given day are for nonvisit patient activity: a patient calls with a question about insurance coverage, a prescription refill, or use of a medication, and this request requires a chart to be pulled. Typically, nurses are involved in such activity and therefore must spend significant time not taking care of patients in the medical sense, but doing clerical work, trying to find files and research information.

A computerized system can give nurses quick access to patient data and eliminate the need for time-consuming chart pulls. They can go back to focusing on what they went to school for: providing medical care to patients.

Q: *Why is it important for vendors to focus on the physicians who are resistant to computer technology?*

A: About 15% to 20% of physicians in most physician organizations are not computer literate. It is a challenge for vendors to develop a simple, intuitive system that will encourage use by all physicians, not just those who are technically savvy. Only after a certain level of comfort with technology is reached will physicians want to embrace more of the system's functionality.

The number-one failure of many systems over the last 20 years is that they started at too high a level from a technology standpoint to get the support needed from those physicians. There are computer systems in physician organizations all over the country that, even after three to five years, have achieved only 30% to 60% acceptance. Most physician organizations never come close to 100% acceptance of an EMR system. Until full physician acceptance can be achieved, EMRs will not create much value for the organization.

Q: *Are older physicians more reluctant to use an EMR?*

A: Older physicians may be a little more reluctant, but if the system is simple enough, they will use it. Sometimes, older physicians are more likely to use systems that are Internet-based because they are more likely to use the Internet for other purposes, like e-mail, shopping, or searching for information.

Q: *What are some other advantages of a Web-based system?*

A: The main advantage has to do with investment. Because of a convergence of high malpractice costs, managed care pressures, and reductions in reimbursement, many doctors are feeling the pinch, and they are reluctant to invest in a sophisticated computer system.

Using a Web-based EMR that is paid for on a subscription basis is much less costly than the traditional way of purchasing a system. A Web-based system can be implemented with the client's existing computer technology. As a result, a Web-based system with a reasonable subscription fee has a very quick return on investment. Considering the resources involved in the pulling, routing, and filing of paper charts, a medium-sized physician group needing to manage several hundred charts per day will be able to see a financial return on the monthly subscription fee in a matter of days.

In addition, by using a Web-based system, physicians do not need to have a lot of skill or hire skilled information technology professionals to manage, troubleshoot, and update the EMR. Implementing the system does not involve technical issues.

Q: *What do you think will be the future of health care information technology?*

A: Personally, I am very excited about the effect information technology will have on the quality and efficiency of health care. In a year or two, physicians will not be able to practice medicine without it. Patients are demanding that health care organizations enable greater patient access to data and more direct electronic involvement with providers.

Payers have seen studies showing that a dramatic reduction in claims management costs can be achieved when the proper information is available to physicians at the point of care. Over the next 12 to 24 months we will see physicians completely change their opinion of EMRs and other computer technologies. Information technology adoption is a major strategy by which we can not only cut down on health care costs, but improve the quality of care as well.

—Edited by Deborah J. Neveleff, in North Potomac, Md. More information on physician practice strategies is available on our Web site *(see page 16)*.

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CONTENTS

Features

Commentary What Happens If Cost Control Fails? 3

Strategy Vendors Can Ensure Compliance 8

Interview Consultant Offers Advice for Raising Physician Productivity 13

Departments

Editorial Increased Efficiency Improves Patient Care 2

Practice Management Privacy Rules Made Simple 6

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