

Top Eight Health Industry Issues in 2008*

PricewaterhouseCoopers' Health Research Institute

For the first time since President Bill Clinton was elected in 1992, the topic of healthcare is the most important domestic issue facing the U.S. population.¹ That means health industry executives will spend much of 2008 discussing, being questioned about, and analyzing how the federal government could affect access, cost, and quality of the current system. In addition to speculating on the implications of the 2008 presidential election, the industry also must adjust to some substantive changes that occurred in 2007. Pharmaceutical and life sciences companies must adapt to a new safety agenda from the FDA, while hospitals will be adjusting to new Medicare MS-DRGs, which could affect their future strategy. For all of the industry, 2008 will be a pivotal year to both react and anticipate.

PricewaterhouseCoopers' Health Research Institute (HRI) has identified areas of concern for health executives and policy makers in the coming year. To provide research-based insight, PwC commissioned a survey of 1,000 consumers and reviewed recent publications from industry and the government. To get the broadest possible input from PwC's network of business advisors, HRI employed an innovative tool called the PwC Thought-Wiki, which is based on similar technology that powers Wikipedia®, an online encyclopedia. This tool incorporated a new level of collaborative authoring and knowledge sharing into HRI's content development, resulting in the following Health Research Institute picks for the top health industry issues in 2008.

1 Give and Take: Significant changes in the way hospitals bill Medicare will create some winners and some losers.

The government wants to pay more accurately for hospital care, which is the largest part of the Medicare budget. So when the new fiscal year began in October 2007, the Centers for Medicare & Medicaid Services (CMS) implemented significant changes to the Inpatient Prospective Payment System to “better recognize severity of illness among patients.”² The new payment system—called Medicare Severity Diagnosis Related Group (MS-DRG)—has 200 more codes than the previous coding system. Now hospitals will have the ability to match patients more accurately to the diagnosis. Hospitals with more severely ill patients will benefit most, although CMS is worried that the majority of hospitals will adopt the Lake Wobegon attitude in which everybody is above average. CMS anticipates an overall higher level of reimbursement to hospitals because patient diagnoses will be documented with more specificity. This increase in reimbursement is evidenced by the average charges tracked by CMS, which were previously estimated at \$15,000 to \$25,000 per patient and which now range from \$18,000 to \$44,000 per patient.

To offset this increase, CMS has adopted a negative 0.6% rate adjustment for fiscal year 2008, with more cuts anticipated in future years. While CMS anticipates that such adjustments will balance out excess fees paid, hospitals aren't so sure. The American Hospital Association estimates that operating and capital payments to hospitals will be reduced by \$13 billion over the next two years.³ A bigger blow may be that hospitals will no longer receive additional reimbursement for certain “never events,” which are cases of specific infections and other maladies acquired in a hospital.

The bottom line: Hospitals need to pay keen attention to coding to ensure they're getting the appropriate reimbursement.

Implications:

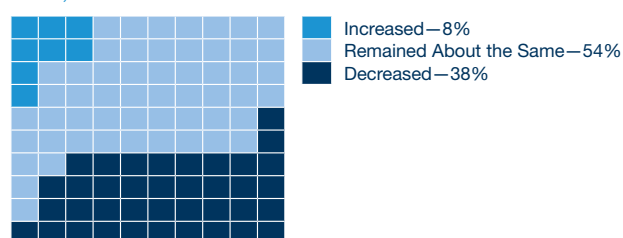
- Specialty hospitals and those that see less acutely ill patients, such as community hospitals and rural hospitals, could see their revenue dip at the expense of urban hospitals that treat patients with higher acuity levels.
- Commercial payers are likely to mirror Medicare's new system as well as drop reimbursement for never events.
- Hospitals may need to hire more coding staff, an area in which shortages already exist.

2 Silver Bullet: Renewed focus is on the FDA's drug safety initiatives.

The high-profile withdrawal of several popular U.S. Food and Drug Administration (FDA) approved drugs over the

past few years has shaken the public's confidence in the FDA's focus on drug safety. (See Exhibit 1.) Consequently, the FDA asked the Institute of Medicine of the National Academies (IOM) to analyze the U.S. drug safety system and provide suggestions for improvement.⁴ As a result of the IOM's report, the FDA announced 41 initiatives in early 2007 to enhance drug and medical device safety, focusing on three themes: improvement in communication, improvement in operations and management, and enhancement of the scientific assessment of drugs' risks.⁵ Results of the FDA's new initiatives include drug applications being rejected or delayed because of safety concerns, the issuance of safety alerts, and label revision requirements.⁶

Exhibit 1: In the past few years, has your confidence in the Food and Drug Administration's ability to ensure the safety of prescription drugs in the U.S. increased, remained about the same, or decreased?



Source: Gallup, Inc., November 19, 2004.

While the FDA has heightened its internal focus on drug safety issues, Congress has also provided the FDA with additional regulatory authority to require safety measures⁷ where in the past it could only request them. For example, drug companies now must submit a risk evaluation and mitigation strategy if serious risks are initially detected in a drug. The document must demonstrate that the drug's benefits outweigh its risks. If a company does not comply, the FDA may impose fines of up to \$10 million.

Congress has also provided the FDA with increased authority over post-market drug safety. The FDA now may require a drug company to conduct additional clinical trials within an agreed-upon time to assess or identify risks associated with a drug after it has been released to the public. The FDA also will actively monitor the use of drugs for any safety issues and mandate warnings on drug labels when problems do appear.

The bottom line: At a time when the public is looking for assurances that the drug supply is safe, the FDA's increased authority and heightened focus could boost the public's trust.

Implications:

- Under the new FDA guidance, the pharmaceutical industry may have more regulatory burdens placed upon it, which could be expensive.
- Physicians and hospitals will need to keep abreast of new restrictions in prescribing and dispensing certain prescriptions.

- Payers will be expected to furnish pharmaceutical purchase data and health insurance claims data to the FDA for identification of patterns of problems with medications.

3 The Doctor Is In: A surge in the number of retail clinics will force states, payers, and policy makers to think about the right model for the delivery of primary care.

Developed from consumer demand for convenient and lower-cost medical care, retail clinics have steadily increased in number. There are now more than 700 retail clinics in discount chain stores, grocery stores, and drugstores throughout the U.S.,⁸ and their numbers are expected to grow up to 3,000 within five years.⁹ Typically staffed by nurse practitioners, retail clinics have drawn the ire of some medical societies, which question their quality and are asking for increased regulation. The American Medical Association, the American Academy of Family Physicians, and several state medical societies are recommending certain operating requirements, including limitations on the scope of clinical services; the creation of a referral system with physician practices; and the use of electronic medical records.

Several states are taking cues from such groups by crafting legislation applicable to retail clinics. Some view retail clinics as a type of physician practice, while others see them as a different kind of medical delivery system altogether. California, for example, requires physician ownership of retail clinics, while Florida requires clinic personnel to disclose their medical credentials to patients.¹⁰

In the selection of care providers, quality of medical care continues to be most important to consumers surveyed by PricewaterhouseCoopers over the past two years. However, medical credentials are not perceived to be as important. The majority of those surveyed are willing to see a nurse practitioner or physician assistant in lieu of a doctor if the care costs less, if the appointment takes less time, or if the information is later shared with their doctor. (See Exhibit 2.)

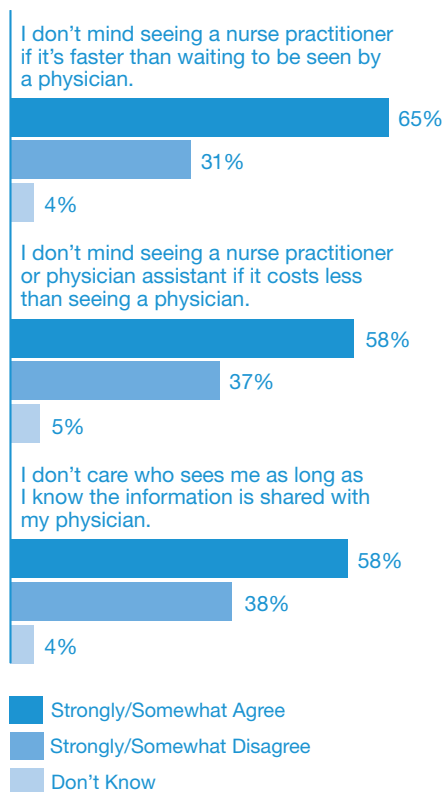
The bottom line: As retail clinics multiply, so will attention from state regulators.

Implications:

- Pharmaceutical companies may need to shift more of their marketing strategy to nurse practitioners.
- Many insurers cover visits to retail clinics because their members demand it, but they need to ensure that the quality is there; lack of regulation and low barriers to entry may attract lower-quality operators to this business.

- Hospitals could benefit from retail clinics if they become an access point for the uninsured. Physician practices and hospital systems need to figure out how to work with clinics to help patients—if they aren't starting up their own retail clinics.

Exhibit 2: Physicians are increasingly busy, and patients often see a nurse practitioner or physician assistant instead of the physician. Please state the extent to which you agree or disagree with the following statements.



Source: PricewaterhouseCoopers' Health Research Institute 2007 and 2008 consumer surveys.

4 Flying Solo: The market for individual health insurance could take off.

While typically more expensive than group health insurance, individual health insurance is the only option for consumers who don't have access to group coverage. Some insurers are already successfully marketing individual health insurance to twenty-somethings, but that market could get much broader if states follow Massachusetts' lead, which requires that all residents have health insurance. There are also health insurance initiatives on the national level, with Democratic presidential candidates mandating healthcare coverage and Republican presidential candidates offering tax incentives for the purchase of individual health insurance.

Approximately one in 10 Americans is covered by individual health insurance, and the market hasn't

increased in the past few years.¹¹ Moving away from the group model of health insurance would be radical, but it offers certain benefits, such as portability—with coverage following the individual rather than the employer. Nearly 98% of consumers polled by PricewaterhouseCoopers thought portable health insurance was a good idea.¹²

But money talks, and whether individual health insurance will become a desirable option for many working-age Americans is questionable. While a majority of consumers surveyed by PricewaterhouseCoopers said they are only willing to pay up to \$500 per year for their personal health insurance, the average annual cost of single coverage was \$4,479 in 2007. Such disparity between the two values is influenced by the fact that employers paid 85% of that cost.¹³ Nevertheless, affordability of health insurance is a key consideration and, clearly, many Americans don't consider individual health insurance—that's not subsidized by either employers or the government—to be affordable.

The bottom line: While tax incentives for the purchase of individual health insurance may help, an individual mandate could do more to move individuals toward buying coverage.

Implications:

- Payers will need to tailor their products and distribution strategies for individuals looking for health insurance coverage.
- Providers could suffer financial consequences if these plans have limited benefits, but they may benefit if more patients have coverage.

5 Breaking the Bank: Retirees are playing a greater role in funding their healthcare coverage—whether they like it or not.

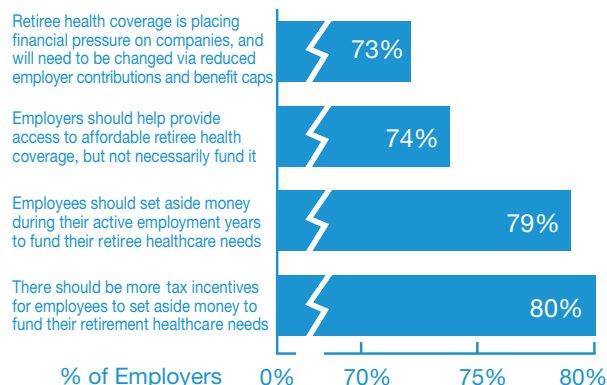
Preparing for upcoming retirement, baby boomers are confronted with how they will pay for healthcare. In the past, many retirees have been comforted by employer promises of retiree medical benefits. But as the population ages and healthcare costs increase, employers are shifting more responsibility for retiree healthcare to their employees, in some cases even after promises have been made.

In a PricewaterhouseCoopers survey of multinational company executives, 73% said they would need to reduce employer contributions and cap benefits. To make up the difference from lost employer contributions, 79% of those surveyed said employees should financially contribute during their working years, and 80% said that the government should provide tax incentives to such employees.¹⁴ (See Exhibit 3.)

Every eight seconds, totalling almost 11,000 people each day, a baby boomer turns 50, and more than 60% of that population has at least one chronic condition, such

as diabetes, arthritis, or cancer. As these individuals age, the overall incidence of chronic conditions will increase. Currently, 80% of Americans 65 and older have at least one chronic disease.¹⁵ While some individuals 65 or older will continue to work by choice, many will continue because of financial considerations, including healthcare coverage. Based on one 2007 survey, nearly one-third of the over-65 workforce will delay retirement.¹⁶ As the population ages and chronic conditions increase, employer funding for retiree healthcare has decreased.

Exhibit 3: In describing your views about retiree health coverage, do you agree at least somewhat with the following statements?



Source: "Tailoring the approach: Employer attitudes and healthcare strategies address distinct issues," PricewaterhouseCoopers' Health Research Institute, April 2007, p.4.

However, some innovative solutions are emerging and continue to evolve that will limit employer healthcare obligations. For example, General Motors Corp. recently addressed its retiree healthcare obligations by transitioning coverage to a union-managed trust, thereby removing itself as the intermediary between retirees and their future healthcare coverage. Other employers are banding together to develop retiree healthcare solutions that provide coverage for pre-65 and post-65 retirees in new ways. Twenty employers have enrolled in the new Retiree Health Access program, sponsored by the HR Policy Association, which provides guaranteed coverage for retirees without a mandated employer subsidy. A defined contribution approach to retiree healthcare called Emeriti Retirement Health Solutions has attracted 48 colleges and universities.

The bottom line: Expect to see more arrangements that provide retirees with a set stipend rather than the traditional promise of open-ended healthcare coverage. Depending on the outcome of the 2008 presidential election, there may also be new options available to the public to pre-purchase retiree health coverage.

Implications:

- Employers will continue to re-examine their approach to retiree healthcare, capping and eliminating liabilities and shifting toward "defined contribution" or "no contribution" approaches.

- Providers may see an increase in patients who cannot afford treatment due to insufficient coverage.
- Payers may see an increase in retirees who purchase supplemental Medicare insurance. However, payers may see an overall decline in retiree healthcare coverage if companies no longer pay for it.
- If pre-65 retirees lose their employer-sponsored retiree healthcare coverage, they may not be able to afford prescription medicines. Pharmaceutical companies can expect to see a large shift toward generics and potentially even an overall drop in usage.

6 I Think I Love You: Big pharmaceutical companies will keep buying and collaborating with life sciences companies to stock their pipelines.

The blockbuster model is drying up for big pharmaceutical companies as patents expire and generic drugs are released to the market. At the same time, costs associated with getting a new drug to market—including sales, marketing, and research and development (R&D)—have skyrocketed. There are fewer new drugs being produced now, resulting in less revenue, compared with 20 years ago.¹⁷ It costs an estimated \$802 million to develop a drug, but less than one-third of the drugs that reach the market “earn enough money to match or exceed the average R&D cost per new medicine.”¹⁸

To address these woes, big pharmaceutical companies are no longer restricting themselves to manufacturing small molecule drugs, but are also investing in biological drugs. While big pharmaceutical companies typically purchase small molecule drug technology and then develop it on their own, life sciences companies, which produce biological drugs, often are not willing to simply sell their research; they also want a vested interest in the outcome. Mergers, collaborative risk-sharing, joint ventures and other co-promotion arrangements between big pharmaceutical companies and life sciences companies are increasingly popular, matching innovative research with financial resources. The first quarter of 2007 had the highest quarterly dollar amount ever recorded for life sciences (biotechnology and medical devices combined) merger and acquisition deals, at \$2.6 billion, and the second quarter was the most active quarter in history, with 223 deals.¹⁹ With these collaborations, life sciences companies are driving the industry in which big pharmaceutical companies once had a significant advantage.

In addition to sharing profits with co-venturers, big pharmaceutical companies may see their profits further reduced by biogenerics—generic copies of biological drugs—which are looming on the horizon. Fortunately for big pharmaceutical companies, biological drugs are difficult to copy, and therefore, biogenerics will be expensive to manufacture, potentially dissuading many

generic pharmaceutical companies from entering that market. Unfortunately for big pharmaceutical companies, lawmakers in the U.S. and abroad may be clearing the regulatory pathway for biogenerics. In the United States, pending legislation could provide the FDA with expanded authorization to review biogenerics in an abbreviated fashion,²⁰ while Europe created a legal framework for review in 2003, and China and India already have biogenerics industries.

The bottom line: Acquisitions and the development of third-party relationships will become more common between big pharmaceutical companies and life sciences companies.

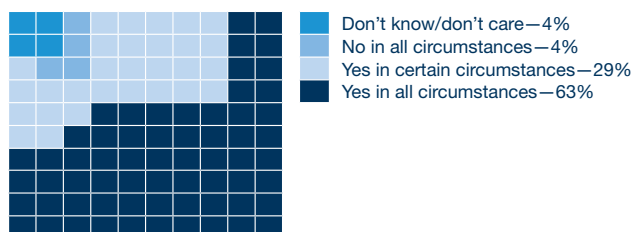
Implications:

- Life sciences companies will need to produce research that demonstrates their value to the pharmaceutical industry.
- The emergence of biogenerics could cause major disruption to pharmaceutical companies’ future revenue streams.

7 Putting Their Hearts on Their Sleeves: This year, hospitals publicly report their corporate responsibility.

Hospitals fill important needs in their communities, and consumers recognize hospitals as an important safety net. Nearly two-thirds of consumers that PricewaterhouseCoopers surveyed said tax-exempt hospitals have an unwavering responsibility to provide medical care for individuals who cannot pay for it. (See Exhibit 4)

Exhibit 4: Do you believe that non-profit hospitals have a duty to provide care to sick individuals, regardless of their ability to pay?



Source: PricewaterhouseCoopers’ Health Research Institute 2008 consumer survey.

However, while tax-exempt hospitals often have reported their community benefit on Form 990 (the annual tax return submitted to the Internal Revenue Service (IRS) and available for public inspection), many hospitals either did not document their community benefit in its entirety or did so inconsistently.²¹ On the 2008 Form 990, the IRS has proposed to ask for a full accounting of community benefit in a uniform manner. The revisions bring a level of standardization and transparency that was previously missing.

Apart from reporting their charity care, hospitals have shown their corporate responsibility in a variety of other ways, including considering the environment via “green” architecture. Green architecture includes use of recycled building materials, water and energy conservation efforts, and consumption of locally grown and organic foods. This environmentally friendly trend is proving to be positive for hospitals not only from a public relations perspective. Hospitals that are building green also receive economic incentives, lessen environmental impact, and create better workplaces for medical staff, potentially leading to reduction in medical errors and improvement in patient healing time.²² Currently, 129 healthcare facilities are registered with Leadership in Energy and Environmental Design—which is recognized as the benchmark for green building designation—and that number is trending upward.²³

The bottom line: Hospitals are in the corporate citizenship spotlight and will want to put their best foot forward.

Implications:

- Hospitals need to establish tracking mechanisms, if they’re not already in place, to accurately report community benefit statistics to the IRS. While the 2008 Form 990 will not be filed until 2009, and the IRS may delay requiring these statistics until even further in the future, such tracking mechanisms will need to be implemented from the first day of the year commencing the reporting requirement.
- If hospitals are refurbishing old buildings or constructing new ones, educated consumers will be interested in how hospitals are addressing their environmental impact.

8 The Land of Golden Opportunities: Asia is poised to be the largest pharmaceutical consumer and pharmaceutical producer in the world.

The rising costs of drug discovery have led pharmaceutical companies to look outside the U.S. for a comparable workforce that is less expensive. Asia has become a primary manufacturing option, providing lower-cost and typically high-quality products. Singapore, for example, is recognized as a premier center in Asia with at least 10 multinational pharmaceutical manufacturing facilities.²⁴

While Asia is an attractive manufacturing outsourcing market, there are clear concerns regarding the uneven protection of intellectual property rights. Seventy-six percent of executives from multinational corporations said they were extremely concerned about intellectual property rights and legal risk.²⁵ However, several Asian governments have introduced and are rigorously enforcing new intellectual property laws. Seventy-four

percent of multinational corporation executives have noted improvement in intellectual property protection over the past five years,²⁶ and as a result, many are turning their attention to R&D in Asia. The new centers are still small investments, though, compared with what is currently being spent on R&D in the West.²⁷

American pharmaceutical companies also have increased their presence in Asia for clinical trials and marketing because of the Asian market’s size, increasing wealth, and heightening awareness of health-related issues. China’s pharmaceutical market currently ranks in the top 10 markets and is estimated to reach number one by the middle of the century.²⁸ Similarly, India’s pharmaceutical market is 13th in the world but is anticipated to grow 80% by 2009.²⁹ Along with the rest of the world, as the substantial Asian population ages and becomes less physically active, chronic diseases have increased, and demand for medical treatment, including pharmaceuticals, has followed.³⁰

On the flip side, several Asian drug companies are hoping to become the next worldwide big pharmaceutical companies, not just contract manufacturers. India, China, and Singapore all have their own pharmaceutical industries, and South Korea, the Philippines, and Thailand are investing increasing amounts in healthcare.³¹ At this time in the U.S., there remains concern over the integrity of drugs made in Asia despite the fact that many of the drugs sold to the American public are made in China and India.³² A substantial majority of U.S. consumers surveyed by PricewaterhouseCoopers are confident that drugs made in the U.S. are safe. However they ranked India and China as last and second to last, respectively, out of 10 countries for drug safety. The 10 countries surveyed were the U.S., Switzerland, Japan, England, Germany, China, Israel, Denmark, France, and India. But with enough education and improvement in regulation by Asian governments, Asian drug manufacturers may have a strong market in the U.S.

The bottom line: American drug manufacturers are playing with a double-edged sword in Asia. On one hand, the Asian market provides high-quality, inexpensive labor and an increasingly favorable market in which to sell pharmaceuticals; on the other hand, Asian pharmaceutical companies may present stiff competition in the world marketplace in the future.

Implications:

- Pharmaceutical companies will want to consider how U.S. consumers perceive the safety of Asian-manufactured drugs.
- If the majority, or at least a large portion, of fundamental intellectual property creation moves to Asia, the West’s dominance and ownership in scientific breakthroughs will rapidly decline.

Conclusion

Healthcare is in the forefront of the collective American mind this year, more so than it has been in over a decade. As consumers are given more responsibility over healthcare decisions—from insurance to drugs to provider options—health executives will be expected to publicly convey their industry’s quality, safety, and affordability. New government standards are being implemented to encourage such disclosure, and it is up to health executives to anticipate what will be required of them and to proactively address those requirements. Such communication is essential to the healthcare industry’s future success.

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