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Cost, Quality and Access-to-Care Issues in the U.S. / Ohio / Northeast Ohio

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Baldwin-Wallace College is pleased to offer its Quarterly Health Care Report by Professor Tom Campanella, director of the Health Care MBA program, as a courtesy to those in the health care sector. In it, Professor Campanella summarizes and comments on what's new on the critical issues of health care costs, quality and access to care at the national and international levels, as well as health care news of interest in Ohio and the Northeast Ohio region.

You can access and view the current report on our website by clicking here, by cutting and pasting the following link: http://www.bw.edu/academics/bus/programs/hcmba/nl/, or via any of the links below. We strongly recommend reading the Quarterly Health Care Report online as this format provides direct access to some interesting and relevant Health Care websites.

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INTRODUCTION

This edition of the Quarterly Health Care Report focuses on proactive initiatives that address some of the fundamental issues impacting cost, quality and access in the U.S. This edition of the Quarterly Health Care Report focuses specifically on potential roles of a Federal Reserve-like entity called the Federal Health Board that is currently being proposed by President-elect Barack Obama's designate for Secretary of Health and Human Services, Senator Tom Daschle.

Costs

Drug Costs

Tom's Comments:

The article below provides the reader with some insight into both the causes as well potential strategies to address escalating drug costs. In past issues of the Quarterly, we have discussed prescription drug cost trends. While the prescription data noted below is only through 2006, the message it provides is very much relevant today. Recently, the good news relating to prescription drug spending is that the cost trend has declined in both 2006 and 2007, mainly as a result of increased utilization of generic drugs.

As this article notes, on a relative basis, prescription drug spending is a small proportion of national healthcare spending (10% in 2006, compared to 31% for hospitals and 21% for physician services.) Nevertheless, given the financial burden on both payers (government/employers) and consumers, it is important from a societal, employer and a consumer perspective that we proactively address prescription drug, as well as hospital and physician cost trends.

In addressing the hospital, physician and prescription drug costs, one must also recognize the value that these services provide and the linkage of these services to each other. For example, initiatives that blindly attempt to reduce prescription drug costs could have a negative impact on both hospital and physician costs. Drugs that allow consumers to better manage their cholesterol or diabetes could prevent heart disease or unnecessary emergency room or physician office visits.

The other take away message from this article is the increased proportion of prescription drug costs that are being paid for by the government, specifically Medicare. Given the competing national priorities, most notably the economy, there will be increased pressure on the federal government to focus on the major entitlement programs, such as Medicare. There will also be increased pressure on Congress to pass legislation to allow or require Medicare to negotiate prices with drug makers.

While direct price negotiations by Medicare with the drug makers appear to be an attractive solution, given Medicare's financial leverage; there actually may be better approaches to address escalating prescription drug costs. As the next article ("Two Ideas to Increase Innovation and Reduce Pharmaceutical Costs and Prices") in the Quarterly notes, countries such as the United Kingdom are evaluating replacing profit and price controls on prescription drugs with a value-based approach to pricing, which would relate the spending for drugs to their incremental clinical and therapeutic value to patients.

Prescription Drug Trends

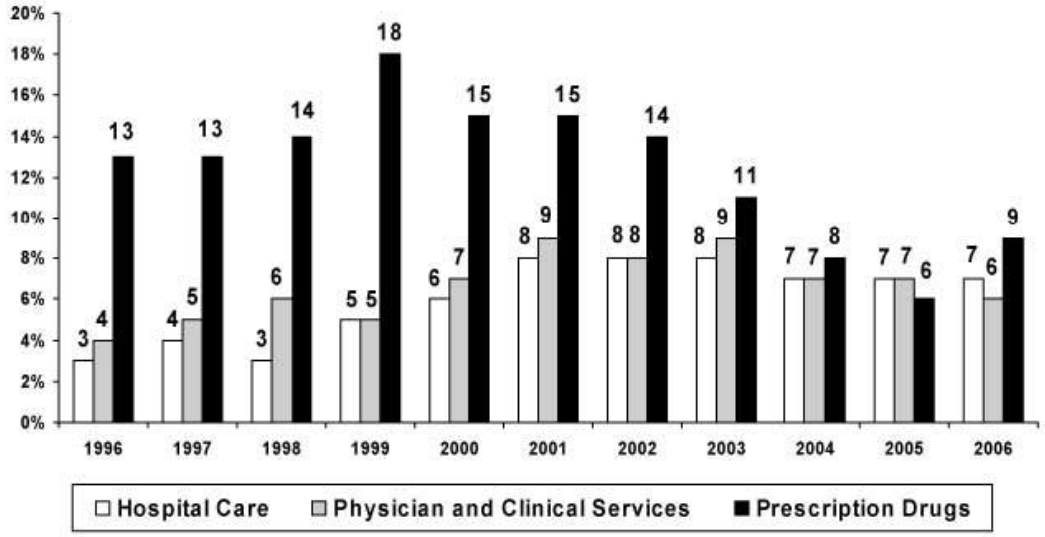
Overview

Prescription drugs are vital to preventing and treating illness and in helping to avoid more costly medical problems. Rising costs and implementation of the Medicare Part D drug benefit in 2006 have highlighted the need for a better understanding of the pharmaceutical market and for new approaches to address increasing prescription costs.

Rising Expenditures for Prescription Drugs

Spending in the US for prescription drugs was $216.7 billion in 2006, more than 5 times the $40.3 billion spent in 1990. Although prescription drug spending has been a relatively small proportion of national health care spending (10% in 2006, compared to 31% for hospitals and 21% for physician services), it has been one of the fastest growing components, until recently growing at double-digit rates compared to single-digit rates for hospital and physician services. In 2006, the annual rate of increase in prescription spending was 9%, compared to 7% for hospital care and 6% for physician services **(Figure 1).**

Figure 1: Average Annual Percentage Change in Selected National Health Expenditures, 1996-2006



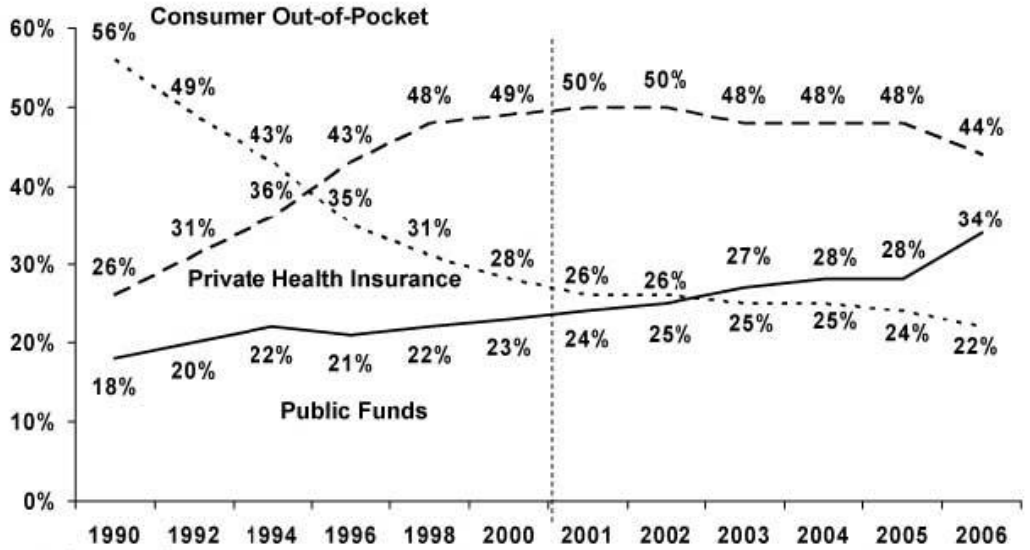
Source: Kaiser Family Foundation calculations using National Health Expenditure historical data from Centers for Medicare & Medicaid Services, http://www.cms.hhs.gov/NationalHealthExpendData/.

Prescription spending growth slowed from 1999 to 2005 because of the increased use of generic drugs, the increase in tiered copayment benefit plans, changes in the types of drugs used, and a decrease in the number of new drugs introduced. The growth in drug spending in 2006 resulted from 1) increased use of prescription drugs, attributed to the implementation of Medicare Part D, new indications for existing drugs, strong growth in several therapeutic classes, and increased use of specialty drugs; 2) lower rebates from drug manufacturers; and 3) changes in the therapeutic mix of drugs.

The share of prescription drug expenses paid by private health insurance increased substantially over the past sixteen years (from 26% in 1990 to 44% in 2006), contributing to a decline in the share that people paid out-of-pocket (from 56% in 1990 to 22% in 2006). The government's share of expenditures remained fairly constant. However, the implementation of the Medicare Part D drug program in 2006 substantially changed the mix of funding sources, as the government's share rose from 28% in 2005 to 34% in 2006, the private insurance portion fell from 48% to 44%, and the consumer out-of-pocket share declined from 24% to 22% **(Figure 2).**

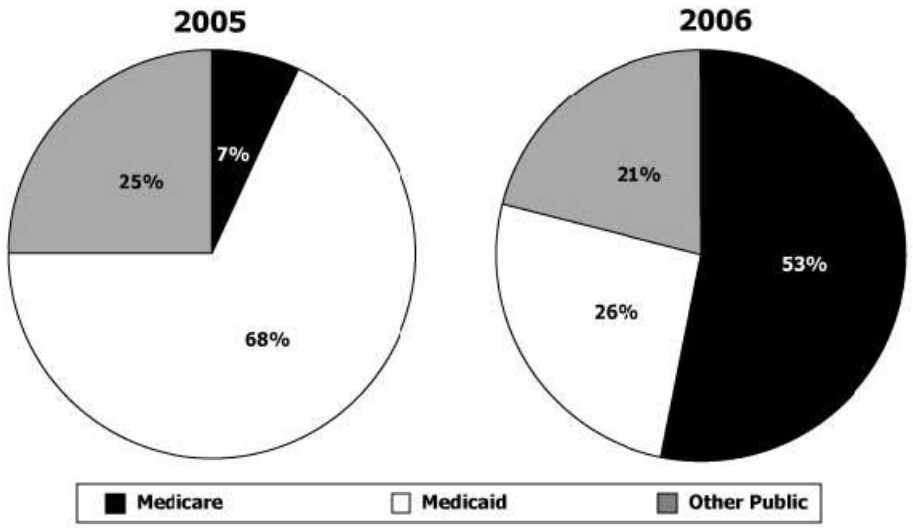
Within public funds, the funding shares changed from 7% Medicare and 68% Medicaid in 2005, to 53% Medicare and 26% Medicaid in 2006 **(Figure 3).**

Figure 2: Percent of Total National Prescription Drug Expenditures by Type of Payer, 1990-2006



Notes: Consumer Out-of-Pocket includes direct spending by consumers for health care goods and services not covered by a health plan and cost-sharing amounts (coinsurance, copayments, deductibles) required by public and private health plans. It does not include consumer premium payments and cost sharing paid by supplementary Medicare policies, which are included in the Private Health Insurance category. May not add to 100% due to rounding.

Source: Kaiser Family Foundation calculations using National Health Expenditure historical data from Centers for Medicare & Medicaid Services, http://www.cms.hhs.gov/NationalHealthExpendData/.



Notes: "Medicaid" includes federal and state funds for Medicaid and the Medicaid State Children's Health Insurance Program (SCHIP) expansion; "Other Public" includes other federal, state, and local expenditures and the Medicaid SCHIP program.

Source: Kaiser Family Foundation calculations using National Health Expenditures historical data from Centers for Medicare & Medicaid Services, http://www.cms.hhs.gov/NationalHealthExpendData/.

Factors Driving Changes in Prescription Spending

Three main factors drive changes in prescription drug spending: changes in the number of prescriptions dispensed (utilization), price changes, and changes in the types of drugs used.

Utilization. From 1997 to 2007, the number of prescriptions purchased increased 72% (from 2.2 billion to 3.8 billion), compared to a US population growth of 11%. The average number of retail prescriptions per capita increased from 8.9 in 1997 to 12.6 in 2007. The percent of the population with a prescription drug expense in 2005 was 59% for those under age 65, and 91% for those 65 and older; the proportions of these populations with a drug expense has changed little since 1997, when they were 59% and 86%, respectively.

Price. Prescription drug prices increased at the same rate in 2006 as in 2005 (3.5%). Retail prescription prices (which reflect both manufacturer

price changes for existing drugs and changes in use to newer, higher-priced drugs) increased an average of 6.9% a year from 1997 to 2007 (from an average price of $35.72 to $69.91), more than two and a half times the average annual inflation rate of 2.6% over the same period. The average brand name prescription price in 2007 was over 3 times the average generic price ($119.51 vs. $34.34). Of the average retail prescription price of $69.91, manufacturers received 78%, retailers received 19% and wholesalers received 4% in 2007.

Changes in Types of Drugs Used. Prescription drug spending is affected when new drugs enter the market and when existing medications lose patent protection. New drugs can increase overall drug spending if they are used in place of older, less expensive medications; if they supplement rather than replace existing drugs treatments; or if they treat a condition not previously treated with drug therapy. New drugs can reduce drug spending if they come into the market at a lower price than existing drug therapies; this can occur when a new drug enters a therapeutic category with one or two dominant brand competitors. New drug use is affected by the number of new drugs (new molecular entities) approved by the US Food and Drug Administration; approvals have fluctuated over the past decade, with 39 approvals in 1997, 27 in 2000, 20 in 2005, and 18 in 2006.

Drug spending is also typically reduced when brand drugs lose patent protection and face competition from new, lower cost generic substitutes. FDA analysis shows that generic competition is associated with lower drug prices on average; the first generic competitor prices its product only slightly lower than the brand-name manufacturer; the second generic manufacturer reduces the average generic price to nearly half the brand name price; prices continue to fall but more slowly as additional generic manufacturers market the product. For products with a large number of generics, the average generic price falls to 20% of the branded price and lower. Approximately three-quarters of FDA-approved drugs have generic counterparts. In 2007, 21% of total prescription drug sales and 65% of total prescriptions dispensed were generic medicines. Generic sales grew 8% from 2005 to 2006.

Advertising. Both prescription use and shifts to higher-priced drugs can be influenced by advertising. After increasing every year since 1996, the total amount manufacturers spent on advertising declined from 2004 to 2005 (from $11.9 billion to $11.4 billion), rose to $12.0 billion in 2006, and fell to $10.4 billion in 2007. The share directed toward consumers (through advertising on television, radio, magazines, newspapers, and

outdoor advertising) decreased from 2006 to 2007 (from $4.8 to $3.7 billion), and the share directed toward physicians (through the sales activities of pharmaceutical representatives and through professional journals) also decreased (from $7.2 to $6.7 billion). Spending for consumer advertising in 2007 was over 4 times the amount spent in 1996 ($3.7 billion vs. $0.8 billion), while 2007 physician advertising was almost 2 times the 1996 amount ($6.7 billion vs. $3.5 billion). The FDA and Congress are considering changes to prescription advertising rules.

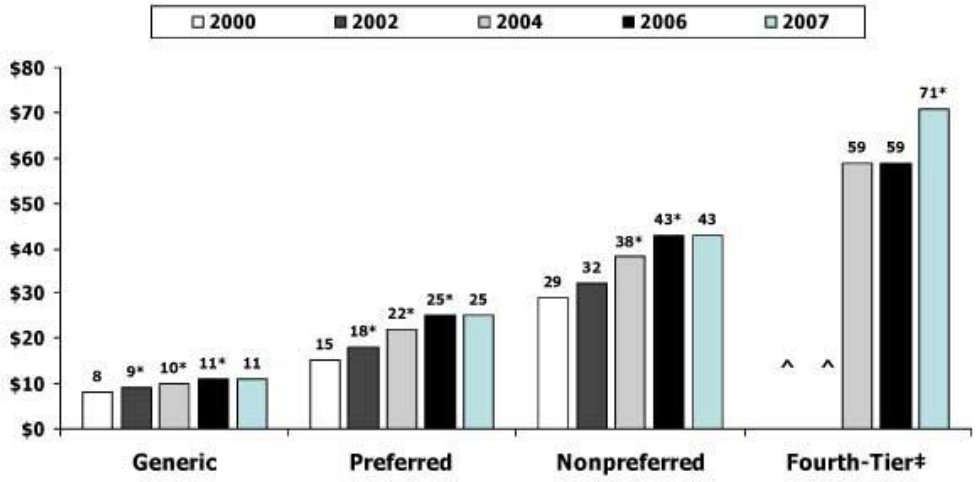
Profitability. From 1995 to 2002, pharmaceutical manufacturers were the nation's most profitable industry (profits as a percent of revenues). They ranked 3rd in profitability in 2003 and 2004, 5th in 2005, 2nd in 2006, and 3rd in 2007, with profits of 15.8% compared to 5.7% for all Fortune 500 firms in 2007. Prescription drug sales were $286.5 billion in 2007, an increase of 3.8% over 2006, and the smallest growth rate since 1961. IMS Health attributes slower sales growth to loss of exclusivity of brand name medicines, fewer new product approvals, the leveling of year-over-year growth from the Medicare Part D program, and the impact of safety issues.

Responses to Increasing Prescription Costs

A variety of public and private strategies as described below, have been implemented to attempt to contain rising costs for prescription drugs.

Utilization Management Strategies. Health plans have responded to increasing prescription drug costs by excluding certain drugs from coverage, using quantity dispensing limits, and increasing enrollee cost-sharing amounts. In 2007, three-quarters (75%) of workers with employer sponsored coverage had a cost-sharing arrangement with 3 or 4 tiers, over 2½ times the proportion in 2000 (27%). Copayments for non-preferred drugs (those not included on a formulary or preferred drug list) increased 48% from an average of $29 in 2000 to $43 in 2007. Copayments for preferred drugs (those included on a formulary or preferred drug list, such as a brand name drug without a generic substitute) increased by 67%, from an average of $15 in 2000 to $25 in 2007 **(Figure 4).**

Figure 4: Among Covered Workers with Three or Four-Tier Prescription Drug Cost Sharing, Average Copayments, 2000-2007



*Estimate is statistically different from estimate for the previous year shown at p<.05.

^Fourth-Tier drug copay information was not obtained prior to 2004.

Source: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2000-2007, Exhibit 9.4, http://www.kff.org/insurance/7672/index.cfm.

Discounts and Rebates. Private and public drug programs negotiate with pharmaceutical manufacturers (often using contracted organizations known as pharmacy benefit managers) to receive discounts and rebates which are applied based on volume, prompt payment, and market share. Manufacturers who want their drugs covered by Medicaid must provide rebates to state Medicaid programs for the drugs they purchase; many states have also negotiated additional rebates, known as supplemental rebates. Several government agencies, including the Department of Veterans Affairs, the Defense Department, the Public Health Service, and the Coast Guard, participate in a program known as the Federal Supply Schedule through which they purchase drugs from manufacturers at prices equal to or lower than those charged to their "most favored" nonfederal purchasers. In order to participate in Medicaid, another program, the Section 304B Program, requires manufacturers to provide drugs to certain nonfederal entities (such as community health centers and disproportionate share hospitals) at reduced prices. Federal legislation to expand this program was introduced in 2007 but has not as yet been enacted.

Medicare. The Medicare Part D drug benefit shifted spending from the private sector and Medicaid to Medicare, making Medicare the nation's largest public payer of prescription drugs in 2006, when Medicare spending rose to 18% of total US prescription spending from 2% in 2005. Under the Medicare Part D legislation, Medicare is prohibited from directly negotiating drug prices or rebates with manufacturers, but will rely on the private Part D drug plans to negotiate these discounts/rebates. In early 2007, the 110th Congress considered but did not pass legislation to allow or require Medicare to negotiate drug prices with drug makers.

Outlook for the Future

HHS projects US prescription drug spending to increase from $216.7 billion in 2006 to $515.7 billion in 2017, a 138% increase in 11 years. The average annual increase in drug spending from the previous year is projected to drop from 8.5% in 2006 to 6.7% in 2007 because of a deceleration in drug price growth, and then rise to 9.6% in 2017, or an 8.2% average annual increase over the 11-year period. Drug spending as a percent of overall health spending is projected to increase from 10% in 2006 to 12% in 2017. HHS projects that over the next decade, drug spending growth will accelerate due to a leveling off of growth in the use of generic drugs, rising utilization rates, and a mild acceleration in new drugs coming onto the market. ("Prescription Drug Trends," Kaiser Family Foundation, September 2008, http://www.kff.org/rxdrugs/upload/3057_07.pdf)

Tom's Comments:

As a follow-up to the comments noted above, the journal article below provides two insightful recommendations that could increase innovation and reduce prescription cost trends. While the prescription drug industry may not be receptive to either of the recommendations, overall these recommendations would be a more attractive alternative to the industry vs. price and profit controls. Furthermore, the squeeze on profits of the pharmaceutical companies could have adverse impacts for society, by reducing innovation incentives, and thereby could lower worldwide access to life-changing treatments in the future.

Specifically, the authors are recommending two proposals for consideration: (1) replacing existing price regulatory structures with a value-based approach to pricing; and (2) moving toward public funding of clinical trials. As the authors noted, "The former can serve to realign

national regulators' budgetary allocations in a non-arbitrary fashion to maximize access to innovative drugs. The latter could simultaneously direct research into more productive areas and reduce the cost of drug development, while having a number of potential ancillary benefits."

Their value-based approach to price would reward companies for producing a drug that has significant clinical benefits over what currently exists today. This value-based approach would be a direct assault on the "me-too" drugs that have broad substitutability between competing brands, and increased incentives for more-fundamental innovations which would provide reasonable and directed incentives for research-based pharma.

The authors further recommend moving toward public funding of clinical trials. As the authors state, "There are other significant problems in ensuring that scarce research dollars are allocated in ways that maximize social returns to innovation. Perhaps the most significant is the growing cost of drug development and, in particular, the cost of clinical trials."

Per the authors, "There are two fundamental arguments in favor of this public funding approach: First, clinical trials should rightly be seen as a public good. Information flowing out of clinical trials, once publicly available, could improve the decision making in R&D as pharmaceutical firms choose better candidates for testing from their libraries. Such access would also obviate costly duplicative R&D. Greater confidence in the quality of testing is a second major argument in favor of public testing, since public funding of trials can reduce conflicts of interest."

Per the authors, "Public funding of clinical trials provides other advantages for advancing innovation and reducing costs. The costs of clinical trials serve as a major entry barrier, reducing competition and raising prices. They also discourage drug companies from engaging in research in particular products; if companies did not have to defray the costs of clinical trials, there would be a lower threshold of required revenues to make R&D worthwhile. As such, there would potentially be profitable opportunities across a much wider range of products. Second, with appropriate guidelines that mandate testing against existing drugs and encourage contracting firms to undertake trials that improve public health, public financing could disincentivise "me-too" drugs."

Currently, most of the discussion surrounding pharmaceutical costs center around two spectrums: the hands off approach and aggressive price and

profit controls over pharmaceutical companies. The two ideas identified in this journal article are examples of a more innovative proactive approach to addressing these concerns. While there may be practical problems with each of these ideas, they do illustrate the potential of finding a win-win solution that both addresses costs and does not only does not discourage innovation but may actually increase innovation.

Finally, as discussed in the commentary relating to Senator Tom Daschle's book within this Quarterly, the two proposals for consideration: (1) replacing existing price regulatory structures with a value-based approach to pricing; and (2) moving toward public funding of clinical trials could be directed by his proposed Federal Health Board.

Two Ideas to Increase Innovation and Reduce Pharmaceutical Costs and Prices

A period of turmoil is imminent for the pharmaceutical industry. The pipe line of new drugs appears to be slowing down, increased generic competition is imminent in several key segments where "blockbuster drugs" are concentrated, and insurers and payers are looking more aggressively for cheaper alternatives. In addition, existing pharmaceutical regulations on prices such as price controls and reference pricing reduce revenues to pharmaceutical companies, and there is increasing pressure to reduce prices through regulation in the United States. This confluence of events will mean significant changes in the industry's structure. Further, the squeeze on profits, it is argued, could have adverse impacts by reducing innovation incentives, and thereby could lower worldwide access to novel treatments in the future.

Given these facts, what policy proposals can be made that will best increase current consumer welfare while simultaneously maintaining or increasing incentives to innovate? We here offer two proposals that should be considered: (1) replacing existing price regulatory structures with a value-based approach to pricing; and (2) moving toward public funding of clinical trials. The former can serve to realign national regulators' budgetary allocations in a non-arbitrary fashion to maximize

access to innovative drugs. The latter could simultaneously direct research into more productive areas and reduce the cost of drug development, while having a number of potential ancillary benefits.

Any reward structure should balance the (expected) marginal benefit of directing innovation of a particular product with its marginal cost. From a social viewpoint, the "innovative" content of a discovery should reflect not simply whether it is non-obvious (and so eligible for patent protection) but whether it affords significant additional clinical benefits. (One of the weaknesses of the empirical literature is that all new chemical entities, or NCEs, are often treated as innovations.) For example, it is now well recognized that there is broad substitutability between competing brands of statins, except at high doses.

The large market for these drugs in the United States and elsewhere, and the relative ease of patenting these innovations, means that there is continued social inefficiency in terms of expended research effort as pharmaceutical companies' direct research into drugs that are similar to existing products. Such drugs sometimes do have some increased therapeutic value (even "me-too" drugs may have slightly different side effects for some patients) and may provide an additional contribution to consumer welfare through product competition.

However, it would be difficult to claim that the marginal social benefit from these drugs equals the marginal cost of innovation. Estimates of total research on standard drugs suggest that these costs constitute 80 percent of research and development (R&D) expenditure.

Use a value-based approach to pricing. Given this social inefficiency, there may be the potential to have well worked out regulations that aid in reducing costs to consumers but also provide reasonable and directed incentives for research-based pharma. In those countries where purchase price can be determined by government entities, linking the price that regulators are willing to pay to a metric of additional value will reduce incentives to provide innovations of marginal benefit, including "me-too" products. This has already been recognized in different contexts.
The Office of Fair Trading in the United Kingdom, for example, has proposed that the country replace profit and price controls with a value-based approach to pricing, which would work to relate the spending for drugs to their incremental clinical and therapeutic value to patients and the broader National Health Service (NHS). Specifically, this policy involves assessing the marginal clinical benefit of additional

drugs through the impact on quality adjusted life-years (QALYs).

Such a policy also has the advantage of reducing the arbitrariness of profit controls. Although it will reduce incentives for "me-too" drugs, it will increase incentives for more-fundamental innovations, reducing the uncertainty of the ability to appropriate returns. Currently, a truly innovative drug may have its profitability destroyed by even an inferior "me-too" drug from a pharmaceutical company that does a better job of marketing.

Public funding of clinical trials. There are other significant problems in ensuring that scarce research dollars are allocated in ways that maximize social returns to innovation. Perhaps the most significant is the growing cost of drug development and, in particular, the cost of clinical trials. One often-cited (but still controversial) set of estimates suggests that the average cost of trials is on the order of $400 million per NCE, a large fraction of total developmental costs. Accordingly, rethinking policy for clinical trials may be one of the simplest and most effective policy changes to increase efficiency in drug innovation. Particularly promising are proposals to publicly fund clinical trials for pharmaceuticals.

The costs for these public clinical trials could be recovered as part of the charges imposed on the sale of drugs. Overall drug prices should be lower as a result of the considerable savings from implementing such a policy.

There are two fundamental arguments in favor of this approach. First, clinical trials should rightly be seen as a public good. Information flowing from clinical trials, once publicly available, could improve the decision making in R&D as pharmaceutical firms choose better candidates for testing from their libraries. This transparency might even include open access to data, which would be made publicly available in the same way in which the government promotes the availability of census and Current Population Survey data. Such access would obviate costly duplicative R&D and would increase oversight, as anyone anywhere in the world could evaluate the outcomes against whatever base line characteristics they choose. Currently, drug companies have been pushing for more restrictive use of data generated by testing, which could reduce access to medicines, especially in third-world countries. Several recent bilateral trade agreements have provisions on data exclusivity that act as an extra layer of protection over and above the patent, without clear social benefits.

Greater confidence in the quality of testing is a second major argument in favor of public testing. Public funding of trials can reduce conflicts of interest, the consequences of which have been evident in several recent scandals in which drug companies seem to have suppressed relevant evidence on safety and efficacy.

These conflicts of interest contribute to the high costs of testing, and even to the high costs of drugs. The implicit or explicit bribing of doctors involved in clinical trials research not only raises costs, but also reduces competition. Doctors participating in trials are more likely to prescribe the drugs once they are certified; given the high switching costs (and the fact that patients typically bear a small fraction of the overall costs), this reduces the effective elasticity of demand. Reduced competition, in turn, results in higher prices and greater rent-seeking expenditures (including on advertising and marketing).

Public funding of clinical trials provides other advantages for advancing innovation and reducing costs. The costs of clinical trials serve as a major entry barrier, reducing competition and raising prices. They also discourage drug companies from engaging in research in particular products; if companies did not have to defray the costs of clinical trials, there would be a lower threshold of required revenues to make R&D worthwhile. As such, there would potentially be profitable opportunities across a much wider range of products. Second, with appropriate guidelines that mandate testing against existing drugs and encourage contracting firms to undertake trials that improve public health, public financing could disincentivise "me-too" drugs.

Under the current system, "me-too" drugs, social benefits of which are unlikely to match the testing costs are tested nonetheless—all the drug companies care about is whether they will be able to appropriate enough of the existing market to compensate for the incremental testing costs. But under public financing (in which the government uses an expected value-based approach) in which there is an arm's length relationship between the contracting firm and the pharmaceutical company, there is little incentive for the firm to undertake such trials.

Moreover, larger pharma firms have an implicit advantage in conducting trials because they are able to use their deep pockets to diversify risk. As such, they are in an advantageous position in relation to their biotechnology counterparts and other smaller firms that are in R&D

partnerships. Smaller biotech companies and others seeking to maintain control over their innovation may be better incentivized and more secure against takeover if they are able to concentrate on innovation and not rely on larger partners to bring their output to market. The diseconomies of scope (combining testing, innovation, and marketing) undermine principles of comparative advantage and are likely to overwhelm whatever economies of scope may exist.

Concluding comments. Given the current state of the industry, and the general erosion of trust in its innovative capacity and its testing, different ideas will need to be considered as the sector finds alternative business models. In general, proposals are hard to come by. These two ideas can simultaneously serve the multiple goals of reducing costs, reducing prices, increasing the overall pace of innovation, and directing more innovation to areas for which social returns are highest. ("Two Ideas to Increase Innovation and Reduce Pharmaceutical Costs and Prices," Arjun Jayadev and Joseph Stiglitz, Health Affairs Web Exclusive, December 16, 2008 http://content.healthaffairs.org/index.dtl)

Comparative Effectiveness Research

Tom's Comments:

The article below provides the reader with a better understanding of how advances in health technology and treatment protocols are incorporated into payers' (Medicare, Medicaid, and Managed Care Organizations) coverage and reimbursement decisions. The article further explores the policy implications of comparative effectiveness research on those coverage and reimbursement decisions by payers.

The author also discusses healthcare quality concerns that both focus on value being received from our healthcare investment and the disparities of healthcare services being provided in the U.S. As the authors stated, "Comparative effectiveness research can not only help in determining what treatments are most effective but, linked to the most appropriate clearinghouse, information could be made available to and used by clinicians in a timely manner." Currently, per the authors, "Studies indicate that an average of 17 years passes before research-generated knowledge, such as that from randomized clinical trials, is incorporated

into widespread clinical practice—and even then the application of the knowledge remains uneven."

As the authors state, "New comparative effectiveness research can add more value and improve upon the information already available by increasing the body of primary research of head-to-head trials that compare new treatments and technologies to those already existing. It can provide insights into whether certain treatments are more effective than already existing options. The research also has the potential to provide information on which patients respond better to specific treatments. Because much of the health care currently provided does not have an underlying evidence base, new comparative effectiveness research should also include studies of existing treatments and technologies. Such analyses could lead to a greater development of evidence-based treatment protocols and a reduction in practice variations."

Current health insurer procedures that are put in place to incorporate new treatment and technology assessment findings into coverage and reimbursement decisions can include the findings resulting from new comparative effectiveness research. An added benefit to providers of health care services would be a major reduction in their administrative costs, which is tied to their navigating through the varied reimbursement and coverage policies of the payers (MCOs and government).

As the authors further state, "Ultimately, the value of comparative effectiveness research depends on its ability to positively influence treatment decisions, not just insurance coverage and reimbursement decisions. Reimbursement policies can influence treatment decisions by more favorably reimbursing treatments which are deemed to be more effective (considering both costs and benefits) and discouraging less effective treatments by reimbursing them at less favorable rates. Pay-for-performance incentives can also incorporate comparative effectiveness research findings and any resulting evidence-based guidelines."

I agree with the authors' assessment that, "Comparative effectiveness research, when effectively integrated and applied into select areas of health insurance, can help refocus the health care delivery system on the value of care received and facilitates a shift toward more evidence-based medicine. In doing so, it has the potential to increase the quality and value of care as well as reduce the variation in health care

treatment and spending across the country that is not associated with better health care outcomes."

Finally, as discussed in the commentary relating to Senator Tom Daschle's book within this Quarterly, comparative (or clinical) effectiveness research could be directed by his proposed Federal Health Board.

Health Insurance Coverage and Reimbursement Decisions

Comparative effectiveness research is being pursued as a way to better assess the value of health care treatment options. Proponents believe that this research can help identify the best courses of treatment and lead to more standardized practices, thus increasing the quality and value of health care while reducing the wide variation in practice patterns.

To provide insights into the potential implications of more formal comparative effectiveness research, it is important to better understand how advances in health technology and treatment protocols are incorporated into the healthcare system. The American Academy of Actuaries' Health Care Quality Work Group developed this issue brief to discuss current assessments of health care quality the process for incorporating new treatment protocols and technologies into health insurance coverage and the policy implications of comparative effectiveness research.

HEALTH CARE QUALITY AND VALUE TODAY

As health care spending continues to rise, significant evidence suggests that the money being spent for health care is not providing adequate quality and value. For example, the Agency for Healthcare Research and Quality (AHRQ) reports that for many of the most prevalent diseases health spending increases faster than the rate of quality improvement.

The ratio of spending growth to quality improvement, however, is not the only indication that individuals may not be receiving enough value from the health care system—findings related to geographic variations in treatments and the prevalence of medical errors also are important factors. Data from the Dartmouth Atlas of Health Care suggests that, despite large differences in Medicare spending across geographic regions, the quality of care is not significantly greater in the higher-

spending areas. Furthermore, the Institute of Medicine estimates that as many as 100,000 Americans die each year due to medical errors.
One reason for such geographic variations and inconsistent quality of care may be the lack of information on what constitutes the appropriate treatments for specific conditions. In fact, a large share of services provided to patients and reimbursed by insurers has no underlying evidence base.

While quality measures are being developed, many of them focus on fairly simple treatment protocols. For instance, in its National Healthcare Quality Report, AHRQ uses 41 core quality measures (and 211 total quality measures) to evaluate the treatments for a number of prevalent conditions. The core measures for heart disease include whether recommended care is received for a heart attack; whether smokers, while hospitalized, are counseled to quit smoking; and whether obese adults are counseled about exercise. These are relatively simple measures, but even with such guidelines there is a significant gap in the quality of care received. AHRQ reports that between 1994 and 2005, 27 of the 41 core measures showed improvement, six declined, and six showed no change. Similarly, a study assessing quality of care by examining the extent to which standard treatment protocols are adhered to concluded that patients receive only 55 percent of the recommended care.

Determining what treatments are most effective is only a first step; the information must be available to and used by clinicians for it to have value. However, studies indicate that an average of 17 years passes before research-generated knowledge, such as that from randomized clinical trials, is incorporated into widespread clinical practice—and even then the application of the knowledge remains uneven. The AHRQ's National Guideline Clearinghouse (NGC) is intended to make medical evidence on treatments for a variety of diseases more widely available, providing information on clinical practice guidelines and appropriate interventions.

HOW NEW HEALTH TECHNOLOGIES AND PROTOCOLS ARE INCORPORATED INTO HEALTH INSURANCE COVERAGE AND REIMBURSEMENT DECISIONS

When new health care technologies and treatment protocols are developed, insurers must determine whether and how to incorporate them into an insurance plan. Decisions need to be made not only regarding whether to cover the new technology or protocol,

but also how it should be reimbursed. Insurers have several resources available to help with these decisions, specifically in terms of assessing existing and new technologies and treatments. Many private insurers subscribe to the services of technology assessment organizations, which evaluate the scientific evidence of emerging health technologies. These organizations focus on issues related to safety, efficacy, clinical indications and, when possible, comparisons of competing technology.

Other insurers perform their own analyses rather than subscribe to an outside assessment organization. Furthermore, most large insurers that subscribe to an outside assessment organization perform some health technology assessment in-house, as well. Other resources for assessment includes federally funded assessment centers, most often housed at various universities. Although there may be only minor variations in assessments across these different resources, how the assessment conclusions are implemented can vary among insurers. For instance, some insurers tend to be fairly restrictive in what they cover, whereas others are less restrictive.

Public payers such as Medicare and Medicaid may also use the analyses of technology assessment organizations; however, their coverage and reimbursement decisions also are influenced by existing legislative requirements and internal procedures. For instance, Medicare processes claims using regional intermediaries, which are required by law to form a physician committee to make local coverage determinations (LCDs). And while some may, these committees are not required to make use of evidence-based health technology assessments in their determinations. Instead, decisions tend to conform to generally accepted regional practice patterns and/or the professional experience of the committee members. At the national level, the Centers for Medicare and Medicaid Services (CMS) periodically provide coverage decisions through federal directives, termed national coverage determinations (NCDs). Such directives are prepared by a review panel that assesses available primary research and relevant descriptive information and may consider testimony from interested stakeholders.

Private health insurance plan documents typically contain provisions that affect whether specific benefits are determined to be covered by the policy. These types of provisions usually come in three forms. First, a plan document could contain language specifying that any covered medical services be of "proven benefit" (i.e., not experimental or

investigational). Second, a plan document could contain language stating that covered services must be "medically necessary." And third, plan documents often contain a list of specific exclusions. For example, most plans specifically exclude cosmetic procedures or speech therapy unless it is restorative. Although they may be covered at times, some more discretionary or lifestyle-related services such as bariatric surgery may be excluded, regardless of supporting clinical evidence. Insurers then make specific coverage determinations based on the information available.

Formal policies are developed proactively whenever possible, using evidence- based health technology assessments to determine whether a health service or procedure is of "proven benefit." The health technologies examined tend to be new and/ or controversial treatments, as opposed to therapies, diagnostics, or other services that have been in use for some time. However, there are often patient-specific requests for services for which no formal policies exist, necessitating brief, focused literature searches and expert opinion.

Beyond coverage decisions, health technology assessments are also used to determine how a medical treatment will be reimbursed. If an insurer decides to cover a particular treatment, the level of reimbursement may depend not only on its cost but also on evidence regarding whether it is proven to be more effective than other existing treatments. A new technology that is more costly, but more effective in the long run, is more likely to be reimbursed at a higher rate than the existing technology.

For instance, total hip replacement prosthesis includes artificial joints made with titanium, ceramic, and other materials. Conventional wisdom is that newer joint replacements made with composite materials will pay for themselves in the long term due to having a longer functional life. However, there are no comparative studies to support that conclusion. As a result, insurers could opt to reimburse the newer joints at the same rate as the older ones or pay the higher price only for younger patients with longer life expectancies. In contrast, local third party administrators could simply reimburse at the higher rate for the "newest" joint replacement, with little review.

Beyond relying solely on an economic assessment of relative long-term costs, insurers could opt to reimburse newer technologies at a higher rate when they are proven to increase safety, be more effective, or reduce recovery times. One example is minimally invasive surgery for heart valve

replacements. Instead of performing open-heart surgery with its inherent risks, the surgeon performs the surgery through small incisions in the patient's chest. For suitable candidates, this has been shown to reduce recovery time significantly and the inpatient stay is generally reduced. Health plans often cover such procedures at a higher reimbursement rate.

As new technology assessments are made, they are often limited by a lack of credible clinical data. Either there are no data at all or the data that are available do not offer enough high-quality evidence comparing the new technology to existing treatments or technologies. New drug trials provide an interesting example of this. Food and Drug Administration (FDA) approval requires that a drug developer show, through controlled clinical trials, that the drug is proven safe and effective. Typically, however, drug efficacy is demonstrated by comparison to a placebo. Furthermore, these clinical trials are often highly targeted and performed on relatively homogenous populations. As a result, they do not show effectiveness compared to other generally available drug or treatment options; the drug's effectiveness when released on a broader, more heterogeneous population; or the effects of long-term use.

POLICY IMPLICATIONS

Health insurers currently utilize health care technology assessments in both coverage determination and reimbursement decisions. Nevertheless, these assessments are often limited in scope and value. New comparative effectiveness research has the potential to be incorporated into the already existing mechanisms for coverage and treatment decisions, as well as help further define and improve the value and quality of health care. Most of the existing research regarding technology assessment is based on secondary research of clinical analyses that are focused on, and rarely go beyond, proving that a treatment is safe and effective.

New comparative effectiveness research can add more value and improve upon the information already available by increasing the body of primary research of head-to-head trials that compare new treatments and technologies to those already existing. It can provide insights into whether certain treatments are more effective than already existing options. The research also has the potential to provide information on which patients respond better to specific treatments. Because much of the health care currently provided does not have an underlying evidence base, new comparative effectiveness research should

also include studies of existing treatments and technologies. Such analyses could lead to a greater development of evidence-based treatment protocols and a reduction in practice variations.

Current health insurer procedures that are put in place to incorporate new treatment and technology assessment findings into coverage and reimbursement decisions can include the findings resulting from new comparative effectiveness research. However, health information systems need to be able to distinguish between specific treatments. Otherwise, health insurers will not be able to set different coverage and reimbursement policies for the different treatment options. This may require that International Classification of Diseases (ICD), Current Procedural Terminology (CPT), and Healthcare Common Procedure (HCPC) codes be finely differentiated to account for these variations.

As the definition of quality of health care is further refined by comparative effectiveness studies, it will likely lead to higher expectations for measuring and evaluating variation around provider performance and member compliance. That data will also be essential for the implementation of potential benefit incentive strategies as well as reimbursement policies. Ultimately, the value of comparative effectiveness research depends on its ability to positively influence treatment decisions, not just insurance coverage and reimbursement decisions. Reimbursement policies can influence treatment decisions by more favorably reimbursing treatments which are deemed to be more effective (considering both costs and benefits) and discouraging less effective treatments by reimbursing them at less favorable rates. Pay-for-performance incentives can also incorporate comparative effectiveness research findings and any resulting evidence-based guidelines.

Comparative effectiveness research, when effectively integrated and applied into select areas of health insurance, can help refocus the health care delivery system on the value of care received and facilitates a shift toward more evidence-based medicine. In doing so, it has the potential to increase the quality and value of care as well as reduce the variation in health care treatment and spending across the country that is not associated with better health care outcomes. ("Health Insurance Coverage and Reimbursement Decisions," Issue Brief: American Academy of Actuaries, September 2008, http://www.actuary.org/pdf/health/comparative.pdf)

QUALITY

Obesity

Tom's Comments:

As we have discussed in prior issues of the Quarterly, life style related diseases impact anywhere from 50% to 70% of our healthcare costs. More importantly, these life-style diseases have a major negative impact on the quality of life of the inflicted. Obesity is an example of such a life style disease that has had a major impact on healthcare costs in our society, as well as a quality of life impact on both children and adults.

The causes of obesity are multi-faceted, including genetics, and consequently the strategies to address this disease must also be multi-faceted. Data has also shown that obesity can impact multiple members of a family, and the best model to address obesity is one that focuses on the family setting.

There is also a financial side to fighting obesity. Payers (Medicare, Medicaid, and Managed Care Organizations) need to evaluate how they are paying for the services that are provided by clinicians and educators. Clinicians and educators need to be fairly compensated for the services provided, and there needs to be recognition that this is a chronic disease that requires ongoing treatment and intersession.

Finally, as in many areas of healthcare, we treat obesity from a silo approach. Collaboration is critical in addressing this disease. This report identifies a number of collaborative approaches to obesity that involve healthcare providers, employers, managed care organizations, immediate family of the person inflicted with obesity, and finally the obese individual.

Finally, as discussed in the commentary relating to Senator Tom Daschle's book within this Quarterly, the proposed Federal Health Board could play a major role in our fight against obesity

Facing the Challenge of Unhealthy Weight

The rapid increase in overweight and obese adults and children during the past three decades is one of the most significant health care challenges facing the United States, with health-related costs that affect everyone. Curbing and ultimately reversing this trend will require understanding, commitment, creativity and collaboration across all parts of society.

In 2007, the America's Health Insurance Plans (AHIP) assembled an Expert Panel on Obesity and Related Screening Measures to improve Health, consisting of health insurance plan chief medical officers and directors, clinicians, researchers, and policy and quality leaders from the public and private sectors.

Panel members discussed the state of the science surrounding obesity screening and treatment and the challenges raised by screening, including communication barriers, cultural and linguistic competency, and the need for appropriate and evidence-based guidance and follow-up.

Based on the work of AHIP Expert Panel and other research and meetings sponsored by the AHIP Obesity Initiative, this report offers the following recommendations for the health care community:

- Make routine body mass index (BMI) screening and interpretation a standard clinical practice for the care of adults and children;
- Equip all types of clinicians with training and tools to communicate with patients about BMI screening, overweight and obesity;
- Connect BMI screening to evidence-based prevention and treatment options;
- Build partnerships among health plans, physicians and clinicians, employers and community groups, in disseminating promising practices;
- Promote cultural competency and reduce racial, ethnic and cultural disparities; and
- Measure and report progress in BMI screening through standardized measures such as the National Committee for Quality Assurance's (NCQA) Healthcare Effectiveness Data Information Set (HEDIS).

This report also examines some of the many innovative programs that health insurance plans and clinicians have developed, in collaboration with employers, schools, community groups and policymakers, to encourage BMI screening and to address the challenge of unhealthy weight among children and adults. ("Facing the Challenge of Unhealthy Weight: Recommendations for the Health Care Community," America's Health Insurance Plans (AHIP), 2008, http://www.ahip.org/redirect/AHIP_ObesityWhitePaper.pdf)

Long-Term Care

Tom's Comments:

One of the most stressful times for people is the search and evaluation process for the most appropriate healthcare for a loved one. When that search focuses on long-term care needs for a parent, it can be especially stressful. The guilt factor of "abandoning" a parent to a "stranger" is stressful in itself. When you combine this with an often confusing and overwhelming process, the process itself, it becomes even more devastating.

In theory, CMS "Star rating" process, adds some easy to understand guidance to this search. As CMS states, "This "Star Rating" should not be looked at in isolation. Ultimately, the most important role that a child can play in this process is to make sure there is a stream of family and friends visiting the parent at different times during the day."

While the rating system is not perfect it is a start, and will evolve over time. In prior Quarterlies, we discussed "price & quality ratings" (See the Quarterly Issues dated: September/October 2008 http://www.bw.edu/academics/bus/programs/hcmba/nl/QHCR_Sept_Oct_2008.pdf or April/May 2007 http://www.bw.edu/academics/bus/programs/hcmba/nl/archives/April07.pdf).

We also discussed the applicability of such a "Star Rating" to acute care hospitals and even physicians. While there would be many challenges to face with such a system, in the long run it may be a better approach to

facilitate the decision-making process than the "word of mouth" system that occurs today. Similarly, due to the caveats of the "Star Rating" system for long-term care facilities, this hospital and physician information should not be viewed in isolation.

Finally, as discussed in the commentary relating to Senator Tom Daschle's book within this Quarterly, the "Star Rating" could be part of a strategy that would promote transparency of costs and quality in the provider system, which also could be directed or facilitated by his proposed Federal Health Board.

CMS Releases New Five-Star Quality Rating System for Long-Term Care Facilities

The Five-Star Quality Rating System was created to help consumers, their families, and caregivers compare nursing homes more easily and help identify areas about which you may want to ask questions. This rating system is based on continued efforts as a result of the Omnibus Reconciliation Act of 1987 (OBRA '87), a nursing home reform law, and more recent quality improvement campaigns such as the Advancing Excellence in America's Nursing Homes, a coalition of consumers, health care providers, and nursing home professionals.

Nursing home ratings are taken from the following three sources of data:

- Health Inspections
- Staffing
- Quality Measures

CMS provides a star rating for each of these three sources, in case some areas are more important to you than others. Then, these three ratings are combined to calculate an overall rating.

Why is this important?

Nursing homes vary in the quality of care and services they provide to their residents. Reviewing health inspection results, staffing data, and quality measure data are three important ways to measure nursing home

quality. This information gives you a "snapshot" of the care individual nursing homes give.

One of the most important things to do is to visit the nursing homes you are considering. If possible, also contact your Long-Term Care Ombudsman or State Survey Agency before making a decision. Take a copy of the Nursing Home Checklist when you visit a nursing home and talk to the nursing home staff about the information on this website.

The Nursing Home Checklist can be found at:
http://www.medicare.gov/NHCompare/static/tabhelp.asp?language=English&activeTab=6&subTab=0version=default

Strengths and Limitations of the Five-Star Ratings

Like any information, the Five-Star rating system has strengths and limits. Here are some things to consider as you compare nursing homes.

Health Inspection Results

Strengths:

- Comprehensive: The nursing home health inspection process looks at all major aspects of care in a nursing home (about 180 different items).
- Onsite Visits by Trained Inspectors: It is the only source of information that comes from a trained team of objective surveyors who visit each nursing home to check on the quality of care, inspect medical records, and talk with residents about their care.
- Federal Quality Checks: Federal surveyors check on the state surveyors' work to make sure they are following the national process and that any differences between states stay within reasonable bounds.

Limits:

- Variation between States: There are some differences in how different states carry out the inspection process, even though the standards are the same across the country.

- Medicaid Program Differences: There are also differences in state licensing requirements that affect quality, and in state Medicaid programs that pay for much of the care in nursing homes.

TIP: The best comparisons are made by looking at nursing homes within the same state. You should be careful if you are trying to compare a nursing home in one state with a nursing home in another state.

Staffing

Strengths:

- Overall Staffing: The quality ratings look at the overall number of staff compared to the number of residents and how many of the staff are trained nurses.
- Adjusted for the Population: The ratings consider differences in how sick the nursing home residents are in each nursing home, since that will make a difference in how many staff are needed.

Limits:

- Self-Reported: The staffing data are self-reported by the nursing home, rather than collected and reported by an independent agency.
- Snapshot in Time: Staffing data are reported just once a year and reflect staffing over a 2 week period of time.

TIP: Quality is generally better in nursing homes that have more staff who work directly with residents. It is important to ask nursing homes about their staff levels, the qualifications of their staff, and the rate at which staff leave and are replaced.

Quality Measures

Strengths:

- In-Depth Look: The quality measures provide an important in-depth look at how well each nursing home performs on ten important aspects of care. For example, these measures show how well the nursing home helps people retain their ability to dress and eat, or how well the nursing home prevents and treats skin ulcers.
- National Measures: The ten quality measures we use in the Five-Star rating are used in all nursing homes.

Limits:

- Self-Reported Data: The quality measures are self-reported by the nursing home, rather than collected and reported by an independent agency.
- Just a Few Aspects of Care: The quality measures represent only a few of the many aspects of care that may be important to you.
- Not Adjusted for the Population: The quality measures are not adjusted for any special characteristics that residents of a particular nursing home may have, compared to most other nursing homes. More specialized nursing homes may look better or worse with respect to any particular quality measure, depending on how different the population is compared to the residents in most other nursing homes.

TIP: Talk to the nursing home staff about these quality measures and ask what else they are doing to improve the care they give their residents. Think about the things that are most important to you and ask about them, especially if there are no quality measures that focus on your main concerns.

Use the Five-Star together with other information

The Five Star Quality Rating System is not a substitute for visiting the nursing home. This system can give you important information, help you compare nursing homes by topics you consider most important, and help you think of questions to ask when you visit the nursing home.

Use the Five-Star ratings together with other sources of information. For example, you can use Nursing Home Compare to search and compare nursing homes by city, state, or zip code. Choosing a nursing home that's near family and friends can be very important to your quality of life in the nursing home. Having family and friends nearby allows for more frequent visits and opportunities for outings. Family members and friends can also talk to the nursing home staff about your care needs, preferences, and gaps in care. Therefore, you may wish to start your search by considering how close you want to be to family and friends, and then use the rating system to compare nursing homes in the area you are considering.("Nursing Home Compare – Five Star Quality Rating," Centers for Medicare & Medicaid Services, http://www.medicare.gov/NHCompare/static/tabhelp.asp?language=English&activeTab=6&subTab=0version=default)

ACCESS TO CARE

Uninsured

Tom's Comments:

As the authors note, this Guide describes the many policy options and strategies that are currently being discussed by key stakeholders, including lawmakers, researchers, employers, health care industry representatives, providers, and advocates. These strategies are organized into the following four sections:

- Strengthen current coverage arrangements;
- Improve the affordability of coverage;
- Improve the availability of coverage;
- Change the tax treatment and financing of health insurance.

Finally, as discussed in the commentary relating to Senator Tom Daschle's book within this Quarterly, programs/initiatives relating to the access to healthcare could facilitated by his proposed Federal Health Board.

APPROACHES TO COVERING THE UNINSURED

While there is general agreement that the problem of the uninsured needs to be addressed, there is little agreement over how best to expand coverage. A wide range of policies targeting every segment of the health care system have been suggested as potential strategies for broadening coverage. These strategies differ in terms of their scope—some seek incremental changes while others would attempt major restructuring of the system—and who they target—some would focus only on the uninsured while others would promote coverage for all Americans. They also offer different mechanisms for achieving coverage expansions.

This Guide describes the many policy options and strategies that are currently being discussed by key stakeholders, including lawmakers, researchers, employers, health care industry representatives, providers,

and advocates. These strategies are organized into the following four sections:

- Strengthen current coverage arrangements;
- Improve the affordability of coverage;
- Improve the availability of coverage;
- Change the tax treatment and financing of health insurance.

These approaches are discrete strategies and can be combined in different ways to achieve broader coverage. The various combinations reflect different views on how the health care system should be organized and financed. This report concludes with a discussion of current health care reform proposals. ("Approaches to Covering the Uninsured: A Guide," Jennifer Tolbert, Jack Ebeler, Tanya Schwartz, Kaiser Family Foundation, December 2008, http://www.kff.org/uninsured/upload/7795.pdf)

Medicaid

Tom's Comments:

Over the years, we have heard the concerns expressed about the future of Social Security, especially with the aging of the baby boomers and the reduced number of employed to finance the system. This concern about Social Security has been partially addressed as most baby boomers now recognize that they will be working longer and, in many cases, will need to find ways to partially add to their income stream beyond relying solely on Social Security and their investments (especially with the most recent economic downturn).

The financial stability of Medicare to many is more of a concern than Social Security, especially given the addition of the Medicare Part D – Drug benefit, along with the aging of the baby boomers, the extension of life of the elderly, and the overall financial challenges faced by the Federal Government from a budgetary perspective.

The future financial outlook of Medicaid for many has been under the radar screen for a number of reasons. Sadly, since Medicaid focuses on the have-nots, unlike Social Security and Medicare which impacts all

Americans, Medicaid financial stability becomes less of a concern for most Americans. Medicaid funding of long-term care could potentially impact a wider selection of Americans, but long-term care needs is an area that most American do not focus on until the need arises.

The financial future of Medicaid, while it may be under the radar screen for most Americans, is actually under more financial stress than Social Security and Medicare. The findings in this report clearly identify some of the key concerns relating to the financial outlook for Medicaid. In addressing these concerns one should not just focus on finding additional income streams for Medicaid or conversely just focus on ill-conceived approaches to cut Medicaid spending. Careful consideration needs to be given to the goals and objectives of this program, which over the years have been encumbered by multiple objectives or programs, all of which are not effective or appropriate for this entitlement.

One of the fundamental problems impacting Medicaid is our lack of a true primary care system that is focused on wellness, prevention and management of chronic diseases.

Finally, we also must seriously evaluate how we finance long-term care. The majority of funding for Medicaid is directed to long-term care (especially in states like Ohio). Given the financial pressures on states and the federal government, Medicaid funding cannot continue to both support the long-term care industry and provide healthcare services to those in need. The appropriate allocation of state and federal dollars to support the needs of the elderly, disabled, poor, etc. will become more of a challenge. Now, more than ever, we must develop reasoned strategies at both the state and federal level to address these multi-faceted needs. As part of this process, very difficult issues will need to be addressed and potentially the proposed Federal Health Board could play a major role in facilitating the planning process.

The Financial Outlook for Medicaid

The joint Federal-State Medicaid program provides health care assistance to certain low-income people and is one of the largest payers for health care in the United States. This report presents an analysis of past Medicaid trends and 10-year projections of Medicaid expenditures and enrollment. Following are the major highlights of the report.

2007 Medicaid Expenditures and Enrollment

- Total Medicaid outlays in FY 2007 were $333.2 billion; $190.6 billion or 57 percent represented Federal spending, and $142.6 billion or 43 percent represented State spending.
- Estimated average Medicaid enrollment was 49.1 million people in 2007. At some point during the year, 61.9 million people, or about one of every five persons in the U.S., were enrolled in Medicaid.
- Per-enrollee spending for health services was an estimated $6,120 in 2007.
- Per-enrollee spending for non-disabled children ($2,435) and adults ($3,586) was much lower than that for aged ($14,058) and disabled beneficiaries ($14,858), reflecting the differing health status of these groups.

10-Year Medicaid Projections

- Expenditures for medical assistance payments represent about 94 percent of all Medicaid outlays and are projected to increase 7.3 percent to $339.0 billion in 2008.
- Over the next 10 years, expenditures on benefits are projected to increase at an average annual rate of 7.9 percent and to reach $673.7 billion by 2017.
- Average Medicaid enrollment is projected to increase 1.8 percent to 50.0 million people in 2008.
- Over the next 10 years, average enrollment is projected to increase at an average annual rate of 1.2 percent and to reach 55.1 million by 2017.

Medicaid in Context of U.S. Health Spending

- Total Medicaid outlays represented 14.8 percent of all U.S. health care spending in 2006.
- Medicaid is the largest source of general revenue spending on health care for both the Federal government and the States. Medicaid represents 40 percent of Federal government's general revenue spending on health care and 41 percent of such spending by States.
- Federal spending for Medicaid accounted for 7.0 percent of the entire Federal budget in 2007 and is projected to account for 8.4 percent by 2013. (2008 Actuarial Report on the Financial Outlook for Medicaid," Christopher Truffer, John Klemm, E. Dirk Hoffman, Christian Wolfe, Office of the Actuary, Centers for Medicare & Medicaid Services, October 17, 2008, http://www.cms.hhs.gov/ActuarialStudies/downloads/MedicaidReport2008.pdf)

Senator Tom Daschle

Tom's Comments:

Senator Tom Daschle has been recently announced as President-elect Barack Obama's designate for Secretary of Health and Human Services. He co-wrote a book with Scott Greenberger and Jeanne Lambrew, titled, "Critical: What Can We Do about the Health-Care Crisis."

Jeanne Lambrew has been selected by Senator Daschle for the role of Deputy Director of White House Office of Health Reform. Jeanne Lambrew is a Senior Fellow for the Center for American Progress and an Associate Professor of Public Affairs at the Lyndon B. Johnson School of Public Affairs at the University of Texas. She specializes in health care and policy and conducts research on the uninsured, Medicaid, Medicare and long-term care.

This book has been difficult for me to find in local book stores, but I was able to order it through Amazon.com. The book review below was written by Jeff Goldsmith in his Health Affairs Blog. Jeff Goldsmith is president of Health Futures, Inc. He is also the author of a book released in 2008 titled, "The Long Baby Boom: An Optimistic Vision for a Graying Generation."

As Jeff Goldsmith states, "The centerpiece of Daschle's argument is that Congress and the administration should be insulated from the politically unmanageable process of determining health benefits and payment strategy under health reform by a Federal Reserve-like entity called the Federal Health Board.

This Board would be filled with presidential appointees (Senate confirmed) with ten-year terms designed to overlap presidencies. Daschle would ask the Health Board to:

- create an evidence-based benefit package consistent across federal agencies but also offered by employers;
- design a Medicare-like public health benefit for those under age 65 to be offered in conjunction with private health plans in a multiple-choice format similar to the Federal Employees Health Benefits (FEHB) program;

- design and manage an evidence-based coverage policy for drugs and procedures that factors in both health and cost impacts;
- suggest research priorities for the National Institutes of Health (NIH);
- analyze federal health data to determine clinical effectiveness;
- promote transparency of costs and quality in the provider system; and
- recommend changes that would "rationalize" the nation's health care infrastructure."

For those of you who have followed the Quarterly over the years, you will note that many of these critical points have been discussed in detail including a potential role of a Federal body focusing on clinical effectiveness research, data gathering and analysis, price and quality rating clearinghouse, provider payment reform, etc.

Overall, I agree with Jeff Goldsmith's perspective that Senator Daschle's centerpiece, the establishment of the Federal Health Board, is a critical first step in addressing the politically sensitive steps that must be evaluated in order to have a "real impact" on healthcare costs, quality and access to care.

As noted in September/October 2008 Quarterly (www.bw.edu/academics/bus/programs/hcmba/nl/QHCR_Sept_Oct_2008.pdf), the major cost drivers in the U.S. are well documented.

Major Healthcare Cost Drivers

1. ***The inappropriate use of high cost technology;***

2. ***End-of- life heroic efforts vs. the more effective utilization of hospice services;***

3. ***Medicare/Managed Care Organizations physician and hospital payment methodologies that incent overutilization and do not reward quality or prevention;***

4. ***Unhealthy life styles;***

5. ***Chronic diseases that are not addressed in a coordinated and sustained manner;***

6. ***An inefficient fragmented health care system that often results in a stagnating tug-of-war between the health care***

stakeholders (e.g. hospitals, physicians, Managed Care Organizations, government, employers, consumers, etc.);

7. ***Clinical practice pattern variation that has had a negative impact on cost and quality;***

8. ***The lack of real engagement of the consumer in the health care purchasing decision;***

9. ***The lack of a coordinated and comprehensive primary care system that is focused on wellness and prevention.***

As noted in the September/October 2008 Quarterly (http://www.bw.edu/academics/bus/programs/hcmba/nl/QHCR_Sept_Oct_2008.pdf) a few fundamental changes could have a major impact on the above cost drivers. The combination of how we pay for healthcare services and linking that payment where applicable to clinical effectiveness research would positively impact the following cost drivers noted above: 1, 2, 3, 5, 6, 7, and 9.

Addressing unhealthy life styles (#4) above, requires a combination of initiatives. First, some of the payment reform and clinical effectiveness initiatives would incent and lay the foundation for a primary care system that would better address wellness and chronic diseases (such as diabetes). There also need to be programs available to assist the consumer in addressing their life style diseases (smoking, obesity, etc.).

Some personal accountability also needs to be built into the system. The government should not play the role of an enabler of unhealthy life-styles. If individuals want to continue to engage in unhealthy life styles (egg. smoking), and not participate in good-faith in smoking cessation programs, then they should be held accountable for their actions by paying significantly higher premiums for their health insurance. This is no different than what already occurs today in the life insurance, car insurance and property insurance industries. Higher risks pay higher premiums.

In order to effectively address these cost drivers, the decision-making process needs to be insulated as much as possible from the political process. The key challenge in instituting a Federal Health Board would be defining their scope of influence and authority, and determining if their

role is more in an advisory capacity vs. responsible for actual implementation.

Approximately 16% of our GDP is dedicated to healthcare, and consequently there are many healthcare stakeholders making large sums of money under the rules of our current system. Stakeholders then have a vested interest to lobby intensely to protect their interest. If the Federal Health Board only plays an advisory role (egg. to Congress), the stakeholders would only have to focus their efforts on Congress to block or support initiatives that serve their self interest.

Politically, it will be difficult for Congress, and possibly even the Administration, to relinquish any real power to the Federal Health Board, but as noted previously, effectively addressing the real healthcare cost drivers and our access to care and quality concerns requires reasoned sustainable changes.

Throughout this Quarterly, I have cited potential roles for the Federal Health Board which would address prescription drug innovation and cost trends, clinical effectiveness research, obesity, quality and cost ratings of healthcare providers, the uninsured, Medicaid, etc. Obviously, all of these issues could not be addressed overnight, but there needs to be a sense of real urgency. Also most of these issues will need to be addressed through sustainable actions, in order to have a "real" impact.

I also agree with Senator Daschle's recent statement to Congress, whereby he likened the problem with healthcare to a pyramid. As he stated, many other countries focus their resources on the base of the pyramid to ensure a strong primary care and wellness system. On top of this foundation of a primary care system they would gradually add higher end care, and at some point at the very high end of care, resources would need to be allocated appropriately.

As Senator Daschle stated, in the U.S. we have focused our resources on the top of the pyramid by financing high-end technology to the detriment of the base of the pyramid, which should be a strong primary care and wellness system.

In order to have a true primary care system we need to incent our medical students to choose these specialties. As part of this incentive, we should set up a system that affords medical students the opportunity to have their student loans forgiven if they choose a primary care specialty.

We need to partner these physicians with physician's assistants, nurse practitioners, clinical educators, etc. to have a true primary care system.

Finally, I am a big believer in universal healthcare. I am also very concerned though, that as a nation, we cannot afford to overlay universal healthcare over an inefficient, high cost, fragmented healthcare system. In the ideal world, we should first "fix" the system, prior to adding universal access. Realistically given the severity of the problem with the uninsured, we should attempt to address both fronts simultaneously. We could initially focus on uninsured children, and then with a sense of urgency we should ideally establish a Federal Health Board with "real" powers to address some of the key healthcare cost drivers noted above.

A Review of Senator Tom Daschle's Book, "Critical: What Can We Do about the Healthcare Crisis"

When Tom Daschle, President-elect Barack Obama's designate for Secretary of Health and Human Services, published a book earlier this year titled *Critical: What We Can Do about the Healthcare Crisis*, I saw the favorable reviews and made a mental note to buy and read it. After Obama's announced choice of Daschle for HHS secretary, this became more salient. It is well worth reading carefully, as it provides some important clues to the likely course of health reform under Obama's administration.

Any book on health policy by a Democrat needs at least three key ingredients:

1) A collection of personal-interest horror stories about well-meaning citizens who've been damaged by our health system (a significant editing challenge since there are, legitimately, millions of these stories).

2) A mention of the widely discredited Himmelstein and Woolhandler fictoid about 31% of U.S. health costs being "administration" (see the McKinsey Global Institute's 2007 "Accounting for the Cost of Healthcare in the United States" for a more rigorous analysis).

3) A mention of the World Health Organization (WHO) study which indicates that we rank 37th in the world in "health care" despite spending trillions more than any other country (dispatched efficiently earlier this year by Cato's Glenn Whitman).

You'll find all three obligatory ingredients in Daschle's book. What is surprising and refreshing, however, is his thoughtful analysis of Congress's epic struggle with health reform, particularly the failure to enact it during the Clinton presidency, when Daschle was a senior member of the Senate Democratic majority. Almost 25% of the book is a superb congressional history of health reform going back to 1914. Daschle has done his homework.

Daschle acknowledges that disunity within his own party played a crucial role in sinking health reform under Bill Clinton, who had Democratic majorities in both houses. He also blistered Clinton and his advisers for wasting critical time dissipating public support for reform, as well as for handing down an absurdly complex and bureaucratic bill that provided "a target the size of Philadelphia" for opponents.

If you accept his critique of the Clinton failure as a clue to Daschle's approach, the key elements of Obama's strategy are likely to be: speed, simplicity, and alignment with congressional health policymakers. Thus, we should expect a couple hundred page bill drafted collaboratively with congressional policymakers. Daschle will certainly not voluntarily produce anything remotely resembling the 1,346-page behemoth Health Security Act so many of us used as a doorstop.

Rather than blaming the Executive Branch alone for the failure to accomplish health reform, however, the book pivots around the most breathtakingly candid declaration of collective incapacity I've ever heard from a former member of Congress. Daschle actually says: "Professional expertise and trustworthiness – these are qualities that Congress lacks when it comes to healthcare."

The Federal Health Board: A Proposal Designed To Depoliticize Benefits Decisions

The centerpiece of Daschle's argument is that Congress and the administration should be insulated from the politically unmanageable process of determining health benefits and payment strategy under health reform by a Federal Reserve-like entity called the Federal Health Board.

This Board would be filled with presidential appointees (Senate confirmed) with ten-year terms designed to overlap presidencies. Daschle would ask the Health Board to:

1) create an evidence-based benefit package consistent across federal agencies but also offered by employers;

2) design a Medicare-like public health benefit for those under age 65 to be offered in conjunction with private health plans in a multiple-choice format similar to the Federal Employees Health Benefits (FEHB) program;

3) design and manage an evidence-based coverage policy for drugs and procedures that factors in both health and cost impacts;

4) suggest research priorities for the National Institutes of Health (NIH);

5) analyze federal health data to determine clinical effectiveness;

6) promote transparency of costs and quality in the provider system; and

7) recommend changes that would "rationalize" the nation's health care infrastructure.

The Federal Health Board is designed to insulate Daschle's former colleagues from pressures that many in Congress find both uncomfortable and distasteful: micromanaging health programs for powerful contributors or constituents: "We'll be able to wrest power from Congress and the White House only when political leaders realize they are incapable of making the technical decisions on benefits that are so crucial in any healthcare system."

Daschle's focus on managing the benefit makes him the first major national political figure to acknowledge publicly the crucial connection between the politics of the mandated benefit and the affordability of universal coverage. If you wish to mandate that either employers or individuals purchase health coverage, you must, at some point, declare what services they are to be legally required to purchase. It's not something you can talk candidly about during a political campaign, because the incentive is to pander to every pressure group and not exclude anything or anyone from coverage.

By focusing on "depoliticizing" benefit and coverage decisions, Daschle has targeted the two areas that, if left to nature, would render federal health reform unaffordable. In a fiscal climate as challenging as that facing the next Congress, this is a prescient concern. Technology coverage and payment policy is, if anything, even more contentious and subject to continuous political micromanagement.

Many health policy experts believe that a more research-based approach to coverage and payment might help rein in medical technology spending, a major driver of health cost inflation. Gail Wilensky, Uwe Reinhardt, and others have long advocated creating a Center for Comparative Effectiveness, modeled on the National Institute for Health

and Clinical Excellence (NICE) in England, to bring available scientific evidence to bear on making coverage and payment recommendations for medical technology. Apparently, Daschle's vision is that the Federal Health Board would perform this function.

Daschle's Approach Could Help Pass Health Reform in a Poor Economy

Tactically, adopting Daschle's approach could enable Obama to pass health reform quickly without putting a stake in the ground on the precise cost of his program – a plus in a rapidly deteriorating fiscal climate. With a congressionally defined benefit, CBO scoring and concerns from fiscally conservative Congress people like the Democratic "Blue Dogs" could quickly sink the process.

Under Daschle's approach, the key decisions about precise benefits, as well as the politically dangerous issue of what individuals would have to pay out of pocket for mandated benefits, could be punted to the Federal Health Board, which could take at least eighteen months to get organized and report to Congress on how to structure the benefit. This would conveniently buy Obama time for the economy to recover, time to find funding for needed federal subsidies to small businesses and the unemployed uninsured, as well as time for business to strengthen enough to afford an employer mandate.

Some in the health policy world have criticized the Health Board idea as an attempt to "take the politics out of politics." The appointment process, of course, is inherently political. And the $2.5 trillion health care "industry" could hardly be expected to be indifferent to who was appointed and how the ground rules for technology evaluation and payment policy are set up, let alone what gets covered by any mandated private benefits or public programs.

Further, Medicare and Medicaid remain crucially integrated into the federal fiscal picture, making it inevitable that Congress considers aggregate funding levels as part of its budget reconciliation process. The politics do not disappear under Daschle's proposal; rather, they are held

at arm's length, submerged in a technocratic process and subject to economic tests. It is also the case that the "evidence" behind evidence-based benefit design and technology coverage decisions is both fragmentary and in a state of evolution. Medical technology development is a learning process – one that certainly could be less expensive than it is now without damaging patients. It is challenging, even with the best of intentions, to subject emerging technologies with limited use and cost data to this process; it is the early use and perhaps overuse of the technologies themselves that help define the boundaries of what is appropriate. (See the excellent discussion of the limitations of technology evaluation in the current issue of *Health Affairs* by Steven Pearson and colleagues reviewing the challenge of CT colonography.)

To set the evidence bar too high too early could further damage an already laboring medical technology industry in the U.S. and drive both research and development overseas. Marked increases in funding for evaluation research would be required to catch up and fill the yawning evidence gap. However, pharmaceutical companies and medical technology firms, who are profoundly threatened by an American version of NICE, are going to have their work cut out for themselves in arguing that we shouldn't have a more rigorous process than we have now.

However, the acid test for Daschle will be his ability to sell his idea of restraining Congress's fine hand to his former congressional colleagues. It is difficult to imagine Henry Waxman, who has formidable expertise on health issues and has in the past relished shaping minute elements of federal health policy, surrendering some of the considerable powers of his newly attained Chairmanship of Energy and Commerce to a body of economists and health policy experts. Similarly, it is difficult to imagine Charles Rangel, an embattled but savvy legislative craftsman as Chair of Ways and Means, setting aside some of his committee's considerable power over the federal health benefit.

Whether Waxman and Rangel and their counterparts in the Senate will ultimately find it in their interest to surrender some of their power to shape

private and public health benefits and coverage remains to be seen. Their new executive branch partner in health reform has certainly paid his dues, and he knows what the world looks like from their point of view. It could make a crucial difference in whether, as many of us hope, health reform actually happens this time. ("Daschle: What can we expect of the Health Czar in Waiting?" Jeff Goldsmith, Health Affairs Blog, December 15, 2008, http://healthaffairs.org/blog/2008/12/15/daschle-what-can-we-expect-of-the-health-czar-in-waiting/)

INTERNATIONAL HEALTH CARE

Information on International Healthcare Systems

Tom's Comments:

As we look at various approaches to address healthcare cost, quality and access to care needs in the U.S., we should also be looking at other countries' approaches to these problems. As we have noted in prior issues of the Quarterly, there is no "silver bullet," all countries are facing challenges in addressing healthcare cost, quality and access to care needs. In fact, many countries have evolved to a two-tiered system that provides base line healthcare for all of their citizens, but allows for access to additional services/providers for those that could afford it.

Each issue of the Quarterly focuses on various areas of interest relating to international healthcare. The links below will provide the reader with some additional sources of information on international healthcare systems as well as health statistics from the World Health Organization.

Finally, as one studies other healthcare systems, we should focus specifically on their approaches in developing a primary care system, which is very lacking in the U.S.; their approaches for integrating clinical effectiveness research into their payment systems; and finally their approaches to developing a nationally and community linked integrated electronic medical record (EMR) system. Many countries have had a national EMR system in place for over 10 years.

- Kaiser Family Foundation provides the reader with an interesting website: http://www.kaiseredu.org/topics_im_ihs.asp?imID=1&parentID=61 This website profiles the major features of a country's health coverage, financing and service delivery policies and provides links to articles with more information.

- Another interesting source of information is the World Health Organization's "World Health Statistics – 2008" http://www.who.int/whosis/whostat/EN_WHS08_Full.pdf

STATE HEALTH CARE

Hospital Based Infections

Tom's Comments:

In past issues of the Quarterly (See October/November 2007 issue for a summary of HBI with additional links to other articles: http://www.bw.edu/academics/bus/programs/hcmba/nl/archives/QHCR_Oct-Nov_2007.pdf), we discussed the importance of developing a reporting system at the state level for hospital based infections. Hospital based infections is a complex issue, and there are no simple solutions. What this reporting system does, is to put on the radar screen for all to see, the status of hospitals' efforts in addressing hospital based infections. Hopefully, this reporting will also foster an environment that will allow for more proactive strategies and action plans to address hospital based infections in a sustainable manner.

Hospital Based Infections are becoming more of a concern for the average person. For the first time, I am hearing people articulate concerns relating to infections for relatively routine surgeries. Some of this concern is based on the increased exposure of these issues from the media, but these concerns are legitimate.

Ohio Hospitals will be Required to Report Infection Information to Consumers

Ohio hospitals will be required to report infection information to consumers, despite an attempt by the Ohio Hospital Association to stop it.

The hospital group had tried to push through legislation that would curtail recommendations for public reporting of patient care.

The Hospital Measures Advisory Council created by a 2006 law, recommended hospitals disclose common infections, and whether facilities are vigilant about hand-washing and other practices that reduce infection risk.

Earlier this month, Springboro Republican Rep. Shannon Jones introduced an amendment that would invalidate much of the council's work. The amendment, attached to an unrelated Senate bill, passed in the House Health Committee. But both the House and the Senate struck it this week after the Ohio health director and others complained that it undermined efforts to inform Ohio consumers.

The advisory council spent 13 months on the reporting requirements, which are groundbreaking for Ohio. Hospitals everywhere face growing demand for accountability of their clinical care and infection rates. Under the plan, hospitals will report on a consumer Web site data on surgical wound infections, antibiotic-resistant staph and clostridium difficile (C. diff), a type of intestinal infection that has risen sharply in recent years.

"I am thrilled the work of the Hospital Measures Advisory Council can continue unhampered," Ohio Health Director Dr. Alvin Jackson said in a prepared statement Thursday. The reporting measures "truly provide Ohioans with the information they want and need to make an informed decision on where to receive care," he said.

Reporting is expected to start in 2009 and be available on the Web starting in January 2010, the health department said. It first goes through a health department rule-making process.

A hospital association spokeswoman said the group is looking forward to

working with the health department and advisory panel.

Officials said some minor changes the hospital group sought were maintained in the legislation. But the controversial elements are gone, said state Sen. Kirk Schuring, a Canton Republican and member of the advisory panel.

The attempt to thwart the reporting measures "violated the integrity of the good work of the Hospital Measures Advisory Council," he said.

("Your right to learn infection rates at Ohio hospitals survives bid to stop it in legislature," Harlan Spector, Cleveland Plain Dealer, December 19, 2008, http://www.cleveland.com/medical/index.ssf/2008/12/19/)

NORTHEAST OHIO

New Undergraduate Health Care Management Major/Minor

Baldwin-Wallace College is proud to announce that we have a new undergraduate major/minor in our Business Division. The Healthcare Management Major/Minor was developed in cooperation with the Northeast Ohio healthcare community. A key input source for the curriculum was four focus groups that represented a cross-section of professionals from all areas of the healthcare community (egg. hospitals, long-term care, physician, managed care, pharmaceutical, social service agencies, etc.). The ultimate conclusion by the participants of the focus group was that a major/minor in health care management was of extreme importance to the Northeast Ohio healthcare industry.

The Health Care Management Major promotes an understanding of America's complex and evolving health care system and increases the competencies of students pursuing careers as managers and leaders in that field. Students will analyze perspectives, methods, and values associated with the delivery, management and finance of health services. They will evaluate health data, payments systems, management practices, ethical principles, public policies, promotional strategies and system designs to discover ways to meet the demand for effective, affordable, efficient and responsible health care.

The major promotes organizational insight and managerial ability for those who desire leadership positions in health-related enterprises. **The curriculum is designed to meet the needs of both health care professionals with technical/clinical degrees as well as those of traditional undergraduate students.** The curriculum in total is also geared toward enhancing the students' oral and written presentation skills as well as overall problem solving skills.

To link below will provide you access to a detailed overview of the Health Care Management Major/Minor as well as the related business program requirements.
http://www.bw.edu/academics/bus/ug/hc/

MARK YOUR CALENDAR

If you are interested in possibly enrolling in the Health Care MBA program at Baldwin-Wallace College, contact Barb Peterson at 440-826-2064 or e-mail her at bpeterso@bw.edu
Keep track of upcoming events in the Business Division of Baldwin-Wallace College on our website: http://www.bw.edu/academics/bus/events/

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