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Shifting the Focus From Cost to Value: Key Stakeholder Perspectives

Schumarry H. Chao, MD, MBA

Babette Edgar, PharmD, MBA

Pamela A. Hymel, MD, MPH, FACOEM

Michael B. Nichol, PhD

Dexter W. Shurney, MD, MPH, MBA

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Editor-in-Chief

Frederic R. Curtiss, PhD, RPh, CEBS
(830) 935-4319, fcurtiss@amcp.org

Managing Editor

Tamara C. Faggen, (703) 323-0170
tfaggen@amcp.org

Peer Review Administrator

Jennifer A. Booker, (703) 317-0725
jmcpreview@amcp.org

Graphic Designer

Laura J. Mahoney, (703) 754-3447
lauramahoney@comcast.net

August Supplement Editor

Kent H. Summers, RPh, PhD

Account Manager

Peter Palmer, (800) 486-5454, ext. 13
peter@promedgroup.net

Publisher

Judith A. Cahill, CEBS
Executive Director
Academy of Managed Care Pharmacy

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POSTMASTER: Send address changes to
JMCP, 100 North Pitt St., Suite 400,
Alexandria, VA 22314.

FACULTY

Schumarry H. Chao, MD, MBA, is president, SHC & Associates consulting firm, Santa Monica, California, and a clinical professor of emergency medicine and family medicine, Department of Emergency Medicine, School of Medicine, and an adjunct professor of pharmacoeconomics, Department of Pharmacoeconomics, School of Pharmacy, University of Southern California, Los Angeles. She received her BS and MBA degrees from the University of Southern California and her MD degree from the University of California, San Francisco; she is board-certified in emergency medicine.

Chao has broad experience in all aspects of the health care industry—as insurer and employer and in delivery system management, the pharmaceutical industry, and health care information technology. She has served as chief medical officer and senior vice president, strategic development, for MedImpact Healthcare System, Inc., where she had responsibility for all clinical product development and pharmacy benefits management, and as vice president and corporate medical director for Aetna Life and Casualty Company, where she was the official national spokesperson on health care reform and policies. Chao also developed and implemented innovative health benefit strategies for the University of Southern California and served as corporate medical director for Security Pacific Bank. She has managed a prepaid medical group and had responsibility for the emergency trauma system in Los Angeles County.

Chao's clients in the health care industry include CALPERS, State of Washington Workers' Compensation, Connecticare HMO, Healthcare Partners Medical Group, China Ministry of Health, and a number of pharmaceutical companies. She currently serves on the Board of Trustees of the Foundation for Managed Care Pharmacy and on the Editorial Board of the *American Journal of Medical Quality*. Recently, she has been elected to the Board of Trustees, University of Sciences, Philadelphia. She continues her involvement in health care in China as a board member of the China Center for Health Economics.

Babette S. Edgar, PharmD, MBA, is vice president, strategic development, Gorman Health Group (GHG), LLC, Washington, DC, where she specializes in formulary management, benefit design, utilization management, disease management, and marketing for the Medicare Part D drug benefit and commercial managed care market segments. Prior to joining GHG, she was the director, Division of Finance and Operations, Medicare Drug Benefit Group, Centers for Medicare and Medicaid (CMS), Atlanta, where she directed building and implementing the formulary and benefit design review processes for the Part D drug benefit. She oversaw the CMS Part D team that developed the agency's marketing guidelines and marketing models and conducted oversight of the marketing review process. Edgar also directed CMS operations for reviewing and monitoring the licensure and solvency of Part D plan sponsors, assisted in developing transition guidance for Part D plans with patients migrating from Medicaid or other benefits, and provided input into the Part D regulations and other subregulatory guidance from a managed care pharmacy perspective.

Previous to her term at CMS, Edgar was vice president, clinical business development, at Caremark/AdvancePCS. She previously served as director of clinical services for Advance Paradigm. She received her BSPHarm degree from Rutgers University College of Pharmacy, PharmD degree from Duquesne University, and MBA from the University of Phoenix.

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Pamela A. Hymel, MD, MPH, FACOEM, is corporate director, integrated health, and medical director, Cisco Systems. In her current position, she is designing a global health and productivity program for Cisco employees. Prior to joining Cisco, Hymel was senior vice president of Sedgwick Claims Management Services and completed 16 years of employment with Hughes Electronics, where she last served as vice president of human resources, medical services, and HR systems. She received her BS degree in biology from the University of California at Irvine, MPH degree from Tulane University, and MD degree from Louisiana State University Medical School. She is board-certified in both internal medicine and occupational medicine and is a fellow of the American College of Occupational and Environmental Medicine (ACOEM).

Hymel has been active in ACOEM, she has served as treasurer and is currently on the board of directors. She is cochair of two committees in ACOEM, working in the area of health and productivity. She has spoken extensively on disability management, health management, and productivity and contributed to numerous articles. Hymel's expertise and benchmark programs have been cited in numerous publications on integrated health management.

Michael B. Nichol, PhD, is an associate professor and chair, Department of Pharmaceutical Economics and Policy, University of Southern California, School of Pharmacy. He also holds joint appointments in the Leonard Davis School of Gerontology and the School of Policy, Planning, and Development at USC. Nichol's research focuses on health care compliance, utility measurement, and longitudinal patterns of care.

He has served as consultant to a number of pharmaceutical and managed care organizations. He also has served on the board of directors of national health policy organizations and several southern California research and health service organizations.

Nichol received his BA degree in political science from the University of Tulsa, MS degree in public affairs from the University of Oregon, and PhD in public administration from the University of Southern California. In 1999, he was awarded the QSAD Centurion Chair at the School of Pharmacy.

Dexter W. Shurney, MD, MBA, MPH, is vice president and national business medical director, Healthways, Inc., Nashville, Tennessee. Prior to joining Healthways, he served as a key strategist in health policy in the department of Global Government Affairs for Amgen Inc. He is also the former chief medical officer and vice president of medical affairs for Blue Cross Blue Shield of Michigan.

Shurney serves on the board of the American College of Medical Quality and represents ACMQ as the organization's delegate to the American Medical Association. He is also active in the National Association of Managed Care Physicians and for 8 years served as the editor of the organization's *Journal of Managed Care Physicians*.

Board-certified in both preventive medicine and utilization review and quality assurance, Shurney received his BS degree from Loma Linda University and his MD degree from Howard University. He completed his internship and residency training at Wayne State University/Detroit Medical Center and holds graduate degrees in business from the University of Detroit/Mercy College of Business and in public health from the Medical College of Wisconsin.

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Introduction: Shifting the Focus From Cost to Value

SCHUMARRY H. CHAO, MD, MBA

TARGET AUDIENCE

Managed care pharmacists and other health care practitioners

LEARNING OBJECTIVES

Upon completion of this program, participants should be able to

1. describe the concept of value in health care and indicate the ways in which current health care must be improved before true value is achieved;
2. identify the ways in which various stakeholders in health care view value and the barriers each perceives;
3. indicate metrics that are most appropriate when examining cohorts of health care recipients;
4. list several innovative approaches to medication management, disease-managed, and patient-centered health care delivery that alone or in combination contribute to value; and
5. differentiate between randomized controlled studies, observation studies, and cost-effectiveness analysis in terms of strengths and limitations and describe how these studies can be integrated when preparing a value proposition.

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Managed care's general approach to escalating health care costs began in around 1985. It involved using a concerted cost management strategy of volume purchasing, screening access to utilization, and substituting less expensive services for more expensive services. On the medical side, managed care employed strategies like restricting physician and hospital networks, implementing benefit design, using prior authorization, and requiring patients to consult primary care physicians prior to specialists. These strategies significantly lowered the average premium costs from the late 1980s through the mid-1990s. The decreased trend, unfortunately, was not sustainable.

Over the past 10 years, premiums have increased at rates far exceeding inflation. As managed care is pressured to control costs, efforts have focused on managing pharmacy costs. Management of pharmacy costs followed the same cost management principles with restricting formularies, restricting networks, benefit design, prior authorization, and generic substitution. The focus on pharmacy benefit management further intensified when President Bush signed the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA), expanding coverage for pharmaceuticals for seniors. The MMA sets new parameters and incentives for health plans and pharmacy benefit managers (PBMs) to perform the role of prescription drug plans (PDPs) to manage pharmaceutical costs. While many of the same cost-management tactics will continue to be applied, the one major difference is the delegation of financial risk to PDPs.

As payers continue to be pressured to manage cost trends, experts question whether or not the historical cost-management model is sustainable. While Figure 1's V-shaped curve demonstrates that costs have responded to these management strategies and utilization tactics, costs have rebounded. With the increase of health care cost trends, payers are again developing and considering strategies to manage costs. Although the strategies are not mutually exclusive, payers appear to be focused on 3 primary strategies: cost management, demand management, and value management.

■ Cost Management

Much has been written about using silo management in health care; this is the practice of keeping similar items—funds, budget line items, departments—separate. Health care managers in all settings have often addressed pharmacy and medical costs separately or, in other words, in silos. Contracting out (or carving out) services to providers who specialize in specific services, like pharmacy benefits, has provided leverage to (1) negotiate the best unit price and (2) control access to the most costly goods or services.

This strategy can be tremendously successful, but it has a few problems. Cost management ignores any isolated decision's impact on overall costs, potential outcomes, and future innovation; it may

Author

Schumarry H. Chao, MD, MBA, is president, SHC & Associates, Santa Monica, California, and a clinical professor, Department of Emergency Medicine, School of Medicine, and an adjunct professor, Department of Pharmacoeconomics, School of Pharmacy, University of Southern California, Los Angeles.

AUTHOR CORRESPONDENCE: Schumarry H. Chao, MD, MBA, President, SHC & Associates, 526 Adelaide Dr., Santa Monica, CA 90402.

Tel: (310) 393-1666; Fax: (310) 458-7822; E-mail: schumarryc@verizon.net

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actually increase overall cost, result in poor outcomes, or discourage innovation. In the marketplace, it creates a vicious cycle. For example, some pharmacists and health care providers may prefer to defer formulary decisions until real-world evidence is available as opposed to using available clinical trials data. This limits access. But limiting access removes any chance of acquiring real-world data, and without data, outcomes cannot be measured. Lacking outcomes, research cannot be conducted to demonstrate value, and this cycle goes around and around. Thus, denying access is a problem; barriers to demonstrating real value within the marketplace or in the real world make measuring outcomes difficult.

■ Demand Management

Demand management—e.g., drug policy tools such as prior authorization—in health care follows the basic business school model. Decreasing demand reduces cost. However, this shifts risk to consumers as purchasers. Third-party payers can limit how much they will subsidize a product or service, so the individuals must decide what they want or are able to afford.

Consumerism

The issue of consumers—their thought patterns, preferences, and behaviors—is a subject of intense scrutiny right now. Somehow, health care needs to balance, with education, the consumer's perception of short- and long-term outcomes and their heightened sensitivity to increasing out-of-pocket expenses. Educating consumers about the direct cost benefits of their purchasing decisions is a start. Unfortunately, health care consumers are often not held accountable for their behavior and have poor adherence and compliance behaviors. These behaviors are least favorable in terms of overall cost and outcomes, and third-party payers are ultimately liable. Additionally, people's ability to pay varies widely. Based on my experience on the employer side and analysis of consumer purchasing patterns, consumers are more interested in immediate experience than in long-term benefit. Based on my personal experience as both a care provider and care manager, modifying patient behavior, even with education, is very difficult.

Health care plans' historical tendency to cover almost everything has created a culture of entitlement; today's tendency is for plans to shift and increase copayments to consumers. Historically low copayments have further magnified the impact of this shift for consumers and, consequently, may influence consumer behaviors more than anticipated. According to a study conducted by and published in *Health Care News*¹ examining the relationship of income to levels of nonadherence, significant numbers of Americans at all income levels made decisions that created situations of nonadherence when copayments increased (Figure 2). Their behaviors ranged from failing to fill their prescriptions and taking medicine in smaller doses or less frequently than prescribed. While these behaviors are more prominent among people in the lowest income brackets, they occurred in all income

FIGURE 1 HMO/POS Rates: Percentage Increase Per Employee Premiums

HMO=health maintenance organization; MMA=Medicare Prescription Drug Improvement and Modernization Act; POS=point of service.

Source: CSFB Benefit Manager Survey.

FIGURE 2 Patient Responses

Taylor H, Leitman R. *Health Care News*, 2001.

brackets. With the average income in the United States about \$40,000, and rates of noncompliance related to increasing copayments quite high in that group, this behavior is of significant concern.

Further evidence of how benefit design and out-of-pocket costs influence patient behavior is the level of generic utilization in consumer-directed health plans. Preliminary data from Lumenos, in terms of the consumer-directed health plans, indicates that consumers who enroll in a \$500-deductible health plan will elect to use generic medication 90% of the time.²

■ Value Management: Consumer-Centered Markets and Value

The implications for a consumer-centered market are tremendous. Value starts being defined in terms of the individual, and because each individual may define value differently, some people will value immediate outcomes while others will be concerned with long-term outcomes. A particular concern is access for people with lower incomes when copayments shift. Even the smallest of copayments can be a significant burden for patients with multiple comorbidities who are on limited incomes. The impact on long-term catastrophic cost, overall health, and overall productivity can be astounding.

Creating Value

Health care systems have the potential to create and sustain a value-driven model. Value means moving the focus from cost to cost/benefit. This creates access using the same tools traditionally used in silos but actually managing the access with demonstrated value for the payers and patients.

From a societal perspective, health care, over the past few decades, has made tremendous improvements that reflect value. Hospital days have declined 56%, the death rate has fallen 16%, life expectancy for both men and women is longer, and the rate of disability in terms of lack of function has gone down by 25%.^{3,4} These accomplishments are commendable, but discussions focusing solely on unit price miss value.

From a payer perspective, value translates into a robust return on investment. Work done by Integrated Benefit Institute in San Francisco has identified the sections that contribute to overall health costs. They determined that group health and workers' compensation comprises 19% of the total, and disability adds another 10%. It is the issue of productivity, however, that consumes the largest portion of the health care dollar, and this constitutes the best reason why employers should remain active participants in health care benefit planning and provision.

In addition, based on analysis of Medstat's data,⁵ chronic diseases contribute to significant loss of productivity for employers. Heart disease, diabetes, migraine, and high blood pressure are among the biggest culprits. These are all conditions that may lead to unproductive presenteeism of from 2.2 to 4.3 hours of an 8-hour day. Better management of these diseases can improve the return-on-investment of health care dollars.⁶

Health care, like any other industry, is ultimately accountable to the people who pay for goods and services. Value-based access pertains to plan designs, health plans, employers, and PBMs because ultimately it will create innovation that continually improves health and overall outcomes.

DISCLOSURES

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Shifting the Focus From Cost to Value: An Employer Perspective

PAMELA A. HYMEL, MD, MPH, FACOEM

ABSTRACT

OBJECTIVE: To review ways in which pharmacists can help health plans shift their focus from cost to value.

SUMMARY: Health care delivery is a continuum. Employers have moved along the continuum looking for value; they are now looking for integrated strategies to decrease cost and improve productivity within the workforce. The key to any integrated strategy is innovative service delivery and ground-breaking partnerships with vendors. Key areas that need to be addressed are medical care, pharmacy, behavioral health, disability, prevention, and presenteeism. Additionally, measuring program effectiveness is becoming more important, especially in terms of continuous improvement.

CONCLUSION: Updating data, fine-tuning plan design to improve effectiveness, and abandoning ineffective efforts is critical. The ultimate goal is to modify the target population's risk.

KEYWORDS: Healthy workforce, Integrated health care, Value, Benchmarks, Disability, Prevention

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The World Health Organization (WHO) defines a healthy workforce using 4 adjectives: healthy, productive, ready, resilient. *Healthy* workforces have fewer health risks, and those workers who have medical conditions are actively engaged in managing their conditions. *Productive* workforces are composed of individuals who are fully functional at work and also at home, a point that engages employees by stressing that productivity is not restricted to the workplace. *Ready* workforces are prepared for change, and *resilient* workforces bounce back when change occurs and continue without devastating health or behavioral effects.¹

Fifteen experts under the auspices of The Institute of Medicine published a book concerning integrated employee health.¹ Initially, this team's task was to design an integrated health plan for the National Aeronautics and Space Administration, but they found that their efforts were transparent enough that they might constitute a white paper or a road map for many other employers. NASA, with its highly skilled workforce working in a high-pressure environment, serves as a prototype for many American businesses. The panel identified the prevalent current perspective and visualized what the desired perspective should be.

The current marketplace's perspective is cost metrics: medical cost or pharmacy costs. The experts believed, however, that the marketplace should look at the economic outcomes of health on workforces. Similarly, they suggested that to improve the well-being of an employer's workforce, the current focus on treatment and disease should shift to prevention, behavior change, and health. An integrated system for managing health within a population includes medical, pharmacy, disability, health risks, life-style risk management, disease management, and presenteeism (the effect of health on productivity or the problem of workers being on the job but, because of medical conditions, not fully functioning), and productivity. This approach breaks the established silo mold.¹

Often, employers fixate on price and avoid discussing value issues. Approaching health care from a value perspective is cutting-edge; only one fifth of the employer marketplace, and usually the largest of employers, is moving in this direction.² A transition can only begin if metrics and measurements are available proving the effectiveness of medications on productivity. Pharmacists, when they discuss tiered formularies, should encourage employers to begin measuring productivity in addition to costs and medical outcomes. This will fill the existing gap between today's reality and tomorrow's necessity.

Value-Focused Health Activities

An American College of Occupational and Environmental Medicine (ACOEM) survey looked at value-focused health activities. This study queried 174 decision makers—medical directors and benefit directors who were embedded with employers—about how they focus on plan design issues,

Author

PAMELA A. HYMEL, MD, MPH, FACOEM, is corporate director, integrated health, and global medical director, Cisco Systems, San Jose, California.

AUTHOR CORRESPONDENCE: Pamela A. Hymel, MD, MPH, FACOEM, Corporate Director, Integrated Health, and Global Medical Director, Cisco Systems, 170 West Tasman Dr., Bldg 5/3, San Jose, CA 92886.

Tel: (408) 527-2615; Fax: (408) 527-6080; E-mail: phymel@cisco.com

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purchasing, and value versus price.² The study's intent was to determine how employers consider value when they make policy and benefit design decisions and the extent to which the concept of value had permeated the employer marketplace. This information could be used to drive the marketplace to look at value. Areas covered by the inquiry included disability, medical care, and pharmacy.

For pharmacy, the objective was to identify external influences on pharmacy benefits (Figure 1). The finding: employers look to benefits consultants and industry benchmarks to design their pharmacy programs. Employers had some interest in innovative benchmarks, so partnering with benefits consultants can help design innovative solutions. The decision makers did not generally consider pharmacy benefit managers (PBMs) to have a significant influence on pharmacy benefit design, however. This indicates that PBMs should be searching for ways to strengthen expertise in this area so they can provide valued consulting to their clients.

The question, "What do you feel your senior managers perceive as most important when you look at your health benefit design?" was revealing. The most frequent answer (85% of respondents rated this issue as moderately or highly important) was "managing health care costs." More telling, "managing productivity" followed this answer in frequency. This implies that senior managers may be beginning to understand that health status affects productivity and good health is worthy of investment.²

Among those surveyed, the most common value-focused activities (VFAs) were providing influenza vaccination, in-house clinics, and "Centers of Excellence" (hospitals that achieve the highest scores for cost-efficiency and cost-effectiveness in treating selected procedures/conditions, based on publicly available patient data). Other common VFAs were wellness programs, incentives for health-related activities, and rewards for perfect attendance. Least common were choosing a health plan to reduce absenteeism and improve productivity and waving medication copayments for good outcomes. (In the 2 years since this study was published, more employers seemed to be eliminating copayments for employees with chronic disease who demonstrate that they comply with taking medication and follow up on testing in order to improve outcomes.) Choosing a health plan for its flexible hours and allowing employees to cash out unused sick leave were also uncommon. The most common VFAs dealing with drug benefits were changing tiers to encourage medication adherence and placing certain medications on the formulary because of their safety profile.²

There was some evidence that companies are planning to implement different activities in the future than those they most commonly performed. Decision makers most often were planning to add or considering adding incentives for health risk appraisals

FIGURE 1 Survey of Medical and Benefits Directors: External Influences on Pharmacy Benefits

PBM = pharmacy benefit management. Lynch WD et al. *J Occup Environ Med*, 2004.

(25%), implementing a wellness program (24%), reducing premiums for health-promotion participants (21%), and choosing a more expensive disease management program because of demonstrated absence and productivity outcomes (21%).² Since evidence that demonstrates what improves productivity is scarce, health care needs innovative partnerships to address future needs and direction.

Creating Successful Businesses

Managing health care costs within a corporation is a component of business success. Employee-centric data is the key. Managers must scrutinize employee metrics and measure the program's effectiveness across what were traditional silos within a corporation. The ability to gather pharmacy, medical, and short- and long-term disability data must be enhanced with data covering work performance (including examining performance evaluations in addition to productivity). This quantifies value and represents integration. Ideally, examining employee-centric data can lead to several actions on the employer's part:

- They may find a net value for their ideal health investment.
- They are likely to understand "total cost."
- They will focus on truly integrated solutions.
- They will be able to define business outcomes.
- They might set best-practice benchmarks.
- Ultimately, they can set realistic and achievable performance objectives.

Thus, value has many different components that contribute to total cost.

Case in Point: WorkWell

Hughes Electronics Corporation established a program in 1995

TABLE 1 Outcome of Hughes' WorkWell Program—Good Returns: Good Results

Cardiac and Back Conditions	Percentage Change 1998-2000	
	Participants	Nonparticipants
Cardiovascular conditions	↓ 12%	↑ 23%
Cardiac treatment per 1,000	↓ 21%	↑ 11%
Rate of back conditions	↓ 8%	↑ 17%
Back treatments per 1,000	↓ 2%	↑ 41%

Use of Health Care for Conditions Not Improved by Health Care (e.g., Viral Colds)	Percentage Change 1999-2000	
	Participants	Nonparticipants
Program participants using care for conditions not improved by medical care	↓ 15%	↑ 29%
Number of such treatments per 1,000	↓ 18%	↑ 19%

and monitored its effectiveness for approximately 10 years. It built on a workers' compensation program and then added an integrated disability management program. When Hughes began to correlate improving employee health and falling disability costs and overall health care costs, it developed a program called WorkWell. The Hughes Medical Plan offered a health risk appraisal with biometrics. Eligible employees were participants in Hughes' preferred provider organization medical plan, and approximately 65% of their population participated. The early Hughes program attracted participants with a gift certificate, discounted participants' annual health care premiums by \$200, and allowed \$250 for preventive health care services with first-dollar coverage.

To receive the incentive, employees had to be low risk or participate in a risk-reduction program if they were high risk. This message encouraged employees to take control and put health odds in their favor. Focusing primarily on medical expenses in the first 3 years of the program, Hughes reduced overall medical plan costs by about \$374 per eligible employee. For WorkWell participants with target conditions, the savings were greater. When Hughes expanded its focus to examine disability after 3 years, the return on investment was 3.8:1. This metric—measuring program effectiveness across health, with a \$144 per employee per year savings, and disability, showing a \$68 per employee per year reduction—reflects program effectiveness.

Employee Engagement

Communicating this program's effectiveness to employees was necessary. Since Hughes did not want to give employees the

impression that company expenditures were the sole concern, they used "Improving your health and your wealth" as a metaphor. The objective was to demonstrate how better health improved participants' medical conditions and decreased their premiums. Because Hughes passed on lower disability premiums to employees, and health care cost increases were mitigated over time, Hughes' employees benefited financially. Hughes was able to demonstrate that program participants had fewer deleterious health conditions and better health (Table 1). In particular, they were able to tell employees that program participation led to fewer cardiac conditions and improved back health, both significant concerns for their workers.

Consumer education was also a focus, and it helped employees become more prudent health care consumers. Employees were taught to distinguish between conditions requiring primary care, emergency care, or self care. Using claims experience, Hughes found that WorkWell program participants responded positively to outreach communication and education. They had lower numbers of visits to emergency departments and were less likely to use primary care for conditions that were appropriate for self care.

Beginning in 1998, the program included a disease management (DM) program, and Hughes also measured its impact. Its DM program focused on major cardiovascular conditions, diabetes, asthma, back pain. The Hughes population was older than the general population (average age 45 years compared with an average U.S. age of approximately 40 years) and predominantly male, so it had greater health risks. Almost 12% of WorkWell members participated in at least 1 program and over 3 years, and medical costs for participants decreased by 21%. Although total pharmacy costs for the 4 DM programs increased and the per-member-per-month (PMPM) pharmacy cost almost tripled, the overall result was noteworthy. Over 3 years, overall PMPM cost declined 15%, inclusive of pharmacy costs. Appropriate use of pharmaceuticals improved overall cost and condition management.

The Boise Experience

Presenteeism in the workplace within the population was also monitored. Hughes examined work quality, work quantity (capacity or output), and added the increasingly important element, personal factors (mental, physical, social, emotional, functional status).

At Hughes's large call center employing 1,500 in Boise, Idaho, health care costs were considerably greater than at their other sites. Disability expense for Boise-based employees was 5 times greater, prompting closer examination of that particular population's health. A health risk assessment found that their risk factors were approximately 3 times that of the rest of the employee population. They had higher rates of diabetes, cardiovascular disease, hypertension, and hyperlipidemia. Boise-based employees were also more likely to smoke. The fact that the average age of Boise employees was much younger than the rest of the Hughes population reinforced the idea that this group had a collective

poor health risk. This group, due to their relative youth, was ripe for intervention.

In Boise, Hughes administered the Health and Performance Questionnaire (HPQ), a brief self-reported instrument designed to assess the impact of health on 4 aspects of work functioning: time missed from work, performance while at work, injuries or illnesses at work, and job turnover.³ Absences related to allergies, obesity, depression, and pain disorders were common. Claims data and health risk assessment fail to collect this data, but the HPQ did; it helped Hughes create a focused program to eliminate drivers of absenteeism and lost productivity. They recognized that no one area drives health costs. In the first year, Hughes had a 7% savings on short-term disability costs and a small reduction in health care trend. More data will need to be collected as the program matures.

WorkWell's message is that a variety of measurement tools, including presenteeism questionnaires and health risk assessments, are necessary to identify health risks and the opportunities for modifiable conditions.

Cisco Systems

Cisco Systems employs about 48,000 employees globally; most of them are shareholders in this company that generated revenue of \$24.8 billion in 2005. The workforce is approximately equally divided among engineers, sales staff, and administrative employees, making it a white-collar workforce. It is also a young workforce—the average age is 39 years. It has a very low turnover rate for the high-tech sector—the average employee has 5 years of service. Cisco's chief executive officer values employee retention, so the company is planning as though current employees will stay until retirement. Their current health risks are known, and medical costs are low. Cisco's hope is to engage employees to mitigate health risks over time.

To accomplish this, Cisco assembled an integrated health strategy that has 4 components. To establish a baseline for risk factors in all areas, Cisco is using its 2005 metrics. As programs are implemented and time passes, the baseline will be used for comparison. Prevention programs are understandably a priority. A tailored architecture called HealthConnections is being used to integrate all health programs in the company under 1 umbrella. Communications that engage employees are also priorities to broadcast and promote the consumer-driven health plans being planned and developed. Cisco is crafting easy-to-use Web-based tools for its employees and partnering with companies that can help employees look at quality and value among its many health care options. Because Cisco Systems specializes in the seamless integration of data, voice, and video, connecting employees electronically with their health plans and physicians is also a key element of the strategy.

FIGURE 2 Transforming to a Culture of Health

HRA=health risk assessment. Towers Perrin, 2005.

This strategy will transform the company into a culture of good health (Figure 2). Because of his interest in the health care marketplace, Cisco Systems' CEO, John Chambers, has embraced this concept. With about one third of Cisco's employees located outside the United States, innovative solutions that can be applied across an international spectrum are necessary. In 2006, Cisco hopes to establish the program in the United States. After that, expansion will follow.

Baseline numbers were determined using a health risk assessment (HRA) created by WebMD, with the HPQ embedded in it to assess presenteeism. Approximately 40% of Cisco employees took the HRA in 2005, and the expectation is that a larger proportion of employees will take it in 2006. The baseline assessment determined that about 70% of Cisco employees have 2 or fewer health risks, and only 2.6% of employees have 5 or more risk factors.

Cisco's challenge is 2-fold: (1) help employees who are in the low-risk area remain low risk as they age, and (2) help the 30% of employees who are in the moderate-to-high-risk area lower their risk. High-risk individuals are substantially more expensive (incurring health costs of approximately \$12,000 annually at age 39 years) than low-risk individuals (who incur costs slightly greater than \$1,000 annually). Changing risk levels requires behavior modification and disease management. If Cisco's program simply maintains all employees at their current risk level, they will save considerable sums on health, disability, and sick leave in the future.

The information from the HPQ is still being tabulated to gather presenteeism data for Cisco, a step that is important for the business case. To build the Health Connections program, Cisco gathered all of its health partners—25 different companies and their representatives—to discuss the collaboration necessary to improve the health of all Cisco employees. PBMs and a number of pharmaceutical firms that have been helpful in sponsoring

programs within the company were included. The goal: leveraging everything offered from all health partners to create the best benefit design and employee program going forward.

A major priority is establishing a behavioral health carve-in to measure outcomes. Each of Cisco's health plans has a PBM. Cisco would like to determine if having primary care physicians, behavioral health specialists, and pharmacists work together ensures that employees who access behavioral health or chronic DM programs are referred appropriately and are adherent with medications. The continuum should often include appropriate medication and counseling, as in the case of comorbid chronic disease and depression.

Cisco is also involved in several connected health programs. The Silicon Valley Health Information Technology Program rewards physicians for adopting health information technology. This pay-for-performance program is examining E-prescribing, electronic health records, and physician/patient messaging. This is a partnership venture with Intel and Oracle, and it involves 10 medical groups in the Silicon Valley area. Each employer has contributed additional funds as incentives for medical groups to adopt this technology. It is Cisco's belief that employees will have better physician access, and they expect that medication adherence will improve and medication error decline. Record keeping should be more comprehensive and accurate, leading to better outcomes.

In the summer of 2006, Cisco plans to begin a pilot program that will reimburse physicians in 1 geographic region for electronic office visits to promote employee access. This should stimulate adoption of secure technology and advance secure and structured physician/patient messaging and electronic prescribing. Employees will probably have fewer absences and enjoy more timely information exchange with their physicians.

Conclusion

Enhancing program integration with employee education will promote employee engagement. Groups targeted for interventions will be more likely to become involved in appropriate programs. Establishing baseline metrics will allow employers to see what programs work and allow for recrafting of programs that are not achieving results. Constant reassessment, looking for opportunities to improve, will be essential, as will working with external partners and innovative designs. This integrated effort will ultimately improve the health of the population over time.

DISCLOSURES

This article is based on the proceedings of a symposium held on April 5, 2006, at the Academy of Managed Care Pharmacy's 18th Annual Meeting and Showcase in Seattle, Washington, which was supported by an educational grant from sanofi-aventis and sponsored by the Benefit Design Institute. The author received an honorarium from sanofi-aventis for participation in the symposium. She reports no affiliations with or financial interest in any commercial organization that poses a conflict of interest with the presentation on which this article is based.

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Shifting the Focus From Cost to Value: A Government Perspective

BABETTE S. EDGAR, PharmD, MBA

ABSTRACT

OBJECTIVE: To examine the federal government's current health care initiatives in the Centers for Medicare and Medicaid Services (CMS) to improve quality of care and cost-effectiveness around the prescription drug benefit.

SUMMARY: The government has a unique perspective on quality and outcome. Pharmacists need a working knowledge of 3 areas: (1) Medicare Part D, (2) medication therapy management efforts, and (3) demonstration projects. All of these will make demands on health care providers but should result in better outcomes data and patient care. All of these areas also have value components, and all have strategic implications as 2006 moves into 2007.

CONCLUSION: CMS does not consider managing cost and providing value to be mutually exclusive and is attempting to move America's health care toward a value-based program.

KEYWORDS: Healthy workforce, Integrated health care, Value, Benchmarks, Disability, Prevention

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The government has a unique perspective on quality and outcome. Some issues are particularly controversial and labor-intensive for stakeholders in the health care environment, such as Medicare Part D, demonstration programs conducted by the Centers for Medicare and Medicaid Services (CMS) that examine the outcomes and values equation, and medication therapy management (MTM) programs. All of these have value components, and all have strategic implications as 2006 moves into 2007.

Medicare Part D

Medicare Part D has been a development and implementation challenge to health care providers, including pharmacists, physicians, health plans, long-term care institutions, and home health care providers. Congress designed a challenging benefit with many moving pieces. Developers of Part D plans have designed creative benefits, taking into account government rules and regulations while making sure that the benefits were cost effective and provided overall quality of care for beneficiaries. Organizations offering Part D plans have had to go through a multistep process to get their plans approved by CMS. These steps include filling out a complicated application, submitting formularies that are regulated by CMS guidelines, and submitting bids (how much the beneficiary, plans, and government are willing to pay for the benefit) for approval. Plans can charge the same amount for all drugs; can charge different amounts for drugs based on whether they are generic, brand, or a preferred brand for that plan; or can charge a percentage of the cost of the drug. Beneficiaries who have limited income or who also qualify for Medicaid (dual-eligibles) can be charged less than beneficiaries who have more robust incomes.

Health care plans have found the workload created by Medicare Part D to be somewhat taxing, and because this is the program's first year, they (like the federal government) have had to learn quickly and make adjustments when and where necessary. The need to plan for 2007 while dealing with requirements for 2006 has complicated things further. Current concerns include the following:

1. deciding whether dual-eligibles will need to be moved to new plans again in 2007 if their current plans' bids are not low enough,
2. reconciling Medicare payments for plans and pharmacies,
3. transitioning patients' medications covered in old plans to Part D plans, and
4. handling last-minute enrollments that could overwhelm current plan systems.

Existing plans prepared for the next wave of enrollment, which was locked in on May 15, 2006. This lock-in is statutory, and beneficiaries may only change plans after this date for the remainder of the calendar year if they are dual-eligibles (who can change

Author

BABETTE S. EDGAR, PharmD, MBA, is vice president, strategic development, Gorman Health Group, LLC, Washington, DC

AUTHOR CORRESPONDENCE: Babette S. Edgar, PharmD, MBA, Vice President, Strategic Development, Gorman Health Group, LLC, 2176 Wisconsin Ave., NW, Washington, DC 20007. Tel: (202) 364-8283, (410) 560-9952; Fax: (202) 244-8324; E-mail: bedgar@gormanhealthgroup.com

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monthly) or have a status change, such as diagnosis of a chronic disease. Also, in mid-2006, some employers who are on mid-year benefit cycles may end up “dumping” their retirees into Part D (dropping current retirees into the government entitlement for an economic advantage to the parent company); this will create additional opportunities and challenges for Part D plans.

For health care providers attempting to implement Medicare Part D, operational issues abound. Numerous agents and brokers are operating, and CMS is starting to intensify its crackdown on unwanted marketing practices in terms of compliance. This could lead to sanctions on the Part D plans. Examples of these practices include the selling of plans door-to-door by agents or the setting up of sales tables for plans too close to areas of clinical practice. In addition, pharmacies are not allowed to steer beneficiaries to a plan based on financial gain for the pharmacy. Pharmacists can make recommendations based on specific patient data, such as the patient's medication profile and match the patients to plans with formularies that offer their medications. CMS has provided a detailed document that outlines which marketing practices are acceptable and which are not.

Plans are also dealing with pharmacy benefit management (PBM) oversight from a subcontractor's perspective. For Medicare Advantage (MA) organizations, formerly known as Medicare+Choice organizations, mastering risk adjustment before 2007 will be a challenge as risk corridors (limits to the profits or losses plans incur if their basic Medicare drug benefit costs are lower or higher than they had estimated based on beneficiaries' disease states) are shrinking. Medicare will begin to reimburse plans more for sicker patients and less for healthy patients.

If plan developers still want to include 3 plans per organization per region, which may position the plans better in the marketplace, they will need to alter their benefit design. Last year, organizations were allowed 3 plans per region, and that number will be reduced to 2 in the coming year, unless plans choose to submit 1 plan with some drug coverage in the coverage gap (or donut hole, resulting from requirements in the Medicare benefit law that cause a gap: Medicare pays 75% of initial drug costs up to \$2,250 after a \$250 deductible for most seniors but then pays nothing until total drug expenses reach \$5,100, after which the government pays 95% of all costs). Most plans that offer some coverage in the gap are doing so for generic drugs at the generic drug copayment rate. Plan developers will seriously need to rethink their marketing and product strategies for this year given the changes in the marketplace.

Demonstration Projects

CMS is coordinating several demonstration projects related to outcomes. These data will be made publicly available to help the plan developers and other stakeholders deal with the most crucial health care issues facing the nation.

For most stakeholders, the Section 641 demonstration is most familiar. Known as the Medicare Replacement Drug Demon-

stration, this initiative paid for certain drugs and biologics self-administered by the patient at home, replacing the traditional approach that covered Medicare Part B drugs only when given in a doctor's office. In addition, newer, more effective medications for rheumatoid arthritis, multiple sclerosis, pulmonary hypertension, and a variety of cancers were also covered. Specific drugs were selected based on criteria developed by physicians and other experts who consulted with CMS.

CMS enrolled 3,200 participants and examined the following patient outcomes: patient perception of benefits, costs of self-administration versus office visits, number of physician visits, administration costs, and emergency department visits. While pharmaceutical companies and others expected that all of the demonstration project drugs would be required to be on the Medicare plan formularies this year, this did not occur. The project is now complete and the outcomes data are being tabulated. The data should be available later this year.

The Section 646 demonstration project tests major system changes to improve quality of care while increasing efficiency across the whole system. It looks primarily at physician compliance with treatment guidelines but also examines variations in utilization and outcomes measurement and research, shared decision making between providers and patients, and culturally and ethnically sensitive health care delivery. CMS intends to use this demonstration to identify, develop, test, and disseminate major, multifaceted improvements to the entire health care system.

CMS's 1-year 2006 Oncology Demonstration Program is also under way. Program developers are looking at specific outcomes: controlling pain, minimizing nausea and vomiting, and reducing fatigue. These 3 areas are significant concerns for patients who undergo chemotherapy. To facilitate the project, CMS has established new G-codes (temporary national codes for items or services requiring uniform national coding between one year's update and the next) for physicians, enabling a \$130 payment in addition to the encounter fee to physicians when they report the data.

CMS is sponsoring numerous other projects, but 2 are of great interest to pharmacists. The CMS E-prescribing demonstration will test initial electronic medication prescribing standards with health care practitioners, Medicare Prescription Drug Plan (PDP) and Medicare Advantage Prescription Drug Plan (MA-PDP) sponsors, and pharmacies. Medicare plans must have established programs using these standards (which will be released in 2008) in 2009 if they plan to participate in E-prescribing. To be prepared for this, stakeholders (e.g., plans, pharmacies) will need to start thinking about this now.

CMS's reinsurance project looks at new methods of providing reinsurance and offers payments that remove disincentives for private-sector plans to offer additional prescription drug benefits to their enrollees. This should demonstrate the effect of filling the gap in coverage by reimbursing participating plans. The capitated payment is equivalent to the amount plans would otherwise

receive from the government in the form of specific reinsurance when an individual plan enrollee reaches the catastrophic attachment point (\$3,600 of out-of-pocket costs).

Medication Therapy Management

CMS has defined an MTM program as one that helps ensure that drugs are used to “optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events, including adverse drug reactions,” in certain high-risk patients. MTM is a clinical quality and utilization program related to drugs and their outcomes that can be furnished through multiple different distribution mechanisms, such as direct pharmacist contact or mailings to targeted beneficiaries. Plans must offer MTM to all beneficiaries who meet their inclusion criteria although beneficiaries can decline the offer. MTM costs are included in the administration costs of bids. CMS intentionally left the criteria for eligibility (see Table 1) vague to encourage innovative programs. Although there are no criteria requiring programs to have measurable outcomes at this point, plans will need to have the ability to measure their outcomes. It is anticipated that measurable outcomes will be required at some point by CMS, and these are necessary to administer a successful program.

CMS has very specific reporting requirements for MTM programs: the number of beneficiaries in the program who met the criteria for the MTM program, the number of beneficiaries who participated in the program, the number of beneficiaries who dropped out of the program, the number of beneficiaries who declined the offer to participate, and total prescription costs. Quality measures are not included in 2006 but will probably be added in 2007.

Plans have implemented various MTM programs, including mandatory generic programs, prior authorization, step therapy, quantity limits, drug utilization review, polypharmacy and disease-specific clinics, brown bagging, adherence/compliance programs, programs similar to the Asheville project (in which pharmacists run in-depth clinical patient consultations), and case management/call center programs. Program complexity ranges from the simple, like utilization management strategies, to the complex, like one-on-one patient and pharmacist interaction. Generally, however, the stronger the direct patient interaction the more expensive the program, and since these interventions are charged to administration costs, funds are usually limited.

Outcomes analyses will require data integration, and CMS Parts A, B, and D data are not going to be integrated until early 2007. So integrated outcomes data will probably not be available from CMS until at least mid-2007, and it is still uncertain how and if CMS will present the results. Plans may be able to do this on their own if they have the sophisticated systems or contractors to do so. Reporting requirements are the focus of 2006 and include the areas of grievances, financial data, exceptions and appeals, overpayment and reversals, generic dispensing rates, call center measures, and disenrollment numbers. Benchmarking and trend

TABLE 1 Required Criteria for Eligibility in an MTM Program

A beneficiary must meet ALL 3 criteria to be eligible for a plan's MTM program:

1. A beneficiary must have multiple chronic diseases
2. A beneficiary must have filled multiple covered Part D drugs
3. A beneficiary must be likely to incur annual costs of at least \$4,000 for all covered Part D drugs

The program must have measurable outcomes and the plan must have the ability to measure them!

MTM = medication therapy management.

analysis will be focus areas for 2007. Although CMS has not released details, some of these areas may be subject to pay-for-performance measures (particularly related to generic dispensing rates) and call center measures.

Benefit Structure: Outcomes

MA plans with MA-PDPs are probably best able to perform outcomes studies. They control both the medical data and pharmacy data, although some plans may not be capable of integrating all data. Often, their PBM companies have the capability to do this for them. The concept of budget siloing—where the pharmacy director and medical director are responsible for their costs in isolation—is a barrier to effective and overall disease and patient management. Disease management (DM) theory suggests that increasing drug costs sometimes decreases medical costs. MA, MA-PDP, and special-needs plans (SNPs; specialized management plans that limit Part D enrollment to dual-eligibles, institutionalized individuals, and those with specific chronic health conditions) are in the best position to implement DM and improve outcomes. In the case of stand-alone PDPs, where the beneficiary can be enrolled in a private fee-for-service (FFS) plan, the incentive is to keep drug costs low. There is little incentive to collaborate with the FFS plan and do perhaps what is best for the patient in terms of improving outcomes and lowering overall health care costs.

This suggests that MTM programs need to be integrated with DM programs and other care management programs to provide the best patient outcomes. If MTM manages medication therapy and DM manages disease, the only thing not being managed is the patient as a whole. A patient-centric approach integrates the DM program with MTM. This approach enhances patient care and is likely to be cost effective. In the Medicare population, it is critical to address polypharmacy, multiple doctors, and coordination-of-care issues. In the current commercial population, care management is difficult because patients do not stay in one plan long enough to measure health outcomes. Dual-eligibles also create an additional problem since Medicare allows them to switch plans every month, making DM and MTM very difficult.

Formularies

The formulary process for Medicare beneficiaries is predicated on 2 basic principles of the statute. It requires that formularies provide broad access to all patients and that they are nondiscriminatory. The Medicare Part D formularies were to mimic best-practice commercial formularies for the Medicare population while maintaining the principles of the statute.

Medicare Part D formularies differ from traditional commercial managed care formularies considerably. They include injectables and vaccines, have dosage forms required by a broad variety of populations (e.g., nursing home residents), and must contain drugs included in certain clinical best-practice guidelines. In addition, there are drugs that can sometimes be covered under Part B and sometimes covered under Part D (depending upon the circumstances); this can also increase administration costs.

In 2007, some trends can be expected. Theoretically, plan administrators know what to expect from a formulary review, as well as how many and what their bids are going to look like. Based on this, it is expected that fewer formularies and benefit designs may be available. Also, the number of SNPs is expected to increase, as will the specialized formularies that accompany them. Hypothetically, managing a particular population, such as diabetics, should lead to better outcomes because the focus is on a particular type of care and the specialized needs of this patient population. Formularies for these specific populations may be unique, containing a broader array of agents for the specific condition or population. Plans will start to move away from the United States Pharmacopeia categories and class system and toward their own categorization systems in order to allow for enhanced manufacturer contracting strategies.

Part D: PBM Issues

For several years, plans and employers have asked for greater transparency from PBMs. Part D is accelerating the rebate transparency issues for plans and CMS because of its reporting and Web requirements. The CMS Web site now allows anyone to see drug pricing, and astute observers will be able to estimate plan rebates. Part D plans also have significant reporting requirements to CMS. Part D reporting requirements include the following:

- For each rebate, provide the contracting manufacturer's name.
- For each rebate, provide the brand name.
- For each unique manufacturer/brand-name combination, provide the rebate amount received in the reporting period specified.
- For each unique manufacturer/brand-name combination, provide the rebate amount requested but yet unpaid for the reporting period specified.
- For each unique manufacturer/brand-name combination, provide the rebate amount received that is associated with a prior reporting period.

From a contracting standpoint, pharmaceutical manufacturers may decide to promote access-based contracts as opposed to

market-share-based contracts; the reasoning is that, from the standpoint of market share, a plan would have had to list the highest potential cost of the drug on the Web site. By doing so, plans may not look quite as competitive as those plans having access rebates.

Strategic Considerations for 2007

Plans used various strategies to be successful in the Medicare Part D marketplace. For example, some plans this year decided to operate at cost or at a loss to create low premiums and attract beneficiary market share. This strategy also capitalized on the way that plans were displayed on the Web site, with lowest premium programs listed first. This could be a strategy again in 2007, but many plans will have to increase premiums to avoid going out of business in 2008.

Sponsors now face the end of aggregate reinsurance, so the loss of higher payments will dictate decreasing costs to maintain profit margins. This will increase the importance of control mechanisms, like step therapy, prior authorization, quantity limits, and strict formularies.

With SNP plans expected to blossom, plans will attempt to achieve total risk adjustment and increase enrollment. Again, dual-eligibles have no lock-out period—they can change plans anytime. In addition, Medicaid reforms will also move A/B/D populations to mandatory managed care plans, and managed long-term care will probably become popular.

In 2006, about 9% of employers moved their retirees into Part D. A little enrollment bump is expected in Part D midyear as a few more employers follow suit. As time goes on, more employer groups are expected to transfer retirees into Part D, with unions, nonprofits, and the public-sector employers probably leading the way because of lack of tax benefits. This is likely to occur because many employers are analyzing their retiree benefits and concluding that they are no longer financially able to support retiree drug coverage even with the employer subsidy of 28%.

Conclusion

Successful Medicare drug programs demand a dedicated staff and a supportive infrastructure. Medicare must be an organizational priority for them since reporting and compliance requirements are onerous. Individual and group sale strategies will be needed, as will aggressive revenue and reconciliation recovery strategies. Most important from an outcomes perspective are aggressive member retention programs; it is less expensive to keep a member than it is to lose one and have to recruit another.

Partnership between manufacturers, health plans, PBMs, grassroots organizations, and patient advocacy organizations is needed to develop a consensus about the meaning of value and to establish outcomes programs.

CMS does not consider managing cost and providing value to be mutually exclusive. Medicare Part D is moving America's health care toward a value-based program. CMS mandates certain

activities, and plans will have to collect outcomes data and report on quality indicators. This should lead to improvements in the quality of data that document outcomes and quality. In the end, patients will benefit.

DISCLOSURES

This article is based on the proceedings of a symposium held on April 5, 2006, at the Academy of Managed Care Pharmacy's 18th Annual Meeting and Showcase in Seattle, Washington, which was supported by an educational grant from sanofi-aventis and sponsored by the Benefit Design Institute. The author received an honorarium from sanofi-aventis for participation in the symposium. She reports no affiliations with or financial interest in any commercial organization that poses a conflict of interest with the presentation on which this article is based.

Shifting the Focus From Cost to Value: A Private Payer Perspective

DEXTER W. SHURNEY, MD, MPH, MBA

ABSTRACT

OBJECTIVE: To present the issues, concerns, and advances possible as private (commercial) payers attempt to incorporate value into their health care plans, using a commercial provider of disease and medication management as a model.

SUMMARY: Most approaches to health care have dealt with persistent or chronic diseases, but, increasingly, payers are expanding their interests to include wellness, high-risk case management, and care management. Technology is crucial in health care today, enabling clinicians to reach out to patients, capture data, and integrate medical and pharmaceutical data. Data integration will help build efficiencies and effective ways to deal with the growing population of patients who have chronic disease. The disease-centric model is being replaced with a patient-centric model. Health care providers must help patients identify their unique motivators and demotivators and encourage them to be self-sufficient partners in their own health care.

CONCLUSION: Adding value to traditional health care is a task that seems daunting at first. It is not insurmountable, however, and ultimately, adding value decreases cost in unprecedented ways.

KEYWORDS: Data integration, Wellness, Prevention, Patient-centered care, Case management

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How do payers and our customers really view value? This discussion addresses value from a different perspective, that of a provider of care management services with a commercial perspective. It attempts to predict what the future holds and describe disease management's DM's value and opportunities, using a large DM and care enhancement company's experience as a case study.

Healthways was established 25 years ago. Initially, it began as Diabetes Treatment Centers of America, and after establishing proficiency in diabetes, Healthways expanded into other disease states. It remains the largest full-service disease management company in the United States, covering 50 million lives and engaging 2 million active participants. Working primarily with health plans, Healthways provides services to about 600 administrative-services-only (ASO) clients. Recently, Healthways expanded into the international arena. The company welcomes external review, collaborates extensively with third parties, is working with the Centers for Medicare & Medicaid Services (CMS) on a chronic care pilot, and emphasizes evidence-based practice.

Figure 1 describes the care spectrum. Most of the Healthways work has been concentrated toward the right-hand side of the spectrum—in the persistent or chronic diseases and DM space—but, increasingly, the company has expanded into wellness and high-risk case management/care management. Integration has already begun and will continue to evolve to build efficiencies and effective ways to deal with the growing population of patients who have chronic disease.

Technology is crucial in health care today, enabling clinicians to reach out to patients, capture data, and integrate medical and pharmaceutical data. The Healthways system captures and tracks information such as National Drug Codes (NDCs) and medical claims data. Extensive real-time information from patients is also collected. Certain patients, who have heart failure, for example, are provided with scales and blood pressure monitoring equipment that are connected to the system. Daily weights and blood pressures are transmitted electronically to clinicians, allowing immediate treatment adjustments or interventions. This comprehensive data collection system also facilitates reporting.

The search for value in health care is accelerating and will continue. Its dimensions are expanding; DM has subtly evolved into care management because patients seldom present with a single disease. The disease-centric model is being replaced with a patient-centric model, so patients who enter a diabetes program will also receive coordinated care for their comorbidities such as heart failure or depression.

Value: A Total Cost Model

The first step is to determine cost trend over time. This starts with identifying the populations' baseline cost and then tracking it over time and comparing it with the cost-trend experience found in health plans' non-DM population. The trend as experienced by the

Author

DEXTER W. SHURNEY, MD, MPH, MBA, is vice president and national business medical director, Healthways, Inc., Nashville, Tennessee.

AUTHOR CORRESPONDENCE: Dexter W. Shurney MD, MPH, MBA, Vice President and National Business Medical Director, Healthways, Inc., 3841 Green Hills Village Dr., Suite 300, Nashville, TN 37215. Tel: (615) 565-5932; Fax: (313) 600-7159; E-mail: Dexter.Shurney@healthways.com

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health plans' non-DM population, whether up or down, will be used as a proxy for the trend the DM population would have experienced absent the DM program. This adjusts for any substantive benefit changes or major cost-control measures the health plan may have instituted during the same period.

Another aspect of total cost is examining all line items that contribute to total cost and making a determination of where the savings actually occurred. Common line items include inpatient stays, outpatient services, physician office visits, pharmacy charges, emergency department visits, and laboratory costs. It is possible and, in fact, likely that pharmaceutical costs may increase due to improved adherence, but reductions in hospitalization, home health care visits, or other line items may lead to an overall decrease in total cost. Note that this example ignores productivity gains, which we know are occurring but are often difficult to capture.

Doing nothing can sometimes look like doing something because of "regression to the mean"—something we try to avoid. To control for regression to the mean, the entire population must be examined, not just the high-cost group in isolation. Regression to the mean is a statistical principle related to how costs associated with individuals move within a population. Some individuals experiencing current high utilization (cost) will have lower costs in a subsequent period. Others experiencing current low costs will have higher costs in a subsequent period. Therefore these subgroups are "regressing," or moving toward a mean or average cost for the group as a whole.

Also, to avoid double counting when data are collected for the total population, diseases are assigned a place in a hierarchy.

The Healthways CMS Pilot

Healthways is currently participating in 2 CMS Medicare Health Support pilot programs that also incorporate key components of medication therapy management. The enrolled population is approximately 43,000, with an average age of 75 years. The population is equally distributed on the basis of gender, and approximately 30% of the group is older than 80 years. Greater than 70% have 5 or more coded comorbidities, and the average number of prescription drugs is 10. When over-the-counter medications and other nonprescription drugs (self-reported by patients) are included, that number increases to more than 14. In this group, annual mortality is 15% to 18%, a cost concern because health costs tend to be greatest in the last 3 to 6 months of life.

Healthways knew that adherence to standards of care (SOC) is

FIGURE 1 Care Spectrum

TABLE 1 Enhanced Medication Management
Total Population—Ongoing

- **Ensure adherence and compliance to prescribed drug regimen**
 - Nonadherence to drug regimen is a leading cause of hospitalizations for those with CHF
- **Ensure right drug, right dose, right frequency**
 - 76% of the elderly had a discrepancy between their recorded prescription and what they are actually taking
- **Reduce adverse drug events**
 - 12.5% of elderly receive the wrong drug
 - Cardiovascular drugs, diuretics, analgesics, hypoglycemic agents, and anti-coagulants represent the most common medication categories with errors
- **Avoid costly care**
 - Appropriate use of medications coupled with compliance, adherence, and monitoring results in decreased emergency room visits, reduced hospitalizations, and avoids rehospitalizations

CHF = congestive heart failure.

an important issue. Our review identified good adherence to certain SOC. Patients in this population tended to have appropriately controlled HbA1c (glycosylated hemoglobin) and lipid levels, have received preventive care, and have good blood pressure control if they had heart failure. On other fronts, however, adherence was poor: blood pressure control in diabetics, end-of-life care, and use of pharmaceuticals all had ample room for improvement. In addition, the prevalence of depression, cognitive decline, social isolation, poor health care literacy, and safety concerns were high, representing a challenge.

The CMS population differed from the Healthways commercial populations in several ways. They were at high risk for hospitaliza-

TABLE 2 Closing Gaps in Cancer Care

Symptom	Prevalence	Impact
Nausea and vomiting ¹	70% – 80%	Withdrawal from treatment
Anemia and fatigue ²	100% – mild 80% – severe	Increased morbidity Decreased quality of life Increased mortality
Pain ³	30% – 50% during treatment 60% – 90% in advanced stage	Increased ER and inpatient usage Decreased quality of life Decreased productivity
Poor communication ⁴	25% of oncologists address the psychological issues	Unnecessary distress Decreased quality of life

1. De Angelis V et al. Presented at ASCO, 2003.

2. Sobrero A et al. *Semin Oncol*, 2001.

3. Fortner BV et al. *J Pain*, 2002.

4. Arora NK. *Soc Sci Med*, 2003.

ER = emergency room.

tion and were often institutionalized or needed greater provisions for hospice or palliative care. They also needed intensive case management, and that precipitated a need for outreach workers. Healthways looked at the population's metrics and built a plan that was more robust in unique ways than that typically employed in a commercial population to address the special needs of this older demographic. Table 1 describes the 4 Healthways tenets and the reasons why they were established.

To date, Healthways considers itself in a learning mode, having encountered some surprises over the course of this study. For instance, the patients in these programs have been more accessible than anticipated. Their propensity toward social isolation, perhaps, has, in some ways, been an advantage, making them more willing to interact with and talk with our clinicians. They are easily engaged and receptive to contact, with more than 95% agreeing to contact either by phone or in person. Depression has been a greater challenge than anticipated, with 24% of the population meeting the diagnostic criteria. This population also has significant medication issues. However, the care coordination issues we anticipated failed to materialize, and physician collaboration has exceeded our expectation. Healthways has included physicians in the program development process in several ways, including physician advisory councils.

Some concerns related to cost management have developed. To avoid loss of value, Healthways is proceeding cautiously to ensure that some services do not fall through the cracks.

Looking Forward, Looking Back

In the past, health care in the United States has lacked the incentives necessary for optimal patient care. A good way to describe it is to say that those who have done more have been paid more. Physicians, for example, are paid by Current Procedural Terminology codes, so the more procedures completed, the more they were (and are) paid. The right incentives must propel clinicians and decision makers toward where the payers want and need health

care to go. The system needs new and better-aligned financial incentives. Disease or care management provides value by establishing a framework. When providers work within a framework that aligns incentives, they should be rewarded.

In the future, reimbursement must increasingly be based on performance and outcomes to address gaps in care (see Table 2 for an example of gaps in cancer treatment). Best performance (outcomes) will require collaboration among all stakeholders in the health care process. Some processes must be reengineered, meaning restructured in novel ways to improve efficiency. Along these lines, Healthways has been asked and is now participating in a few pay-for-performance programs through health plans.

Members (or patients) have a responsibility to be involved in this change, not only as the targets of cost shifting but also as full-fledged health care team members. Health care teams should focus on behavior changes to reduce risk factors. Maximizing the patient's effectiveness on the team requires several steps. Ample information must be available to the patient, and patients need education about their pattern of health care consumption and its effectiveness. Health care providers also need to help patients gain insight into the discrepancy between their health needs and wants and help them become independent and informed in their choices. Resolving needs and wants discrepancies often occurs via a motivational interview process that leads the member to the point that they want to change. It goes beyond providing information, or creating lifestyle awareness. It is really about motivating the individual to weigh the pros and cons and make suitable choices and mapping the steps they will take to achieve their goals. Self efficacy occurs when clinicians give patients the tools and confidence to succeed.

Conclusion

Adding value to traditional health care is a task that seems daunting at first. It is not insurmountable, however, and ultimately, adding value decreases costs in unprecedented ways.

DISCLOSURES

This article is based on the proceedings of a symposium held on April 5, 2006, at the Academy of Managed Care Pharmacy's 18th Annual Meeting and Showcase in Seattle, Washington, which was supported by an educational grant from sanofi-aventis and sponsored by the Benefit Design Institute. The author received an honorarium from sanofi-aventis for participation in the symposium. He is employed by Healthways, Inc., the subject of his article.

The Role of Outcomes Research in Defining and Measuring Value in Benefit Decisions

MICHAEL B. NICHOL, PhD

ABSTRACT

OBJECTIVE: To identify ways that health care leaders at all levels can quantify the value proposition, thus influencing health care delivery and improving patient care.

SUMMARY: Payers and providers need to support, with rigorous research, the value proposition for customers. Outcomes research focusing on clinical and cost-effectiveness analysis can provide an understanding of successful, replicable interventions. Randomized controlled trials and observational studies can be used to reinforce and refine the business proposition in health care, and they can be integrated to target populations needing health care services. Evaluations using clinical and outcomes research can also predict what is likely to be successful in the future. To maximize the business value of projects, they must incorporate a prospective evaluation component that includes asking the right research questions, identifying an appropriate time period, including a targeted population, articulating a replicable intervention, and determining the correct statistical analysis.

CONCLUSION: Well-designed studies to analyze specific patient populations and their patterns of care can be used to determine a generalizable model to refine successful interventions that meet the critical value proposition for employers.

KEYWORDS: Randomized controlled trials, Observational studies, Cost-effectiveness analysis, Medication possession ratio, Adherence, Compliance

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The ability to demonstrate value is a tremendous concern in health care. This creates opportunities for analytic applications that provide employers and policymakers with meaningful information. Since employers continue to fund a considerable proportion of health care insurance coverage in the United States, these applications have to demonstrate the business proposition. Payers and providers need to quantify the value proposition—a summary of the customer segment, competitor targets, and the core differentiation of one's product from the offerings of competitors—for customers through rigorous research. Fortunately, in the recent past, health services research improvements have focused on health care's growing need for sophisticated information. Clinical and outcomes research has been used to enhance our understanding of successful interventions, methods for increasing quality, and evaluation of the cost-effectiveness of chronic care interventions. Most important, these clinical and outcomes evaluations have assisted in defining population-based targets. By summarizing and disseminating these results, employers may be convinced that health investments will improve the corporate bottom line.

A critical component of future studies is the need to ask the right research questions. All too often, investigators fail to ask the questions that are most meaningful for health care payers, including employers. For example, employers may be interested in clinical outcomes as an intermediate indicator of the value of their investment, but they would be most interested in determining whether health care interventions create cost advantages. The nature of the cost advantages must include direct costs, such as reduced hospitalizations, physician visits, and medication use. But employers also expect that these studies will extend to the key elements that affect their enterprise: presenteeism, absenteeism, and contributions to their profit statement. This requires a new orientation in outcomes research and the need to develop measures, techniques, and methods that translate clinical and cost parameters to company profitability. The only way that this effort can be fruitful is through multidisciplinary efforts to extend health outcomes research methods.

Research Approaches

The 2 principal research approaches are randomized controlled trials (RCTs), which are designed to show causation, and observational studies (OBSs), which reflect more of a real-world setting. A third approach is cost-effectiveness analyses (CEAs), which incorporate data from the 2 prior study types to develop an understanding of health care value. Each type of study has a place in expanding our understanding of health care interventions, and these studies can be integrated to increase impact. OBSs and CEAs are being used much more frequently to inform the design and interpretation of results from randomized trials. Two familiar

Author

MICHAEL B. NICHOL, PhD, is an associate professor and chair, Department of Pharmaceutical Economics and Policy, School of Pharmacy, University of Southern California, Los Angeles.

AUTHOR CORRESPONDENCE: Michael B. Nichol, PhD, Associate Professor, Department of Pharmaceutical Economics and Policy, School of Pharmacy, University of Southern California, 1540 E. Alcazar St., CHP 140, Los Angeles, CA 90089. Tel: (323) 442-1464; Fax: (323) 442-1462; E-mail: mnichol@usc.edu

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FIGURE 1 Use of Studies in Deriving and Evaluating Benefit Designs

CEA = cost-effectiveness analysis; OBS = observational study; RCT = randomized controlled trials.

examples are the Women's Health Initiative and the Anti-hypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) studies. Figure 1 demonstrates how we can incorporate RCTs and OBSs within the context of available evidence to focus our understanding of health care value and to refine future study designs. It is important to note that the integration of these study types is dynamic: as new studies become available, key components of the cost-effectiveness model may be revised and integrated. This then yields new estimates of the benefit generated by a health care intervention (e.g., medication or care management). The results of the CEA can then be evaluated using traditional study designs.

Currently, most health care interventions designed to improve health care outcomes and value propositions fail to incorporate available information to target the population of interest and to tailor the intervention appropriately. Figure 1 illustrates that it would be helpful to build cost-effectiveness models to determine key questions and assumptions that may drive our understanding of the value of specific interventions. Subsequently, health care leaders might consider the value of conducting randomized trials within the context of their employee populations to test these questions. The implementation of the Part D benefit expansion in Medicare, for example, might reasonably include a test of the value proposition for drug coverage in the targeted population.

RCTs give strong internal validity but are not necessarily indicative of the real world. Many commentators have remarked about the difficulty of designing real-world RCTs to address key health outcomes questions. OBSs, on the other hand, suffer from their own set of validity threats. For example, these studies generally do not include methods for controlling patient selection.

To compensate for this, physicians or care managers may target interventions to specific populations or may use the intervention more frequently in certain clinical situations. This targeting compromises our ability to conclude that the intervention, rather than the population, was the cause of any positive outcomes. Further, neither the provider nor the patient is blind to the intervention; consequently, either or both may be positively (or negatively) predisposed to the intervention, and this may affect the results. In short, OBSs suffer from the fact that alternative explanations for the outcomes can be abundant, and lack of uniformity in targeted populations, protocols, and providers remains problematic. But OBSs generally have large study populations and allow researchers to observe behavior outside the rigid constraints of a randomized trial protocol. They also allow comparisons among multiple treatments simultaneously, tend to be less costly than RCTs, and can be conducted over a period tailored to the study's objectives.

Although opinions vary about the utility and validity of RCTs and OBSs, academics and formulary decision makers consider results generated from RCTs most valid and results of OBSs as less valid because they may overestimate treatment effects. However, an interesting series of articles in the *New England Journal of Medicine* in 2000 illustrates how RCTs and OBSs frequently produce similar results. One of these articles analyzed articles published in 5 major medical journals from 1991 to 1995. They identified meta-analyses of RCTs and meta-analyses of either cohort or case-control studies that assessed the same intervention. The mean results of the OBSs were remarkably similar to those of the RCTs. Topics assessed included effectiveness of bacille Calmette-Guerin vaccine in preventing active tuberculosis, mammography and mortality from breast cancer, cholesterol levels and death due to trauma and all-causes, treatment of hypertension and stroke, and treatment of hypertension and coronary heart disease. They concluded that the results of well-designed OBSs (with either a cohort or a case-control design) do not systematically overestimate the magnitude of the effects of treatment as compared with the results of RCTs on the same topic.¹ This indicates that, in some cases, clinical trials and OBSs may produce similar results, thus providing better evidence regarding internal and external study validity. By suggesting the dimension of a treatment effect that researchers can expect, RCTs can at least help researchers determine the sample sizes needed to test a question in an observational cohort.

Observational data can also be used to identify patterns of care and appropriate intervention targets and population cohorts. From these data, it may be possible to tailor incentives and interventions to obtain positive outcomes. Consider the study that sought to measure patients' persistency in taking their anti-hypertensive medications. The study population comprised patients who had recently initiated therapy. The purpose of this study was to determine whether and when newly started patients discontinued medication therapy. The measures of persistence

included time to discontinuation, switch, or augmentation; medication possession ratio (the percentage of time in the study that a medication was in the patient's possession); and proportion of days covered with medication (PDC; the percentage of patients in a treatment cohort who had a medication in their possession at any given time). Figure 2 plots the findings on PDC.²

The PDC analysis provides insight into medication-taking behavior by determining whether each patient has medication available (through refills) each day in the year following the initiation of therapy. Figure 2 shows that a significant percentage of the cohort drops therapy in the first 31 days. In other words, more than 40% of patients discontinued antihypertensive therapy in the first month. The graph also reflects that some people refill their prescriptions late, and adherence drops again at the end of 60 days. At approximately 90 days, persistence appears to stabilize, as those individuals who have continued therapy at 90 days appear to continue their antihypertensive medication use for the remainder of the 1-year period. Those started on angiotensin-converting enzyme inhibitors have a better persistency compared with those who might have started on diuretics.²

This leads to several conclusions:

- Particular classes of drugs may have greater persistence benefit than others.
- Patients who are persistent 90 days after initiating therapy are likely to continue using the medications for at least a year. It's not clear that it is cost effective to target these individuals for adherence interventions.
- Patients who fill only one 30-day prescription may be expensive targets for adherence intervention programs since they may need complicated efforts to improve their responsiveness to treatment.
- Intermittent users (those who fill their initial 3 medications with some delays) may be appropriate targets for adherence interventions. It remains to be seen whether these interventions are cost effective.

Most importantly, this approach does not simply identify a behavior problem. It also stimulates consideration of the interventions needed to change patient behavior and the costs associated with those interventions.

Many OBSs, as with the data in Figure 2, address limited periods of analysis, and lengthening the observation period can reveal some interesting and important findings. An OBS conducted with collaborators at the University of Southern California, the University of California at Los Angeles, and Cedars Sinai Hospital in Los Angeles examined the effects of ethnicity on a systemic lupus erythematosus population's health care utilization and direct medical costs. This study addressed a controversy in the field: people of color and whites react very differently to this disease, and some preliminary studies have implied that African Americans tend to become sicker more quickly and to incur additional health care treatment costs. To the contrary, the results showed that the total cost of care for whites and African Americans were increasingly similar during the 8 years of the study.³ Hispanic patients

FIGURE 2 Initial Medication Ownership Rate

ACE=angiotensin-converting enzyme; Beta=beta-blocker;

CCB=calcium channel blocker.

Patel BV et al. 5th Annual Workshop on Pharmaceutical Outcomes; DIA; 2004.

tended to have shorter eligibility periods compared with other cohorts (approximately 50% versus 70% were eligible at month 36, respectively). Over time, the cost of care for Hispanics, including inpatient use, prescription costs, and outpatient/physician services costs, was dramatically lower than that for other cohorts. Since these are observational data, it's not possible to determine the cause of these differences, but it is clear that the differences between whites and African Americans are smaller than the differences between Hispanics and either whites or African Americans.

Thus, RCTs are powerful research designs that demonstrate cause and effect within limited populations, and OBSs provide insight into the real-world use of health services, costs, and interventions. Each study has its own set of limitations, but both can be used to provide meaningful outcomes for employed populations.

Cost-Effectiveness Analysis

The CEA (which considers cost minimization/cost consequence, cost effectiveness, cost utility, and cost benefit) has become a useful tool in comparing particular types of medication products or classes. However, these analytic approaches can provide important insight into areas of general health policy questions that can be used by employers. A recent CEA we conducted on the transition of second-generation antihistamines (SGAs) from prescription to over-the-counter (OTC) status is an example.

First-generation antihistamines (FGAs), many of which have been available OTC for years, have been associated with increased risk of unintentional injuries, fatalities, and reduced productivity. Although manufacturers of SGAs expressed concern regarding the use of these products over the counter, the U.S. Food and Drug

FIGURE 3 Pharmaceutical Costs (Rx Dollars/9 Months) in Two 9-Month Periods Versus CDS

This figure applies *k*-means clustering techniques to derive 5 population groups that share characteristics on the Chronic Disease Score (CDS, a drug-based comorbidity index) and total dollars spent in a 9-month time period. This sample of diabetics was derived from a Medicaid managed care plan providing financing in a single county of California. Data analysis identified 5 clusters of patients. C3 and C4 had similar patient demographics, total medication costs, and CDSs. Medication costs and CDSs increased in C2 and C1 and were highest in C5. Thus, C5 was at highest risk of morbidity and mortality and was the costliest group to treat. Rx=prescription.

Administration considered an evaluation of their prescription status in 2003. Using a societal impact perspective (amelioration of allergic rhinitis symptoms and avoidance of motor vehicle, occupational, public, and home injuries and fatalities), a study of the cost-effectiveness of moving SGAs to OTC status was conducted.⁴ We used a simulation model, comparing the transition to OTC status with retaining prescription-only status for a hypothetical cohort of individuals with allergic rhinitis. Costs and effectiveness estimates were obtained from the medical literature and national surveys. The study found that OTC SGA availability was associated with mean annual savings of \$4 billion (range: \$2.4 billion to \$5.3 billion) or \$100 (range: \$64 to \$137) per allergic rhinitis sufferer and 135,061 time-discounted quality-adjusted life-years (range: 84,913 to 191,802). Even when the study assumptions were varied dramatically, cost savings were realized. The impact to society was positive, mainly because of reduced adverse outcomes related to FGA-induced sedation.

As noted in Figure 1, CEA and cohort studies can also be used to identify the programs that work and the populations that can best be targeted. Based on previous research, it is reasonable to

expect that today's high-cost patients will be tomorrow's high-cost users, but some high-cost users regress to the mean. Of critical importance is the determination of the interventions that might successfully alter high-cost users' behavior so that they become low-cost users. Population-clustering approaches show some promise in the identification of specific groups of patients; combined with the evaluation of intervention effectiveness, these population-clustering approaches may help us develop targeted approaches with some likelihood of success.

Figure 3 provides an example of clustering analysis in a Medicaid diabetes population. This study focused on a sample of Medicaid members in southern California over an 18-month period. The purpose of this study was to determine the extent to which patients maintained stable patterns of use between the first 9-month period and the second 9-month period available for analysis. It was expected that deriving transition clusters may illuminate groups with shared characteristics that are precursors to more expensive health care patterns. Total medication costs, patient age, and comorbidities (using the Chronic Disease Score [CDS]) were measured. Using the data in the 2 periods, 5 clusters were revealed. This graphical depiction of the clusters shows that 2 populations were very similar, 2 had some similar characteristics, and 1 cohort was distinctly different from the others. Individuals among the population clusters experienced very different cost transitions, but those within the clusters showed similar cost profiles. These patient characteristics could potentially be used to develop targeted interventions and to test the extent to which they resulted in clinical and cost improvements. It would be particularly interesting to test the use of clustered populations in directing some of the interventions that have been addressed in other parts of this supplement:

- Adjusting patient cost through coupons, vouchers, or copayments
- Encouraging adherence
- Targeting members in greatest need (e.g., the elderly, users of multiple medications)
- Promoting best practices (e.g., safety, reduction in multiple medications)
- Maximizing patient-reported outcomes (e.g., quality of life, preferences)

Is the Medicare Prescription Drug Improvement and Modernization Act of 2003 a Step Back in the Short Term?

The creation of Part D medication coverage introduced a massive shift in insurance that will affect health care for the foreseeable future. The structure of the benefit for the dually eligible population, for example, may create significant barriers to continuity of care. This population is allowed to change coverage every month, and the participation requirement results in short-term coverage variability that will be difficult to change without legislation. From the perspective of the researcher, the law may also compromise data availability for long-term research. As the lupus

study demonstrated, the availability of longitudinal data may affect the nature of our conclusions regarding patterns of care. Even if such data are available, it may be difficult to distinguish effects of the policy change from the effects of benefit design or the effects of patient behavior. Issues associated with consumer-directed health plans will change the market dynamic dramatically, and it is important to maintain an active monitoring process to determine whether the consequences of change are as intended.

The legislative provisions for health savings account (HSA) expansion are already creating movement away from employer coverage. To some degree, employers simply seek a consistent and manageable health benefit cost structure, and HSAs help them meet this goal. However, employers will also need to understand the role that benefit design plays in employee health care behavior. For example, if increased out-of-pocket costs negatively affect medication adherence, how will employee productivity be affected? Identifying the best methods for communicating health information to employees will be key to success, and translating health care investment dollars into return on investment for employers will be the insurer's responsibility.

Conclusion

Many leaders in the research field are beginning to consider the application of their work to health care value. In the last 3 to 4 years, the National Institutes of Health (NIH) has augmented its traditional basic research with applied research in a bench-to-bed-side focus. NIH has mandated that at least 30% of its budget be directed toward research projects that will be translated to improving patient care. There is also increasing recognition that the real world is considerably different from the artificial environment of a clinical trial. Patient behavior and the presence of multiple comorbidities may affect responsiveness to care and may demand greater attention to care management. Clearly, our approach to the value proposition must be multidisciplinary and should include populations that are representative of disease, ethnicity, and population diversity.

Employers, insurers, and researchers all have roles in directing the health care system toward positive change. The complexity of the health care environment increases the likelihood that unintended consequences may result from even simple and seemingly transparent changes. In the absence of studies to quantify the additional value of therapeutic interventions, therapies—drugs and other health care interventions—will essentially evolve into isolated commodities. By focusing only on the purchase of health care interventions, the critical effect of this care on personal health and the value of improved health to society goes unrecognized.

DISCLOSURES

This article is based on the proceedings of a symposium held on April 5, 2006, at the Academy of Managed Care Pharmacy's 18th Annual Meeting and Showcase in Seattle, Washington, which was supported by an educational grant from sanofi-aventis and sponsored by the Benefit Design Institute. The author received an honorarium from sanofi-aventis for participation in the symposium. He reports no affiliations with or financial interest in any commercial organization that poses a conflict of interest with the presentation on which this article is based.

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Shifting the Focus From Cost to Value: Key Stakeholder Perspectives

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Shifting the Focus From Cost to Value: Key Stakeholder Perspectives

1. What 4 adjectives does the World Health Organization use to define a healthy work force?
 - a. Healthy, protective, ready, resilient
 - b. Healthy, productive, ready, resilient
 - c. Healthy, productive, realistic, resilient
 - d. Hearty, productive, ready, resilient
2. The main premise of the White Paper produced by 15 experts under the auspices of The Institute of Medicine is that integrated employee health should look at
 - a. the costs of pharmaceuticals.
 - b. the costs of medical services.
 - c. the aerospace industry's labor mix.
 - d. economic outcomes of health on workforces.
3. An American College of Occupational and Environmental Medicine (ACOEM) survey looked at value-focused health activities. Which of the following statements is true about their findings?
 - a. Decision makers have actually moved farther away from value-focused activity.
 - b. Vaccination is a rarely used value-focused activity.
 - c. Across the board, all decision makers look at economic outcomes rather than cost.
 - d. The decision makers did not generally consider that pharmacy benefit managers had significant influence on pharmacy benefit design.
4. With what should managers augment pharmacy, medical, and short- and long-term disability data?
 - a. Data covering administrative costs
 - b. Data covering temporal relationships
 - c. Data covering work performance
 - d. Data covering employees' other insurance

5. Select the sentence that is true.
 - a. Enhancing program integration with employee education will promote employee engagement.
 - b. Groups targeted for interventions are less likely to become involved in appropriate programs.
 - c. Establishing baseline metrics allows patients to select programs.
 - d. Intermittent reassessment, looking for an opportunity to improve, is not as important as working with external partners and innovative designs.
6. What is a dual-eligible as defined by Medicare Part D?
 - a. Beneficiaries who also have private insurance
 - b. Beneficiaries who also qualify for industry-sponsored indigent care programs
 - c. Beneficiaries who also qualify for Medicaid
 - d. Beneficiaries who also qualify for disease management
7. After May 15, 2006, Medicare beneficiaries are locked into their plans unless
 - a. they contact a senator or federal representative to intervene.
 - b. they are dual-eligibles (who can change monthly) or have a status change such as diagnosis of a chronic disease.
 - c. they agree to new copayments.
 - d. they complete a complicated form.
8. Select the best definition of risk corridors.
 - a. Limits to the number of beneficiaries any plan can enroll
 - b. Geographic areas of the country where Medicare beneficiaries are concentrated
 - c. Diagnoses that are closely associated with poor outcomes
 - d. Limits to the profits or losses plans incur if their basic Medicare drug benefit costs are lower or higher than they had estimated based on beneficiaries' disease states
9. Which of the following is true?
 - a. Section 641 demonstrations pays for certain drugs (but not biologics) self-administered by the patient at home, replacing the traditional approach that covered Medicare Part B drugs only when given in a doctor's office.
 - b. Section 641 demonstrations promotes use of certain drugs and biologics self-administered by the patient at home, thus eliminating office visits.
 - c. Section 641 demonstrations is a disease management project that trains physicians to do comprehensive medication management.
 - d. Section 641 demonstrations has found that paying for certain drugs and biologics self-administered by the patient at home is not cost effective.
10. Which of the following is not a component of the Section 646 demonstration project?
 - a. Major systems changes to improve quality of care while increasing efficiency across the whole system
 - b. Physician compliance with treatment guidelines
 - c. Variations in utilization and outcomes measurement and research
 - d. Siloed decision making wherein the physician directs all care
11. Which of the following are outcomes being examined in the 2006 Oncology Demonstration Program?
 - a. Controlling depression, minimizing nausea and vomiting, and reducing fatigue
 - b. Controlling pain, minimizing mucositis, and reducing fatigue
 - c. Controlling pain, minimizing nausea and vomiting, and reducing thrombosis
 - d. Controlling pain, minimizing nausea and vomiting, and reducing fatigue
12. Select the statement about CMS's medication therapy management (MTM) program that is false.
 - a. It helps ensure that drugs are used to "optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug reactions," in certain high-risk patients.
 - b. MTM is a clinical and utilization program surrounding drugs and complementary and alternative medicines to prevent adverse outcomes.
 - c. CMS intentionally left the criteria for eligibility vague to encourage innovative programs.
 - d. It contains no criteria requiring programs to have measurable outcomes at this point, but plans will need to have the ability to measure them.
13. The formulary process for Medicare beneficiaries is predicated on 2 basic principles of the statute:
 - a. Formularies must provide broad access to patients with complex needs and be nondiscriminatory.
 - b. Formularies must limit access to all patients and be nondiscriminatory.
 - c. Formularies must provide broad access to all patients and be nondiscriminatory.
 - d. Formularies provide broad access to all patients and discriminate based on patients' level of disability.

14. What is the first step in determining cost trend over time?
 - a. Identifying the populations' baseline cost
 - b. Identifying diseases that would benefit from disease management
 - c. Soliciting patient buy-in
 - d. Soliciting manager buy-in
15. Select the sentence about regression to the mean that is false.
 - a. Regression to the mean is something health plans promote.
 - b. To control for regression to the mean, the entire population must be examined, not just the high-cost group in isolation.
 - c. Regression to the mean is a statistical principle related to how individuals move within a population.
 - d. Some individuals experiencing current high utilization (cost) will have lower costs in a subsequent period. Others experiencing current low costs will have higher costs in a subsequent period. Therefore, these subgroups are "regressing," or moving toward a mean or average cost for the group as a whole.
16. What is a value proposition?
 - a. A summary of findings from a randomized controlled trial that demonstrates improved outcomes
 - b. A summary of the customer segment, competitor targets, and the core differentiation of one's product from the offerings of competitors
 - c. A summary of the similarities between products that provide value
 - d. A summary of proposed actions that will improve care
17. Which of the following is a type of real-world study?
 - a. Randomized controlled study
 - b. Cost-effectiveness analysis
 - c. Observational study
 - d. None of the above
18. Medication possession ratio is
 - a. the percentage of time in the study that a medication was in the patient's possession.
 - b. the percentage of patients in a treatment cohort that had a medication in their possession at any given time.
 - c. the percentage of patients in a treatment cohort that had a disease amenable to drug treatment at any given time.
 - d. the percentage of time in a month that a medication was in the patient's possession.
19. Select the statement that is false?
 - a. Particular classes of drugs may have greater persistence benefit than others.
 - b. Patients who are persistent 90 days after initiating therapy are likely to continue using the medications for at least a year. It's not clear that it is cost effective to target these individuals for adherence interventions.
 - c. Patients who fill only one 30-day prescription may be the preferred targets for adherence intervention programs because they may need help more than others.
 - d. Intermittent users (those who fill their initial 3 medications with some delays) may be appropriate targets for adherence interventions. It remains to be seen whether these interventions are cost effective.
20. Which of the following statements is true concerning Medicare Part D?
 - a. The structure of the benefit for the dually eligible population, for example, may create significant barriers to continuity of care.
 - b. Dually eligible beneficiaries are allowed to change coverage every month, and the participation requirement results in short-term coverage variability that will be difficult to change without legislation.
 - c. From the perspective of the researcher, the law may also compromise data availability for long-term research.
 - d. All of the above

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