The Boehringer Ingelheim Pharmacy Benefits Report

Boehringer Ingelheim

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Letters from the Report Co-Chairmen

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Health and Productivity as a Business Strategy

A study from ACOEM sheds important new light on the complex interplay between chronic disease in the workforce, employer medical and pharmacy spending, and productivity

While America's business community faces a host of critical challenges, few are as daunting as the condition of our health care system and its impact on the American workforce. For years, experts have warned that the American health care system is on a collision course with several economic and demographic trends that have serious consequences for employers–and these predictions are now beginning to play out.

The transition of 80 million baby boomers into retirement age and a documented increase in chronic disease represent the arrival of a "silver tsunami" that will seriously impact employers' ability to remain productive and competitive in the global economy. Chronic health conditions are on the rise across all age groups, and it is expected that in the near future, those conditions will cost employers heavily as they provide medical benefits for employees and absorb the costs of absence and of long- and short-term disability claims.

In short, the health condition of America's workforce can now be considered a factor of greater importance than ever in the overall health care reform debate. Without a healthy, able and available workforce, the United States will find it impossible to thrive in an increasingly competitive global marketplace.

In this context, the need is rising for employers to better understand the impact of poor health on their productivity, especially in view of the huge health care cost outlays. While some employers have begun to examine workforce health more closely in recent years in the face of these trends, their efforts have tended to focus on clinical and medical cost issues rather than on the underlying issue of how health conditions impact overall productivity.

In response to this need, the American College of Occupational and Environmental Medicine (ACOEM) recently initiated research in order to more fully understand the link between health and workforce productivity. In a major, two-phase study, we have assessed the full impact of a wide range of health conditions in the workplace on productivity, factoring in both medical/pharmacy costs as well as other health-related productivity costs, including absenteeism and presenteeism (a condition in which employees are on the job but not fully productive). ACOEM, working in strategic collaboration with Alere (formerly Matria Healthcare) and Integrated

Benefits Institute (IBI) focused this "Health and Productivity as a Business Strategy" study on identifying leading chronic conditions that drive health-related costs. The results were reported in two articles in the *Journal of Occupational and Environmental Medicine*.[1,2]

Phase I of the research study identified the total cost impact of health on the financial bottom line for four employers with a total of 57,000 employees. In Phase II, we added six employers, for a total of ten companies ranging in size from 1,407 to 38,413 employees. The multi-employer study integrated medical and pharmacy claims data, employee self-reported health-related presenteeism and absentee data from the validated Health and Work Performance (HPQ) survey, and health-related lost productivity data to determine the "full cost" of specific medical conditions.

The results of our study provide a strong wake up call for U.S. employers: it appears that poor employee health is costlier than they think. In general, U.S. employers may be significantly underestimating the overall costs of poor employee health, while failing to fully assess the diseases and health conditions that drive these costs.

Our study found that certain disease conditions are costing employers much more heavily than they realize–including back/neck pain, depression, and fatigue and sleeping disorders.

The results of Phase I of our study showed that, on average, for every $1 employers spend on worker medical/pharmacy costs, they absorb up to $4 of health-related productivity costs. These costs are manifested largely in the form of presenteeism, absence and disability. The study also found that when taking this "full cost" view of medical conditions, some conditions are far more costly to the employer than previously realized, and that the cost-ordering of conditions changes relative to solely a medical and pharmacy claims-cost perspective. In addition, Phase I demonstrated that the siloed approach of focusing solely on portions of health-related spending, such as medical/pharmacy costs, is a flawed strategy.

Our study of health conditions comprised a broad range of employee types, from executive managers to clerical support staff. Health conditions reported ranged from those widely experienced in the workforce (seasonal allergies, for example) to uncommon conditions such as heart failure and chronic obstructive pulmonary disease (COPD). Our research indicates clearly that the conditions considered in the study are significantly associated with elevated absenteeism and presenteeism and as a consequence can have a major impact on productivity.

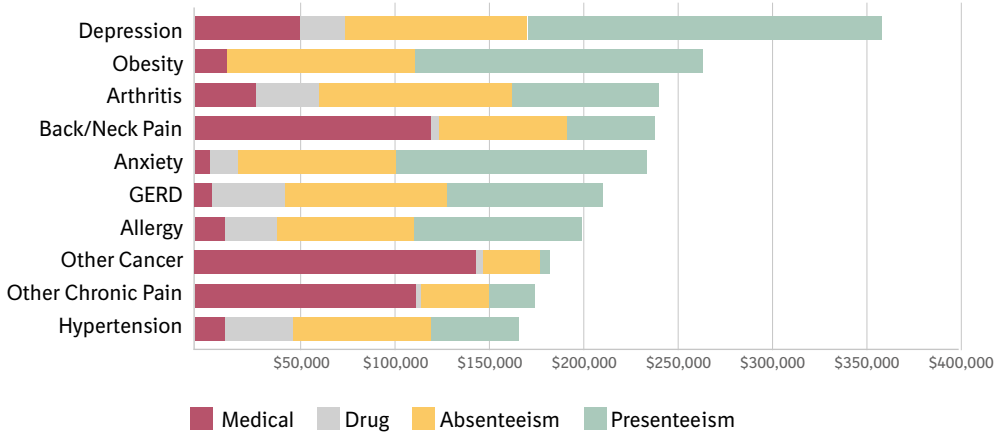
Phase II of our study refined the methods of determining health-related productivity loss and examined variations by treatment, comorbidities, and occupations, while continuing to provide a framework for promoting health and productivity as a business strategy. In broad terms, the results of the study suggest that the first step in addressing the quality of health care as it relates to functional outcomes of health-related productivity is to measure total (medical, pharmacy, and productivity) costs of health conditions as a baseline, then implement targeted interventions, followed by measurements of the total cost impacts at established times following the intervention.

Key Highlights

Our study generated enlightening results from matching medical + pharmacy claims costs to presenteeism and absenteeism costs (measured by the HPQ health-related productivity measurement instrument) at an individual level and then aggregated across unique populations. We were able to experience the benefit of robust sample size and variation of workforce age, sex, and occupation demographics as well as continued improvement of measurement methodologies to provide more refined estimates of health-related productivity loss. Key findings include the following:

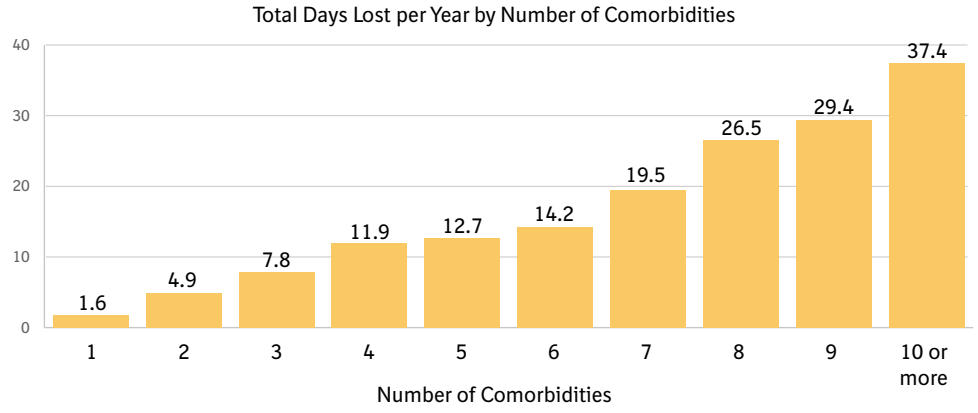
- At an aggregate population level across the 25 health conditions assessed, on average, for every $1 of medical + pharmacy costs there are $2.30 of health-related productivity costs in presenteeism and absenteeism.
- When health-related presenteeism and absenteeism costs and medical and pharmacy costs for a specific health condition are examined, the costs vary widely, but for most of the top ten health conditions, absenteeism and presenteeism costs accounted for greater than 50% of overall costs (See Figure 1).

Figure 1: Top 10 Health Conditions by Total Cost–Phase 2 Study



- The greatest impact in productivity losses is found when we focus on people with comorbid conditions rather than any one condition by itself. In other words the greater the number of comorbid conditions in people, the greater the productivity loss (See Figure 2).

Figure 2: Number of Comorbid Conditions and Days of Productivity Lost (Per Person Per Year)



There is little consistency across the two phases of the study in the medical conditions that are estimated to have the strongest adverse effects on work performance. This is perhaps not surprising given the differences in sample composition and in the assessment of conditions. However, several consistencies in the results are especially noteworthy. First, COPD and coronary heart disease are found in both phases to be among the strongest predictors of absenteeism, but not among the strongest predictors of presenteeism. Second, depression, and fatigue are found in both phases to be among the strongest predictors of presenteeism but not among the strongest predictors of absenteeism. Third, chronic pain is found in both phases to be among the strongest predictors of both absenteeism and presenteeism.

Summary

As employers accurately assess their employee health strategies, they will find that their most compelling cost issue is the link between poor health and reduced productivity. In Phase I of the "Health and Productivity as a Business Strategy" study we found that, on average, for every $1 employers spend on worker medical/pharmacy costs, they absorb $2 to $3 of health-related productivity costs. These costs are manifested largely in the form of presenteeism, absenteeism, and disability. Our earlier research also showed that in addition to common chronic conditions such as cancer, heart disease, and diabetes, a host of other conditions–ranging from musculoskeletal/pain, depression, and fatigue to anxiety and obesity–are the most significant drivers of total health-related costs in the workplace. In Phase II of the study, we refined methods and examined variations by treatment, comorbidities, and occupations, which provided further validation to the concept of linking health and productivity as a business strategy.

Employers of all sizes and types can use strategies based on the relationship between health and productivity to lower health risks, reduce the burden of illness, improve wellness and human performance, and enhance the quality of life for workers and their families, while reducing total health-related costs. Such programs help employers more accurately determine which health conditions have the greatest impact on overall productivity and then design strategies to help their employees prevent or better manage these conditions.

As employers seek to gain a better understanding of key medical care issues, they struggle with sources of information on workforce health. Traditionally, employers and their supplier partners have relied upon medical and pharmacy claims to meet their information needs. As employers have broadened their attention to health risks and "business-relevant outcomes" such as productivity, however, they are looking to new sources of information. Employee self-reported data, such as the information found in health risk assessments and absence and presenteeism, are becoming an increasingly important part of the employer's tool chest of information. Our study suggests that these tools can be extremely effective.

Through a more complete understanding of the full cost of poor health achieved by combining direct costs and productivity costs, there is significant opportunity to design health enhancement and absence management strategies that will provide optimal business outcomes. In an environment in which health costs are skyrocketing, health promotion and health protection measures aimed at the nation's

workforce could have significant long-term impact, potentially saving billions in costs. Furthermore, the positive impact of reaching large populations through the workplace extends beyond those currently employed. Families of the employed, retirees and other beneficiaries could also benefit from integrated health and productivity strategies implemented by the nation's employers.

The fundamental philosophy driving the adoption of these strategies is that good health is not only of great value to individuals and populations, but also of great value to business and industry. It is important for all employers–whether small, medium, or large–to look beyond health care benefits as a cost to be managed and rather to the benefits of good health as an investment to be leveraged. Ultimately, a healthier, more productive workforce can help drive greater profitability for employers as well as a healthier economy for our nation.

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Andrew Webber
President and CEO

Advancing Care with the Patient-Centered Medical Home

Several studies have shown that patient-centered medical homes are able to drive improvements in quality of care and patient experience

What makes health care so interesting is its dynamism, but that, of course, demands flexibility, open-mindedness, and foresight. That is how the industry is slowly transforming itself from treating illness to preventing disease, from one-size-fits-all solutions to personalized ones, to an integrated health care system debunking the traditional, siloed approach.

While controlling costs and improving consumer health are top of mind for all stakeholders–payers, providers, purchasers, and patients–the strategies to achieve those two goals are varied and complex. Some of these initiatives certainly have the power to drive the industry–the patient-centered medical home (PCMH), wellness and prevention programs, consumer-driven health care, chronic care management, value-based insurance design (VBID), transparency, and health information technology (HIT).

While health care may be compartmentalized, it is refreshing to see that many of the most current "flavors of the day" (and hopefully of the future) focus on building synergies to change the way health care is accessed, delivered, and purchased.

Health reform legislation–the Affordable Care Act and the Reconciliation Act–signed into law by President Barack Obama in March of 2010, should further some of these strategies, with first-dollar coverage by plans for certain evidence-based preventive care and immunizations, electronic transaction standards, transparency requirements, and cost-sharing limitations.

Specifically, reform is helping to make the idea of the PCMH, and its improved access to care and holistic approach, even more of a reality. It has allowed for:

- State options to provide health homes for enrollees with chronic conditions, including Medicaid beneficiaries.
- A demonstration project that allows qualified pediatric providers to be recognized and receive payments as an Accountable Care Organization (ACO) under Medicaid.
- Establishment of the Center for Medicare and Medicaid Innovation, which will research, develop, test, and expand innovative payment and delivery models to improve quality and reduce the cost of care.
- Grants to fund training in family medicine, general internal medicine, and general pediatrics.
- Expanded access to primary care and general surgery services.
- Payment for primary care physicians (PCPs) of no less than 100% of Medicare payment rates in 2013 and in 2014 for providing services under Medicaid.

In addition, as 32 million uninsured people start receiving health care, the majority in 2014, the medical home and its team of providers are well suited to meet these needs.

Unfortunately, the PCP is becoming an extinct breed because of relatively low reimbursement and long hours; primary care, however, is associated with reduced care costs and improved quality.[1]

Compared with the 2008 National Resident Matching Program (NRMP), which places applicants for postgraduate medical training positions into hospital residency programs, the 2009 program shows that 70 fewer positions were filled in family medicine. At the same time, 18 fewer positions were filled in primary care internal medicine. Too few graduates in family medicine have been matched through the NRMP to effectively meet the nation's needs for PCPs.[2] The Patient Centered Primary Care Collaborative (PCPCC), a coalition dedicated to developing and advancing the PCMH concept, defines the model as "an approach to providing comprehensive primary care for children, youth, and adults." It combines coordinated team-based care, a physician-directed medical practice, a personal physician as the first patient contact, safe and high-quality care, and a whole-person orientation.

Only 65% of adults under the age of 65 report that they have access to a PCP, and only half of that group say they received all recommended screenings and preventive care.[3] That's just not good enough. While we agree the PCMH is not a magic bullet, the model has promoted better access to care, improved communication between providers and patients, and more coordinated care. The concept is not new, having first been introduced by the American Academy of Pediatrics in 1967. Its evolution has been nothing short of surprising with a number of large employers, including city and state governments, and health plans picking up the medical home gauntlet and running with it.

We are finding that employers consider medical homes as a way to reduce gaps in care, increase access, improve patient self-management, emphasize preventive services, and align payment between providers and purchasers/payers.

Several studies have shown that PCMHs are able to drive improvements in quality of care and patient experience. A PCMH demonstration project developed by a health care system studied patient and staff experiences and found less staff burnout, higher quality care, and improved patient satisfaction.[4]

In conjunction with NBCH, PCPCC created *The Patient-Centered Medical Home: A Purchaser Guide*, that provides an overview of the model and potential strategies for purchasers to use in developing a medical home, from participating in a regional pilot and incorporating PCMH into insurer procurement and assessment activity, to aligning payment strategies and engaging consumers.

NBCH's health plan assessment tool, eValue8, gathers benchmarks in areas including prevention and health promotion, adoption of HIT, member and provider support, disease management, provider performance measurement, and patient

safety. The information enables coalitions and purchasers to identify "best in class" results-oriented health plans and networks, inform rate negotiations and set performance guarantees; and determine health care consumer/employee education opportunities.

In addition, the National Committee for Quality Assurance, in conjunction with national provider-related professional organizations, has created PCMH standards in different areas, including access and communications, patient tracking, care management, performance reporting, and advanced electronic communication. Known as the Physician Practice Connections-Patient-Centered Medical Home program, it recognizes physicians on three different levels based on points accrued by achieving guidelines.

In a recent white paper, "Aligning Incentives and Systems: Promoting Synergy Between Value-Based Insurance Design and the Patient-Centered Medical Home," which NBCH developed in collaboration with PCPCC, we describe some companies who are early adopters of the PCMH concept and VBID as complementary strategies.

The white paper emphasizes that VBID is based on the premise that utilizing appropriate incentives built into the benefit design can encourage employees to select higher value health services, while the PCMH creates incentives for physicians to deliver more effective primary care services, and for employees to choose them.[5] Whirlpool Corporation, the world's leading manufacturer and marketer of major home appliances with 70,000 employees worldwide, introduced a three-year PCMH model in 2010 to leverage its 10 occupational health facilities managed by health coaches, pharmacists and employee assistance program counselors. Based in Benton Harbor, Michigan, Whirlpool initiated its medical home with the goal of increasing the number of employees who take advantage of enrollment in disease management programs.[5]

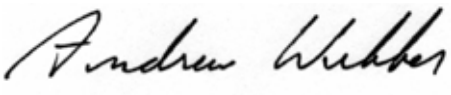
The primary elements of the strategy are: 1) access to care, coordination of care, education support, and individualized care planning for employees and dependents numbering 2,000; 2) incentives for physicians based on each PCMH participant; 3) employee incentives, including more favorable copayments and deductibles, quarterly rewards for using preventive services, and access to some chronic disease medications at no charge; and 4) a patient registry promoting care coordination and outreach.

Early indicators show an increase in the number of members seeking preventive services. "The advantage of the medical home is that the physician can tailor the services to the presenting patient, explain why those services are important for that individual, and help that member to maximize the value of his or her plan," says Susan Pavlopoulos, manager, global medical management for Whirlpool.

"As physicians are perceived to be the most trusted source of medical information, this assistance is welcomed and accepted by patients," she continues. "At this point in our medical home pilot, PCP's are doing a great job of helping members to walk through their current state of health and developing a care plan, jointly setting realistic health goals. I am hopeful that this pilot project will result in reduced overall medical and pharmacy costs through the introduction of technology and the

elimination of unnecessary and duplicate services" (Susan Pavlopoulos, e-mail communication, March 30, 2010).

PCMH is well positioned to head off the collision course of fewer primary care physicians and an influx of previously uninsured people seeking health care. VBID is all about getting the most value for one's health care dollar by reducing barriers to effective care.[6] Both the medical home model and VBID form a compelling synergy that aligns reimbursement and cost sharing with high-value services, incorporates HIT, delivers evidence-based medicine, focuses on the patient, and emphasizes integrated, coordinated care.



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Executive Summary

Executive Summary

The Boehringer Ingelheim Pharmacy Benefits Report **delves into the experiences of 183 employer organizations, 100 managed care organizations (most respondents are pharmacy directors or medical directors and represent health plans), and 54 pharmacy benefit managers (PBMs) and specialty pharmacy (SP) executives, centering around the pharmacy benefit.**

Cost is the top concern for employers, health plans, pharmacy benefit managers, and specialty pharmacy providers.

The report relates the views and projections of these key stakeholders on benefit design, pharmacy benefit management, utilization and cost management strategies, specialty pharmacy policies and tactics, medication adherence, and value-based insurance design (VBID). In many instances, the three groups react similarly to the survey questions, perhaps indicating a meeting of the minds among stakeholders. There is no doubt that cost is a top concern for all.

The following is a synopsis of the most significant results of the *Pharmacy Benefits Report*, representing the perspectives of employers, health plans, and PBMs/SP providers. Three separate sections found later in the report provide details on how each segment responds to a variety of questions about the pharmacy benefit.

Employers

Although employers emphasize medication adherence and productivity as important concerns, actual measurement of both is infrequent.

In weighing the financial impact of employee health, employers are less likely to take into consideration presenteeism (40%), productivity and long-term disability (both 47%), which are more difficult to quantify, than absenteeism (74%), workers' compensation (58%), and short-term disability (53%).

More than two-thirds (67%) of respondents say they have increased or are likely to increase copayments or coinsurance for branded drugs.

Many employers have not embraced value-based insurance design (VBID), partly because of a lack of clarity as to what VBID entails.

As with managed care organizations and PBMs/SP providers, employers lack a consensus on what defines SP. Descriptions at the top of employer lists are bioengineered drugs (43%), self-administered injectables (42%), and drugs requiring special handling and/or storage (37%).

Although face-to-face coaching is accepted as an effective means of managing chronic conditions, few employers use it because of its high cost. The majority of employers are using phone-based coaching, online self-help, and education and printed materials.

Employers evaluate the success of disease management programs through overall cost savings and through improved adherence and better outcomes.

Employers predict higher pmpm cost growth than do health plans.

Health Plans

The majority of HMOs, PPOs, Medicare Advantage Prescription Drug plans (MA-PDs), and stand-alone Prescription Drug Plans (PDPs) share the same priorities in the utilization management techniques they use. Quantity limits are the most common method used by HMOs, PPOs, and MA-PDs, while taking the number two spot for PDPs. On the other hand, prior authorization is most utilized by PDPs, while ranking second for the other three types of plans. Step therapy ranks third, and mandatory generic substitution and specialty pharmacy programs rank either fourth or fifth for all health plan options.

Health plans use a variety of strategies to manage specialty pharmacy: quantity limits for selected drugs, step therapy for selected drugs, maximum-day supply limits, and mandatory generic substitution. Some of these strategies were introduced in 2009, are new in 2010, or are planned for the near future.

Health plans predict that per member per month (pmpm) cost trends for the next 12 months will be in the 0% to 5% range, while employers predict cost growth of 5% to 10%.

Utilization management techniques adopted by the different health plan options are similar across the board. Quantity limits is the most common method used by HMOs, PPOs, and MA-PDPs, while in the number two spot for stand-alone PDPs. Generic substitution is the most important tool of health plans for managing the cost of most therapeutic classes, followed by generic therapeutic alternatives, and step therapy.

Pharmacy Benefit Managers/ Specialty Pharmacy

Cost management of specialty pharmaceuticals is overwhelmingly the top concern (94%) of PBMs and specialty pharmacies, followed by appropriate utilization (70%), and clinical outcomes (47%).

Survey respondents are most concerned with pharmacy costs associated with treating chronic conditions, especially diabetes (77%), gastrointestinal disorders (65%), hyperlipidemia (64%), asthma (61%), and depression (58%).

Concerns about the cost of specialty pharmacy are often related to cancer care for both oral medications and infused biologics, 72% and 69%, respectively. First ranked in concern is rheumatoid arthritis, by 76% of respondents. Multiple sclerosis is of concern to 60%.

PBM/SP providers rely on a variety of strategies to control specialty pharmacy utilization and costs. As many as 79% set quantity limits for selected drugs in 2009, plan to introduce quantity limits in 2010, or are likely to start setting quantity limits. PBMs/SPs also favor (have already introduced or plan on introducing) step therapy for selected drugs (78%), and setting maximum day supply limits (81%).

More emphasis on medication adherence is seen as contributing to improved patient health (98%), better outcomes (96%), fewer adverse events (93%), and lower pharmacy costs (86%).

Methodolgy

Methodology

Throughout the first half of 2010, Boehringer Ingelheim conducted survey research of employers, health plans, and pharmacy benefit managers/specialty pharmacy.

A total of 337 respondents shared their experiences and opinions on cost sharing, utilization and cost management strategies, benefit design, and specialty pharmacy. The result is the first edition of *The Boehringer Ingelheim Pharmacy Benefits Report*.

To gain the perspective of employers, employee benefit managers nationwide were surveyed, including executives at more than 60 business coalitions and subscribers to *Employee Benefit News*. Responses were received from 183 employers. About one-fifth of employer respondents are affiliated with manufacturers, 13.4% are in a wholesale/retail business, and the rest are scattered throughout a variety of industries, including education, hospitality, finance, and health care services, with 6.1% from non-profit organizations and 4.5% from local government agencies.

A total of 100 managed care executives responded to the survey. More than three-fourths of respondents (76.3%) represent health plans and 77.4% of these respondents are either pharmacy or medical directors. About one-third each represent national, regional, and single state-based organizations. These plans serve a member population ranging from 1,200 to more than 54 million and cover multiple products, including HMOs (34.5%), PPOs (22.5%), managed Medicare plans (16.3%), and managed Medicaid plans (16.4%). The majority of their members have a pharmacy benefit. More than half of plans contract directly with an external pharmacy benefit manager (PBM) not owned by the plan.

The third group surveyed included 54 pharmacy benefit managers (PBMs) and specialty pharmacy (SP) providers, the majority of whom are clinical pharmacists (38.9%), senior management (25.9%), or pharmacy directors (16.7%).

Almost half (45%) of PBM respondents are with independent PBMs, while 31.9% are affiliated with PBMs owned by a health plan, and 23.4% with a health plan owned by a PBM. On the specialty pharmacy side, 32.4% of respondents are from independent organizations, 26.5% are with a PBM-owned SP, and 23.5% are affiliated with an SP owned by a retail pharmacy.

Survey participants were invited to complete the questionnaires using confidential and secured Internet platforms or via fax. Market research methods were used to collect and analyze the data. The findings are not to be misconstrued as representative of the products, strategies, and concerns of large employers, large health plans, or the pharmacy services industry.

The survey research was conducted in cooperation with the American College of Occupational and Environmental Medicine, the National Association of Managed Care Physicians, and the Biologic Finance and Access Council.

337

respondents shared their experiences and opinions on business and clinical issues related to the pharmacy benefit.

Part 1: Findings from Employer Research

Part 1: Findings from Employer Research

Part 1 of *The Boehringer Ingelheim Pharmacy Benefits Report* examines the views of 183 employer organizations on pharmacy benefit management, formulary, drug costs, specialty pharmacy, presenteeism/absenteeism, and chronic disease management.

Diabetes is the top chronic disease concern for employers.

The research detailed in *The Boehringer Ingelheim Pharmacy Benefits Report* shows that while the majority of employers are concerned about medication non-adherence and its contribution to higher overall costs and negative clinical outcomes, few employers have programs to measure the extent of adherence. Other key findings:

- Chronic diseases of most concern to employers are diabetes (90%), hypertension (86%), depression (84%), asthma (76%), and chronic obstructive pulmonary disease (COPD) (74%). Among less common conditions, treatments for cancer, including infused biotech and oral medications, command the highest concern for managing costs (88% and 87%, respectively).
- Although medication non-adherence is known to contribute negatively to clinical outcomes and related costs, only 17.6% of employers are measuring it.
- The majority of employers (63%) are using pharmacy benefit designs with three tiers (generics, preferred brands, and non-preferred brands).
- Employers do not agree on a single definition for "specialty drugs." Biotechnically engineered drugs (43%) and self-administered injectables (42%) are the most common definitions.
- Employers are implementing a variety of drug benefit management strategies, with 78% offering or likely to offer incentives for generic substitution; 67% increasing or likely to raise copayments or coinsurance for branded drugs; and 56% mandating or likely to mandate specialty pharmacy (SP) distribution of specialty drugs.
- When employers are asked about their health care management priorities, controlling health plan costs (93%) and pharmacy costs (84%) expectedly lead the list.
- Presenteeism (40%), productivity, and long-term disability (both 47%), which are difficult to measure, are taken into consideration less than absenteeism (74%), workers' compensation (58%), and short-term disability (53%).
- Employers are not currently implementing value-based insurance design (VBID) in great numbers though many are considering doing so.
- Although face-to-face coaching is an effective means of managing chronic conditions, few employers use it because it also is one of the most costly techniques. The majority of employers are using phone-based coaching, online self-help, and education and printed materials.
- Although the health care industry continually discusses aligning

99%

of employers surveyed cover health care costs for active employees.

incentives to promote improved health, such as lower copayments or premiums for using selected drugs and providers, the majority of companies are not offering such incentives to encourage participation in disease management programs.

- Employers evaluate the success of disease management programs through overall cost savings and through improved adherence and outcomes.

Interpreting the Findings

The following medical and pharmacy benefit experts reviewed the survey research and shared their insights:

- Randy Vogenberg, PhD, principal, Institute for Integrated Healthcare (IIH), Sharon, MA, and executive director at the Biologic Finance & Access Council program, Jefferson School of Population Health, Philadelphia
- Ed Kaplan, national health practice leader, Segal Company, employee benefits consulting firm, New York, NY
- Christopher V. Goff, president and CEO, Employers Health Purchasing Corporation of Ohio, Canton
- Larry Boress, president/CEO, Midwest Business Group on Health, Chicago
- Heidi Lattig, independent health, wellness and productivity consultant, Easton, PA

Research Results

Employer-sponsored Benefits

The highest concentration of employer respondents (23%) have 1,000 to 2,499 employees. Medium-sized to large organizations with 5,000 to 19,999 employees (22%) and small ones with 101 to 199 (20%) rank second and third, respectively. Most organizations (93%) cover health care costs for active employees and their dependents (86%) with an employer contribution. On the other hand, half do not offer any coverage to Medicare Part D eligible

Figure 1: Which of the following employee groups receive prescription drug coverage from your organization? (Check one for each category)

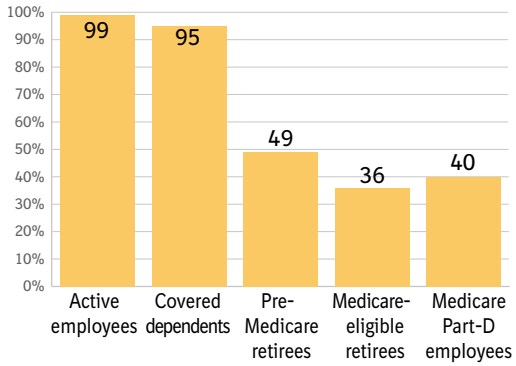
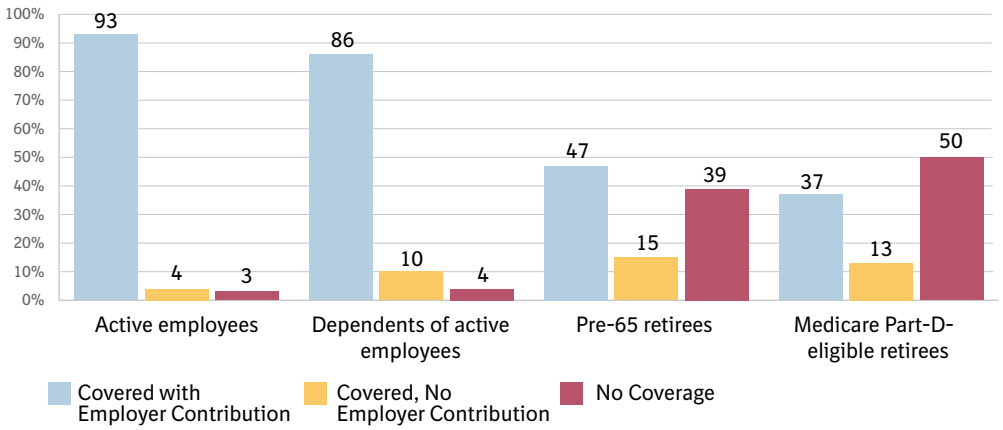


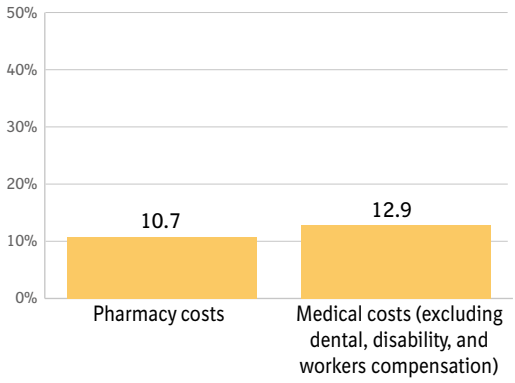
Figure 2: Please indicate which groups of current or retired U.S. employees receive health care benefits from your company or coalition:



retirees, while 39% don't cover early retirees (younger than age 65).

Nearly all employers surveyed offer prescription drug coverage to active employees (99%) and dependents (95%), while half of pre-Medicare retirees have pharmacy coverage. Lower percentages of Medicare-eligible retirees (36%) and Part D beneficiaries (40%) receive drug coverage from employers.

Figure 3: What annual percentage change in healthcare costs for active employees and dependents did your organization experience in 2008?



Respondents estimate that pharmacy costs rose 10.7% between 2007 and 2008, which is higher than the 9.2% increase expected by Aon Consulting. The projected increase in medical costs by respondents of 12.9% similarly exceeds Aon's estimate of 10.6%.[1]

In this survey, 59% of active employees and dependents are enrolled in PPOs with 17% in HMOs. Ed Kaplan observes that 20 years ago enrollment in HMOs was 30% to 40% and notes the current trend towards more flexible options. Consumer-driven health plans (CDHPs) with or without health savings accounts have only

Pharmacy costs increased **10.7%** from 2007 to 2008, while medical costs rose 12.9%.

Figure 4: What is your expectation of health care cost trends in the next 12 months?

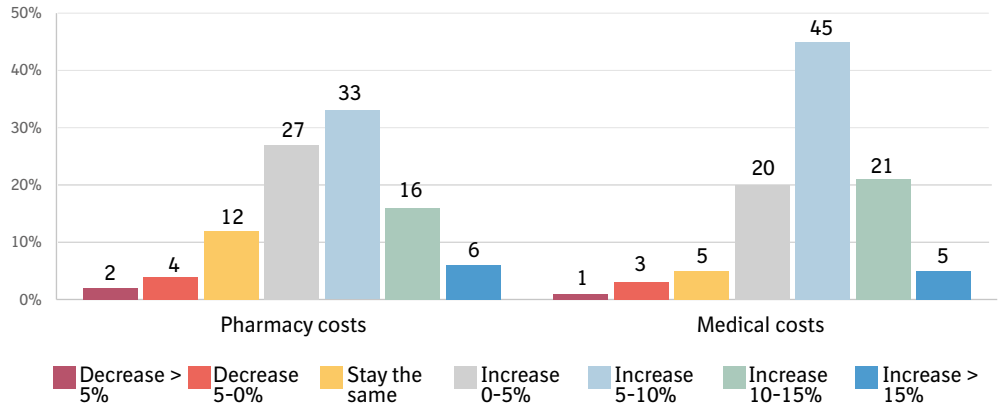
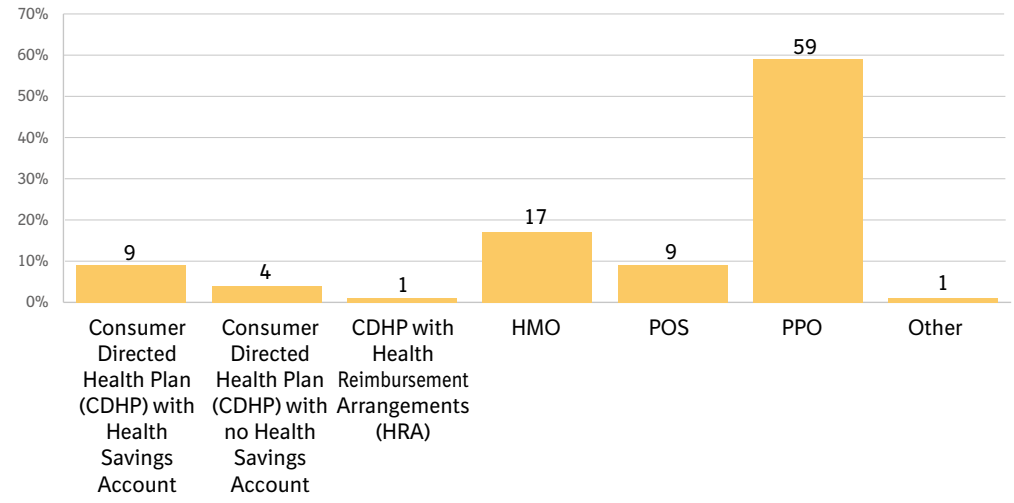


Figure 5: What percentage of active employees and dependents are enrolled in each type of health plan?



HMO enrollment peaked at **33%** in 2001 and has been declining ever since.

attracted 9% and 4%, respectively.

"The CDHPs don't seem to be magic bullets," says Heidi Lattig. "These plans place the burden of decision-making on employees and their families, who often times are not aware of, or have access to, the necessary tools such as physician quality data, or they have not developed the skills and perspective required to effectively manage those choices. However, if the plans are packaged with appropriate tools, education, incentives, and engagement techniques, they can work."

Lattig suggests that individuals' decisions regarding the consumer-directed model are more often based on the wallet, not efficacy that could improve long-term results. "Employers need to invest now in the health management skills of their employees and dependent population to achieve health status and cost improvements down the road," she explains.

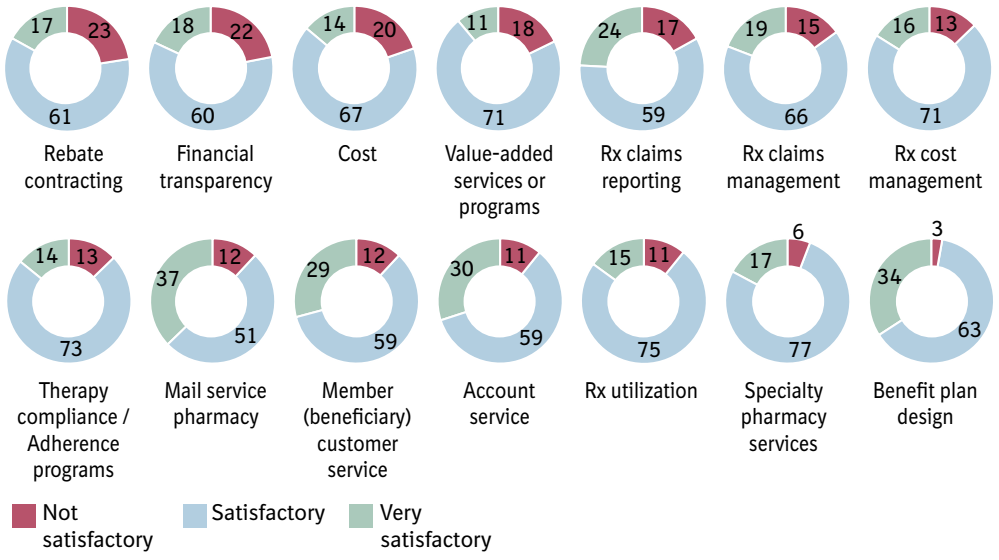
Smaller employers have been slower to adopt high-deductible CDHPs. Mercer's 2009 National Survey of Employer-Sponsored Health Plans, however, shows that in 2009, CDHP offerings among employers with 10 to 499 employees jumped from 9% to 15%. This helped drive the percentage of all covered employees enrolled in CDHPs from 7% to 9%. For small employers, enrollment in PPOs was flat at 69%, while enrollment in HMOs fell from 23% to 21%. HMO enrollment peaked at 33% in 2001 and has been eroding ever since.[2]

Christopher Goff notes that CDHPs were originally designed for employers with fewer than 500 employees, but that large employers turned out to be the early adopters, offering the plans as just one of several choices. Now he sees companies with 100 to 2,500 employees looking at the design as full replacement coverage.

Employers on PBMs, Consultants

Most employers are neither "dissatisfied" nor "very satisfied" about most aspects of their PBM services. When "satisfactory" and "very satisfactory" responses are combined, 97% approve of benefit plan design, followed by specialty pharmacy services (94%), drug utilization (90%), account service (89%), customer service for employees and mail service (both 88%), and adherence programs (87%). More than one-fifth

Figure 6: How satisfied are you with the following aspects of your pharmacy benefit management organization?



(22%) expresses dissatisfaction with financial transparency, second only to rebate contracting (23%).

Randy Vogenberg, PhD, sees the lower than 50% "very satisfactory" responses as an opportunity for change and innovation in pharmacy benefit design.

More than twice as many employers rely on their consultants/brokers (49%) as on their PBMs (23%) for advice on pharmacy benefit design. Kaplan attributes the lack of PBM influence to a credibility gap in the eyes of employers. As many as 39% turn to their health plan for advice on drug benefit design.

Cost-sharing Strategies

Employers are using a variety of employee cost contribution strategies, with copayments the most common (56%); a combination of copayments and coinsurance nears 50%. In addition, 57% utilize annual deductibles. "A copayment has less significance than coinsurance regarding inflation," Larry Boress notes. He anticipates that copayments will remain for generics but expects that coinsurance will become more popular with greater use of SP drugs.

Lattig concurs, saying that coinsurance better represents an employee's fair share and sees a trend in that direction as cost sharing increases. "In addition to wanting employees to be educated on just how much the employer is contributing toward their medical care, employers want employees to pay their fair share of the ever escalating costs in an effort to drive consumerism. Employers can achieve both of these goals through use of coinsurance," she says.

Employers are twice as likely to rely on consultants than PBMs for advice on pharmacy benefit design.

Figure 7: Rate the level of influence the following advisers have concerning prescription benefit design for your organization:

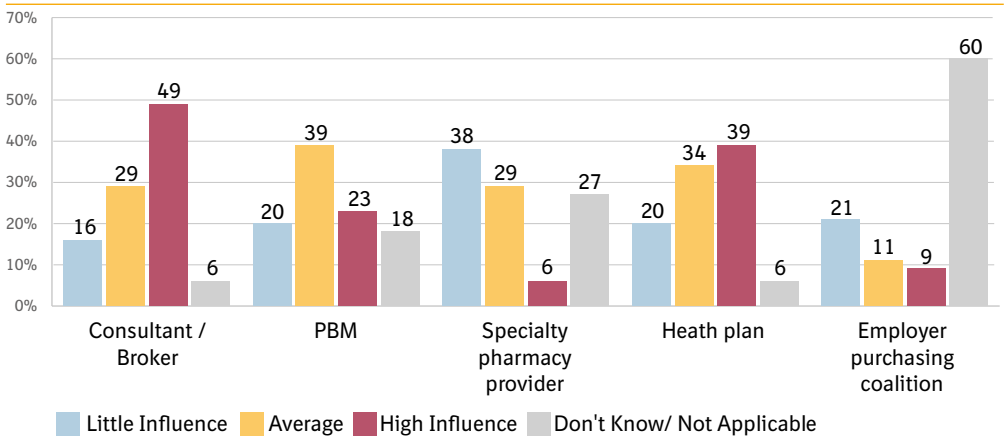
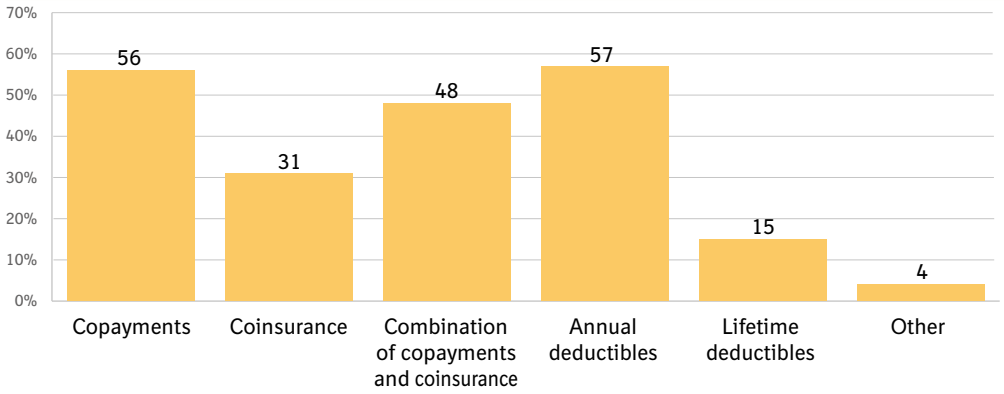


Figure 8: Which of the following employee cost-contribution strategies are used by your organization's largest benefit plan?



A fourth tier represents specialty drugs for some plans and lifestyle drugs for others.

There is some debate over requiring copayments instead of coinsurance for SP, notes Boress, to ensure that costly but much needed biologics remain accessible and affordable.

Goff says that 50% of his book of business–the 90 employer members of his purchasing coalition–use coinsurance.

Benefit Design Tiers

A three-tiered formulary (generics, preferred brands, and non-preferred brands) is the most commonly used pharmacy benefit model, while the single-tier and five-tier models receive the least play. Two-tiered and four-tiered formularies garner 10% and 17%, respectively. Kaplan is concerned that as employers push more cost share to employees, a fourth tier for specialty drugs will become too costly.

Boress notes that a fourth tier may be interpreted differently in each formulary design, representing SP for some and lifestyle drugs for others.

Products and Programs Covered

Although smoking cessation and weight loss are recognized as common preventive measures in reducing the risk of chronic conditions, such as COPD, heart disease and diabetes, 26% and 45% of employers, respectively, do not cover drugs or products in these categories. In comparison, drugs for acne are covered

Figure 9: If tiered, what type of structure is used most often in your organization's prescription benefit plan design (s)?

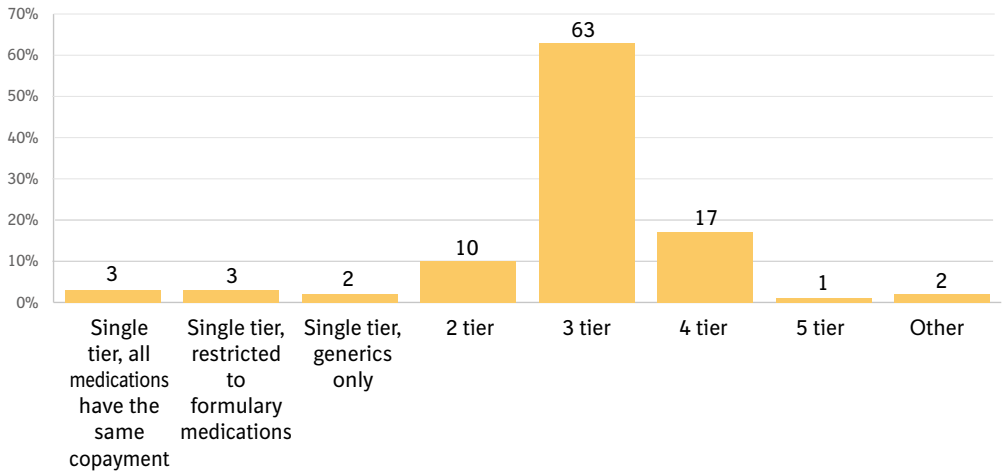
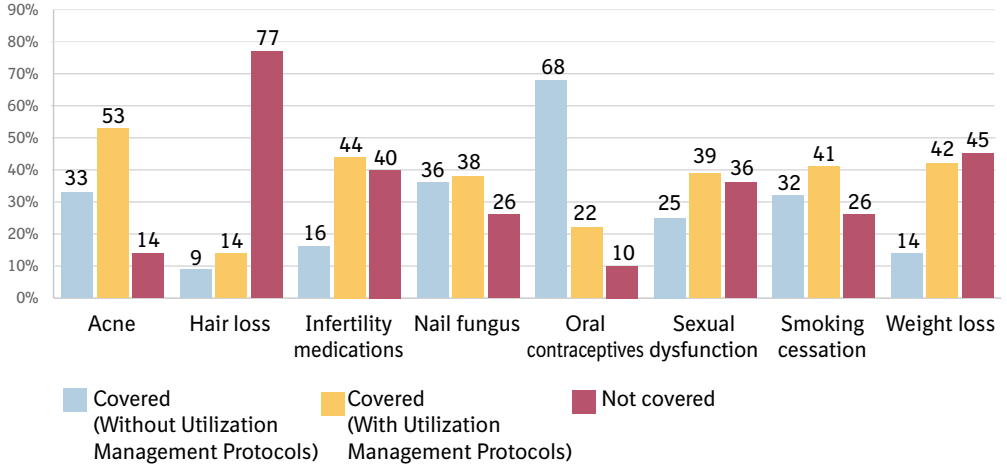


Figure 10: Does your largest prescription benefit plan cover the following medications or products?



by 86% of employers, although 53% of those require a utilization management protocol.

Smoking cessation programs are the most popular health and wellness programs offered, with 73% providing them. More than half of employers surveyed (53%) by Health2 Resources and the National Association of Manufacturers offer smoking cessation programs to employees, with weight management and programs to increase physical activity levels not far behind.[3]

As many as 90% of employers cover oral contraceptives, about a fourth of which combine coverage with utilization management protocols. At least 25 states have laws requiring insurers to cover any Food and Drug Administration (FDA)-approved contraceptives. Employer-based coverage is the primary form of health insurance for 64% of women of reproductive age.[4]

More than half of employers cover over-the-counter (OTC) proton pump inhibitors (PPIs) , while coverage of other OTC drug categories has not picked up as much steam. Boress notes that the availability of OTC PPIs should generate savings for companies. He adds that it makes sense to cover OTC drugs in therapeutic categories with prescription versions to potentially lower physician visit costs. Only 7% of employers cover OTC aspirin.

Vogenberg says that covering OTC drugs may just be the most cost-effective way to offer coverage for certain medications without changing benefit design and at the same time, saving money.

Kaplan is all for the use of OTC products if abuse is not an issue. “If OTC drugs are half the price of generics, what will stop some users from stockpiling medications for their friends or relatives?’ he asks. “As copayments rise, the OTC drugs are even more appealing and can be just as effective. Of course, if the cost of an OTC drug is more expensive than a generic prescription, coverage makes no sense.” His other concern is that the doses of OTC products may be lower, making it necessary to take more to achieve the same result.

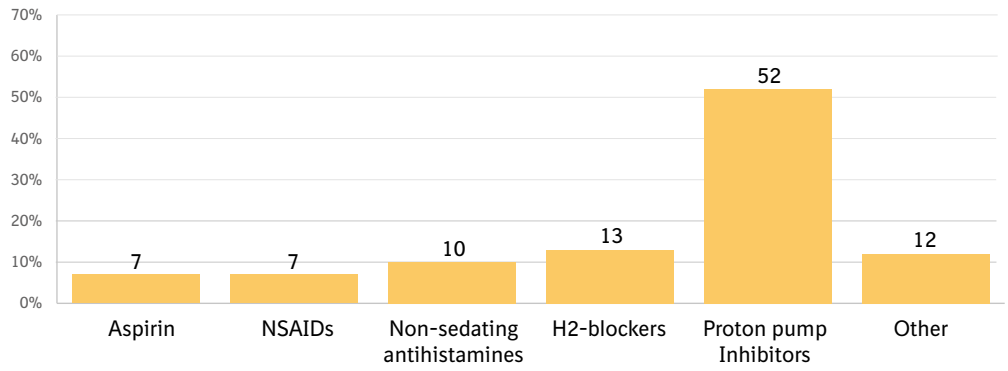
Defining Specialty Drugs

Employers have trouble agreeing on a definition of “specialty pharmacy.” At the top of employer lists are biotechnically engineered drugs (43%); self-administered injectables (42%); and drugs requiring special handling and/or storage (37%). High-cost unit drugs are used as a definition by only 25% of employers.

Specialty drugs generally include prescription medicines that are used to treat complex, chronic conditions and require special administration, handling, and care management. Many specialty drugs are used to treat conditions such as

Smoking cessation programs are the most popular wellness programs, with **73%** of employers offering them.

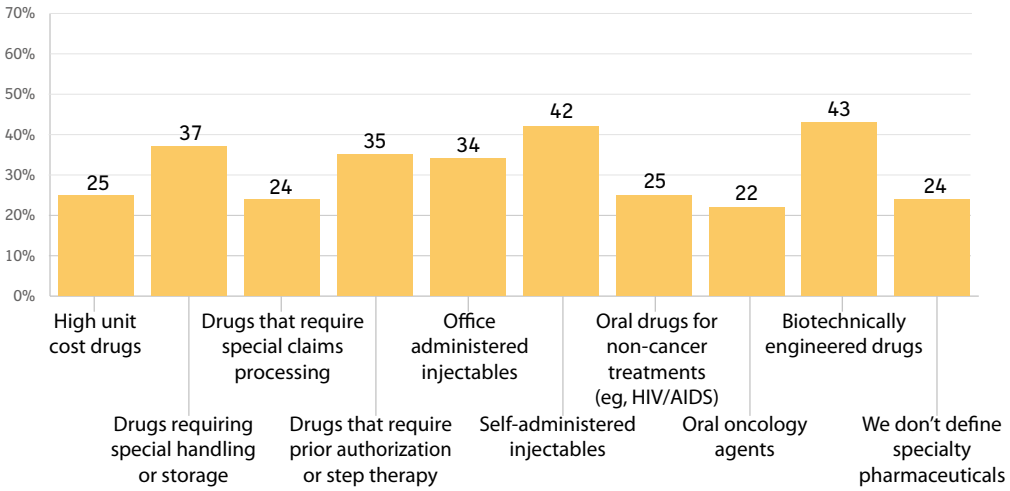
Figure 11: Which of the following OTC products are covered under your largest prescription benefit plan?



52%

of employers cover specialty pharmacy drugs under their prescription drug plan.

Figure 12: How does your pharmacy plan define specialty drugs?



cancer, rheumatoid arthritis (RA), and multiple sclerosis (MS).[5]

Lattig is not surprised that employers cannot agree on a definition of SP as many of them rely on their PBMs to make decisions related to specialty products. Vogenberg adds that not having a commonly recognized definition may make if difficult to determine the cost of a drug and how to most effectively manage it.

Specialty drugs are among the most costly drugs available, with prices that can range from $5,000 to more than $300,000 per year.[6]

Vogenberg says the $1,459 monthly cost threshold for defining specialty pharmaceuticals is too low, estimating that the average is closer to $2,500.

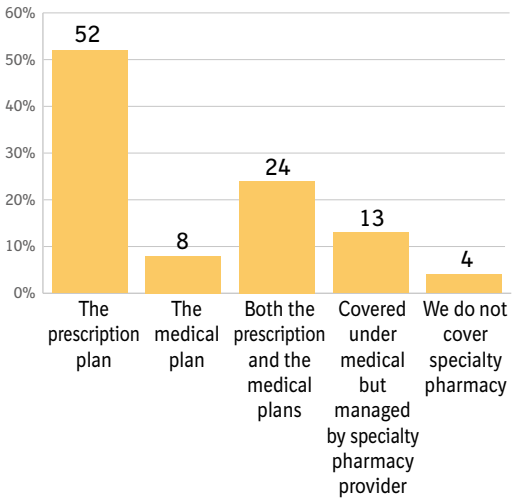
If your organization defines specialty pharmaceuticals as high cost drugs, what is that cost threshold per month? **$1,459**

Covering Specialty Drugs

More than half of employers cover SP under their prescription drug plan with another quarter selecting a combination of pharmacy and medical plans. All in all, 45% have chosen the medical plan to some degree. Boress sees an increasing number of employers selecting a combination of medical and pharmacy plans.

"The perception is that more SP drugs are covered under the pharmacy benefit than the medical one, but there is a trend towards the latter for two reasons," says Vogenberg, who estimates that only 40% of SP drugs are covered under the pharmacy benefit, with 60% covered under the medical benefit. "First, physicians oversee the administration of many SP drugs that are either infused or injected and second, some drugs may not be self-administered by a patient nor by a caregiver, but require supervision by a physician or other medical professional because of its risk profile."

Figure 13: How does your largest benefit plan cover specialty drugs?



Managing Costs

The following chronic diseases garner the most concern (categories 3-5) from employers: diabetes (90%), hypertension (86%), depression (84%), obesity (81%), gastrointestinal disorders (80%), hyperlipidermia (77%), asthma (76%), and COPD (74%).

Goff is surprised that there is not more concern for hyperlipidemia with a leading treatment as one of the top 10 drugs in terms of cost. He says he also expected a larger variance in concern about viral vs bacterial infections–both were viewed with the same level of concern (67%)–although viral agents are much less costly. Finally, he expected that interest in pain (78%) and migraine (64%) would have been higher.

Boress says that obesity and depression are often looked upon as lifestyle issues, but concern expressed by employers is an indication of a greater understanding of their impact on cost and productivity.

Although the majority indicates that conditions such as diabetes, hypertension, and obesity are major concerns, Vogenberg is not convinced that most employers really understand the prevalence among their populations and likely have no one to analyze related claims. "If a condition is not generating top spend, employers are not aware of its contribution to the total cost of care," he says.

Kaplan suggests that employers are more sophisticated than 10 years ago and have more trend data available. He is surprised

Employers are beginning to realize that obesity and depression impact costs and productivity.

Figure 14: How is specialty pharmacy benefit design determined for your organization?

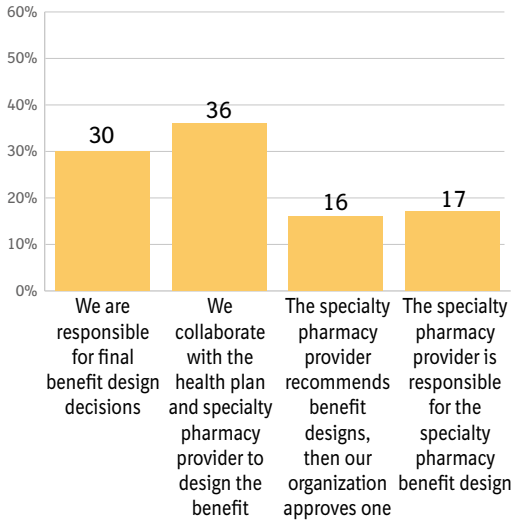
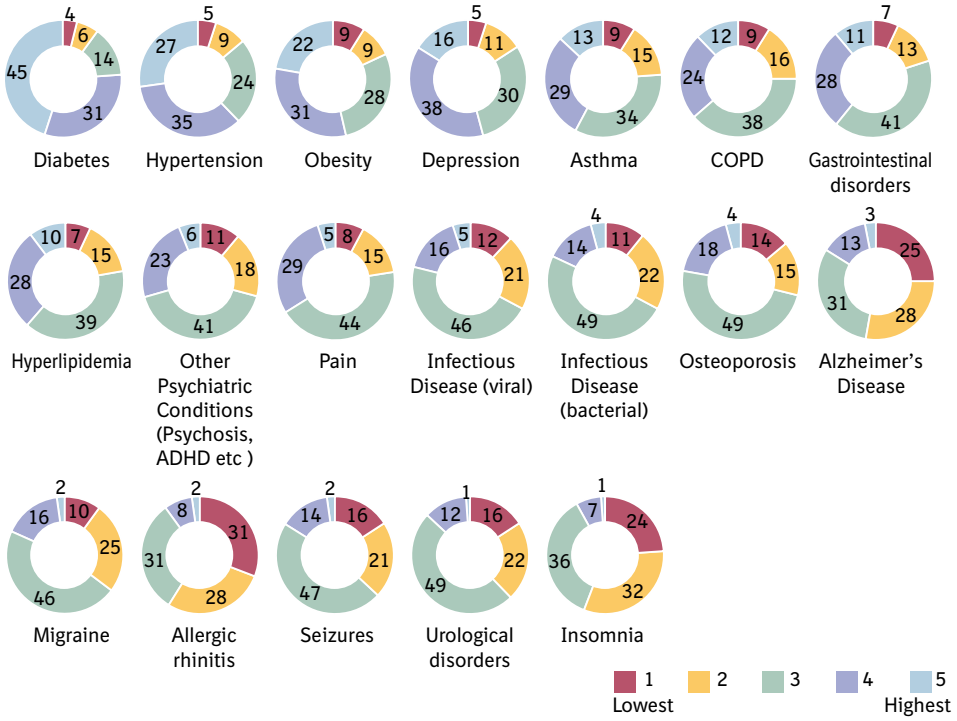


Figure 15: My organization is most concerned with managing the pharmacy costs of these conditions:



Many employers are not well-equipped to support employees with COPD.

that gastrointestinal disorders and hyperlipidemia have not attracted as much attention, as PPIs and statins can be big cost drivers. He expected that diabetes and obesity, conditions often in the news, would generate a high level of concern.

High-cost but less common conditions, such as hepatitis, MS, and RA, caught the attention of employers, but not to the highest level. Vogenberg says that employers are increasingly interested in more tightly managing RA and MS, as new agents hit the marketplace and costs increase.

Cancer treatments, including both infused biotech and oral drugs, capture the interest of most employers (88% and 87%, respectively). Forty-three percent of employers with more than 500 employees, and 48% with 20,000+ employees offer cancer management programs, and 53% and 63%, respectively, provide health advocacy services.[2]

Managing COPD

Nearly half of employers (49%) lack knowledge about how to recognize COPD, while 60% say it is difficult to diagnose because patients may have

Figure 16: My organization is concerned with managing the pharmacy and specialty pharmacy costs of these conditions and categories:

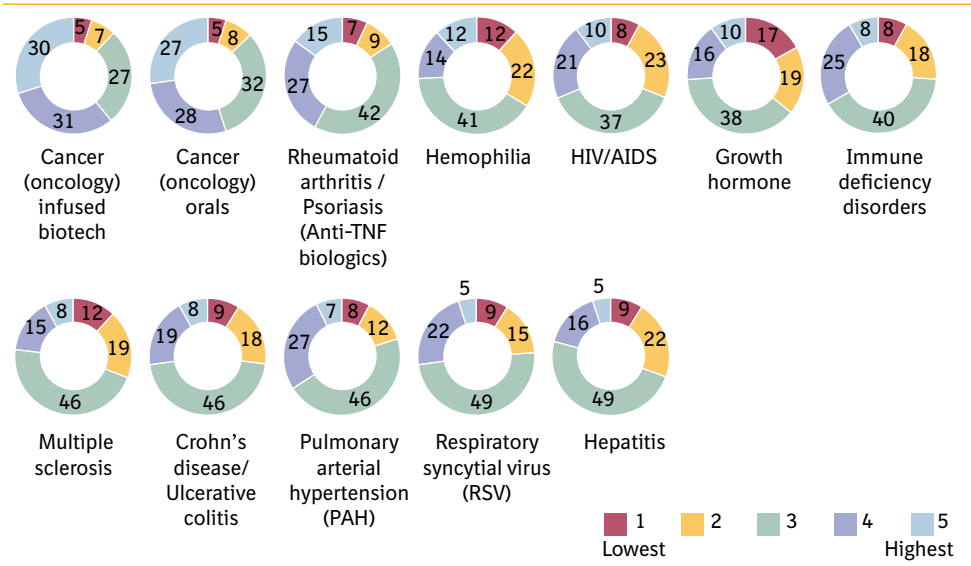


Figure 17: What barriers do you see in the diagnosis of COPD?

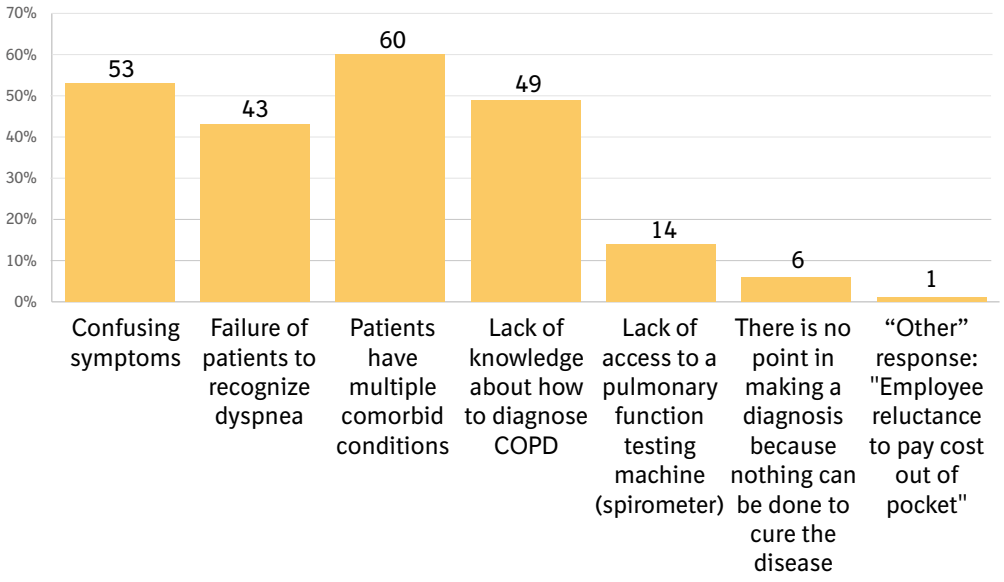
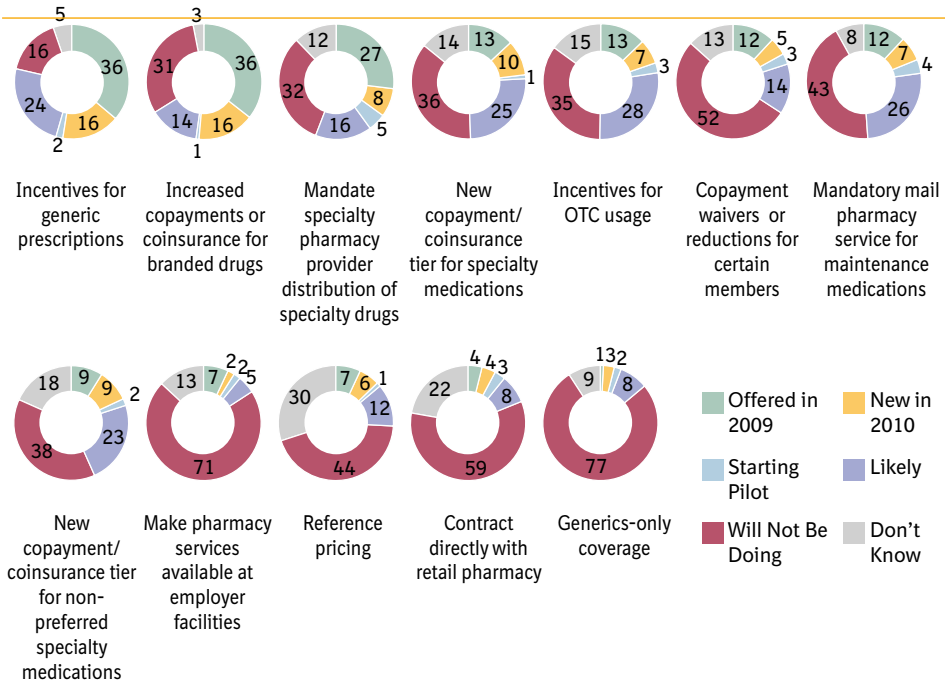


Figure 18: Which of the following prescription benefit design strategies are being implemented for active employees?



comorbidities or confusing symptoms (53%). Lattig agrees that many employers are not well-equipped either to recognize COPD or to support their employees with the condition, and are unsure what their role should be. "Once a diagnosis is made by a health care professional, employers can be helpful in two ways–by offering tools and resources to employees and dependents that augment discussions with their physicians and then by supporting them in managing their condition proactively on a daily basis," Lattig adds.

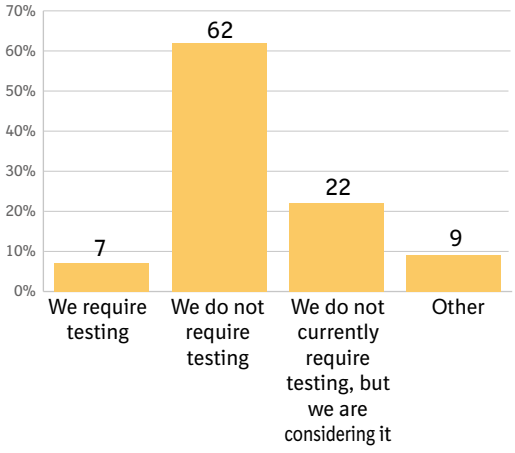
Benefit Design Strategies

Employers are implementing a variety of drug benefit management strategies, with 78% offering or likely to offer incentives for generic prescriptions; 67% increasing or likely to increase copayments or coinsurance for branded drugs; and 56% mandating or likely to mandate SP provider distribution of specialty drugs.

The majority will not be introducing generics-only coverage (77%) or making pharmacy services available at the workplace (71%). Reference pricing has not taken hold, with only 14% using it and 44% unlikely to implement it. Under reference pricing, one "reference drug'" is chosen from a group of drugs deemed equally safe and effective. Its price is covered but if employees want a more expensive drug from that group they have to pay the difference. Goff says he is surprised that even that many are using it, more than those that utilize generics-only coverage (6%).

All of the contributors agree that genomic testing should not be a

Figure 19: What is your policy for requiring genomic testing to determine patient receptivity before authorizing biologic therapy where success depends on genomic profile?



Employers are implementing a variety of drug benefit management strategies.

Medication adherence is recognized as important by employers but typically is not measured.

requirement for certain biologic therapies and that more data on the screenings are needed; however, 29% of respondents say they do require testing or are considering implementing it.

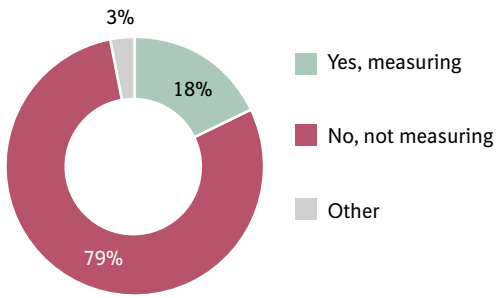
The Importance of Medication Adherence

Medication adherence, while recognized as important by employers, is typically not measured. "The single most important reason why health status doesn't improve is because of medication non-adherence," says Boress. He attributes a lack of adherence measurement (79.5%) to a stronger focus by employers on cost, few standardized tools to measure it, insufficient data from health plans and PBMs, and failure to look at medication adherence by drug category or disease state. Of the 3 billion prescriptions dispensed annually in the United States, 40% are not taken as directed, and patients do not even pick up 12% of them.[7]

Contrary to what respondents indicate, a survey by Aon Benfield shows that medication adherence is among employers' top health management objectives.[8] Admittedly, being concerned about adherence and measuring it can be worlds apart.

Medication nonadherence or not taking medication as prescribed contributes to poorer health, more frequent hospitalizations, and a higher rate of mortality, as well as resulting in $290 billion annually in additional medical costs.[9]

Figure 20: Is your organization measuring patient therapy adherence (compliance)?



According to Vogenberg, non-adherence is not on many employers' radar screens. "They think that if utilization is lower, they save money,' he says. "Unfortunately, they put drug costs into a silo without looking at the impact on total medical costs."

Health Care Management Priorities

When employers are asked about their health care management priorities, cost expectedly leads the list. Although improving employee health elicits a 74% response (combining 4 and 5 responses), implementing more employee health management programs weighs in at just 57%.

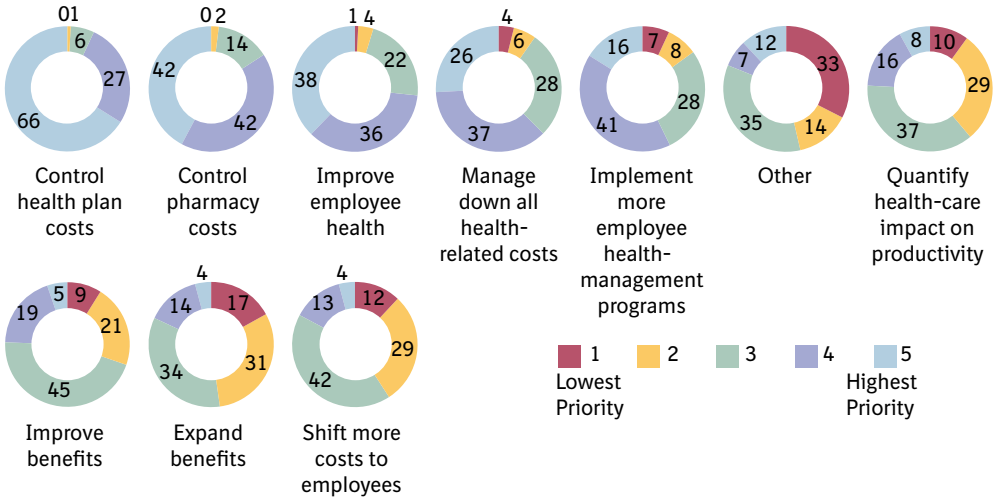
Of factors considered in determining the value of therapy or drug regimen, improved outcomes (76%) was first, just ahead of price (76%). Efficacy and safety received a 65% response, which Lattig expected to be higher and in line with price and outcomes.

Only 22% of respondents considered productivity in determining the value of a drug regimen. "Productivity is difficult to measure and often times employers are not skilled at measuring it," says Lattig. "In addition, a drug regimen is typically part of an overall treatment plan, making it more cumbersome to ferret out the productivity related to the drug vs other treatment modalities. For those that do attempt to measure it, their savings numbers may be challenged by the C-suite in that they are often considered soft-dollar savings and much less relevant to business decisions than hard-dollar savings."

Measuring Indirect Costs

Besides presenteeism (40%), productivity and long-term disability, which are more

Figure 21: What are your organization's health care management priorities?



difficult to measure, are taken into consideration less often than absenteeism (74%), workers' compensation (58%) and short-term disability (53%). "Many of these factors are managed in a silo without any knowledge of their impact on each other," Kaplan says.

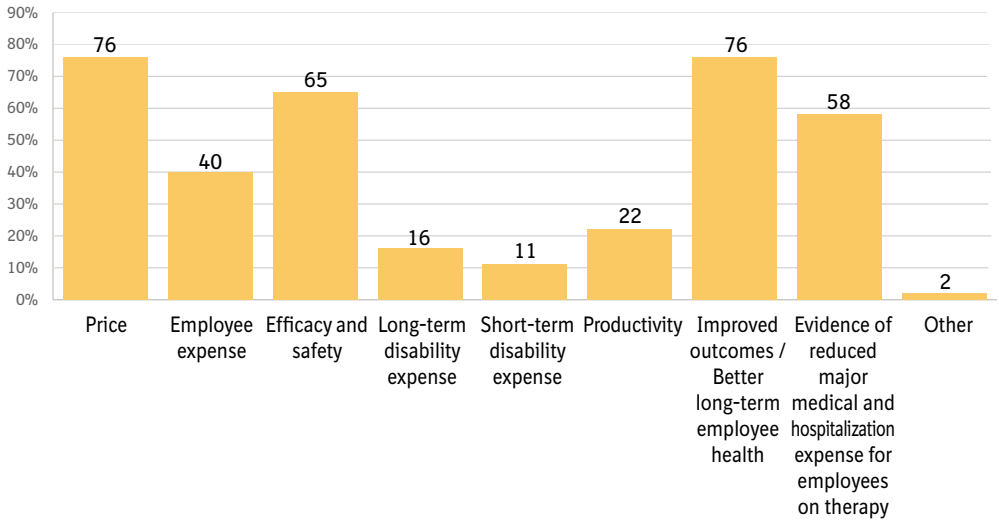
Lattig emphasizes the importance of productivity and presenteeism but admits that fewer absences and evidence of lower workers' compensation costs are more tangible to corporate executives. That said, Lattig believes that there are ways–requiring organizational commitment to do the analysis–to quantify the indirect impact of poor health and poor health care that would provide a powerful decision tool to business leaders in thinking about how and when to invest in improving the health status of their employees.

With many employers using a paid time off system that doesn't distinguish between vacation and sick days, they may not be aware of why their employees are absent, which according to Goff makes it difficult to measure how absenteeism is related to health.

When employers are asked if they measure lost productivity, only 15% say they do. Nearly half (47%) do not have sufficient data, while half say that they do not have a methodology for

In determining a treatment's value, outcomes were ranked on par with cost.

Figure 22: Which of the following factors do you consider when determining the value of a therapy or drug regimen?



Just
15%
of employers measure lost productivity.

measuring productivity. Boress acknowledges that few employers–especially those that offer paid time off to their employees or do not use time cards–measure indirect costs, such as presenteeism and absenteeism, even though they have a large impact on overall costs.

Presenteeism is of low interest with only 8% measuring it, while 65% say they measure absenteeism and 26% measure employee engagement. Lattig says that more companies are investing in wellness than presenteeism and hoping that the investment in wellness will drive not only hard dollar improvements in medical costs, but in absenteeism and presenteeism. "Ultimately, the investment will have a tangible impact on product or service quality and unit costs–all of which does have a meaningful impact on business profit margins," she says.

Health-related productivity costs are significantly greater than medical and pharmacy costs alone. On average, every $1 of medical and pharmacy costs is matched to $2.30 of health-related productivity costs and can vary by condition.[10] The study suggests that many employers miss an opportunity to improve productivity and their bottom line by failing to recognize and prioritize health conditions when they develop integrated employee health benefit strategies.

A survey on health and productivity management by Integrated Benefits Institute shows that employers more frequently measure sick days and disability absences–usually through administrative and claims data–than they measure presenteeism or health-related lost productivity. Employers recognize the value of measuring outcomes but typically cite insufficient resources as reasons for not doing so.[11]

Figure 23: Does your organization measure lost productivity?

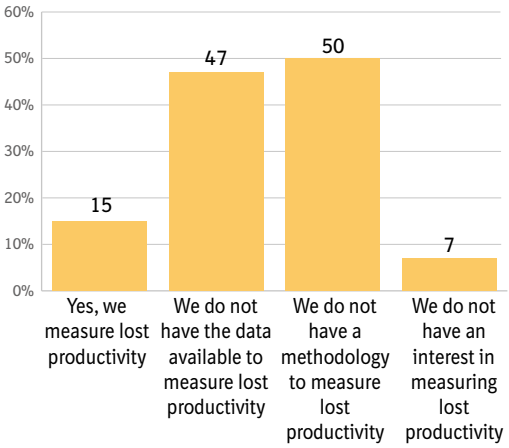


Figure 24: When measuring the financial impact of employee health, does your organization consider the following in addition to direct costs?

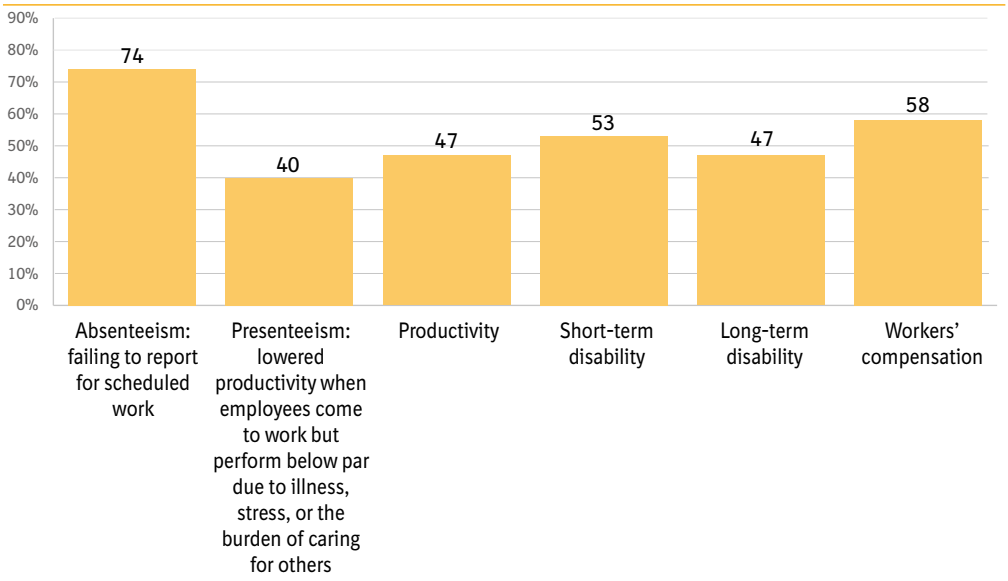
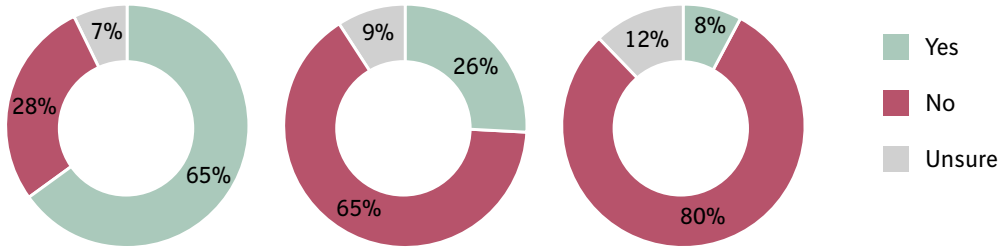


Figure 25: Is your organization measuring:



Absenteeism: failing to report for scheduled work

Employee engagement: the level of connection that an employee feels for the organization, influencing greater discretionary effort in his or her work

Presenteeism: lowered productivity when employees come to work but perform below par due to illness, stress, or the burden of caring for others

Boress reiterates his concern about employers not measuring productivity because they prefer to show hard dollar savings–only 27% agree or strongly agree that productivity is the best way to measure the value of employee health, while 50% remain neutral. However, he notes that 93% agree or strongly agree that worker health is important to organizational performance. "Employers understand the value of good health, but they are still not measuring it," Boress says. Responses to a previous question about a company's health care management priorities bears this out: only 24% say that quantifying health care's impact on productivity is a high or highest priority.

Again, employers are showing interest in productivity but are not necessarily doing anything about it. As many as 87%

Employers agree that worker health is important to organizational performance.

Table 1: Please indicate your professional opinion of the following statements:

	1 Strongly disagree	2	3 Neutral	4	5 Strongly Agree
Worker health is important to organizational performance.	3%	1%	4%	35%	58%
Medical and pharmacy benefits are an important investment in organizational productivity.	4%	1%	11%	36%	49%
It is important for an organization's management to understand the economic value of employee health.	3%	2%	8%	39%	48%
Employee health is an asset that an organization can manage, not just an expense.	2%	6%	21%	39%	31%
Productivity is the best way to measure the value of employee health.	4%	20%	50%	22%	5%
It is easy to determine the long-term value of most medications.	14%	39%	38%	7%	2%
It is easy to determine the long-term value of medications for chronic diseases.	11%	25%	43%	18%	4%
We determine the value of therapy by looking at outcomes as well as cost.	8%	20%	35%	31%	6%
Organizations incur $2.30 in productivity losses for each dollar spent on health-care and pharmacy costs due to unhealthy employees who are absent or continue to work even while ill.	5%	9%	68%	14%	4%
When employees are asked to make a substantial contribution to the cost of their health care through high deductibles and copays, they are empowered to make better decisions about their care.	11%	20%	28%	30%	10%
Lower employee cost contributions increase use of medical services but do not substantially increase productivity or employee health.	5%	14%	36%	36%	9%
When employees are asked to make a substantial contribution to the cost of their health care, they often opt not to get the care they need because of financial considerations.	4%	12%	27%	38%	19%

23%

of employers are considering implementing value-based insurance design, while 10% have adopted or are piloting the approach.

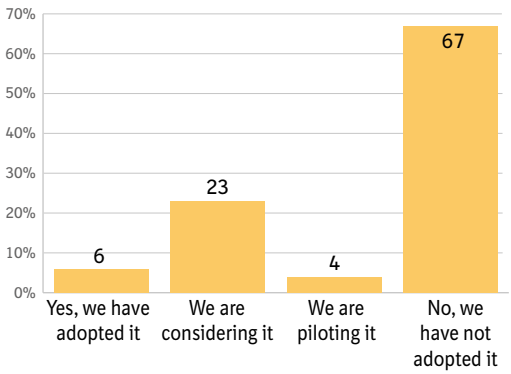
agree or strongly agree that it is important for an organization's management to understand the economic value of employee health, and 85% agree or strongly agree that medical and pharmacy benefits are important investments in organizational productivity. (See "Investing in Health and Productivity Management as a Business Strategy," page 71.)

Value-based Insurance Design

Two-thirds of employers have not adopted value-based insurance design (VBID) (67%). Goff notes that most VBID programs supported by employers are larger, self-insured organizations.

The contributors agree that there is no common definition of VBID, at least as indicated by study responses, which may be one reason that uptake is not particularly high. Two-thirds of employers could not offer a definition of VBID, believing it to be limited to the original Pitney Bowes model of waiving copayments for medications used in the treatment of a specific disease. Boress suggests that VBID efforts do not always target the right populations and when adherence doesn't improve, they dump the program. "We need to help employers to understand about measuring outcomes so that they can introduce VBID," he says.

Figure 26: Has your organization adopted "valued-based insurance design"?

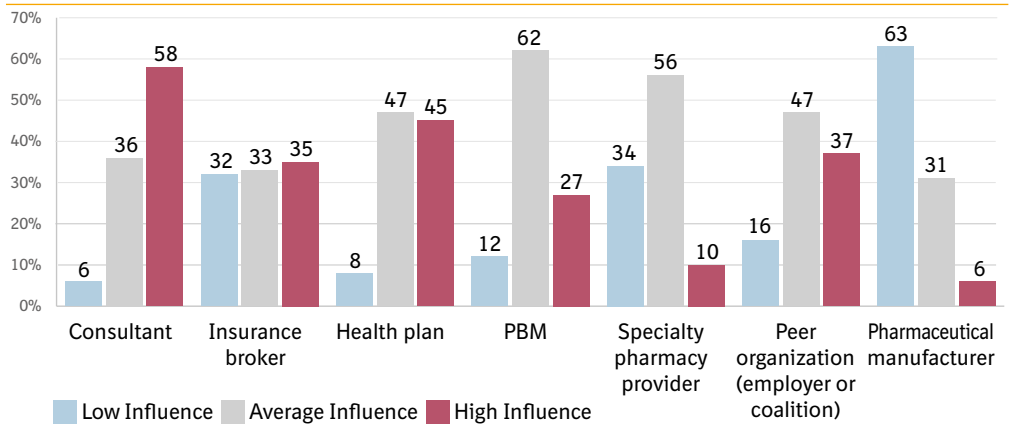


Mirroring responses to an earlier question about the influence of various entities on pharmacy benefit design, consultants, and health plans come out on top regarding implementation of VBID. Fifty-eight percent of employers believe that consultants have a high degree of influence, while 45% say plans do. Only 27% and 10% say PBMs and SP providers have a high degree of influence, respectively.

Managing Chronic Conditions

Phone-based coaching, online self-help, and education and printed materials are overwhelmingly the most popular ways to manage chronic conditions. Although focus groups have shown that face-to-face coaching is preferred by employees, Boress says, many companies feel it is too expensive. Kaplan concurs that face-to-face coaching and support groups, which ranked the lowest with respondents, are expensive but can make

Figure 27: Who would be most influential in helping your organization implement value-based benefit design?



a big difference. Lattig advocates for phone-based coaching as a cost effective program component, but notes that it should be accompanied by a series of localized and workplace-based modules and resources that support a health-focused corporate culture.

"For some employers," Lattig continues, "it can be a migratory strategy, starting with a telephonic approach. Once savings are generated, employers can justify the expense to management and intensify their approach through on-site coaching, thus effectively 'self-funding' the additional expense of the program."

A 2010 survey by Hewitt Associates found low participation rates among employees for patient education and support programs. Despite two-thirds of companies offering a nurse counseling phone line in 2009, only 13% of employees on average used the program; 61% of employers were satisfied with the results.[12]

The majority of companies do not offer incentives to encourage participation in disease management programs. Incentives seem to be used more often to promote wellness programs, such as smoking cessation and weight loss. However, the survey conducted by Health2 Resources and the National Association of Manufacturers finds that as many as two-thirds of all companies offer incentives with their health and wellness programs.[3]

Findings from a report by the National Business Group on Health and Towers Watson show that in 2009 only 26% of companies offered financial incentives for participation in disease management programs, while 40% provided such incentives for smoking cessation programs and 34% did so for weight loss programs. Similar percentages are expected for 2010.[13]

The majority of disease management programs for employees are administered by a health plan, ranging from 69% for COPD and depression to 66% for hypertension. Many employers administer their own programs for smoking cessation (22%) and weight loss (29%). Approximately one-quarter of employers also turn to contractors to undertake programs for smoking cessation (34%) and weight loss (32%).

Lattig is not surprised that plans accept the most responsibility because she says they are the most equipped to administer an integrated program. "Many employers and business leaders expect the solution to chronic condition management to be in the health plan; therefore, they look

Employers favor phone-based coaching to manage chronic conditions.

Figure 28: If your organization offers special programs to help manage chronic conditions, what is being offered?

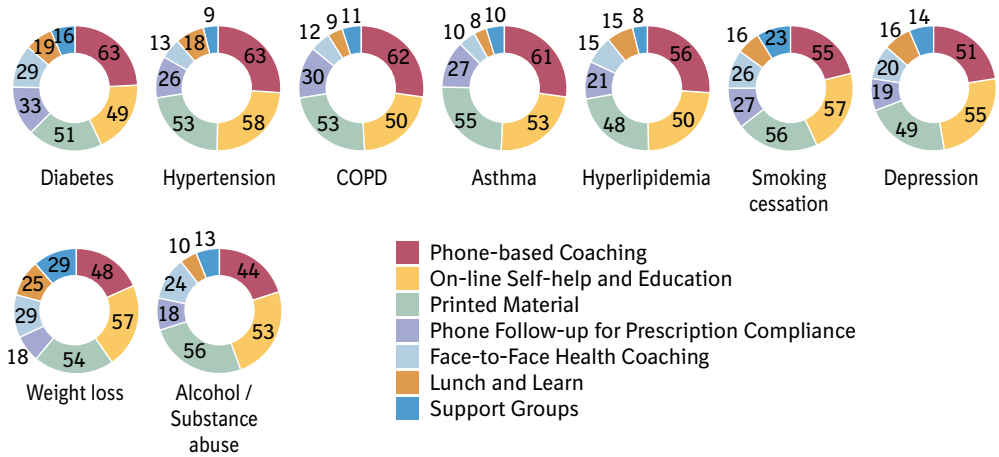
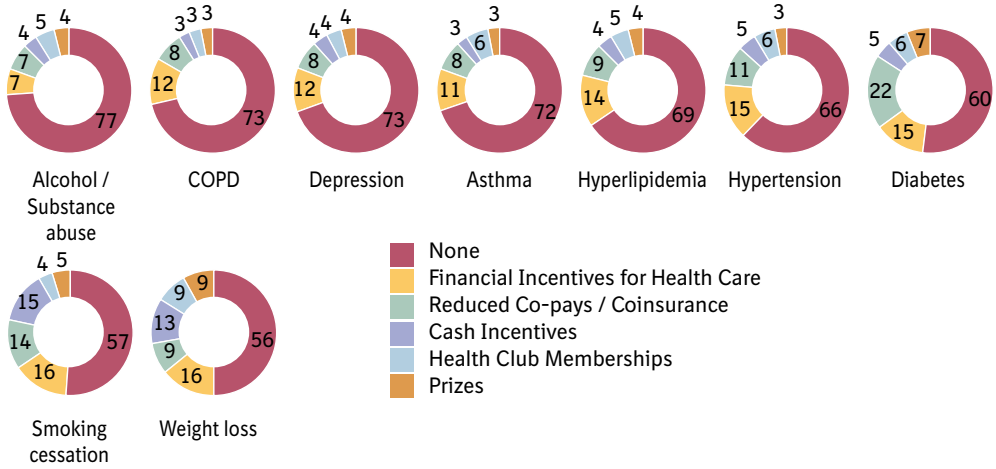


Figure 29: What incentives do you offer to participants in these programs?



Employers are most likely to offer incentives to participate in weight loss programs.

to outsource solutions through an integrated approach expending as few internal resources as possible to manage programs, regardless of the outcomes they expect to achieve," she adds.

Overall cost savings, improved compliance, and improved outcomes were the most common references for measuring outcomes of disease management programs.

Figure 30: How do you measure outcomes?

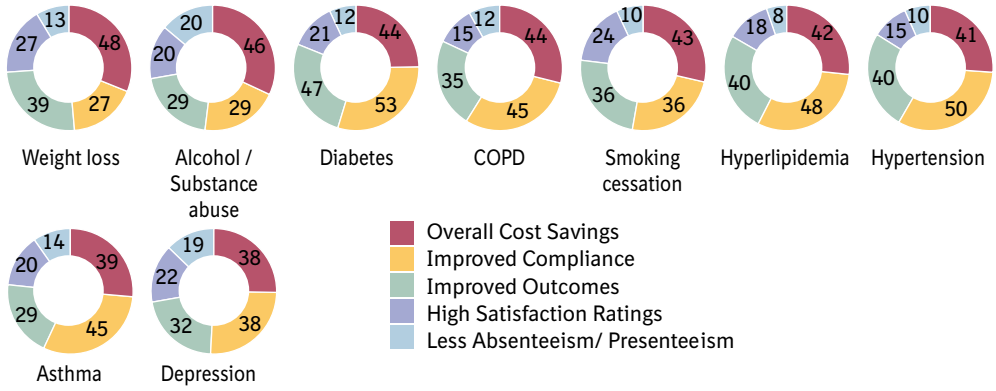
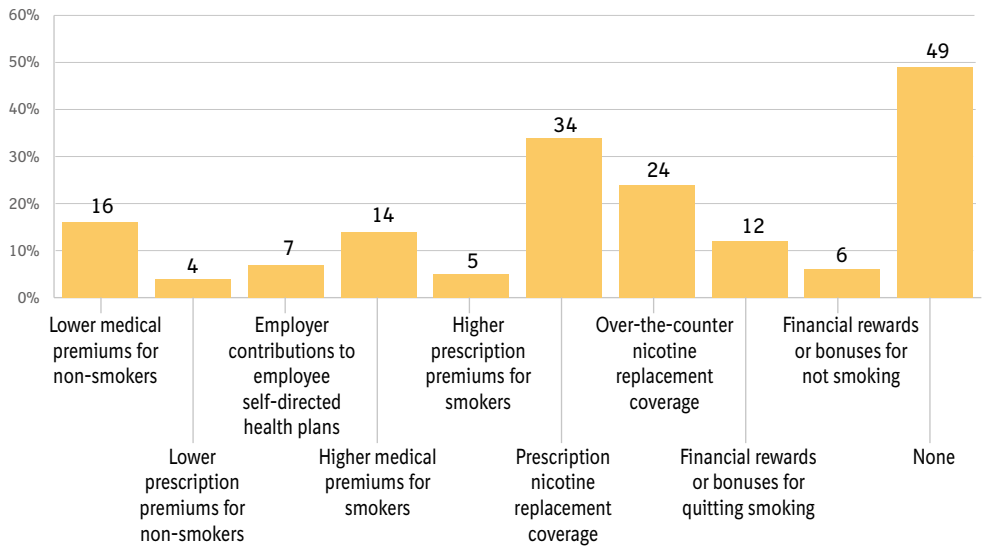


Figure 31: What benefit plan design options does your organization currently have in place to support COPD management and/or smoking cessation?



More than half (57%) of employers say they currently invest in long-term solutions to improve the overall health and productivity of their workforce, down from 62% in 2009, while 95% are primarily focused on controlling their annual health care costs.[12]

Nearly half of employers do not support the management of COPD or sponsor smoking cessation programs. The most commonly used design option is prescription nicotine replacement coverage (34%), a percentage that Lattig considers low, as the incentive is easy to administer. "Because COPD is often the result of smoking, the real issue is supporting smoking cessation," she explains.

It is clear that employers make little distinction between incentive-based initiatives to support COPD management and smoking cessation, and punitive measures. Only 4% charge lower pharmacy premiums for non-smokers, while 5% increase premiums for smokers. Implementing lower medical premiums for non-smokers is favored by 16% of respondents, while 14% increase those premiums for smokers.

Prescription Drug Coverage for Retirees

Two-thirds of employers do not offer prescription drug coverage for Medicare retirees. According to Towers Watson, only 14% of employers have introduced or expanded Medicare Advantage individual plan offerings for Medicare retirees, with only 2% planning to do so in 2009-2010; nearly one-fourth (23%) plan to reduce or eliminate subsidized coverage for current retirees.[14]

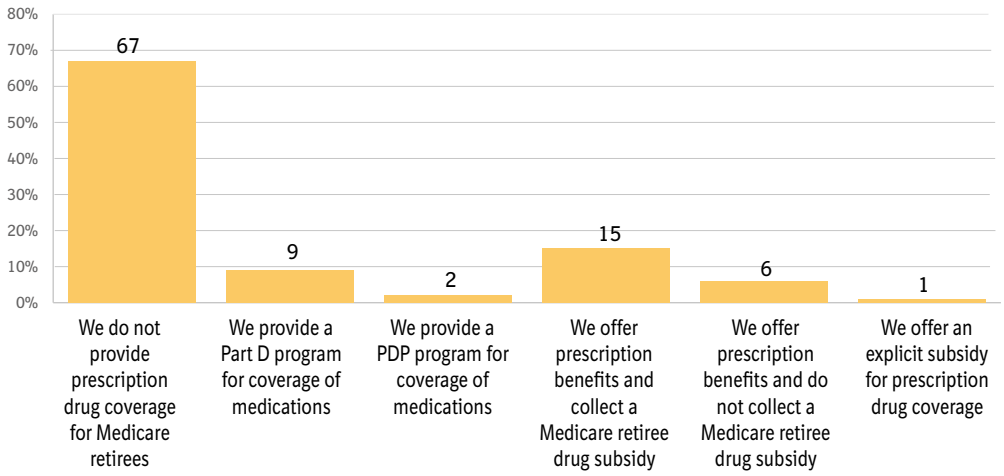
Goff expected that the percentage offering pharmacy benefits and collecting a Medicare retiree drug subsidy would be higher, especially for self-insured employers. Under the Medicare Prescription Drug Modernization Act of 2003, the Medicare Retiree Drug Subsidy (RDS) program provides financial incentives, in the form of direct payments, to employers that continue to provide prescription drug benefits for their retirees, instead of abandoning the plans in response to the inclusion of such benefits under Medicare.[15]

Lattig believes that employers are waiting to see the impact of health care reform legislation on Medicare before making any key decisions on coverage, as illustrated by the one-third of employers who intend not to implement

34%

of employers offer coverage of prescription nicotine products.

Figure 32: Which of the following statements best describes your organization's strategy for Medicare retiree prescription drug coverage?



Two-thirds of employers do not provide prescription drug coverage for retirees.

Table 2: If your organization offers prescription benefits to Medicare-eligible retirees, how likely is your organization to implement the following healthcare cost-management strategies?

	Offered in 2009	New in 2010	Piloting	Likely	Would Not Consider	Don't Know
Reduce retiree health-care benefits	6%	14%	1%	16%	39%	24%
Tighten restrictions on eligibility	7%	10%	1%	24%	41%	16%
Change benefit plan design	9%	12%	3%	34%	25%	18%
Change employer subsidy/ Cost sharing	9%	10%	1%	28%	31%	19%
Eliminate employer subsidy	6%	3%	1%	12%	49%	29%
Eliminate Part D coverage	3%	3%	0%	9%	50%	34%
Offer Part D coverage	18%	6%	0%	11%	37%	28%
Drop prescription drug coverage entirely	3%	3%	0%	7%	64%	23%
Add a tier for specialty pharmaceuticals	12%	7%	0%	25%	31%	25%
Make no changes	5%	5%	0%	33%	28%	30%

any health care cost management strategies related to prescription drug coverage for Medicare-eligible retirees. If they are inclined to do anything, they are or will be changing benefit plan design (45%), adding a tier for SP (44%), or changing their employee cost-sharing formula (47%). (See "Employers Face Changes with Reform Legislation," page 73.)

Part 2: Findings from Health Plan Research

Part 2: Findings from Health Plan Research

Part 2 of *The Boehringer Ingelheim Pharmacy Benefits Report* examines the views of 100 managed care executives. Findings of the health plan survey reveal managed care organizations' efforts and expectations in the areas of benefit design, cost and utilization management, medication adherence, and specialty pharmacy.

Oncology drug costs are a top concern of health plans.

Key findings include:

- The majority of HMOs (51.2%) and PPOs (54.1%) expect per member per month (pmpm) costs to increase 0% to 5% during the next 12 months as do nearly half of Medicare Advantage-Prescription Drug (MA-PD) plans, 40% of stand-alone Prescription Drug Plans (PDPs), and 42.6% of managed Medicaid plans.
- The majority of commercial plans use an open formulary, while about half of Medicare plans use a closed formulary.
- Most plans, whether commercial or Medicare, have not built four or more tiers into their formulary to accommodate non-preferred specialty or lifestyle drugs.
- Quantity limits, prior authorization and step therapy head the list of utilization management techniques of plans. The least used tools are coverage of over-the-counter (OTC) drugs and mandatory mail service for maintenance medications.
- Generic substitution is the most important tool used by health plans for managing the cost of most therapeutic classes, followed by generic therapeutic alternatives, and step therapy.
- Diabetes continues to lead the list of chronic conditions for which commercial plans most want to contain costs. Respondents also express concern over rising costs of hyperlipidemia, hypertension, asthma, and chronic obstructive pulmonary disease (COPD). On the specialty pharmacy side, oncology infused and oral drugs, the use of anti-tumor necrosis factor (TNF) drugs in the treatment of rheumatoid arthritis (RA), and multiple sclerosis (MS) medications present the most concern to plans regarding costs.
- Plans are trying a variety of new and/or additional strategies to manage specialty pharmacy, with many having implemented quantity limits for selected drugs, set maximum day supply limits, increased the number of drugs requiring prior authorization, and developed distribution limited networks in 2009. Less popular strategies include eliminating cost-sharing differentials for self-administered vs physician-administered drugs, making cost-sharing independent of drug and administration channels, reducing or waiving member copayments for certain drugs, and implementing a value-based insurance design (VBID) for some therapeutic categories.
- Plans are most worried about cost (81.9%), appropriate utilization

Most health plans expect a pmpm increase of up to 5% over the next 12 months.

(73.1%), and clinical outcomes (65.9%) in managing specialty pharmacy.

- As plans begin to realize the impact of drug adherence on their overall costs and the health status of their members, they cite the following as important or very important as the top three results of better adherence: improved patient health (94.7%), patient participation (90.5%), and better patient care outcomes (88.3%).
- Nearly one-third of health plans say they have implemented value-based insurance design (VBID) in at least one therapeutic category.
- Evidence-based medicine (EBM) has influenced managed care organizations in a variety of ways: two-thirds of health plans say that EBM has influenced their practice guidelines; 62.9% have used findings to change their formulary; and 56.2% have changed their disease management strategies. Much smaller proportions have used EBM to implement VBID (12.4%) or set provider incentives (11.2%).

Interpreting the Findings

The following medical and pharmacy benefit experts reviewed the survey research and shared their insights:

- Maria Lopes, MD, former chief medical officer, Group Health, Inc, New York, NY
- Tamara Howerton, RPh, clinical pharmacist, Medicare, Health Alliance Medical Plans, Champaign, IL
- Jacqueline Rothschild, RPh, former pharmacy director, AmeriChoice, Phoenix; currently with a PBM
- Bonnie May, RPh, consultant pharmacist, University of Massachusetts Medical School

A pharmacy director at a Northeast regional plan also contributed his thoughts.

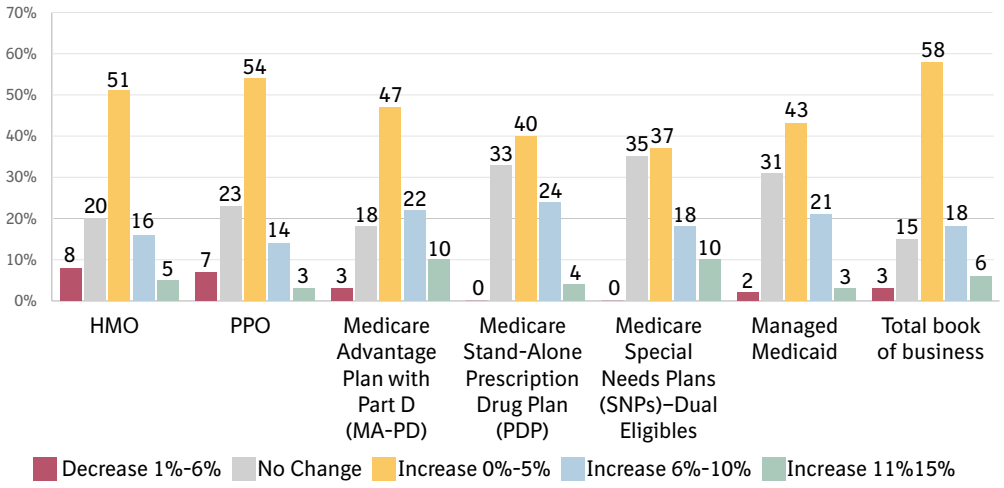
Research Results

Pharmacy and Medical Cost Trends

The majority of HMOs (51.2%) and PPOs (54.1%) expect per member per month (pmpm) costs to increase 0 to 5% during the next 12 months, as do 47.2% of Medicare Advantage-Prescription Drug (MA-PD) plans, 40% of stand-alone Prescription Drug Plans (PDPs), and 42.6% of Managed Medicaid plans.

Maria Lopes, MD, notes that the high cost of specialty pharmacy will have an influence on respondents' projections in the future. Randy Vogenberg, PhD, adds that specialty pharmacy trend increases

Figure 33: What is your expectation of per member per month (pmpm) pharmacy cost trends in the next 12 months for the following lines of business?



are beginning to outpace non-specialty pharmacy trend savings.

Although prices of generics fell, along with the negative rate of general inflation, overall prescription drug prices increased by an average of 5.4%. Brand-name drug costs grew by 9.3%, while specialty drug prices increased by 10.3% in the 12 months ending in September 2009–exceeding any growth seen in the previous seven years (during which specialty drug price increases ranged from 1.7% to 9.3%).[16]

Projections from the Centers for Medicare and Medicaid Services (CMS) fall right in line with a 4.5% increase in drug spending growth expected for 2010.[17]

Making Formulary Decisions

Open formularies are most common among commercial health plans, used by 54% of HMOs and 66% of PPOs reporting. Closed formularies are used by just over half (51%) of the Medicare MA-PD plans reporting. Few respondents report having generics-only plans.

A three-tier formulary (generics, preferred brands, non-preferred brands) is most common for commercial plans (44% for HMOs and 37% for PPOs), while a four-tier formulary–often including specialty or lifestyle drugs–is more popular for Medicare plans (28% for MA-PD and 25% of PDP).

Nearly 11% percent of workers are in plans that have four or more tiers of cost sharing for prescription drugs.[18]

Plan Benefit Design

Responses for average copayments are in line with findings of the Kaiser Family

Specialty pharmacy trend increases are beginning to outpace non-specialty trend savings.

Figure 34: What type of formulary is used most frequently in your health plans?

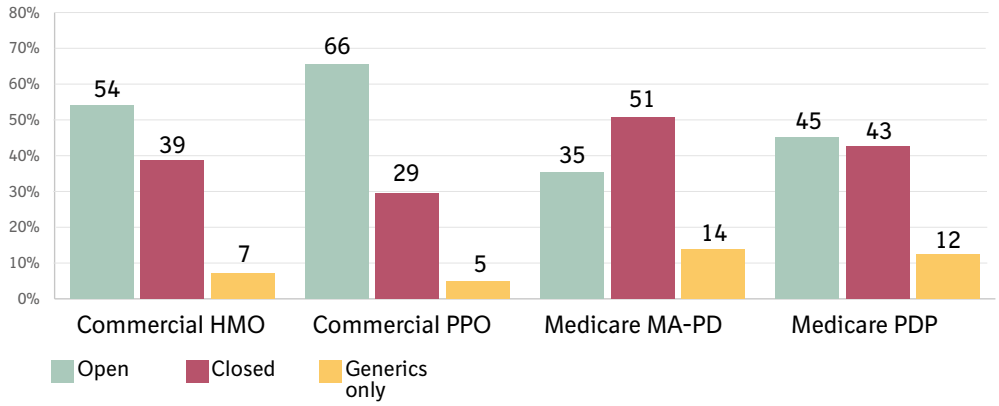
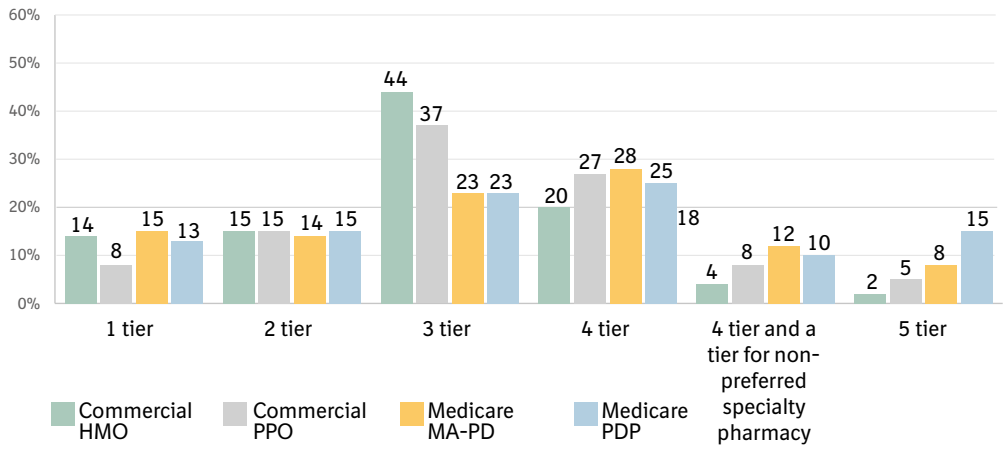


Figure 35: What type of tier structure is used most frequently in your health plans?



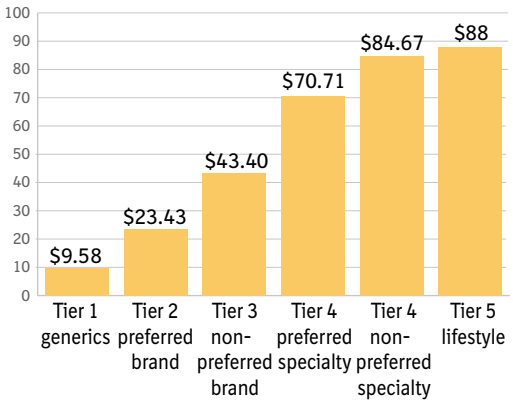
Of all OTC therapeutic categories, plans are most likely to cover proton pump inhibitors.

Foundation, with estimated copayments of $10, $27, and $46 for first-, second-, and third-tier drugs, respectively.[18]

Bonnie May challenges the high average copayment of $88 for lifestyle drugs, arguing that most payers do not cover lifestyle drugs, such as those used for hair loss.

Tamara Howerton says it makes sense that plans report coverage for few OTC pain medications, as their use affords little cost savings. However, she supports coverage of OTC proton pump inhibitors (PPIs) because of their high utilization for ulcers and the high cost of branded PPIs.

Figure 36: For your largest commercial plan, please indicate the average member contribution: Copayment ($)



Managing Utilization/Costs

Utilization management techniques adopted by different health plan options are similar across the board. Using quantity limits is the most common technique of HMOs, PPOs, and MA-PDs, while taking the number two spot for PDPs. Prior authorization is most utilized by PDPs, while ranking second for the other three lines of business. Step therapy ranks third for all lines of

Figure 37: Which of the following over-the-counter (OTC) products are covered by your largest benefit plans?

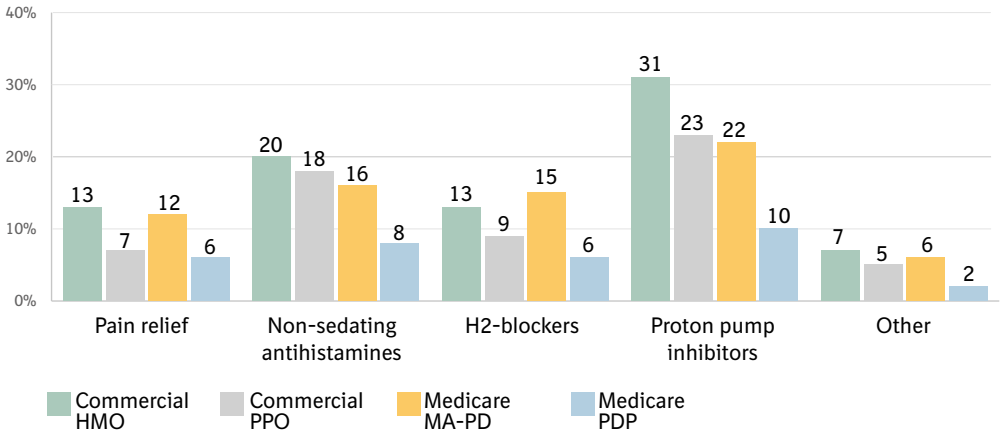


Table 3: What utilization management techniques do you use? Responses are ranked.

	HMO	PPO	MA-PD	PDP
Quantity limits	1	1	1	2
Prior authorization	2	2	2	1
Step therapy	3	3	3	3
Mandatory generics	4	5	4	4
Mandatory specialty pharmacy programs	5	4	5	5
Half-tab programs (pill splitting)	6	7	6	6
Selected brand-name exclusions	7	6	7	7
OTC coverage	8	8	9	8
Mandatory mail service pharmacy for maintenance medications	9	9	8	9

business. Mandatory generics and specialty pharmacy programs rank either fourth or fifth for all health plan options. OTC coverage and mandatory mail service for maintenance medications rank at the bottom of the list for all respondents.

Diabetes (89.2%), hyperlipidemia (72.2%), and asthma (70.0%) rank as the conditions of greatest concern for commercial benefit plans.

Although Alzheimer's disease elicited less concern than many other conditions, Lopes says it is a disease ripe for cost containment efforts because of the aging population, growing prevalence, anticipated availability of generics, and new drug treatments in the pipeline.

Plans are also concerned about rising costs associated with depression, a common comorbid condition with cancer and heart disease.

Bonnie May notes that concern over managing costs for COPD has lessened from last year, which she attributes to the implementation of Healthcare Effectiveness Data and Information Set (HEDIS) measures that have resulted in better management of the condition.

In reporting their concern over rising pharmacy and specialty pharmacy costs, commercial plans cite cancer treated with oral agents as their number one concern (80.3%), followed by RA (75.9%), cancers treated with infused biotech drugs (71.5%), and MS (62.0%). Again, May suggests that those conditions generating less concern are probably being better controlled. A pharmacy director with a regional plan in the Northeast expressed some

Diabetes is the condition of greatest concern for commercial health plans.

Table 4: My organization's largest commercial benefit plan is concerned with managing the pharmacy costs of these conditions:

	1 Least Concerned	2	3	4	5 Most Concerned
Allergic rhinitis	25.3%	36.3%	25.3%	7.7%	5.5%
Alzheimer's disease	16.5%	30.8%	35.2%	11.0%	6.6%
Asthma	0.0%	4.4%	25.6%	41.1%	28.9%
COPD	2.2%	3.3%	37.4%	33.0%	24.2%
Depression	2.2%	3.3%	35.9%	35.9%	22.8%
Diabetes	1.1%	0.0%	9.8%	28.3%	60.9%
Gastrointestinal disorders	3.3%	8.8%	35.2%	33.0%	19.8%
Hyperlipidemia	3.3%	3.3%	21.1%	33.3%	38.9%
Hypertension	2.2%	5.4%	27.2%	31.5%	33.7%
Infectious disease (bacterial)	6.6%	24.2%	44.0%	17.6%	7.7%
Infectious disease (viral)	4.4%	23.3%	44.4%	22.2%	5.6%
Insomnia	9.9%	33.0%	41.8%	12.1%	3.3%
Migraine	5.6%	21.1%	46.7%	21.1%	5.6%
Obesity	20.9%	19.8%	31.9%	16.5%	11.0%
Osteoporosis	5.5%	14.3%	44.0%	27.5%	8.8%
Psychosis	4.4%	13.2%	42.9%	24.2%	15.4%
Other psychiatric conditions (anxiety, ADHD, etc.)	3.3%	11.1%	40.0%	34.4%	11.1%
Pain	2.2%	8.9%	33.3%	40.0%	15.6%
Seizures	5.6%	16.9%	50.6%	20.2%	6.7%
Urological disorders	10.1%	25.8%	46.1%	14.6%	3.4%

Health plans are most concerned about the specialty costs of infused biotech cancer drugs, followed by anti-TNF biologics for RA.

Table 5: My organization's largest commercial benefit plan is concerned with managing the pharmacy and specialty pharmacy costs of these conditions and categories:

	1 Least Concerned	2	3	4	5 Most Concerned
Cancer (oncology) infused biotech	4.4%	3.3%	20.9%	27.5%	44.0%
Cancer (oncology) orals	3.3%	2.2%	14.3%	42.9%	37.4%
Crohn's disease/Ulcerative colitis	3.3%	7.7%	37.4%	35.2%	16.5%
Growth hormone	7.6%	9.8%	31.5%	27.2%	23.9%
Hemophilia	8.7%	14.1%	29.3%	27.2%	20.7%
Hepatitis	5.5%	8.8%	35.2%	37.4%	13.2%
HIV/AIDS	9.9%	8.8%	38.5%	27.5%	15.4%
Immune deficiency disorders	7.9%	7.9%	44.9%	27.0%	12.4%
LMWH (low molecular weight heparin)	7.8%	14.4%	38.9%	27.8%	11.1%
Multiple sclerosis	6.5%	5.4%	26.1%	37.0%	25.0%
Pulmonary arterial hypertension (PAH)	5.5%	9.9%	38.5%	30.8%	15.4%
Respiratory syncytial virus (RSV)	6.6%	14.3%	37.4%	24.2%	17.6%
Rheumatoid arthritis/Psoriasis (Anti –TNF biologics)	2.2%	5.5%	16.5%	36.3%	39.6%

Table 6: What has been your organization's primary benefit design strategy for managing the cost of the following therapeutic classes?

	Generic Substitution	Generic Therapeutic Alternatives	Higher Copays	Increased Coinsurance	Creation of Formulary Tier	Management by Specialty Pharmacy	Step Therapy	Prior Authorization
Anticonvulsants	56.8%	22.7%	5.7%	2.3%	12.5%	0.0%	9.1%	12.5%
Antivirals	47.6%	25.0%	4.8%	1.2%	11.9%	7.1%	4.8%	14.3%
Antibiotics	61.2%	25.9%	3.5%	0.0%	8.2%	1.2%	5.9%	9.4%
Immunosuppressants	37.9%	18.4%	9.2%	3.4%	12.6%	19.5%	6.9%	13.8%
Antihypertensives	57.8%	28.9%	5.6%	0.0%	10.0%	0.0%	23.3%	2.2%
Lipid-lowering drugs	48.4%	35.5%	5.4%	2.2%	10.8%	0.0%	24.7%	8.6%
Antidiabetic agents	47.2%	27.0%	2.2%	1.1%	14.6%	1.1%	19.1%	10.1%
Ulcer/GERD therapy	44.1%	34.4%	6.5%	1.1%	14.0%	0.0%	29.0%	11.8%
Narcotic agents	49.4%	29.2%	4.5%	1.1%	12.4%	1.1%	12.4%	20.2%
Non-narcotic agents	59.5%	28.6%	4.8%	0.0%	10.7%	1.2%	9.5%	7.1%
Bisphosphonates	51.7%	31.0%	2.3%	1.1%	14.9%	2.3%	25.3%	11.5%
Antihistamines	54.7%	30.2%	9.3%	3.5%	8.1%	1.2%	14.0%	8.1%
Asthma agents (Inhaled steroids and beta agonists)	40.2%	26.8%	7.3%	0.0%	19.5%	1.2%	24.4%	7.3%
Anorexiants	41.3%	20.0%	6.3%	1.3%	10.0%	1.3%	6.3%	30.0%
Antidepressants	50.0%	28.9%	3.3%	0.0%	15.6%	0.0%	27.8%	11.1%
Antipsychotics	43.5%	22.4%	7.1%	0.0%	18.8%	1.2%	17.6%	10.6%
Antianxiety agents	65.1%	28.9%	2.4%	0.0%	10.8%	0.0%	9.6%	3.6%
Hypnotics	58.0%	27.3%	5.7%	1.1%	10.2%	0.0%	22.7%	5.7%
Migraine therapy	46.5%	31.4%	3.5%	1.2%	17.4%	2.3%	17.4%	10.5%
Smoking deterrents	36.0%	13.3%	8.0%	1.3%	18.7%	1.3%	5.3%	25.3%
Erectile dysfunction agents	17.3%	9.3%	20.0%	4.0%	16.0%	1.3%	5.3%	40.0%

concern for the relatively low level of attention paid to managing the costs of HIV/AIDS (42.9%).

Although use of growth hormones generates concern (51.1%), Lopes anticipates that lack of clinical differentiation among available agents may stimulate preferred contracts with manufacturers to better contain costs, "and when a regulatory pathway for biosimilars is developed, that ought to drive competition," she adds.

When plans are asked how they manage cost for a variety of therapeutic classes, generic substitution is the primary strategy cited for every category, followed by generic therapeutic alternatives, which rank second in every class but immunosuppressants, anorexients, smoking deterrents, and erectile dysfunction agents. Creation of a formulary tier plays the next largest role for the majority of categories.

Implementing Specialty Pharmacy Strategies

Health plans use a variety of strategies to manage specialty pharmacy, many of which they introduced in or before 2009, and others they plan to implement in 2010. The most popular ones originating last year are implementing quantity limits for selected drugs (66.0%), requiring step therapy for selected drugs (64.3%), setting maximum day supply limits (62.9%), and implementing mandatory generic substitution (54.6%). Among the strategies meeting the most resistance are making cost-sharing independent of drug category and

28%

of plans are looking to start linking prescription drug and medical claims.

Table 7: Has your organization implemented the following specialty-pharmacy management strategies for your largest health plan?

	Offered in 2009	New in 2010	Likely to Start	Will Not Do	Don't Know N/A
Introduce a formulary tier for self-injectables	29.3%	5.1%	17.2%	24.2%	24.2%
Introduce tiers for preferred and non-preferred injectables/specialty drugs	29.9%	5.2%	24.7%	17.5%	22.7%
Increase patient cost sharing	30.6%	11.2%	19.4%	22.4%	16.3%
Implement quantity limits for selected drugs	66.0%	8.2%	16.5%	3.1%	6.2%
Increase number of therapeutic categories requiring prior authorization	53.7%	8.4%	15.8%	8.4%	13.7%
Require step therapy for selected drugs	64.3%	7.1%	13.3%	6.1%	9.2%
Mandate use of specialty pharmacy providers for selected drugs	50.5%	10.1%	19.2%	14.1%	6.1%
Implement therapeutic interchange	32.3%	6.3%	15.6%	31.3%	14.6%
Move major medical drugs under the pharmacy benefit	22.4%	6.1%	25.5%	25.5%	20.4%
Reduce physician payment	15.5%	5.2%	20.6%	32.0%	26.8%
Implement a value-based benefit design for some therapeutic categories	17.7%	6.3%	27.1%	27.1%	21.9%
Reduce or waive member copayments for certain medications	27.6%	3.1%	9.2%	37.8%	22.4%
Move to ASP pricing for specialty pharmacy	18.8%	8.3%	26.0%	18.8%	28.1%
Increase alignment of physician incentives	15.6%	11.5%	25.0%	18.8%	29.2%
Implement mandatory generic substitution	54.6%	9.3%	15.5%	7.2%	13.4%
Add differential copayment for multisource brands	36.8%	8.4%	14.7%	16.8%	23.2%
Implement an oral oncology program	25.0%	6.3%	34.4%	7.3%	27.1%
Carve out specialty pharmacy formulary	23.4%	4.3%	18.1%	27.7%	26.6%
Make patient cost sharing independent of Rx and administration channel	13.5%	3.1%	17.7%	31.3%	34.4%
Eliminate patient cost-sharing differentials for self-administered vs physician-administered Rx	16.0%	2.1%	13.8%	35.1%	33.0%
Set maximum day supply limits	62.9%	7.2%	13.4%	6.2%	10.3%
Link prescription and medical claims	29.9%	11.3%	27.8%	10.3%	20.6%
Have a limited distribution network for specialty drugs	50.5%	11.3%	15.5%	8.2%	14.4%

Most specialty oral drugs and self-injectables are covered under the pharmacy benefit.

administration channel, and reducing physician payment.

"The responses validate the use of introducing tiers for preferred, and non-preferred injectables/specialty drugs, and for self-injectables (almost a third offered them in 2009, with 24.7% likely to implement), step therapy, and increased cost-sharing (30.6%) as ways to manage specialty agents in the current environment," says Lopes.

Vogenberg notes that while many plans discuss cutting physician reimbursements, only a small number have actually done so. The survey indicates that 15.5% did so in 2009, and only 5.2% plan to reduce physician payment in 2010. Close to one-third indicate they will not use this strategy.

Respondents define "specialty pharmaceuticals" in a variety of ways without any strong consensus on one definition; however, special handling/storage (65%) and biotech-engineered drugs (68%) are the most common. Although half of respondents define special pharmaceuticals as "high unit-cost drugs" and as "oral oncology agents," Howerton is surprised that the percentages are not higher for those, as well as for defining specialty as "drugs requiring special handling or storage." May concurs with Howerton on the smaller-than-expected consideration of special pharmacy as high unit-cost drugs.

Figure 38: How does your organization define specialty pharmaceuticals?

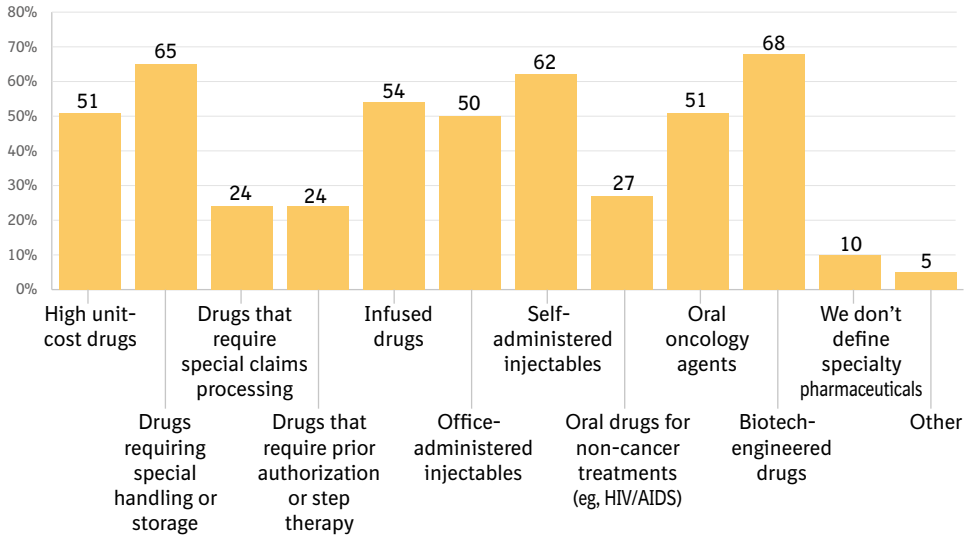
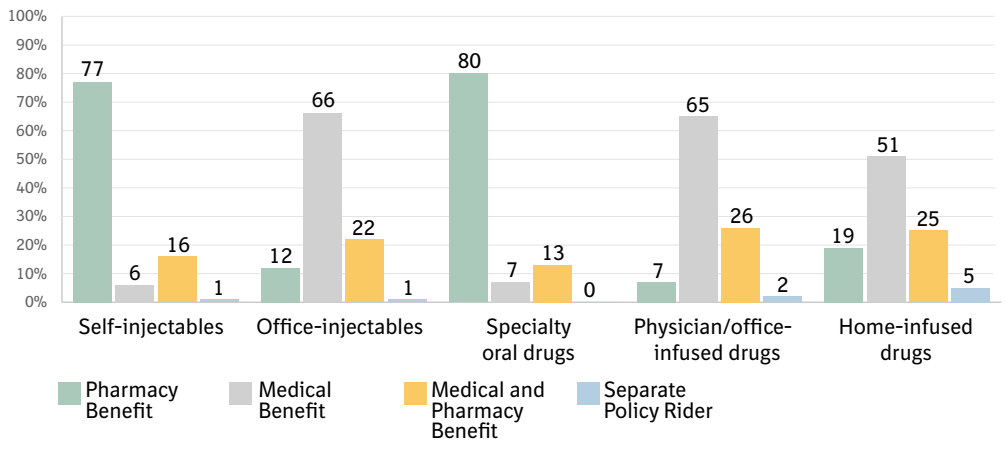


Figure 39: How does your largest health plan cover specialty pharmaceuticals?



CMS defines specialty drugs as medications that cost more than $500 for a one-month supply. Recently, the specialty drug category has expanded to include oral medications that fit CMS' definition–primarily oral oncologics and drugs with alternative or new delivery systems.[19]

As expected, the majority of health plan respondents agree that self-injectables and specialty oral drugs are covered under the pharmacy benefit, while office injectables and office-infused drugs fall under the medical benefit. Lopes says she is seeing a movement towards more coverage under specialty pharmacy. She believes that SP coverage will enable payers to better leverage prices for a preferred agent; achieve effective pull-through; track utilization; and create improvement in adherence, which for some conditions, such as hepatitis C, is critical to improving outcomes and reducing medical costs.

About one-quarter of plans are covering office-infused and home-infused drugs under both the medical and pharmacy benefits.

Respondents are demanding a range of capabilities from their specialty pharmacy providers, with better discounts (64% indicating cost as an ever important issue), followed by

Cost management, followed by appropriate utilization, are the specialty pharmacy issues of chief concern.

Figure 40: Rate importance of the following specialty pharmacy provider capabilities to your organization:

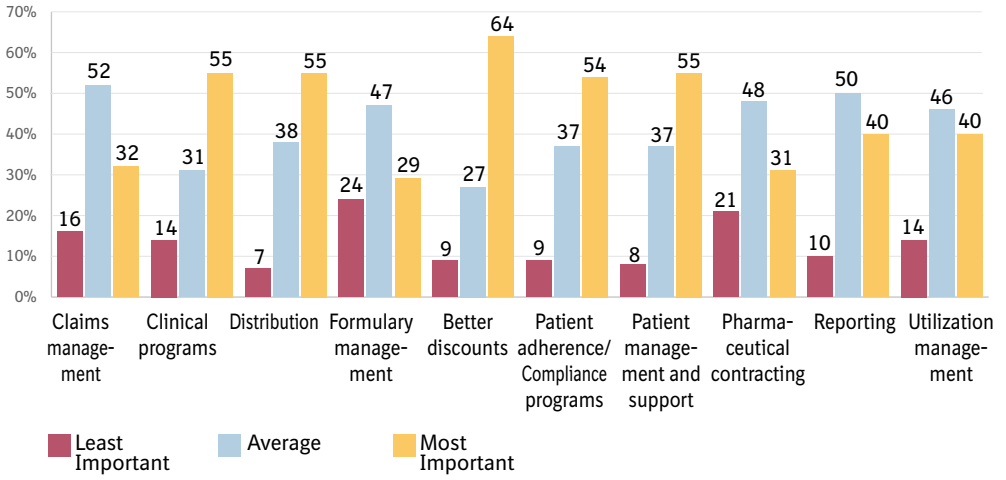
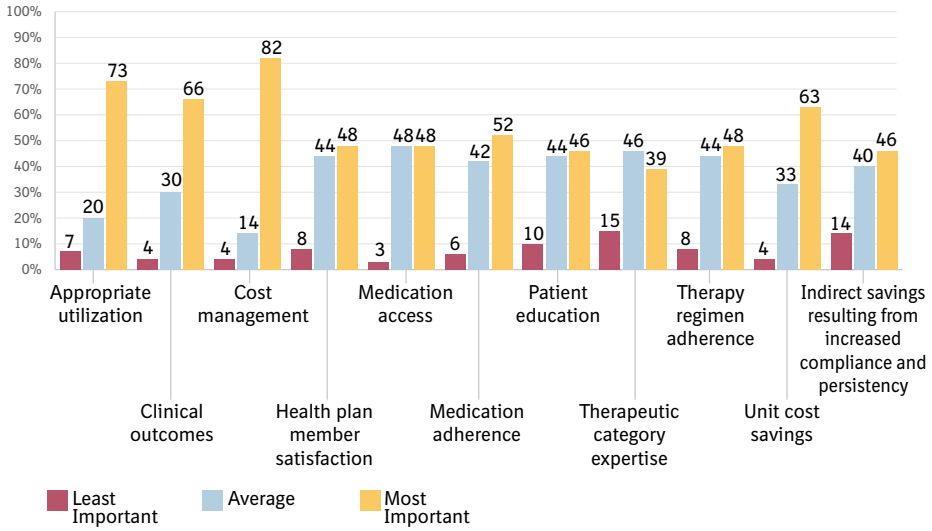


Figure 41: Indicate the specialty pharmacy issues of greatest concern to your organization:



Physician pushback remains a top challenge to incorporating specialty pharmacy services in benefit plan design.

distribution, clinical programs, and patient management and support (all three 55%); and medication adherence programs (54%).

Lopes says that specialty pharmacies are particularly effective at raising medication adherence levels as pharmacists can ensure that patients are taking medications appropriately and are refilling their prescriptions on a timely basis. "Patient management and support go hand-in-hand with clinical and compliance programs," she says.

In line with respondents' preference for certain capabilities from their specialty pharmacy providers, pharmacy issues of greatest concern are cost management (82%), appropriate utilization (73%), clinical outcomes (66%), unit cost savings (63%), and medication adherence (52%).

Despite efforts around value- and patient-focused care, respondents still concentrate on cost and the economics associated with use of pharmaceutical products, Vogenberg says.

Respondents report that their biggest challenges in integrating special pharmacy services into their benefit designs are physician pushback because of anticipated revenue loss (52%), disruption of physician practices by requiring SP ordering through specialty providers (46%), and patient disruption (40%). Lopes attributes patient disruption to confusion over the benefit and concern over its affordability.

Vogenberg notices that this year there is less concern about the inability to "crosswalk" National Drug Codes

Figure 42: Does your largest health plan mandate use of its specialty pharmacy provider for:

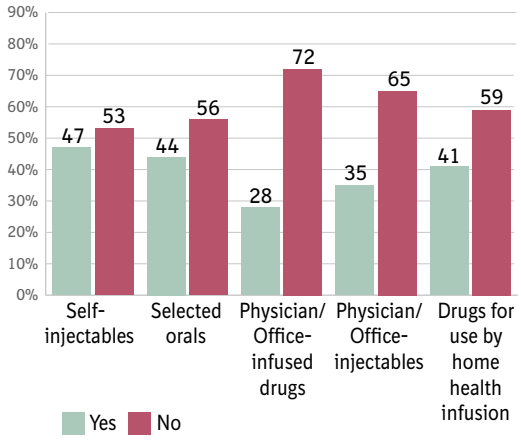
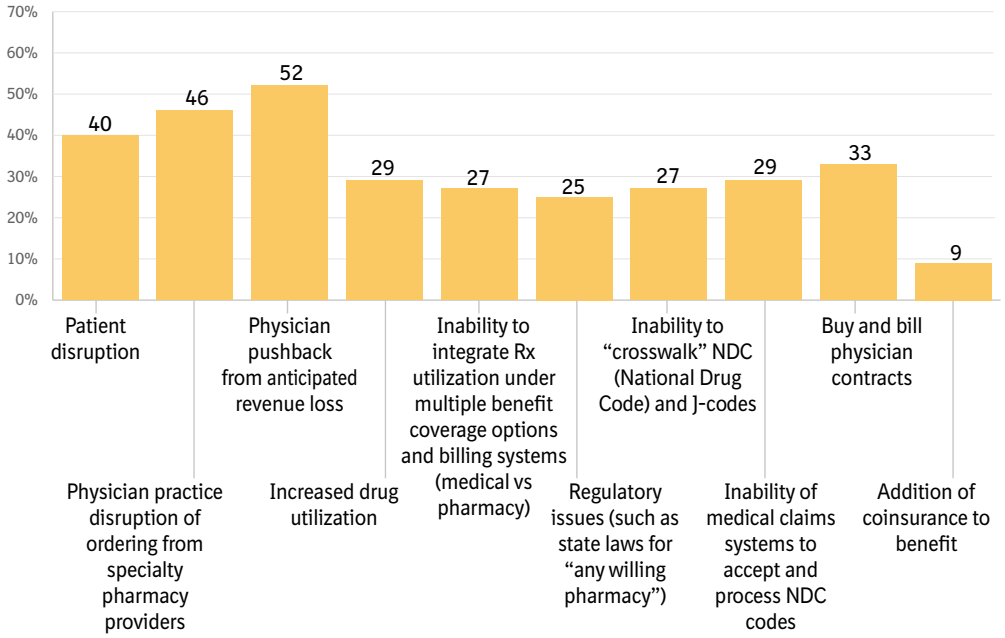


Figure 43: What are the top challenges in incorporating specialty pharmacy services into benefit plan designs?



(NDCs) and J-codes, which has been facilitated through technology. He adds, "To get the most value from a therapy, plan sponsors should focus first on ensuring that patients are being appropriately selected for treatment. Value has been traditionally defined as quality divided by cost. Value propositions should, then, focus on effectiveness and affordability in measurable terms."[19]

Although specialty pharmacy–through tiered design, patient support, an exclusive delivery network, and capped monthly out-of-pocket costs–is proving its value in cost savings, while increasing access and adherence, and managing drug utilization, the majority of payers do not mandate use of a specialty provider in any drug category. Lopes notes that buy and bill is still allowed in some cases, although the level of reimbursement may have been reduced. "Use of specialty pharmacy for some categories may be mandated, but payers are more cautious in other classes including oncology due to physician pushback," she says.

Many survey respondents indicate that they are already implementing a variety of special pharmacy benefit plan designs, including setting maximum 30-day supply limits (59.8%), sponsoring a limited distribution network for specialty drugs (58.8%), requiring prior authorization for more drugs (49.5%), and establishing formulary management programs in selected drug classes and disease states (45.8%). About one-third

Most payers do not mandate use of a specialty pharmacy provider in any drug category.

Table 8: What changes in specialty-pharmacy benefit plan design and management are you implementing?

	Currently Doing	New in 2010	Likely	Unlikely	Don't Know/ Not Applicable
Tiering copayments to incent usage of preferred specialty pharmacy products	32.7%	2.0%	22.4%	20.4%	22.4%
Adding coinsurance	27.6%	7.1%	12.2%	30.6%	22.4%
Setting maximum 30-day supply limits	59.8%	6.2%	10.3%	10.3%	13.4%
Having a limited distribution network for specialty drugs	58.8%	3.1%	15.5%	9.3%	13.4%
Setting deductible levels to incent use of a specialty pharmacy	15.5%	5.2%	15.5%	35.1%	28.9%
Establishing formulary management programs in selected drug classes and disease states	45.8%	6.3%	25.0%	10.4%	12.5%
Requiring prior authorization for more drugs	49.5%	7.2%	23.7%	6.2%	13.4%
Contracting with a single specialty pharmacy provider	44.8%	5.2%	11.5%	22.9%	15.6%
Using therapeutic interchange for biologic therapies	19.8%	2.1%	25.0%	33.3%	19.8%
Using specialty pharmacy providers to control infusion medications covered under the medical benefit	29.2%	2.1%	29.2%	18.8%	20.8%
Adopting the average sales price (ASP) reimbursement methodology in health plan	19.8%	8.3%	31.3%	14.6%	26.0%
Mandating use by plan members of specialty pharmacy providers in benefit plan design	41.7%	4.2%	25.0%	14.6%	14.6%
Requiring physicians to obtain medications from specialty pharmacy providers	32.0%	4.1%	27.8%	15.5%	20.6%
Narrowing therapeutic categories to obtain manufacturer rebates or favorable pricing	38.5%	4.2%	22.9%	17.7%	16.7%
Introducing a separate specialty pharmacy benefit design	20.6%	7.2%	16.5%	33.0%	22.7%
Requiring failure on preferred specialty product before approving use of a non-preferred product	41.8%	5.1%	24.5%	12.2%	16.3%
Adopting brand-to-generic switching as biogenerics/biosimilars receive FDA approval	21.4%	10.2%	39.8%	8.2%	20.4%
Requiring genomic testing to determine receptivity for biologic therapy	13.7%	6.3%	24.2%	27.4%	28.4%

71%

of plans have a high level of concern regarding Medicare plans and issues of fraud and abuse.

each say they have no intention of using therapeutic interchange for biologic therapies (33.3%), introducing a separate specialty pharmacy benefit design (33.0%) or adding coinsurance (30.6%). Although there is currently no regulatory approval pathway for biosimilars in the United Sates, the recently enacted health care reform legislation calls for the development of just such a pathway.

Despite physician pushback, nearly a third of payers (32.0%) are requiring physicians to obtain medications from specialty pharmacies.

Medicare Prescription Drug Coverage

Covering generic drugs in the coverage gap for Medicare Part D leads the list of benefit design changes offered in 2009 (33.7%). In 2010, most PDPs (80%) do not offer gap coverage, and none offer full coverage of all generic and branded drugs in the gap. Of the PDPs and MA-PDs that do offer some coverage, only 2% are predicted to cover all generics–down from 14% in 2008.[20]

Fraud and Abuse Concerns

Fraud and abuse continue to be important for Medicare plans, with 71% citing high or very high concern. Howerton says that the fact that the survey even elicited 6% of respondents

Figure 44: What is your organization's level of concern for managing fraud, waste, and abuse for prescription drugs covered under your Medicare plans?

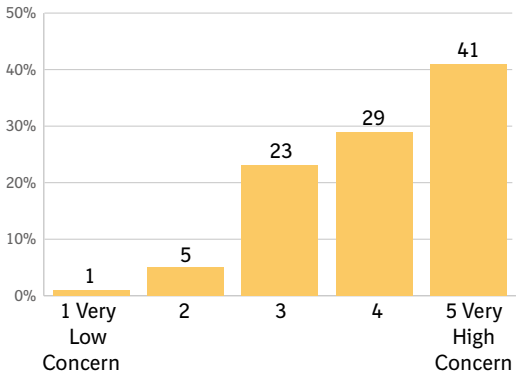


Table 9: If your organization offers or administrates Medicare prescription coverage, what benefit design strategy changes are you making?

	Offered in 2009	New in 2010	Likely to Start	Will Not Do	Don't Know/Not Applicable
Make no changes	28.4%	8.6%	8.6%	21.0%	33.3%
Reduce retiree health-care benefits	6.2%	4.9%	9.9%	40.7%	38.3%
Tighten restrictions on eligibility	7.3%	4.9%	11.0%	36.6%	40.2%
Increase copayments	12.2%	20.7%	17.1%	17.1%	32.9%
Increase deductibles	11.1%	17.3%	14.8%	27.2%	29.6%
Cover generic prescriptions in the coverage gap	33.7%	2.4%	16.9%	16.9%	30.1%
Cover branded prescriptions in the coverage gap	8.6%	2.5%	11.1%	43.2%	34.6%
Change formulary	22.2%	19.8%	18.5%	11.1%	28.4%
Cover Part D excluded medications	19.5%	2.4%	8.5%	35.4%	34.1%
Change employer subsidy/cost sharing	6.2%	9.9%	11.1%	24.7%	48.1%
Eliminate employer subsidy	2.5%	1.3%	7.5%	37.5%	51.3%
Eliminate Part D coverage	2.5%	1.3%	5.0%	53.8%	37.5%
Dropped prescription drug coverage completely	2.5%	1.3%	6.3%	53.8%	36.3%
Offered Part D coverage	41.3%	2.5%	10.0%	12.5%	33.8%

who say fraud and abuse are of little concern indicates that they must feel confident that someone in the organization is handling the problems. "No one should consider fraud and abuse of little concern," she says. "Either they don't know enough about fraud and abuse or have never been audited."

Lopes explains that the more important concern should be broader data capabilities to assist with detection and recovery. "Payers need to be more aware of trends in both provider and member fraud and abuse to identify and prevent them," she says.

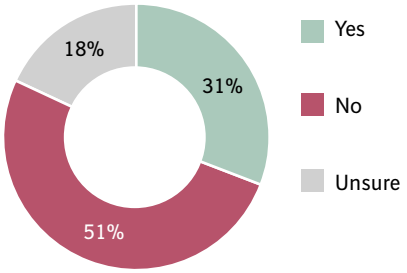
Many responding organizations do have fraud management programs in place. As many as 59.5% currently audit prescription drug claims, and nearly half perform onsite audits and/or desk audits of pharmacies.

Value-based Insurance Design

Nearly one-third (31%) of plans have implemented value-based insurance design (VBID) for at least one therapeutic category. Many (18%) are unsure, reflecting the confusion that surrounds VBID and its potential benefits.

By aligning financial incentives among all stakeholders, VBID encourages the use of high-value care while discouraging the use of low-value or unproven services.[21]

Figure 45: Has your organization adopted value-based insurance design (VBID)?



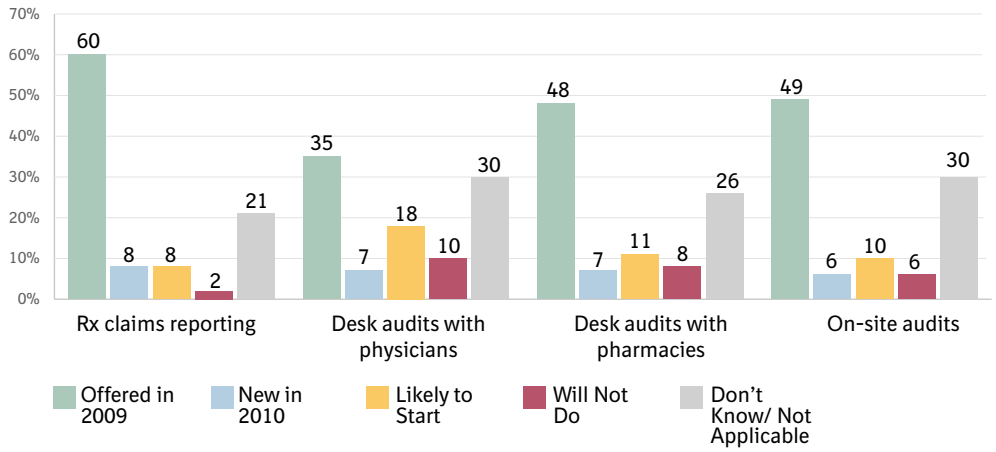
This year, respondents are much more aware of VBID than they were last year, at which time nearly 80% did not plan to adopt it, compared with half that have no plans to include VBID this year. Although more plans are interested in VBID, there is still only a 31% adoption rate, which Lopes attributes to the availability of lower cost generics, failure to realize a short-term return on investment, and hesitancy in investing in improving outcomes for plan members, who may only be short-term beneficiaries.

Offsetting the added costs of collecting lower copayments, and the related increased use of high-value services, are the savings incurred by reductions in future adverse events that are avoided by achievement of better clinical outcomes.[22]

31%

of plans have implemented value-based insurance design for at least one therapeutic category.

Figure 46: How likely is your organization to implement the following Medicare fraud management programs?



95%
of plans link medication adherence with improved patient health.

As far as defining VBID, about one-third of respondents say it refers to programs that are outcomes-based rather than just focused on cost, while 36.5% do not have a definition.

Diabetes, the focus of many early VBID programs–for example, the Asheville Project in Asheville, NC, and the Center for Value-Based Insurance Design at the University of Michigan–still remains a leading condition for management through VBID. The promise of value-based designs remains to be incorporated into mainstream insurance products largely because of inherent problems in defining value, Vogenberg says.

Effect of Medication Adherence

Many plans acknowledge the importance of medication adherence. It is considered to have an "important " or "very important" impact on improved patient health (95%), patient participation (91%), and better patient care outcomes (88%).

The statistics highlight the need for improved medication adherence; nearly three out of four Americans report that they do not always take their medications as directed. Almost half (49%) of those polled said they had forgotten to take a prescribed medicine, and nearly one-third (31%) had not filled a prescription they were given. Nearly

Figure 47: Does your organization have value-based programs for any of the following?

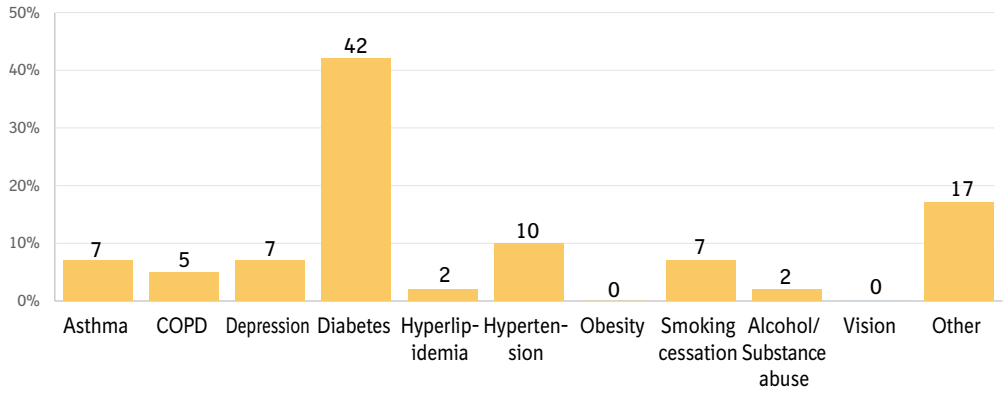
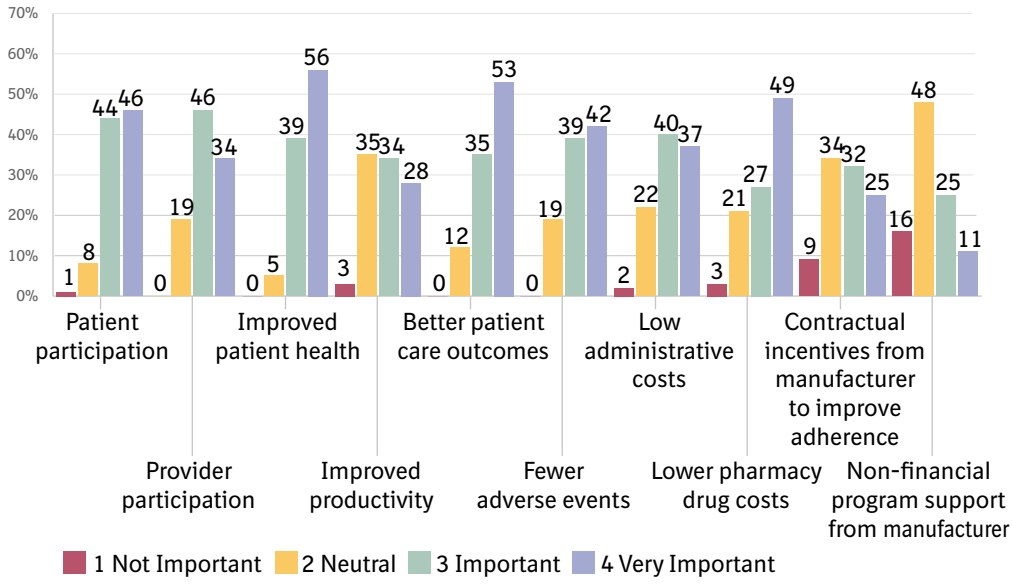


Figure 48: Which features of better medication adherence are important to your organization?



one-quarter (24%) had taken less than the recommended dosage.[23]

There are correlations between low rates of medication adherence and poorer clinical outcomes, such as increased hospitalizations and higher mortality rates; and between lower adherence rates and increased medical costs. Among diabetes patients, those with high levels of adherence had total annual health care costs averaging $8,886, while patients with low levels of adherence had almost twice the total annual health care costs, averaging $16,498.[24]

Lopes says that as chief medical officer of a health plan, she invested in improving medication adherence for some chronic diseases, including diabetes, asthma, and COPD, which she sees as contributing to overall lower medical costs, better outcomes, improved patient care, fewer adverse events, and improved HEDIS measures.

Health plans cite lower medical costs and improved patient health (both 87%) as important or very important features of medication adherence for plan sponsors, with improved productivity coming in at 82%. Lopes adds that employers in particular will benefit from improved productivity. "Productivity is important to employers but not as important to plans that don't even have access to that data," May says.

Vogenberg adds that productivity remains difficult to measure and the current economic recession has resulted in more back-to-basics management of health care services, as well as of cost.

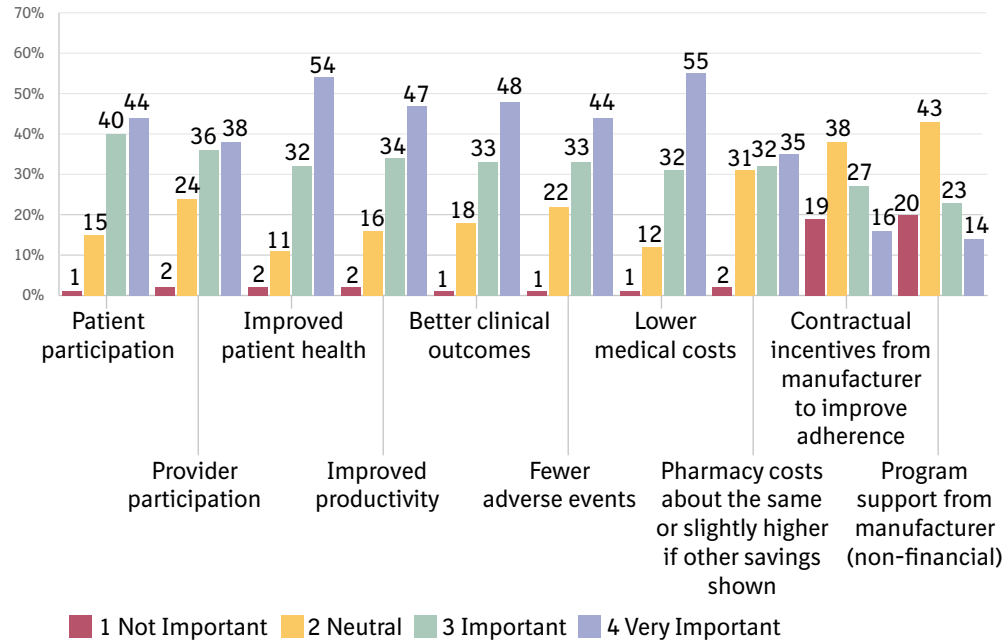
Using Evidence-Based Medicine to Make Decisions

Asked which factors they pay attention to (important and very important) when evaluating evidence-based medicine (EBM) studies, respondents cite study design and results (both 90%), followed by the length of a study (84%), and how study results may impact the delivery of care (82%). Overall, respondents say that all factors play a role.

"There is a growing importance in payers' eyes that the evaluation of a study be predicated on its design, length, real world clinical relevance, and its outcomes," Lopes says.

Cost management, followed by appropriate utilization are the specialty pharmacy issues of chief concern.

Figure 49: Which features of better medication adherence are important to your plan sponsors?



In weighing evidence-based medicine findings, 90% of plans analyze study design and results.

Figure 50: Which features of evidence-based medicine (EBM) studies are most important to your organization?

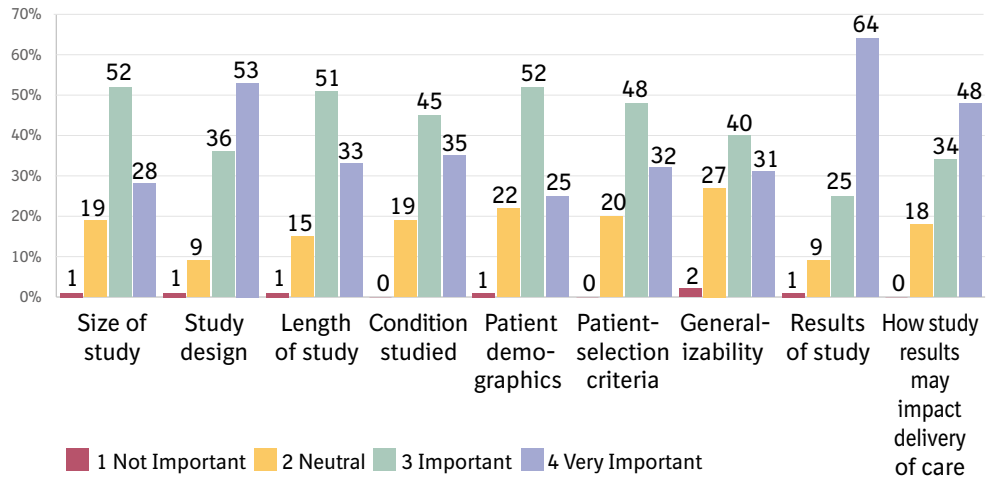
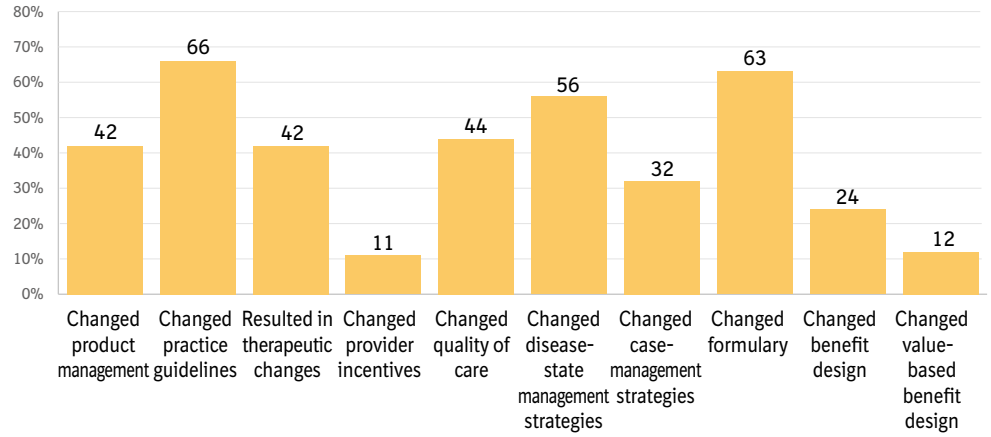


Figure 51: How have evidence-based medicine studies influenced your organization?



EBM has influenced managed care organizations in a variety of ways. About two-thirds of health plans say that EBM has influenced their practice guidelines; 63% have used it to change their formulary; and 56% have changed their disease management strategies. A few have used EBM to change value-based benefit design (12%) or provider incentives (11%).

Vogenberg points out that we are just seeing the start of EBM study-based change being adapted into managed care benefit strategies and designs.

Introduction of Comparative Effectiveness Research

When asked which types of comparative effectiveness research (CER) may be most valuable, 82% of respondents (4 and 5 responses combined) say comparisons of pharmacotherapies by diagnosis; followed by comparisons of patients enrolled in disease management programs with those that are not (75%); comparisons of pharmacotherapy by FDA-labeled indication (72%); and comparisons of procedures and pharmacotherapy by diagnosis (70%). Fewer than half of respondents think that comparisons of surgeries and procedures by diagnosis would be valuable.

Now that the promise of CER is near, with a $1.1 billion infusion from The American Recovery and Reinvestment Act of 2009, payers are applauding its entry into the health care environment, foreseeing an impact on clinical

Figure 52: What types of comparative effectiveness research (CER) would be most valuable to your organization?

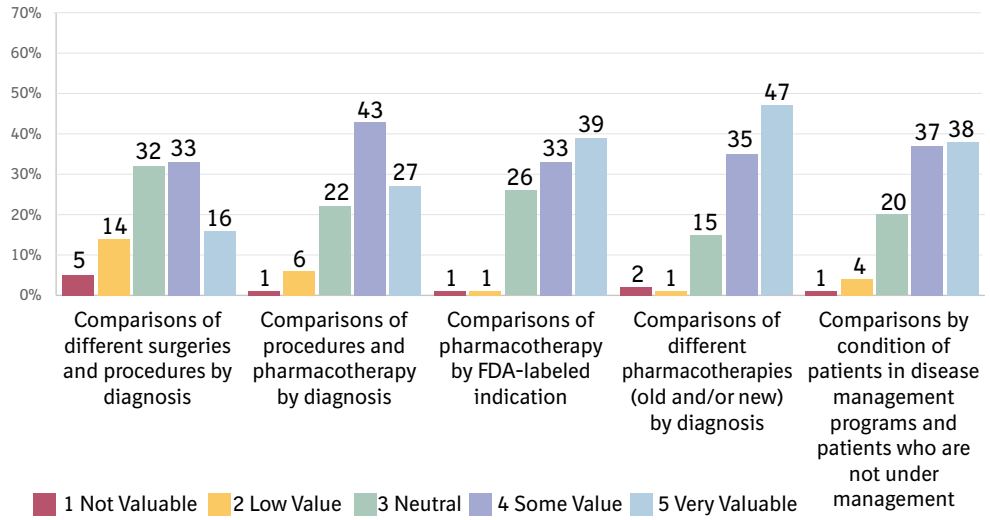
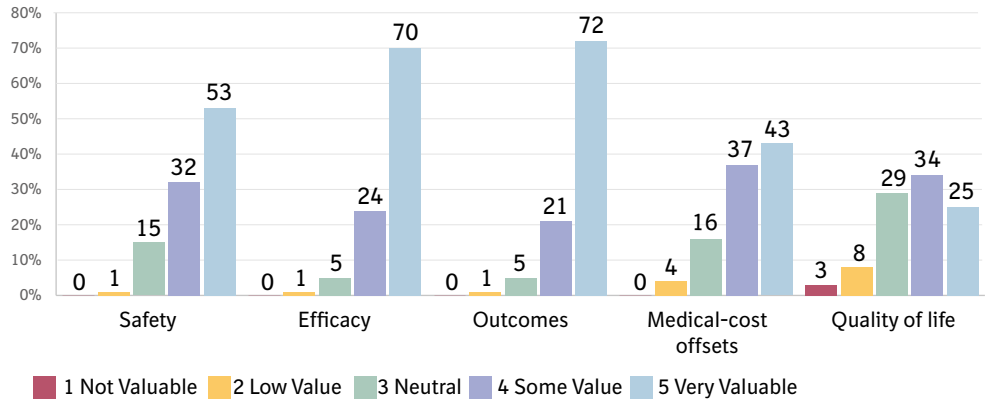


Figure 53: Which aspects of comparative effectiveness research (CER) will be most valuable to your organization?



outcomes (72%), efficacy (70%), and safety (53%). One-quarter see an impact on quality of life, which May says is dependent on addressing comorbidities and polypharmacy.[25]

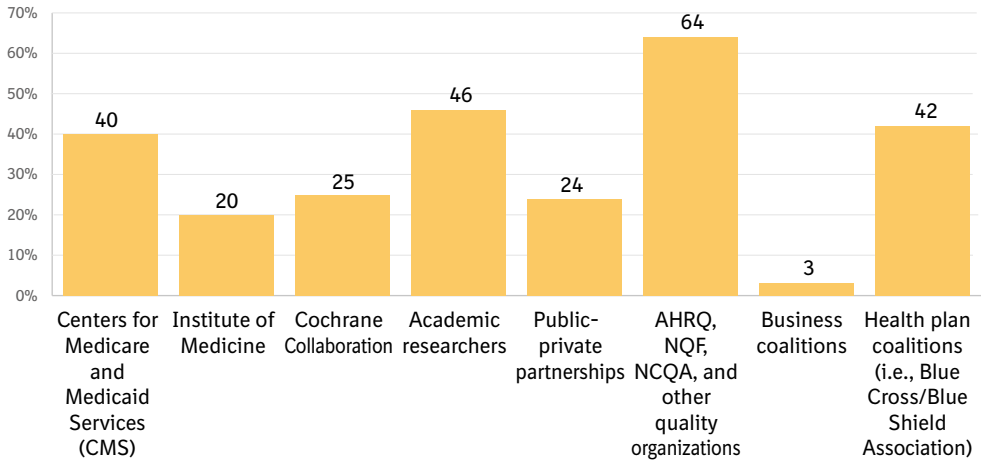
While payers will be looking to a variety of sources for help in developing CER, almost two-thirds cite national quality organizations, such as the National Committee on Quality Assurance (NCQA) and the Agency for Healthcare Research and Quality (AHRQ) as prime examples. They also put their trust in academic researchers (46%), health plan coalitions (42%), and in CMS (40%), all of which Lopes says have the credibility and capability to impact significant health policy changes. "Independent third parties and the government can help develop criteria for CER and affect what commercial payers do," she says. (See "New Push for Comparative Effectiveness Research," page 75.)

Representing a small health plan, Howerton takes pride in what her organization has accomplished, relying on its own critical data research and on information from professional organizations such as the American Diabetes Association. "We create our own criteria based on the best available evidence-based medicine," she explains.

66%

of health plans say evidence-based medicine findings have influenced their practice guidelines.

Figure 54: To whom will you be looking for leadership in developing comparative effectiveness research (CER)?



87%

of plans agree that e-prescribing can help enforce formulary compliance at the point of care.

Has E-Prescribing Caught On?

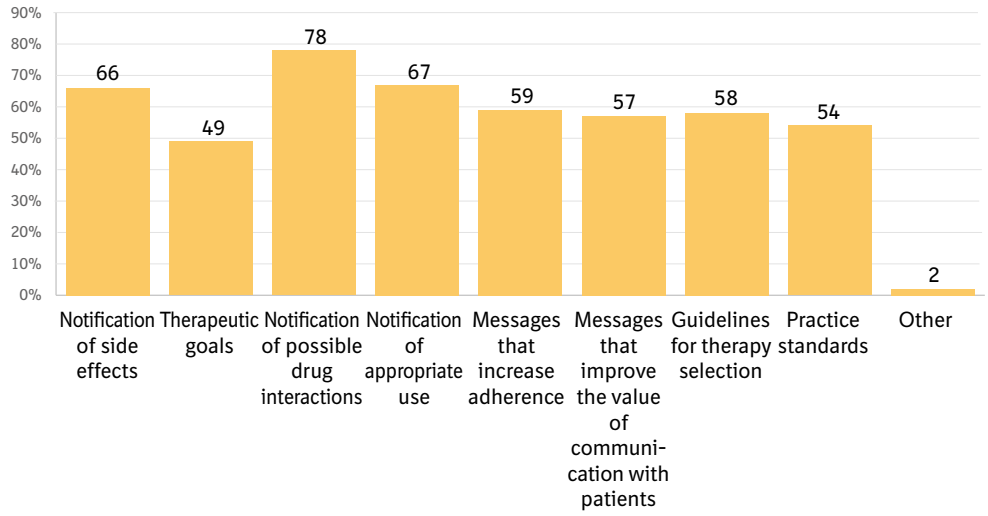
Electronic prescribing (e-prescribing) systems that allow physicians to select lower cost or generic medications could save $845,000 per 100,000 patients per year and possibly more system-wide. Complete use among physicians of an e-prescribing system with formulary decision support could reduce prescription drug spending by up to $3.9 million per 100,000 patients per year.[26]

As many as 86.6% agree or strongly agree that e-prescribing and health information technology enforce formulary compliance; 80.3% believe that the technology can enhance the delivery of specific information at the

Table 10: Please indicate your degree of agreement or disagreement with the following statements concerning electronic prescribing (e-prescribing) and health information technology.

	Strongly Disagree 1	Disagree 2	Neutral 3	Agree 4	Strongly Agree 5	On 1 to 5 scale
E-prescribing can greatly improve patient compliance–especially filling the first script	1.0%	8.2%	25.8%	39.2%	25.8%	3.8
E-prescribing systems that allow access to published clinical data at the point of care can increase prescribing of brand drugs	1.0%	10.4%	36.5%	32.3%	19.8%	3.6
E-prescribing can greatly diminish the prescribing of brand drugs on account of better access to generic equivalents	2.1%	5.2%	24.7%	43.3%	24.7%	3.8
E-prescribing can enforce formulary compliance	0.0%	1.0%	12.4%	52.6%	34.0%	4.2
E-prescribing can enhance the delivery of specific information at the point of care	0.0%	2.1%	17.7%	56.3%	24.0%	4.0
E-prescribing systems are adequate in preventing drug interactions	0.0%	11.3%	37.1%	33.0%	18.6%	3.6
E-prescribing data should be shared among health plans	3.1%	6.3%	38.5%	37.5%	14.6%	3.5
E-prescribing data should be shared with plan sponsors	3.2%	10.6%	44.7%	27.7%	13.8%	3.4
E-prescribing data should be shared with employers	5.3%	16.0%	41.5%	24.5%	12.8%	3.2
E-prescribing data should be shared with academic researchers	2.2%	6.5%	46.2%	33.3%	11.8%	3.5
E-prescribing data should be shared with quality management organizations	3.2%	6.5%	40.9%	36.6%	12.9%	3.5
E-prescribing data should be shared with commercial pharmaceutical researchers and manufacturers	18.1%	25.5%	36.2%	12.8%	7.4%	2.7
E-prescribing can be used as a platform that personalizes the delivery of care	1.1%	6.4%	35.1%	37.2%	20.2%	3.7

Figure 55: What additional information would you look for in an e-prescribing system?



point-of-care; and 68.0% say the technology can generate better access to generics.

The number of prescribers routing prescriptions electronically increased from 74,000 at the end of 2008 to 156,000 by year-end 2009, representing about 25% of all office-based prescribers. In addition, approximately 85% of community pharmacies in the United States routed prescriptions electronically at the end of 2009.[27]

E-prescribing is expected to receive a boost as a result of a policy change by the Drug Enforcement Administration, which recently announced that it will allow doctors to prescribe narcotics, antidepressants and other controlled medicines electronically in the near future.

Congress provided additional impetus towards the widespread adoption of e-prescribing with passage of the American Recovery and Reinvestment Act. The Act offers incentive programs within Medicare and Medicaid for physicians and hospitals that adopt and use electronic health records, including the use of e-prescribing.

Lopes emphasizes the value of e-prescribing in avoiding medical errors and improving medication adherence through better decision support tools and communication with the treating physician.

She agrees with respondents that e-prescribing can uncover potential drug interactions (78%) and side effects (66%), as well as serve as a tool to improve care coordination and communication with patients.

Vogenberg expects rapid expansion of e-prescribing capabilities over the next three to five years, as the recent infusion of health information technology funding will enable more linkages.

Rapid expansion of e-prescribing capabilities is expected over the next three to five years.

Part 3. Findings from Pharmacy Benefit Managers/ Specialty Pharmacy Research

Part 3. Findings from Pharmacy Benefit Managers/Specialty Pharmacy Research

Part 3 of *The Boehringer Ingelheim Pharmacy Benefits Report* reflects the experiences and intensions of 54 representatives of pharmacy benefit managers (PBMs) and specialty pharmacy (SP) in managing drug costs and utilization. As many as 83% of these organizations have a national presence.

Specialty drugs make up 12.8% of total pharmacy spending.

Spending for specialty drugs covered under the pharmacy benefit increased 15.8% in 2008, accounting for 12.8% of total pharmacy spending, while unit cost growth increased 11.5% due to price inflation and new drug approvals in 2007 and 2008.[28] IMS Health showed that of all drugs dispensed in the United States from September 2007 to September 2008, 63.7% were generic products.[29] Both trends will demand a watchful eye and heighten the need to better manage the cost and utilization of specialty pharmacy drugs while paying attention to the growing impact of generics.

Among the highlights of *The Pharmacy Benefits Report*:

- Sixty-eight percent of PBMs/SP respondents estimate that the cost of non-specialty brands per member per month (pmpm) will increase between 0% and 10%; 64% believe the same spread will affect generics, and 59% estimate that the cost of specialty drugs will rise between 6% and 15%.
- Three-tier benefit designs (generics, preferred brands, and non-preferred brands) are still the most commonly used benefit design for both commercial and Medicare plans although nearly a quarter of Medicare stand-alone Prescription Drug Plans (PDPs) uses four tiers. Higher tiers are typically designated for preferred specialty drugs, non-preferred specialty drugs, and lifestyle medications.
- Survey respondents are most concerned with pharmacy costs associated with treating chronic conditions, especially diabetes (77%), gastrointestinal disorders (65%), hyperlipidemia (64%), asthma (61%), and depression (58%). Concerns about the cost of specialty pharmacy are often related to cancer care, including both oral medications and infused biologics, 72% and 69%, respectively. First ranked in concern is rheumatoid arthritis/psoriasis (anti-TNF biologics), 76%. Multiple sclerosis is of concern to 60%.
- Heading the list of specialty pharmacy management strategies currently being used for plans or likely to be implemented are maximum day supply limits (81%), quantity limits for selected drugs (79%), and mandating the use of SP providers for selected drugs (78%).
- Coming as no surprise, cost is the leading concern in managing specialty pharmaceuticals (94%), followed by appropriate utilization (70%), and clinical outcomes (47%).
- Respondents are currently using or are likely to implement preferred product strategies for SP (65%), use

Generics are expected to now account for **61%** of all prescriptions.

of financial incentives to steer patients toward preferred SP providers (63%), and transitioning to biosimilars once they become available (61%).

- More emphasis on medication adherence is seen as contributing to improving patient health (98%), better outcomes (96%), fewer adverse events (93%), and lower pharmacy costs (86%).
- Findings of evidence-based medical studies have influenced PBMs/SP providers to adjust formularies (61%), make therapeutic changes (59%), and alter practice guidelines (53%).

Figure 56: What percentage of prescriptions is filled with generics?

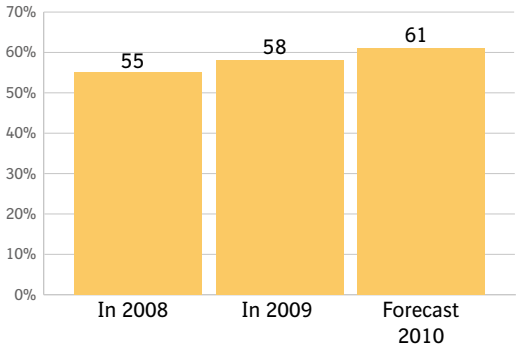
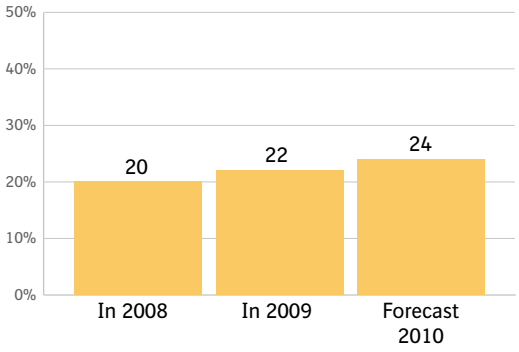


Figure 57: What percentage of prescriptions is considered specialty pharmacy?



Interpreting the Findings

The following medical and pharmacy benefit experts reviewed the survey research findings and shared their insights:

- Keith Perry, president, PharmEfficiency, Yarmouthport, MA
- Irene Gale, RPh, former senior director for a PBM, Placitas, NM
- Susan Hayes, principal, Pharmacy Outcomes Specialists, a benefits consulting firm, Chicago

The vice president of a national PBM also contributed his thoughts.

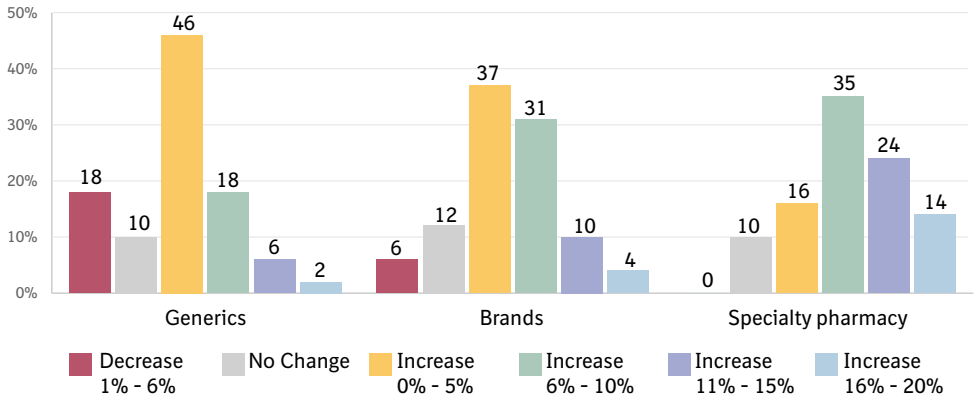
Research Results

Growth of Generics, Specialty Pharmacy

The percentage of generic drug use by PBMs has risen steadily from 55% in 2008 to 58% in 2009, with an expected increase to 61% of all prescriptions in 2010. At the same time, the use of SP has expanded, rising from 20% of all prescriptions in 2008 to 22% in 2009, with an anticipated jump to 24% in 2010.

Although most respondents (46%) think the cost of generics per member per

Figure 58: What is your expectation of per member per month (pmpm) net pharmacy cost trends (after copayment and rebates) in the next 12 months

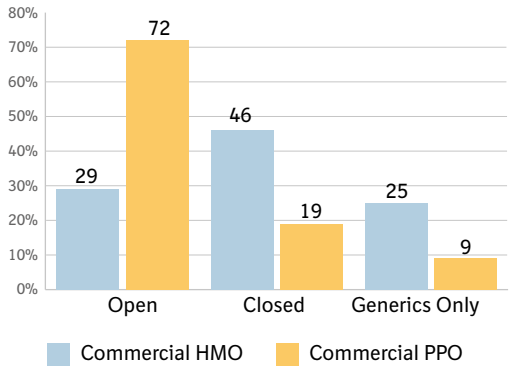


month (pmpm) will rise 0% to 5%, as seen similarly in the managed care predictions, 35% predict that specialty pharmacy will increase 6% to 10%. Respondents are unsure as to whether brand cost will increase will increase 0% to 5% (37%) or 6% to 10% (31%).

Overall, Keith Perry notes that 59% expect that SP costs pmpm will increase 6% to 15%; 64% estimate generics will rise 0% to 10%; and 68% are expecting an increase of 0% to 10% for branded drugs.

Susan Hayes says she anticipates that brand costs will rise by as much as 11% to 16% because of price increases to make up for eroding margins. She also believes that pmpm SP costs will increase by more than 6% to 10% because of the number of new products expected to enter the marketplace, and due to their high cost. The pharma pipeline is filled with hundreds of SP products. Some of them will add to the existing SP options within a therapeutic class, but others will be the first therapies available for particular diseases, many of them rare. Orphan drugs to treat these rare conditions can easily cost hundreds of thousands of dollars per person per year.

Figure 59: What type of formulary is used in the largest benefit plans managed by your organization?



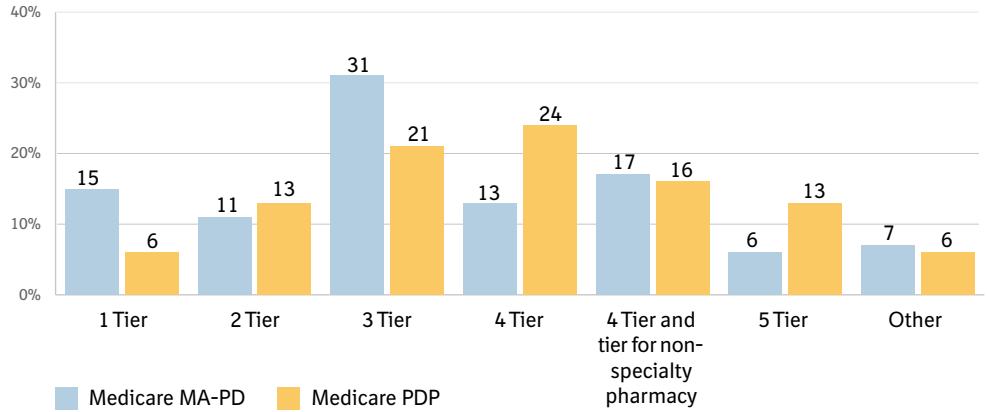
Perry adds that highly managed plans, such as Kaiser Permanente, are more likely to opt for a closed formulary. With a closed formulary, plans do not cover nonformulary drugs, so members must pay full cost for these drugs. On the other hand, nearly three-fourths of less managed PPOs have an open formulary. Members can obtain drugs not on the formulary, but typically must pay a higher copayment.

Designing the Pharmacy Benefit

A substantial majority of Medicare Part D plans used specialty tiers in 2008, according to other research. The percentage of plans using specialty tiers increased in 2006 to 2008 from 63% to 76% of prescription drug plans (PDPs), and from 67% to 90% of Medicare Advantage-Prescription Drug (MA-PD) plans.[30]

Perry notes that the survey responses show that copayments in commercial plans are higher for generics, preferred and non-preferred brands than in

Figure 60: What type of tier structure is used for the largest Medicare benefit plan managed by your organization?



59%

of PBMs/SP providers expect that specialty pharmacy pmpm costs will increase 6% to 15% over the next 12 months.

Plans have added more tiers to slow growth of the drug spend.

Figure 61: For your largest commercial plan, please indicate the average member contribution:

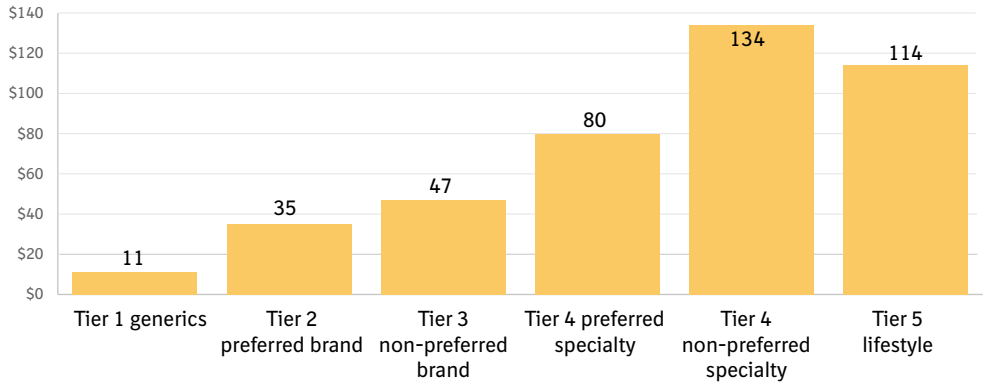
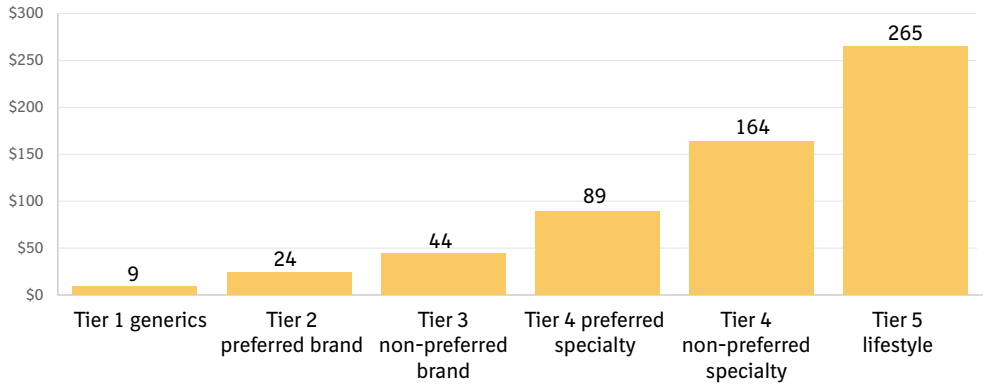


Figure 62: For your largest Medicare plan, please indicate the average member contribution:



Medicare plans, while the latter lists higher copayments for preferred and non-preferred specialty drugs and for lifestyle medications compared to commercial plans.

As plans try to mitigate growth of the drug spend, many have added more tiers to their formularies that have higher member out-of-pocket contributions. Reduced member contributions for drugs in the lower tiers helps incentivize members to choose less costly therapies.

There is a limit of 25% coinsurance for specialty tiers, but Medicare plans can raise it to 33% if they offset the higher coinsurance with lower deductibles. However, this can lead to member out-of-pocket contributions of hundreds of dollars for some drugs, which has the potential to impact adherence. For instance, some self-injectable SP drugs may cost $1,000 pmpm, resulting in $250 in out-of-pocket costs.

Persons with Medicare coverage who take SP drugs may find themselves entering the doughnut hole coverage gap, which for 2010 occurs when they reach $2,830 in medication costs. They are then responsible for all of their medication costs until their out-of-pocket contribution reaches $4,550. At that point, catastrophic coverage kicks in, and member out-of-pocket share falls to 5%.

Most PDPs and MA-PDs with specialty tiers employ either 25% or 33% coinsurance, with a gradual trend toward higher coinsurance levels.[30]

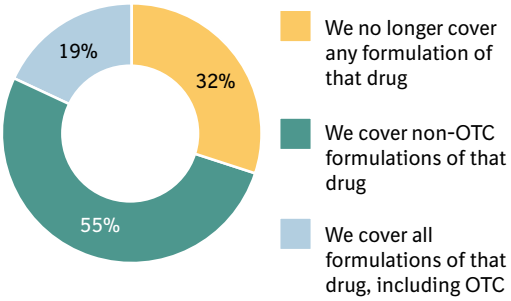
The average pharmacy deductible for a commercial plan is $704 versus $499 for a Medicare plan. Perry explains that the discrepancy may be because Medicare reimbursement is typically lower than

If your largest commercial benefit plan has a pharmacy deductible, what is it?	**$704**
If your largest Medicare plan has a deductible, what is it?	**$499**

commercial plans, resulting in a cost shift to commercial payers to cover the shortfall.

More than half of respondents (55%) say they cover prescription formulations of a drug that is available over-the-counter (OTC), while 19% cover all available formulations.

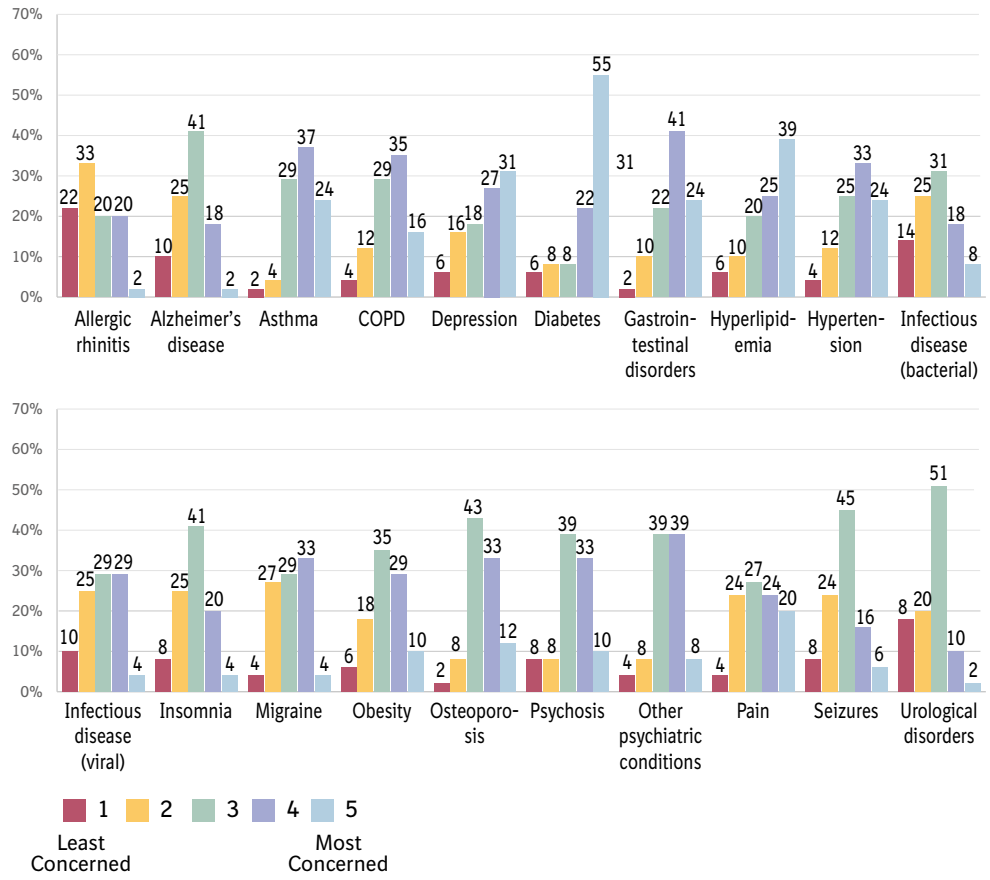
Figure 63: If a drug has a formulation that is OTC, do you cover prescriptions for that drug?



All of the report contributors expected that common chronic conditions, such as diabetes (4 and 5 responses combined, 77%) and asthma (61%), would be top-of-mind, not because the medications to treat them are costly, but because the overall treatment costs of the diseases are high. A vice president of a national PBM says that he was not expecting pain medications to cause so much concern (44%). "Most plans and PBMs don't focus on pain medications unless they are being abused; they are not that expensive," he says. Cancer, using both oral medications and infused biologics, tops the list of pharmacy and SP costs (72% and 69%, respectively) for conditions requiring the use of costly biologics. With about 800 cancer drugs in the pharma pipeline, cost concerns for oncolytic therapies are not likely to ease up soon. The PBM vice president is surprised by the large percentage of respondents (52%), who are concerned or very concerned about human growth hormone, which he says is now available as a generic version and in a category for which utilization management tools,

55%
of respondents cover prescription formulations of OTC drugs.

Figure 64: My organization's largest commercial benefit plan is concerned with managing the pharmacy costs of these conditions:



Benefit design strategies for managing cost vary by therapeutic class.

such as prior authorization, can be employed.

The growth of SP biologic generics has been hampered by the fact that there has not been a regulatory pathway in the United States to allow the FDA to approve them. However, the Patient Protection and Affordable Care Act, signed into law in March 2010, creates an approval pathway for these drugs. As many biologics' patents have already

Figure 65: My organization's largest commercial benefit plan is concerned with managing the pharmacy and specialty pharmacy costs of these conditions and categories:

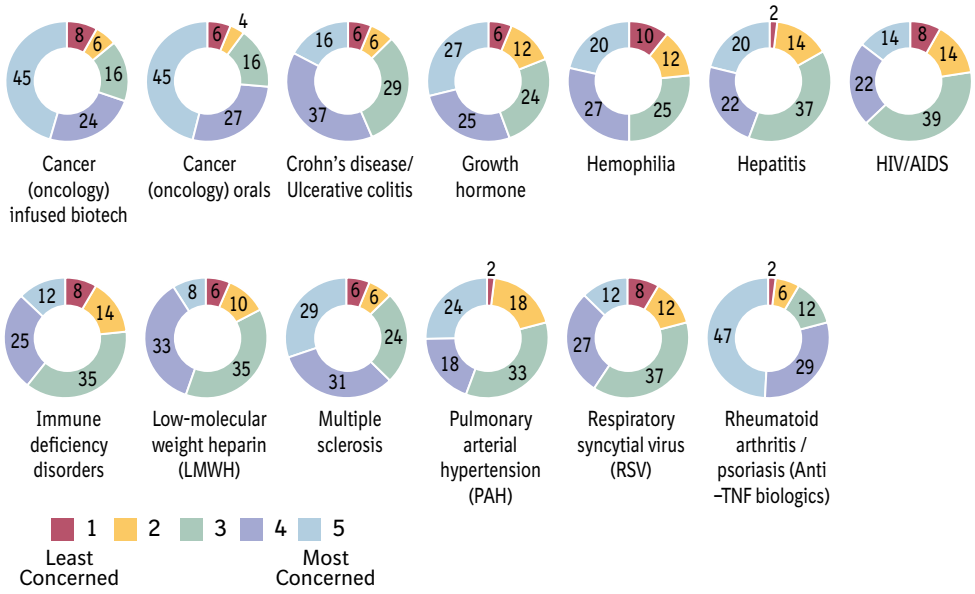


Figure 66: What has been your organization's primary benefit design strategy for managing the cost of the following therapeutic classes?

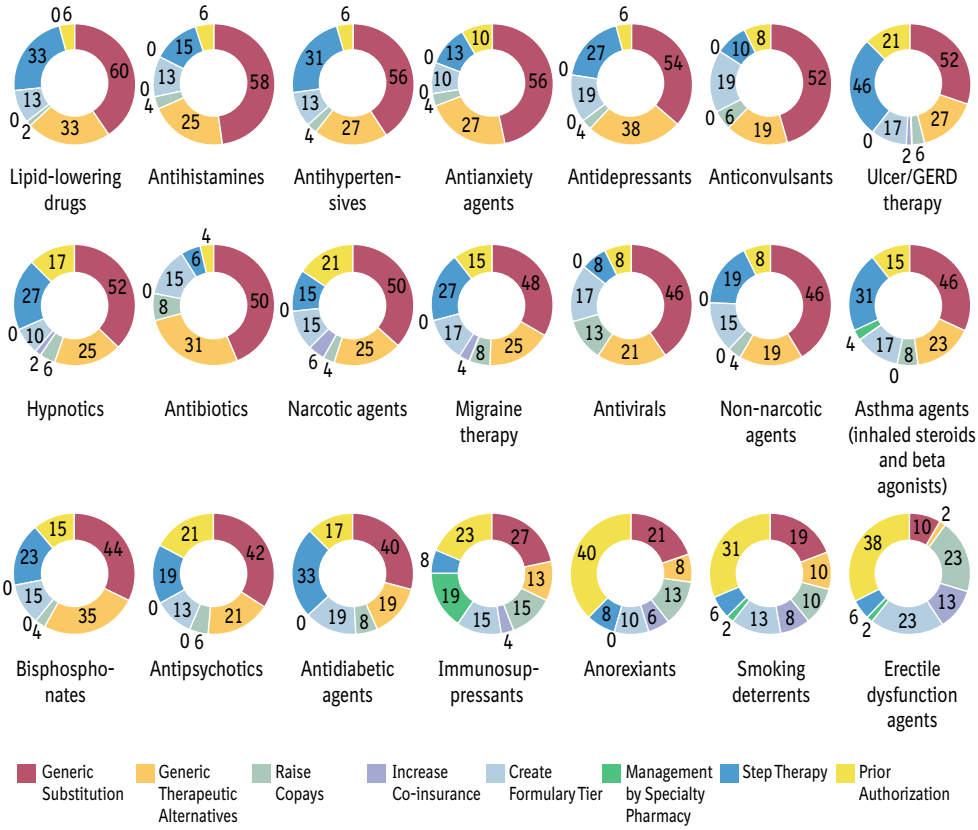
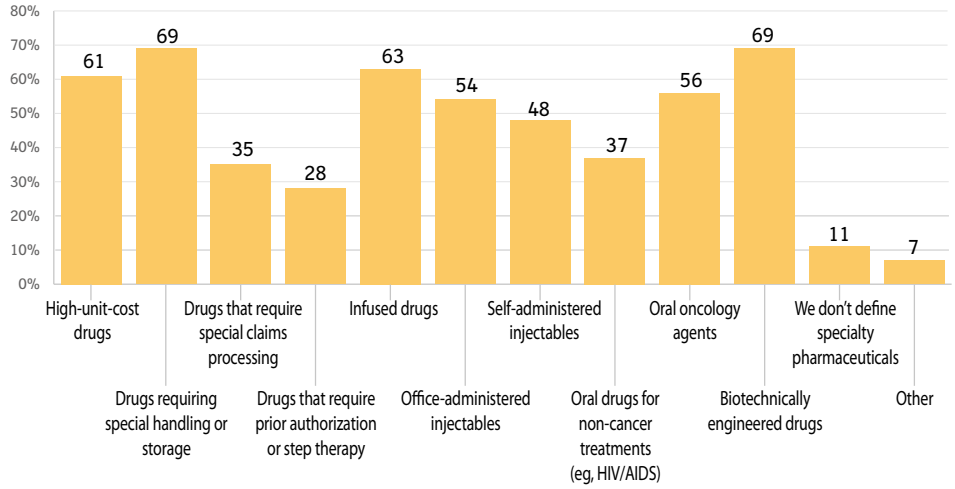


Figure 67: How does your organization define specialty pharmaceuticals?



expired and companies have gained valuable experience with manufacturing generic biologics to sell in other countries, these therapies could begin to hit the U.S. market as early as 2012.

Perry notes that the conditions for which treatment costs can be managed by strategies, such as prior authorization, step therapy, and increased cost-sharing, invite more concern from respondents because they can actually make these changes.

Generic substitution, generic therapy alternatives, step therapy, and prior authorization are the most widely used strategies for managing the cost of most therapeutic classes.

Strategic Planning for Specialty Pharmacy

PBMs/SP providers are most in agreement with defining SP as drugs requiring special handling or storage (69%), bio-engineered drugs (69%), infused drugs (63%), high-unit cost drugs (61%), and oral oncology agents (56%). The FDA has not established a formal definition for specialty drugs. The Centers for Medicare and Medicaid Services (CMS) has established a minimum cost threshold that a drug must meet to be placed on a specialty tier under Medicare Part D. In 2007, $500 per month was the minimum amount; in 2008, 2009 and 2010, that minimum amount was $600.

PBMs/SP providers employ many cost containment strategies for SP in working with commercial plans. More than half of PBMs (56%) already set maximum day supply limits with 25% likely to set them; half have developed a limited distribution network for specialty drugs with 29% anticipating doing it; nearly half implemented quantity limits for selected drugs in 2009, with 30% likely to do so; and 37% already mandate the use of SP providers for selected drugs with 41% likely to do so. More than one-third (35%) require step therapy for more drugs with 43% planning to do so; and 77% are already adding therapeutic categories requiring prior authorization or planning to do so. The proportion of those undertaking therapeutic inter-change as of 2010 is 36%, while 30% will not implement the strategy.

Last year, 72% indicated that they required prior authorization as a benefit strategy, while 68% set maximum 30-day supplies, and 62% developed a limited distribution network for specialty drugs.

More than half of respondents (56%) were

The Patient Protection and Affordable Care Act creates a regulatory approval pathway for biosimilars.

Cost is the top concern in managing specialty pharmacy, followed by appropriate utilization.

setting maximum day supply limits in 2009, and 23% are likely to do so. Half had developed a limited distribution network for SP in 2009, while 25% are likely to create one. More than one-third (37%) say they will not eliminate patient cost-sharing differentials for self- vs physician-administered drugs.

Irene Gale confirms that more management strategies are needed as additional SP products enter the marketplace and costs increase. She notes that PBMs are struggling with how to cover physician-administered drugs and linking prescription drug and medical claims; 35% are likely to implement the latter in anticipation of better outcomes. She also expects that limited distribution networks will be implemented by most plans and PBMs in the next year or two.

The bottom line is never far from anyone's thoughts, ranking as the primary concern (94%) for managing SP. "Everyone is always trying to get their arms around cost," Gale says.

Appropriate utilization (70%) is the second issue of most concern. An example of inappropriate utilization is when patients continue to take medication after it is no longer needed.

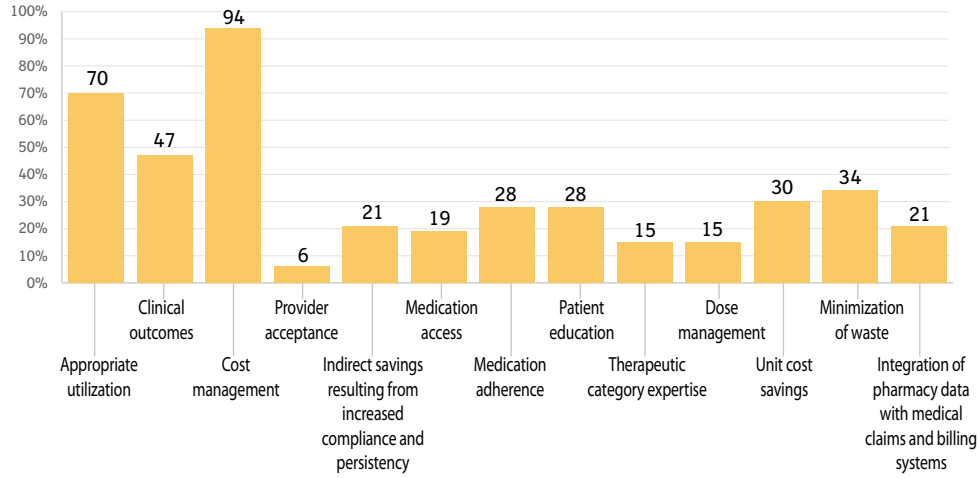
When asked what techniques are used to manage the cost of SP, more than 90% agree that patient care management (96%), quantity limits (92%), and prior authorization (92%) are "effective" or the "most effective" tools. Prior authorization goes hand in hand with trying to manage appropriate utilization.

These findings align with results from a survey sponsored by the Foundation for Managed Care Pharmacy (FMCP), which concludes that the top anticipated results of disease/care management for patients using SP are cost control (78%) and utilization management (69%). The FMCP survey, however, ranks medication adherence as number one (84%), with outcomes at 67%, compared with the 39% of this report's respondents who say adherence is a major concern,

Table 11: How likely is your organization to implement the following specialty pharmacy management strategies for your largest commercial benefit plan?

	Offered in 2009	New in 2010	Likely to Do	Will Not Do	Don't Know
Introduce separate tiers for preferred and non-preferred specialty pharmacy	31%	4%	25%	14%	25%
Increase patient cost sharing	24%	2%	40%	18%	16%
Increase number of therapeutic categories requiring prior authorization	24%	12%	41%	4%	20%
Implement quantity limits for selected drugs	49%	8%	22%	6%	16%
Require step therapy for more drugs	35%	4%	39%	4%	18%
Mandate use of specialty pharmacy providers for selected drugs	37%	10%	31%	6%	16%
Implement therapeutic interchange	28%	8%	12%	30%	22%
Move major medical drugs under the pharmacy benefit	28%	6%	26%	22%	18%
Implement a value-based benefit design for some therapeutic categories	22%	6%	24%	20%	27%
Move certain drugs or drug classes to lower copayments	24%	4%	20%	28%	24%
Carve out specialty pharmacy formulary	33%	4%	29%	16%	18%
Making patient cost sharing independent of Rx administration channel (oral vs injectable)	18%	10%	20%	20%	33%
Eliminating patient cost-sharing differentials for self- vs physician-administered Rx	6%	2%	16%	37%	39%
Setting maximum day supply limits	56%	2%	23%	6%	13%
Linking prescription and medical claims	23%	4%	35%	12%	27%
Having a limited distribution network for specialty drugs	50%	4%	25%	6%	15%

Figure 68: What are your clients' top concerns about managing specialty pharmaceuticals?



and the 47% who chose clinical outcomes.[31]

For biologic prescriptions, respondents ranked medication adherence third (64%, combining 4 and 5 responses) after cost management (84%) and appropriate utilization (76%). The PBM vice president says the lower interest in adherence is due to a greater focus on cost reduction, as well as medication wastage (61%).

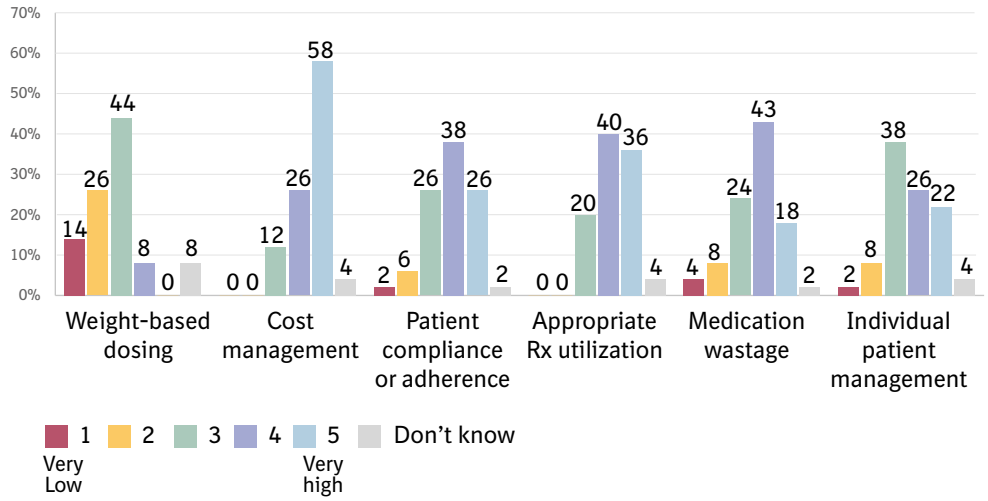
More than half of respondents indicate that that their largest health plan mandates the use of an SP provider for self-injectables (56%), and oral specialty drugs (53%). The PBM vice president anticipated that as many as 70% to 80% would mandate use of a SP provider for self-injectables and fewer than half would do so for physician-administered injectables.

As exemplified by current practice, 2010 adoption and "likely to implement," respondents are adopting preferred product strategies for SP (65%), adding financial incentives to steer patients toward preferred SP products (63%) and plan to switch to biosimilars once they become available (61%). Perry agrees that encouraging use of preferred product strategies can serve as an effective strategy to manage SP drugs, which is made possible by the increasing number of biologics in the marketplace and in the number of "therapeutically

56%

of respondents say their largest plan mandates use of a specialty pharmacy provider for self-injectables.

Figure 69: Rate your client's level of concern with the following biologic prescription issues:



65%

of respondents are adopting preferred product strategies for specialty pharmacy.

Figure 70: Does your largest commercial health plan mandate the use of a specialty pharmacy provider for:

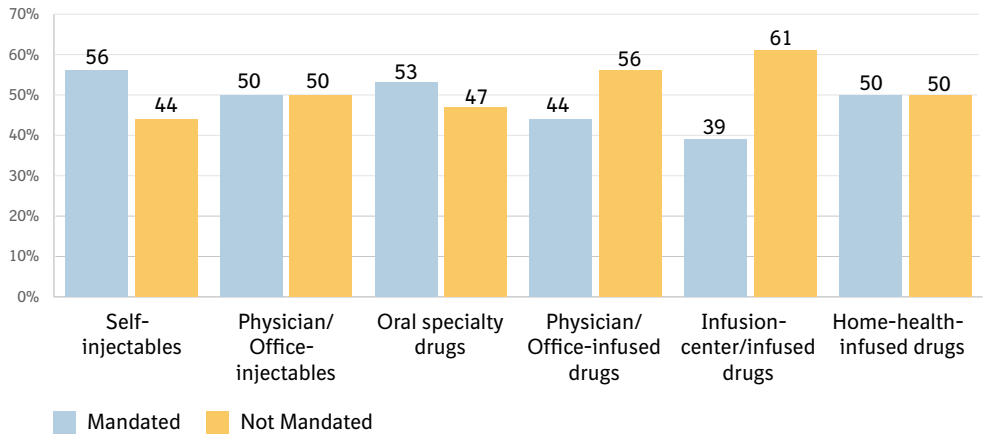
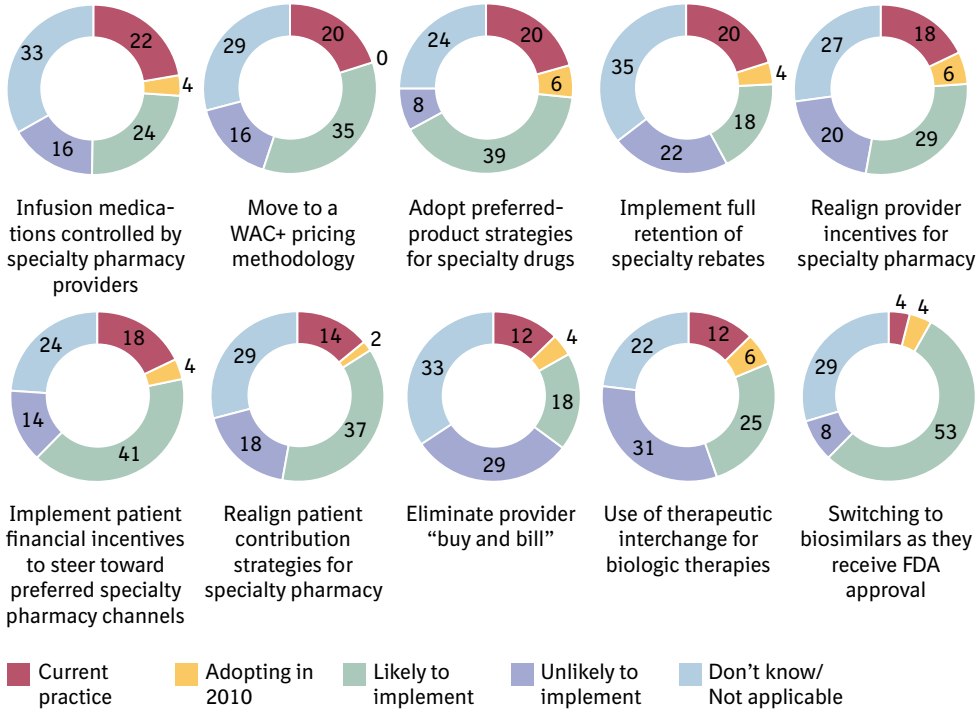


Figure 71: What is the likelihood that your largest commercial health plan or employer will implement the following?



equivalent" preferred choices.

More than half of respondents say they are currently moving to a wholesale acquisition cost (WAC)+ pricing methodology or are likely to implement one despite the continued use of reimbursement formulas based on average wholesale price (AWP). The AWP is not considered an accurate reflection of market prices for drugs and its use is being phased out. The PBM vice president predicts that the WAC methodology will be used more frequently in the future because it is already being used for rebate contracting. "WAC also is updated frequently," he says. "As for the average sales price (ASP) methodology, the issue is that pricing updates are not timely."

"Ultimately, the goal is to have a fair, representative value placed on a product within the channels of distribution," says Randy Vogenberg, PhD.

The Value in Benefit Design

PBMs and SP providers view

value-based insurance design (VBID) quite positively, with 46% agreeing or strongly agreeing with the statement: "Value-based benefit designs are effective strategies for managing an organization's total health care costs."

Although VBID has many different definitions, one of the more accepted ones is: by aligning financial incentives, VBID encourages the use of high-value care while discouraging the use of low-value or unproven services.[22]

Gale agrees with respondents (71%) that patient cost-sharing should be independent of the administration route.. "Patients should receive the drugs best suited for them, regardless of the cost to the PBM," she says. "The emphasis should be on the health and welfare of patients."

Using VBID to manage overall health care costs is accepted by 46% of managed care pharmacy experts targeted by the FMCP's Fourth Annual Emerging Trends Survey. One-quarter of respondent organizations offered VBID packages in 2009 and another quarter have them under development–a significant increase since 2007.[31] In another question in this survey, 19.6% say they have adopted VBID and 14.6% say they are in the process, while as many as 61% are considering adopting VBID. The same proportion of respondents who do not have a clear definition of VBID also are unsure about adopting it.

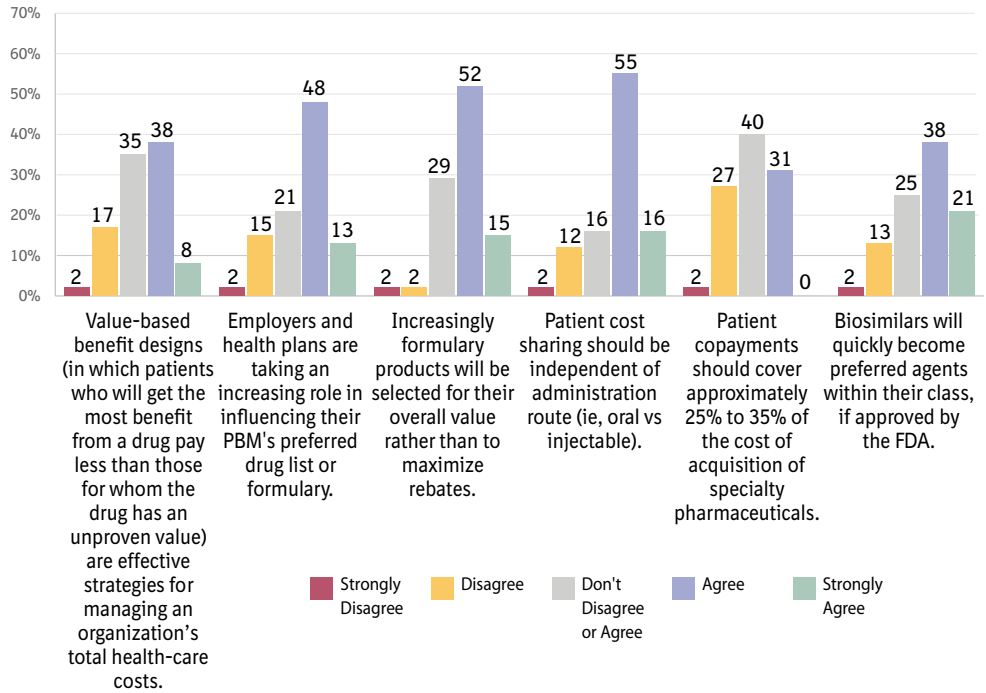
PBMs are moving slowly in their attempt to impose more cost-sharing on patients for SP drugs. Fewer than one-third agree that copayments should cover approximately 25% to 35% of the acquisition cost of the SP drug. Perry applauds the two-thirds of respondents who favor value over maximizing rebates to determine what goes on formulary.

As part of a push towards PBM greater transparency, the PBM vice president says, employers are playing a larger role in influencing their PBMs' formularies (61%). However, he emphasizes that the employer should play a role, but not be the deciding party, because PBMs have the expertise to determine formulary placement.

46%

of PBMs/SP providers view value-based insurance design as an "effective strategy" for managing total health care costs.

Figure 72: Please indicate your professional opinion about each of the following statements:



Better medication adherence is seen as linked to lower medical costs.

The Importance of Medication Adherence

PBMs/SP providers noted that patient participation (92%, combining important and very important responses) and provider participation (90%) have an important effect on medication adherence, which also ties closely with improving patient health (98%), better outcomes (96%), fewer adverse events (93%), and lowering pharmacy costs (86%). The PBM vice president attributes concern with the benefits of adherence to the high cost of specialty drugs.

Respondents hypothesize that employer sponsors share similar opinions about medication adherence, placing improved health on top (98%, important and very important responses combined), followed by better clinical outcomes (96%), patient and provider participation (91% and 85%, respectively) and fewer adverse effects (92%). Plan sponsors are also believed to lean towards lower medical costs (91%) and improved productivity (83%) as "important" or "very important" features. Productivity generated a 74% response.

What does medication adherence entail? "Is it that patients are taking the medication or that they are taking it as prescribed by their doctors?" asks Hayes.

Figure 73: Which features of increased medication adherence are important to your organization?

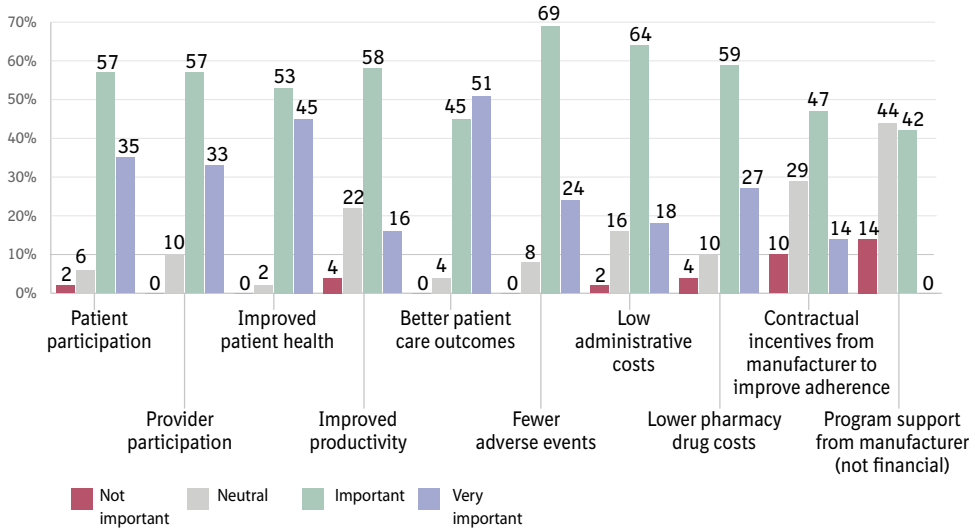
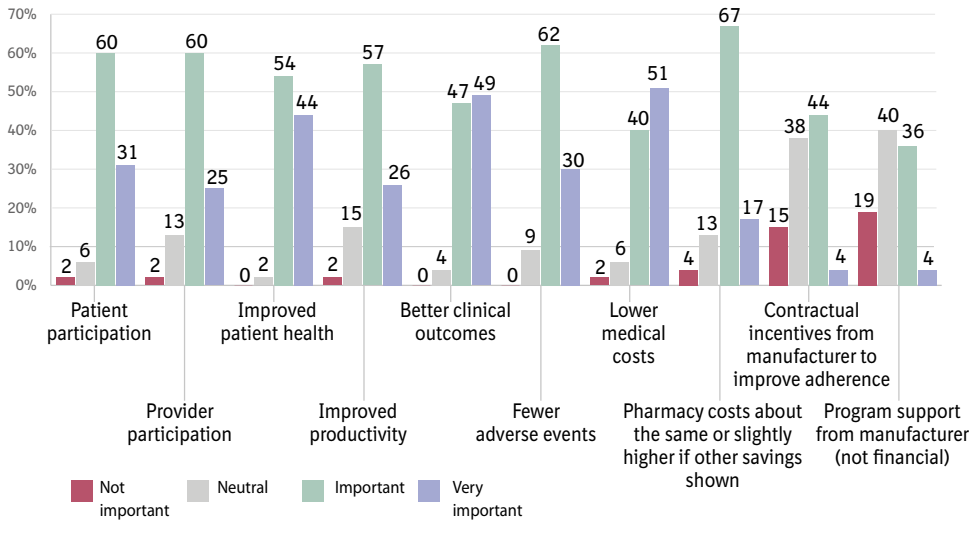


Figure 74: Which features of better medication adherence are important to your plan sponsors?



The Influence of Evidence-Based Medicine

PBMs/SP providers consider study design especially important in evidence-based medicine, followed by study results, study size, and length of study.

Findings of evidence-based studies have resulted in changes in formularies (61%), therapeutics (59%), and practice guidelines (53%). Besides efficacy, if evidence-based studies determine a drug has a safer profile than a similar one, or two drugs are just as efficacious but one costs less, that should drive formulary and therapeutics changes.

Evaluating Comparative Effectiveness Research

The majority of respondents find that comparative effectiveness research (CER) is "valuable" or "very valuable" in making comparisons of different pharmacotherapies by diagnosis (84%), pharmacotherapies by FDA-labeled indication (76%), and by condition of patients in disease-management programs compared with patients who are not under management (72%). Both the American Recovery and Reinvestment Act of 2009 and the Patient Protection and Affordable Care Act, signed into law in 2010, provide funding for CER.

Analyzing Claims Data

Pharmacy claims data are a key tool for managing the pharmacy benefit. Gale is surprised that there are even 15% of respondents who don't analyze claims data, but agrees with the top three reasons for analyzing and using claims

61%

of PBMs/SP providers say findings from evidence-based studies have resulted in changes in formularies.

Figure 75: Which features of evidence-based medicine studies are most important to your organization?

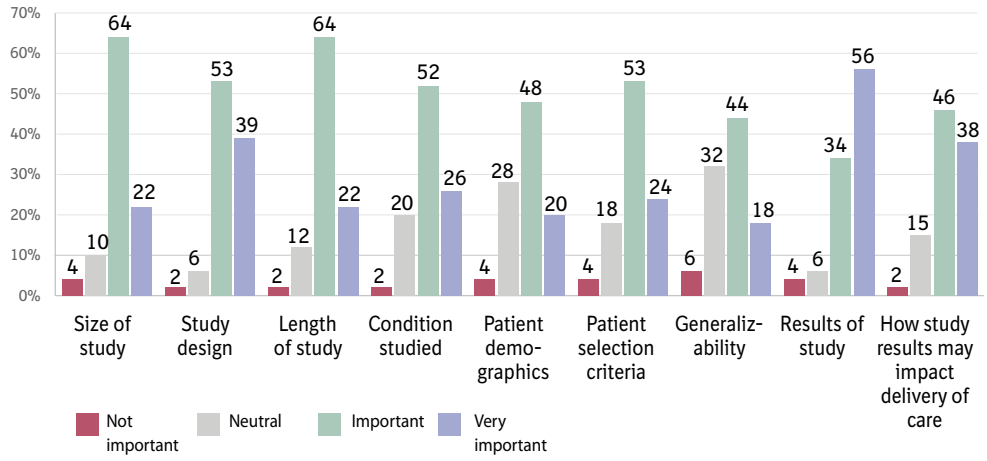


Figure 76: How have evidence-based medicine studies influenced your organization?

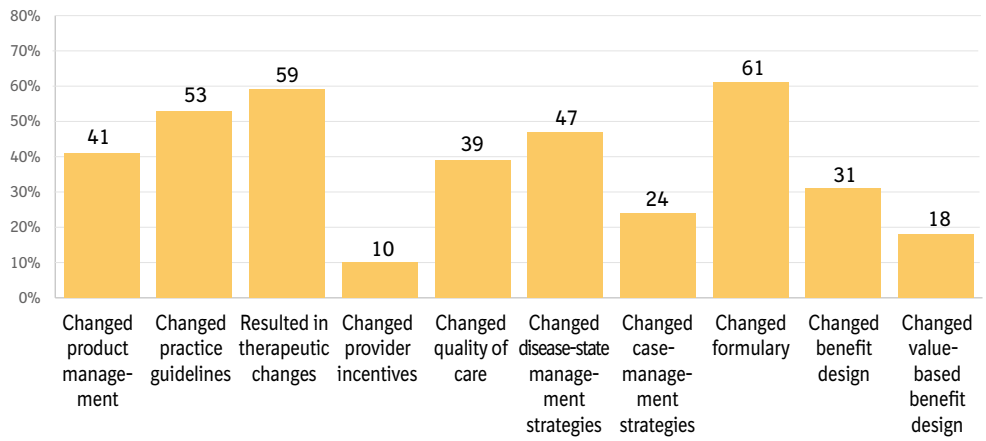
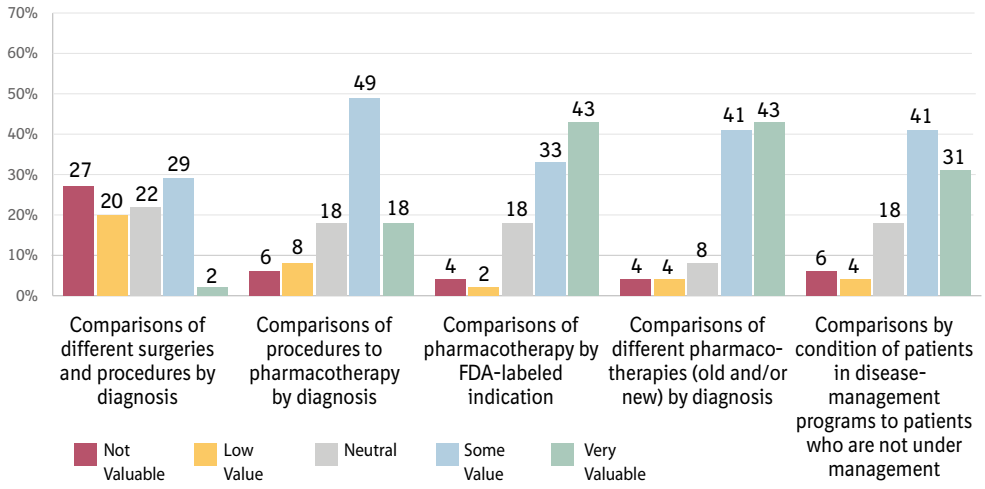
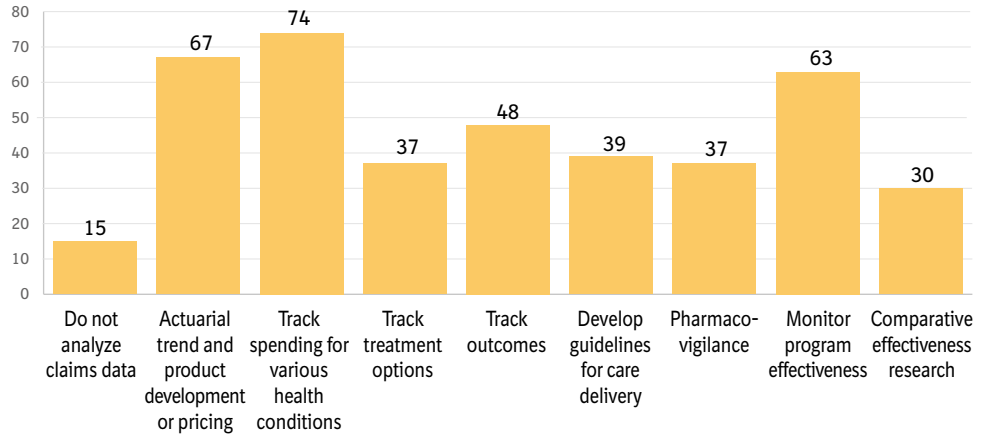


Figure 77: How have evidence-based medicine studies influenced your organization?



Pharmacy claims data are a key tool for managing the pharmacy benefit.

Figure 78: How does your organization analyze and use the pharmacy claims data you receive?



data: to track spending for various health conditions (74%), to inform about actuarial trend and product development or pricing (67%), and to monitor program effectiveness (63%). "The latter enables PBMs to evaluate how cost effective programs such as step therapy are, and decide if they should be continued or eliminated," she says.

The Future of E-prescribing

Respondents zeroed on two main benefits of e-prescribing: e-prescribing can enhance the delivery of specific information at the point of care (82%, agree and strongly agree responses combined), and e-prescribing can enforce formulary compliance (74%).

When asked what information e-prescribing offers, the top choices were: notification of possible drug interactions (82%); notification, of potential side effects (64%) and guidelines for therapy selection (62%).

Figure 79: Please indicate your degree of agreement/disagreement with the following statements concerning electronic prescribing (E-prescribing) and health information technology.

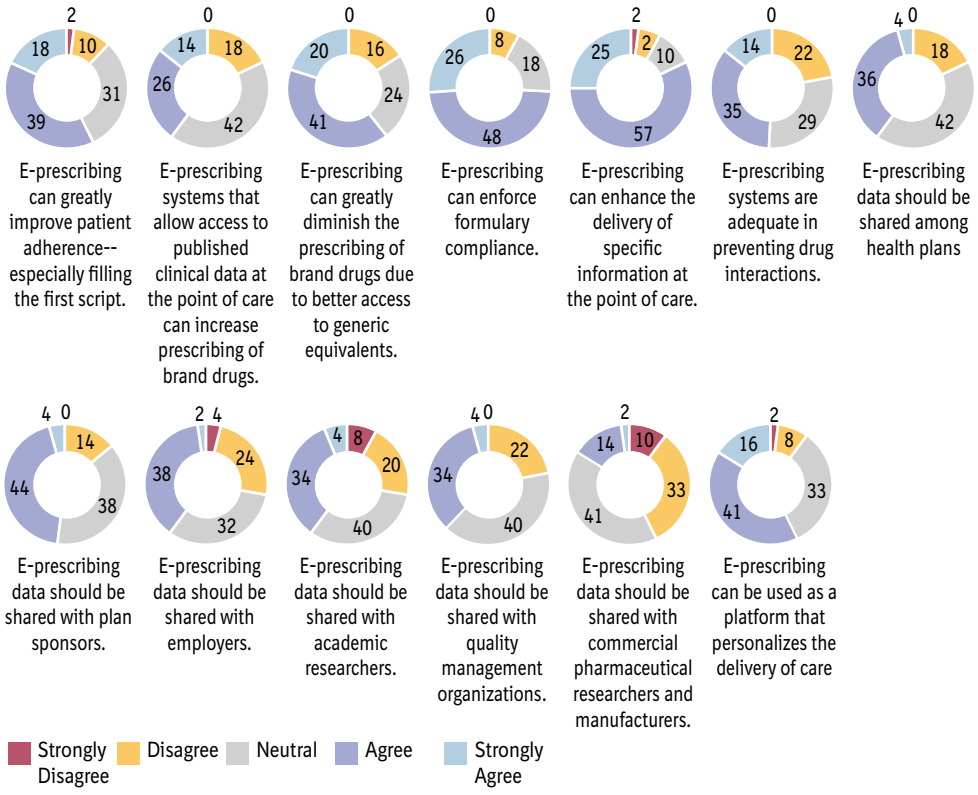
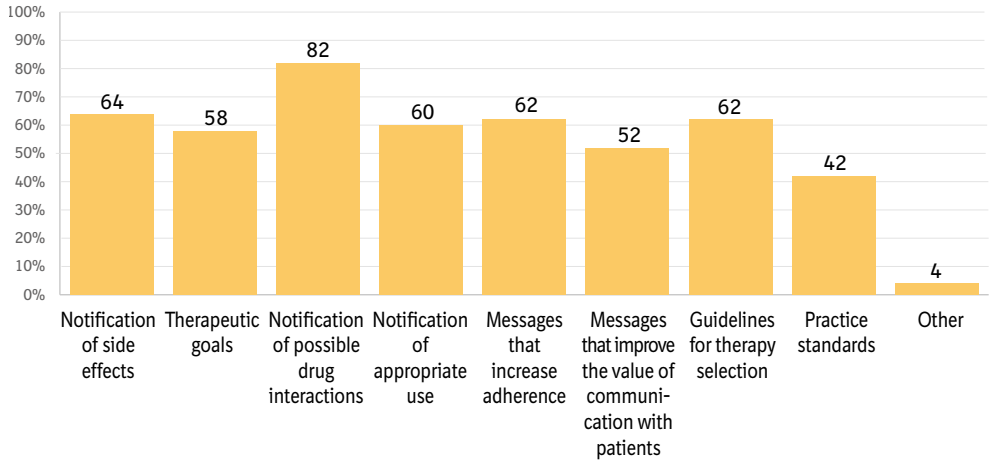


Figure 80: What additional information would you look for in an e-prescribing system?



82%

of respondents say e-prescribing can enhance the delivery of specific information at the point of care.

Emerging Trends in Managed Care

Emerging Trends in Managed Care

Investing in Health and Productivity Management as a Business Strategy

Nationwide, chronic diseases cost more than $1.0 billion in lost productivity annually, according to the Milken Institute. The Institute's research looks at diabetes, hypertension, stroke, heart disease, pulmonary conditions, cancer, and mental disorders and estimates a 42% increase in cases of the seven disease states by 2023.[1]

Although employers are aware that health-related factors can contribute to lost productivity among their employees, measuring the impact gets short shrift. The Integrated Benefits Institute (IBI) recently conducted a survey with Harris Interactive of nearly 450 employers, exploring perspectives on health and productivity management (HPM), measurement of key outcomes, how well HPM initiatives are meeting their goals, and plans for the near future. Overall, one in three employers do not measure productivity-related outcomes.[2]

Employers are more likely to measure sick days and disability absences–usually through administrative and claims data–than presenteeism and lost productivity. Absences prove to be the most commonly measured outcome; only about one in 10 employers do not measure them, while almost half do not measure presenteeism.[2]

The IBI research also reveals that 65% of employers believe that reducing medical and pharmacy costs is a primary outcome of HPM initiatives, while 90% consider reducing health-related lost productivity as a primary or secondary outcome.[2]

Thomas Parry, PhD, president of IBI, attributes the lower focus on measuring lost productivity to insufficient staff and financial resources and lack of data and know-how. The IBI survey findings support Parry's observations: nearly half of employers do not measure lost productivity because of insufficient staffing resources; one-third cite financial limits; 43% say they don't know how to measure it; and 43% say insufficient data is the primary reason.[2]

The American College of Occupational and Environmental Medicine defines HPM as "the joint management of the many types of programs and services designed to address all dimensions of employee health, including medical benefits, disability and workers' compensation programs, employee assistance programs (EAPs), paid sick leave, health promotion, and occupational safety programs."[3]

Rewards of Investing in HPM

In analyzing its return on investment (ROI) from employee wellness programs, Highmark Blue Cross Blue Shield, a health plan based in Pittsburgh, reported saving $1.3 million from 2001 to 2005, primarily because its annual health care expenses were $176 lower per participating employee.

Highmark's expenses for its wellness programs totaled $808,958 during the four-year time period and savings were $1.34 million, yielding an ROI of $1.65 for every $1 spent on wellness initiatives.[4]

Parry says that senior management wants to know what it's getting for its investment in HPM and needs more than cost reduction as a return. "They want initiatives to promote business objectives and outcomes," he says. "Conceptually, employers understand what drives lost productivity, but don't know how to get their arms around its measurement." He adds that measuring productivity is a survival strategy for any company.

HPM in a Slow Economy

Andrew Webber, president and CEO of the National Business Coalition on Health, is concerned that the present economic climate is not conducive to making investments in HPM, but he is optimistic that the environment will improve. "After an employer understands its employee population's health risks, the next step is to make decisions with limited resources," he says.

Webber is a strong advocate of prevention and behavior change–two elements making a business case for wellness programs. "We need a combination of incentives, a supportive work environment, social networking, friend and family support, coaching, follow-up, and an emphasis on primary care," he says. "It's critical that we change the way care is delivered. There is an opportunity to transform health care, which is still focused on treatment of acute illness." Webber emphasizes the importance of assessing the total costs of disability and illness among an employer population beyond looking at just health care claims.

Modeling tools exist to help employers deal with the critical issue of measuring lost productivity, presenting global evidence about the effects of poor health on productivity and presenteeism based on industry and similar workforce data. IBI's Health and Work Performance-Select (HPQ-Select) is just such an instrument; it generates valid data on the broader workplace costs of chronic health problems. Parry recommends to employers that they start with the best possible broad evidence and then take steps to quantify evidence within their organizations.

IBI's studies point to the usefulness of self-report tools, such as HPQ-Select, as a means of going beyond claims data to discover interventions that will have the greatest impact on reclaiming lost productivity due to absenteeism and presenteeism.[5]

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Employers Face Changes With Reform Legislation

With the passage of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, employers are facing changes that will affect how they provide their employees with health care coverage.

Raymond Brusca, vice president of Benefits at Stanley Black & Decker, which manufactures hand and power tools in Towson, Maryland, says he has to live and breathe the nuances of health care reform. The self-insured company, a recent merger of Black & Decker and Stanley Works, covers 14,000 lives and had planned to make changes in its benefit offerings in 2011. Brusca acknowledges in a phone interview (April 1, 2010) that the health care reform legislation will have an impact and expressed the following concerns about specific provisions:

- Extended coverage for young people ages 19 to 26 years under their parents' insurance.
- Free preventive care under new private plans. Brusca says that the company already covers immunizations, Pap tests, and mammograms without any employee cost-sharing but worries that "preventive" will be applied too broadly.
- Elimination of lifetime limits on coverage. Stanley Black & Decker currently has a $2 million lifetime cap.
- Elimination of discrimination against children under age 19 with pre-existing conditions, which the company's benefits already accommodate.
- Elimination of prior authorization for emergency services. "This will definitely have an effect on costs, especially when about 50% of persons who receive emergency care don't really need to go to the emergency department," he says.
- Decreases in the maximum annual amount contributed to a health savings account or flexible savings account eligible for tax deduction from $5,000 to $2,500. While $5,000 could be contributed tax-free previously, now $2,500 will be taxable.

Michael Martakis, director of Benefits for Sharp Electronics Corporation in Mahwah, New Jersey, is taking a "wait and see" attitude for now and anticipates most changes won't take effect until 2014. Like Brusca, Martakis also views the end of pre-existing condition barriers, elimination of a lifetime maximum, coverage for dependents up to age 26, and the reduction in the amount that could be contributed tax-free in health savings accounts with skepticism concerning possible cost savings to employers. Neither Sharp nor Stanley Black & Decker, however, will be plagued by the reform provisions that affect early retiree and retiree benefits.

The legislation eliminates deductions on tax-free subsidies for companies that provide drug benefit programs to Medicare-eligible retirees. Caterpillar Inc. and Deere & Co., among others, have stated that because of the end of the tax-free subsidy, they will have to take a $100 million and $150 million one-time charge, respectively. Although the provision doesn't go into effect until 2013, the two companies say they have to record the charges during the period in which the law was signed.[1]

Other provisions that may affect employers:

- Bans on the use of health savings accounts to buy over-the-counter drugs without a prescription.
- Restrictions on the use of annual limits on coverage.
- Gradual elimination of the Part D coverage gap.
- A 40% excise tax on high-cost health coverage.
- A shared responsibility mandate requiring employers to offer "affordable" coverage to fulltime employees or pay a penalty.[2]

On the plus side for employers, the legislation provides for tax credits immediately to small businesses of up to 35% of premiums if they choose to provide coverage. The tax credits will jump to 50% of premiums in 2014. Provisions also include a temporary reinsurance program for employers providing benefits to early retirees who are not Medicare-eligible. The program reimburses employers for 80% of retiree claims between $15,000 and $90,000.[2] In addition, the legislation provides for a regulatory pathway for biosimilars, which should lead to reduced drug costs.

"Right now, employers are struggling to assess the provisions of reform and their impact," says Steve Wojcik, vice president, Public Policy, National Business Group on Health, representing large employers on health care issues. "Ultimately, we want to make sure that employees and their dependents get the best value in care and coverage they can. 'Value' is the whole impetus behind reform."

Cathy Smith, benefits manager, LaBarge Inc, an electronics manufacturer services company in St. Louis, may speak for many employers when she says, "We are still in the process of estimating the cost impact to our company from health reform, which may in turn impact our plan benefits/offerings in the future."

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New Push for Comparative Effectiveness Research

"Comparative effectiveness research will enable us to compare drugs head to head in the real world, not drugs to placebos in a clinical trial," says T. Jeffrey White, PharmD, MS, director, Drug Evaluation and Clinical Analytics, Clinical Pharmacy Strategies, WellPoint, Inc, in a phone interview (March 18, 2010).

Comparative effectiveness research (CER) received a tremendous boost with the infusion of $1.1 billion in funding provided by The American Recovery and Reinvestment Act of 2009.

The concept of CER is not new; the Blue Cross and Blue Shield Association founded its Technology Evaluation Center in 1985 to assess the impact of medical technologies through reviews of clinical evidence of their effectiveness. The ECRI Institute, a non-profit organization that conducts evidence-based testing in health care, entered the arena of CER 40 years ago, providing health care technology assessment, and a health device and health care product comparison system.

The Congressional Budget Office defines CER as "a rigorous evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients." Such research can compare the clinical effectiveness of similar treatments, competing drugs, and medical procedures to drug therapy.[1]

CER may help inform insurers about decisions on coverage and payment for certain treatments; however, some stakeholders are concerned that using such research to make coverage decisions will limit the autonomy of physicians and restrict patients' access to different treatments. [2]

CER Put in Motion by Insurers

HealthCore, a subsidiary of WellPoint, analyzed medical and pharmacy claims from more than 50,000 patients in eight health plans using one of six types of asthma treatment regimens between 2003 and 2005. Users of oral controllers were significantly better at adhering to their medication regimens than users of inhaled corticosteroids. After the study, WellPoint's National Pharmacy and Therapeutics Committee decided to keep the oral controller on a less costly, preferred formulary tier and remove prior authorization requirements. Although the study showed that patients taking oral medications were more adherent to the medication regimen, those on inhaled drugs, if they remained adherent, had better clinical outcomes.[3]

"WellPoint's National Pharmacy and Therapeutics Committee requested the comparative effectiveness study to help ensure that its drug formulary for asthma therapies was aligned with their real-world use and outcomes," said Joseph Singer, MD, vice president of Clinical Affairs for HealthCore. "We believe the study to be the first comprehensive comparative effectiveness research study on all asthma controller medications." [3]

CER and the Public and Private Sectors

Jean Slutsky, director, Center for Outcomes and Evidence, Agency for Healthcare Research and Quality (AHRQ), emphasizes that CER measures effectiveness, not efficacy, the former being a more challenging undertaking conducted in a real world environment. "CER helps us learn about different treatments for different patients and provides options as to what will work best," she said in a phone interview (April 1, 2010). "CER is a concerted effort to determine where information is most needed and invest in those areas," she added.

AHRQ developed the Effective Health Care Program, which funds individual researchers, research centers, and academic institutions to produce effectiveness and CER studies for clinicians, consumers, and policymakers. The research topics are prioritized by services, such as prevention, treatment, or cure of diseases and conditions that impose high costs on patients; by patient populations, such as low-income groups, women, children, minorities, and the elderly; and by conditions, including cancer, cardiovascular disease, depression, diabetes, obesity, arthritis, and infectious diseases.

CER also has the support of the business community. The National Business Group on Health (NBGH) advocates for more reliable, independent information on the effectiveness of medical interventions compared with other treatment options.[4]

NBGH supports the following CER principles:

- Significant and stable investment is needed for CER.
- The scope of CER should address the full spectrum of health care treatments, including pharmaceuticals, medical devices, and surgical procedures, and other interventions.
- Scientific integrity and independence are paramount.
- CER should be based on scientific evidence.
- The processes for identifying research priorities, conducting research, validating science, and disseminating results should be transparent.
- Any entity that commissions or conducts CER should involve stakeholders, including employers, in setting priorities and disseminating research.
- Governance should assure accountability.
- CER should help physicians and patients identify whether medical interventions work better in specific populations, or work differently in different individuals based on clinical trials.

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Conclusions

Conclusions

In three separate surveys, employers, health plan executives, and PBMs/SP providers were asked similar questions on a range of issues related to the pharmacy benefit. Their responses are compared on utilization and cost management strategies, expectations for pharmacy cost increases, benefit design, and evidence-based medicine.

- Per member per month (pmpm) pharmacy cost trends for the next 12 months vary with 33% of employers predicting cost growth of 6% to 10%, while 57% of health plans and 33% of PBMs/SP providers predict more modest cost growth of 0% to 5%. However, 35% of PBMs/SPs expect specialty pharmacy to increase by 6% to 10%. The pharmacy cost trend is exceeded by the medical cost trend.

- All three groups rank cost as their number one concern in managing pharmacy benefits.

- The majority of employers, plans, and PBMs are generally using three-tiered formularies (generics, preferred brands, non-preferred brands).

- Employers are implementing a variety of drug benefit management strategies, with 78% offering or likely to offer incentives for generic prescriptions; 67% increasing or likely to raise copayments or coinsurance for branded drugs; and 56% mandating or likely to mandate SP provider distribution of specialty drugs.

- Copayments are the most common method of cost-sharing though coinsurance is frequently used with specialty pharmacy drugs.

- Employers, plans and PBMs generally agree on the conditions that generate the most concern in terms of managing costs: diabetes, asthma, hyperlipidemia, chronic obstructive pulmonary disease (COPD), and hypertension, and also cancer and rheumatoid arthritis.

- Employers find COPD a difficult condition to manage because of confusing symptoms and also because patients often have comorbid conditions.

- Value-based insurance design (VBID) is generally viewed positively although implementation is slow. Of health plan executives, 31% say they have implemented VBID for at least one therapeutic category, most often diabetes. Among employers, 23% say they are considering adopting VBID. Nearly half (46%) of PBMs/SP providers view VBID as an “effective strategy.”

- Health plans have already used evidence-based study findings to alter guidelines (66%) and formularies (63%); their influence is expected to only increase.

- Employers emphasize their interest in productivity, but few actually measure it. Instead, they are more likely to measure costs associated with absenteeism, workers' compensation, and short-term disability.

- Health plans are second to consultants in influencing employers on pharmacy benefit design; PBMs are third.

- Employers generally express satisfaction with services of PBMs though they are least satisfied with rebate contracting and financial transparency.

- Health plans say that the biggest challenge to incorporating specialty pharmacy services into benefit plan design is physician pushback.

- Plans are trying a variety of new and/or additional strategies to manage specialty pharmacy, with many having implemented quantity limits for selected drugs, set maximum day supply limits, increased the number of drugs requiring prior authorization, and developed limited networks in 2009.

- All three groups agree on the importance of medication adherence and its relationship to improved health; however, only about 18% of employers say they measure adherence.

- As plans begin to realize the impact of medication adherence on their overall costs and health status of their members, they cite the following as "important" or "very important" as the top three results of better adherence: improved patient health (95%), patient participation (90%), and better patient care outcomes (88%).

- PBMs/SP providers say that medication adherence has a strong impact on improved patient health (98%), better outcomes (96%), fewer adverse events (93%), and lower pharmacy costs (86%).

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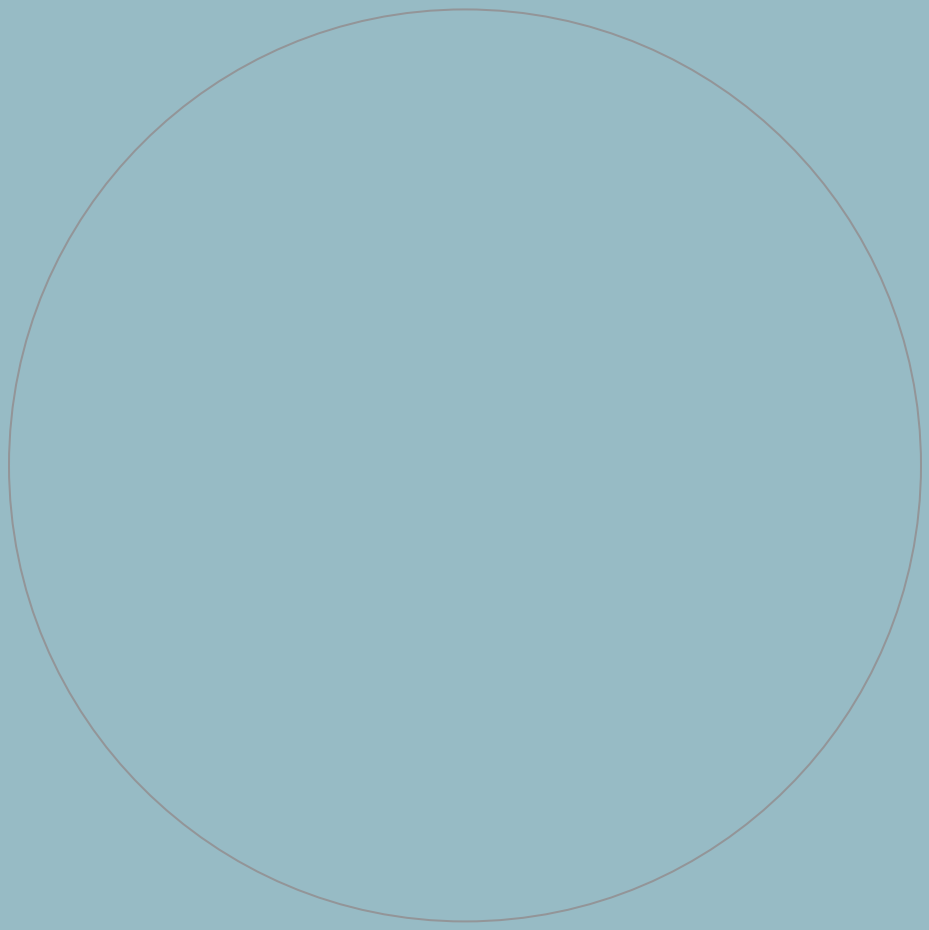

Suggested uses for this report:

- Presentations
- Comparisons
- Benchmarking
- Formulation of policies
- Business plans
- Budgeting
- Strategic forecasting
- Analysis and trends

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