The Boehringer Ingelheim Medicare Part D & Patient-Centered Medical Home Report

Boehringer Ingelheim

2010-2011 Edition

Contents

Letter from the Report Chairman

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Integrating Health Care Silos

Today, most health care is delivered in silos, separating the provision of chronic and acute care, pharmacy and medical services, inpatient from outpatient care, and primary from specialist care. Realizing that health care delivered in silos is taxing our system and fragmenting care, we are continually looking for improvements.

What's needed is a holistic approach to care delivered in an integrated health care environment. The coordinated, personalized care approach promised by the patient-centered medical home (PCMH) may just be what the doctor ordered. Although models such as the PCMH may not yet be top-of-mind for most health plans, the concept is certainly gaining traction; 65% of plan respondents in *The Boehringer Ingelheim Medicare Part D & Patient-Centered Medical Home Report* indicate efforts to implement a PCMH or express interest in starting one.

Embedded in the medical home model are two touchstone characteristics: 1) a physician-led team responsible for patients' ongoing care, and 2) care coordinated and/or integrated across all elements of the health care system with the use of patient registries, health information technology (HIT) , and health information exchange. These concepts, along with others, are outlined in the "Joint Principles of the Patient-Centered Medical Home," developed jointly by the American College of Physicians, the American Academy of Pediatrics, the American Academy of Family Physicians, and the American Osteopathic Association.[1]

Although coordination of care results in improvements in care and reductions in waste and unnecessary services, it is not always clear how to accomplish these goals.

An evaluation by the Patient-Centered Primary Care Collaborative illustrates the benefits of medical homes, notably more effective and efficient care than is provided by systems that do not invest adequately in the delivery of primary care.[2] The result: is reductions in the number of emergency department visits and inpatient hospitalizations in a short time-frame, leading to savings in total health care costs as well as better quality care. The study shows that at a minimum, savings offset the new investments in primary care in a cost-neutral manner, and in many cases, appear to reduce total costs per patient. Group Health Cooperative of Puget Sound and Genesee Health Plan are two examples of health plans that have successfully reduced total medical costs by investing in medical homes.

According to an analysis by the Wisconsin Academy of Family Physicians of research conducted by the Dartmouth Institute for Health Policy & Clinical Practice, patients with severe chronic disease, who live in states in the US that relied more on primary care, have[3]:

Item #2

- lower Medicare spending (inpatient reimbursements and Part B payments);
- lower resource inputs (hospital and intensive care unit [ICU] beds and total physician, primary care, and medical specialist labor);
- lower utilization rates (physician visits, days in ICUs, days in hospital, and fewer patients seeing 10 or more physicians); and result in
- better quality of care (fewer ICU deaths and a higher composite quality score).

Despite demonstrated benefits of a more integrative approach to health care, silos continue to dominate our health care landscape. One reason for the continued reliance on silos is that it is easier to reduce individual costs in a single compartment, such as pharmacy, but more difficult to reconcile the impact that any decrease in expenditures has on total costs. Reducing expenditures in one silo, such as pharmacy, could cause overall health care costs to rise. Although coordinated care requires additional investments in primary care, technology, and integration, the results could reduce the total cost of care.

Improved medication adherence, one objective of the PCMH, illustrates the value of coordinated care. Although medication utilization will increase as adherence improves, the goal is to prevent higher-cost hospitalizations and additional physician visits down the road. An investment in improved medication access and management may increase the pharmacy budget but reduce or slow the growth of overall health care costs.

Perhaps nowhere is the need to integrate silos demonstrated more clearly than by plan respondents' view of the PCMH. Two survey questions ask which features of the PCMH model are most important and what are plans' expectations for a PCMH. Coordinated care is seen as one of the most important attributes of the PCMH (according to 99% of health plan respondents), requiring primary care physicians (PCPs) to move outside of their traditional silo to oversee such aspects as medication adherence and preventive care.

There is also strong agreement about the value of investing in HIT to support the medical home. Nearly 72% of plans surveyed say that more support is needed for HIT, while many agree that the model will improve patient records (70%), patient outcomes (66%), and adherence to therapy (62%).

The US government is investing billions to promote the use of electronic medical records, sharing the expectation of health plans responding to our survey that an investment in HIT will reduce overall health care expenditures significantly.

As Medicare leads the charge to hold payers more accountable for patient outcomes, as measured by the National Committee for Quality Assurance and other organizations, payers will be forced to find ways to deliver improved outcomes while reducing overall expenditures. One solution to coordinating care in a systematic way might be the patient-centered medical home and all of its related principles.

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Executive Summary

Executive Summary

The Boehringer Ingelheim Medicare Part D & Patient-Centered Medical Home Report **profiles a market in flux as health plans seek to fine-tune their business strategies while also adapting to a changing regulatory environment. Here are highlights of the report on Medicare Part D and on the patient-centered medical home (PCMH):**

The top 5 therapeutic categories in drug spend are: diabetes, hyperlipidemia, hypertension, cancer, and depression.

Medicare Part D

- Part D plans are aggressively marketing to younger and healthier populations. Both Prescription Drug Plans (PDPs) and Medicare-Advantage Prescription Drug plans (MA-PDs) are marketing to persons under age 65 (68% and 80%, respectively) and persons who are aging into Medicare eligibility (76% and 84%, respectively).

- Although a majority of MA-PDs and PDPs say they will not make any changes in their Part D benefit designs in 2010, 53% of MA-PDs and 45% of PDPs say they will increase copayments, and 45% of MA-PDs and 54% of PDPs expect to increase premiums.

- Nearly one-third of members of both MA-PDs and PDPs reached the donut hole coverage gap in 2009.

- One consequence of patients reaching the coverage gap is a significant drop-off in medication adherence, according to 71% of Part D plans. However, 60% of respondents say their members have switched from branded medications to covered generics to better weather the expenses in the coverage gap.

- MA-PDs and PDPs list the same top five therapeutic categories in drug spend: diabetes, hyperlipidemia, hypertension, cancer, and depression.

- While Part D plans deploy a variety of utilization management techniques, generic substitution is used most often (77%), followed by prior authorization (58%), formulary alignment (48%), and step therapy (46%). There has been a steady increase in the use of utilization management techniques since 2007.

- The appeal rate for prescriptions requiring prior authorization is 10% for MA-PDs and 11% for PDPs; MA-PDs approve half of the appeals, while PDPs approve 45%.

- Only 29% of MA-PDs and 37% of PDPs cover over-the-counter (OTC) products in step therapy.

- Part D plans are using a variety of strategies for minimizing problems associated with polypharmacy: 80% rely on medication therapy management (MTM), 76% screen for drug-drug interactions at point-of-sale, 61% are utilizing e-prescribing

66%

of health plans say PCMHs will improve patient outcomes.

or electronic medical records, and 53% share patients' medication histories with patients' other physicians.

- Although just a little more than half of Part D plans (55%) are currently offering personal consultations with members, this will likely increase beginning in 2010 because of new rules that mandate an interactive person-to-person consultation.

- When plans are asked if their organizations offer financial incentives to physicians to provide high-quality care, 37% answer affirmatively and another 31% say they are planning to implement pay-for-performance (P4P); 40% say they have no plans to implement P4P.

- Of the plans that offer financial incentives for physicians to provide high-quality care, 94% provide such incentives for chronic care management of diabetes and 81% do so for managing cardiovascular diseases. Nearly 60% incentivize physicians for care management of asthma, while half target management of chronic obstructive pulmonary disease (COPD).

- When asked what information should be accessible to providers via HIT and e-prescribing, plans indicate support for notification of possible drug interactions (91%), treatment alternatives (85%), guidelines for therapy selection (83%), notification of drug adverse effects (77%), and practice standards (74%).

- Part D plans overwhelmingly agree or strongly agree that widespread adoption of HIT will improve patient outcomes (77%), improve accountability (76%), and standardize provider performance (66%).

Patient-Centered Medical Home

- Key features of a patient-centered medical home (PCMH), according to health plans, include: an emphasis on continuous, preventive care (99%, combining important and most important responses), primary care physicians (PCPs) as coordinators of care (99%), and use of evidence-based medicine and guidelines (96%).

- Nearly three-quarters (72%, combining agree and strongly agree responses) say that more health information technology (HIT) support is necessary, while many agree that PCMH will improve patient records (70%), patient outcomes (66%), and patient adherence to therapy (62%).

- Nearly half of respondents are developing HIT to share formulary and practice guidelines with providers, while 30% are revising their reimbursement schedules and 29% are working with other plans in their regions to integrate HIT for the provider network.

- Most Part D plans (65%) have expressed interest in supporting the medical home concept by implementing one, developing a pilot, or gearing up toward implementing one. This includes plans that: have implemented one throughout the system (16%); have implemented a medical home with providers who support the model (12%); are

piloting one (19%); or consider the PCMH as part of the accountable care organization (ACO) initiative (18%).

- Although half of respondents indicate that they use internal standards to recognize providers in their medical homes, 43% rely on the PCMH qualifications set by the National Committee for Quality Assurance (NCQA). Thirty percent have no set standards.

- Despite advocacy by the Patient-Centered Primary Care Collaborative (PCPCC) for the incorporation of medication therapy management (MTM) into the medical home, only half of survey respondents say they will provide MTM services as part of a PCMH.

- For those medical homes that provide MTM services, more than half (58%) of plans expect MTM reimbursement to stay at the same rate as what former MTM providers were receiving or at the provider contracted rate; another 29% say the reimbursement should be incorporated into the patient coordination fee.

- Respondents indicate that HIT is an important tool in supporting PCPs in a medical home. HIT improves health information exchanges between plans and providers (83%), and provides formulary information (75%) and practice guidelines to providers (63%). HIT plays a critical role in the adoption of the medical home model: nearly half of plans say they have developed HIT to help access formularies and practice guidelines, while 45% have developed health information infrastructures and exchanges.

- True to the concept of the PCMH, 76% of respondents say they will target PCPs in their initial efforts, while 28% will target multispecialty group practices, and 26% will include medical specialist providers.

- While 54% of Part D plans expect the Centers for Medicare and Medicaid Services to take the lead on developing the PCMH, most of the PCMH thought leaders believe that the agency is moving too slowly. Plans also look to quality organizations, such as the NCQA (42%), and to health plan coalitions (31%) for leadership.

77%

of plans starting PCMHs expect to target primary care physicians.

Methodolgy

Methodology

Throughout the first half of 2010, Boehringer Ingelheim Pharmaceuticals, Inc, conducted survey research with medical directors, pharmacy directors, and clinical pharmacists, two-thirds of whom are affiliated with a health plan, on practices related to participation in the Medicare Part D prescription drug program and patient-centered medical homes. The total number of respondents is 100.

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 health plans or the pharmacy services industry.

The survey research was conducted in cooperation with the National Association of Managed Care Physicians and the Patient-Centered Primary Care Collaborative.

The Boehringer Ingelheim Medicare Part D & Patient-Centered Medical Home Report: A Comprehensive Guide

The Boehringer Ingelheim Medicare Part D & Patient-Centered Medical Home Report provides a comprehensive resource and reference guide for Medicare Part D drug plan medical directors, pharmacy directors, clinical pharmacists, and PBM/specialty pharmacy executives. The analysis can be used to help readers compare and benchmark their performance; strengthen their member services; sharpen business tactics; improve clinical outcomes; and better understand the Medicare regulatory and business environment to guide future Medicare plan design decisions. In addition, *The Boehringer Ingelheim Medicare Part D & Patient-Centered Medical Home Report* explores respondents' opinions of the Patient-Centered Medical Home (PCMH) concept: what features are important; objectives of the medical home; how providers are supported; use of incentives; rate of adoption and implementation; and reimbursement issues. The PCMH concept is also the focus of the Centers for Medicare and Medicaid Services' Advanced Patient Care demonstration project.

Medicare Part D: A Market in Flux

Medicare Part D: A Market in Flux

The first part of *The Boehringer Ingelheim Medicare Part D & Patient-Centered Medical Home Report* explores the strategies, goals, and experiences of health plans in offering stand-alone prescription drug plans (PDPs) and Medicare Advantage Prescription Drug (MA-PD) plans. The report highlights information on cost and utilization management tools such as: prior authorization and step therapy; medication therapy management (MTM); health care reform legislation and Part D; changes in benefit design and formularies; and future efforts of plan pharmacy directors and medical directors.

27.7
million Medicare beneficiaries were enrolled in Part D plans in 2010.

In 2010, the number of PDPs totaled 1,576, down from 1,689 in 2009, with an average of three fewer plans per region.[1] During the same time period, the number of MA-PDs decreased to 1,828[2] from 1,991.[3]

As of February 2010, 27.7 million Medicare beneficiaries were enrolled in Medicare drug plans (including 17.7 million in PDPs and 9.9 million in MA-PDs),[3] compared with a total of 26.5 million beneficiaries in June 2009.[3] Enrollment in Medicare Part D plans represents about 60% of the total Medicare beneficiary population.[3]

Although the data for this report were collected prior to the March 23 passage of health care reform legislation, this information can be used as a baseline for comparison as the new provisions take effect. The Patient Protection and Affordable Care Act (PPACA) will bring changes over the next decade, including expanded drug coverage in the "donut hole" coverage gap in the Medicare Part D program. In 2010, beneficiaries will receive a $250 rebate from the Centers for Medicare and Medicaid Services (CMS) if they incur expenses in the donut hole. Beginning in 2011, beneficiaries whose drug costs reach the donut hole threshold will receive a 50% reduction on the total cost of brand name prescription drugs while in the coverage gap. CMS will phase in additional discounts on the cost of both brand and generic drugs.[4]

By 2020, Part D enrollees will receive a 50% discount from pharmaceutical manufacturers on the cost of brand name drugs, plus a 25% federal subsidy (phased in beginning in 2013).[4]

According to new guidance issued to Part D sponsors on May 21, 2010, CMS is speeding up the process by guaranteeing that Medicare Part D beneficiaries will see a 50% savings on brand name and some authorized generic drugs when they enter the coverage gap in 2011.[5] Also in 2011, 75% of the cost of generic drugs in the gap will be subsidized by CMS, while beneficiaries will pay the remaining 25% of drug costs out-of-pocket (OOP).[4]

Finally, between 2014 and 2019, the new program will reduce the OOP amount that qualifies an enrollee for catastrophic

Medicare Part D prescriptions accounted for 20.6% of all retail prescriptions in 2010.

coverage, further reducing OOP costs for those with high prescription drug expenses. (Beneficiaries are eligible for catastrophic prescription drug coverage in 2010 only after they pass through the donut hole and reach the $4,550 threshold. At that point, beneficiaries are responsible for cost sharing of $2.50 for generic drugs and $6.30 for brands.)[4]

The health care reform legislation will effectively close the coverage gap by 2020; rather than paying 100% of prescription drug costs in the coverage gap, beneficiaries will be responsible for only 25% of the costs. In addition, between 2014 and 2019, the OOP amount that qualifies a beneficiary to receive catastrophic coverage will decrease.[4] The Congressional Budget Office estimates that closing the coverage gap will cost the US government $42.6 billion by 2019.[6]

The PPACA's new provisions will likely open the door to new issues affecting delivery of care under Medicare:

1. Whether pharmaceutical manufacturers will continue to discount brand name drugs.
2. The effect of a 21.2% reduction in Medicare reimbursement of physician services.
3. Will there be a decline in the use of generics because of discounts offered in the coverage gap on both brands and generics?
4. How will insurers modify their benefit designs in light of the coverage gap phase-out?

Health care reform legislation also: eliminates the tax deduction on Retiree Drug Subsidy (RDS) payments for employers, which could lead employers to drop coverage for retirees and increase the size of the individual market; mandates that plan sponsors beginning in 2011 must include all covered Part D drugs in a category or class on formulary, as defined by the Department of Health and Human Services; provides for incentives in 2012 to plans who achieve quality goals; and reduces the Part D premium subsidy for high-income beneficiaries.

Medicare Part D prescriptions accounted for 20.6% of all retail prescriptions in 2010, up from 19.8% in 2009 and 19.3% in 2008, according to IMS data.[7] The top 15 Medicare Part D drug classes in 2010 are: cholesterol reducers, renin angiotensin antagonists, adrenergic blockers, narcotic analgesics, antidepressants, diuretics, anti-ulcerants, non-insulin diabetes agents, calcium blockers, anti-infectives, thyroid hormone, seizure disorder agents, antiarthritis agents, bronchodilators, and bone density regulators. Of the top 15 Medicare Part D drugs that account for 28% of all Medicare Part D retail prescriptions, 13 are generics.[7]

Interpreting the Data

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
- Randy Vogenberg, PhD, principal at the Institute for Integrated Healthcare (IIH), Sharon, MA; executive director, Biologic Finance & Access Council Program, Jefferson School of Population Health, Philadelphia
- Keith Perry, president, PharmEfficiency, Yarmouthport, MA
- Richard Stefanacci, DO, MGH, MBA, AGSF, CMD, Center for Aging Research, Education & Support (CARES), University of the Sciences, NewCourtland LIFE

Program medical director, Philadelphia, PA
- Jack Hoadley, PhD, research professor, Health Policy Institute, Georgetown University, Washington, DC
- Glenda Owens, RPh, MHA, formerly vice president, pharmacy services, Arcadian Health Plans, Oakland, CA
- Tamara Howerton, RPh, clinical pharmacist, Medicare, Health Alliance Medical Plans, Champaign, IL

Research Results

A little more than half of the health plan survey respondents offer both MA-PDs and PDPs. The percentage of covered lives enrolled in MA-PDs is 57%, while 43% are members of a PDP.

Health plans seem to see more opportunity for MA-PDs than for PDPs. While 42% of survey respondents say they increased the number of regions in which they offer PDPs, 46% increased the number of regions for MA-PDs. More than half of MA-PDs (54%) planned to increase their number of regions in 2010, compared with 45% of PDPs.

Randy Vogenberg, PhD, contends that MA-PDs offer a more integrative approach to health care and deliver more value to CMS.

The number of Part D plans increased sharply between 2006 and 2007, remained relatively steady between 2007 and 2008, and decreased modestly between 2008 and 2009.[8] The number of PDPs available in 2009 ranges from a low of 45 in Alaska to a high of 57 in the region covering Pennsylvania and West Virginia.[8]

The number of MA-PD plans has increased by about 50% since 2006, from 1,333 plans in 2006 to 1,991 plans in 2009, with a very modest increase since 2008.[8]

Richard Stefanacci, DO, says that the additional plans being offered make sense in terms of utilizing existing administrative staff, expanding geographic coverage, and seeking return on investment.

Of Part D plans that withdrew from some regions, more than half (54%) say

Figure 2: If you have withdrawn from some regions, why?

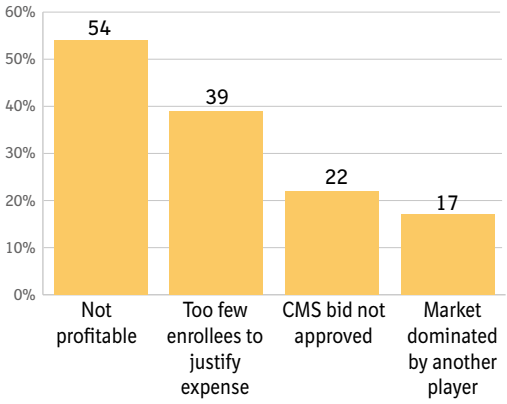
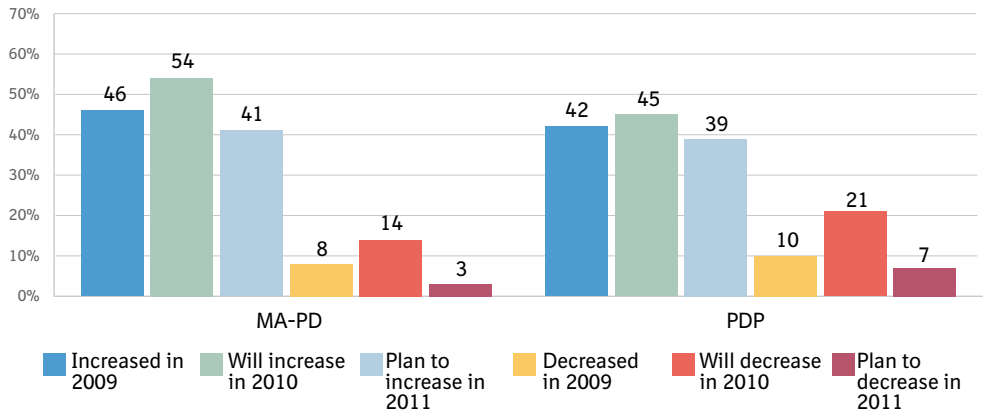


Figure 1: How has your organization changed the number of regions in which it offers Medicare Part D Plans?



Health plans seem to see more opportunities for MA-PDs than for PDPs.

Many plans have increased cost sharing.

Figure 4: What is your most likely strategy for marketing Medicare MA-PD offerings to the following groups?

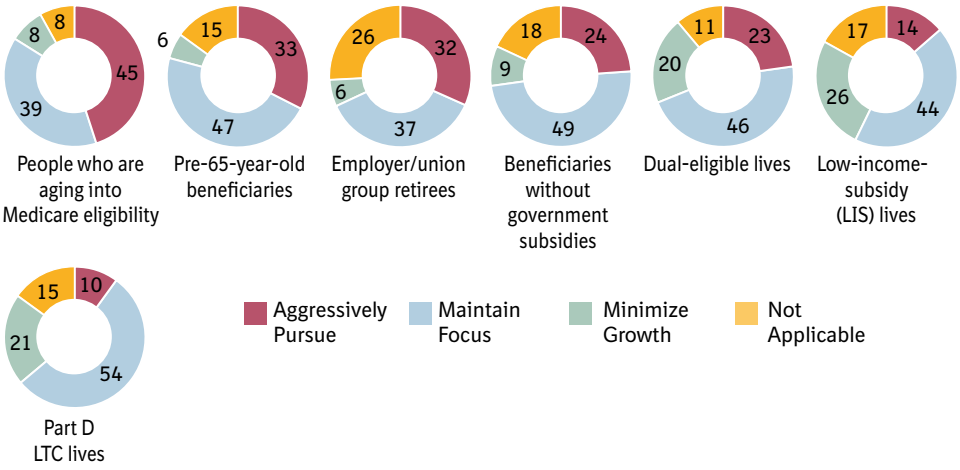
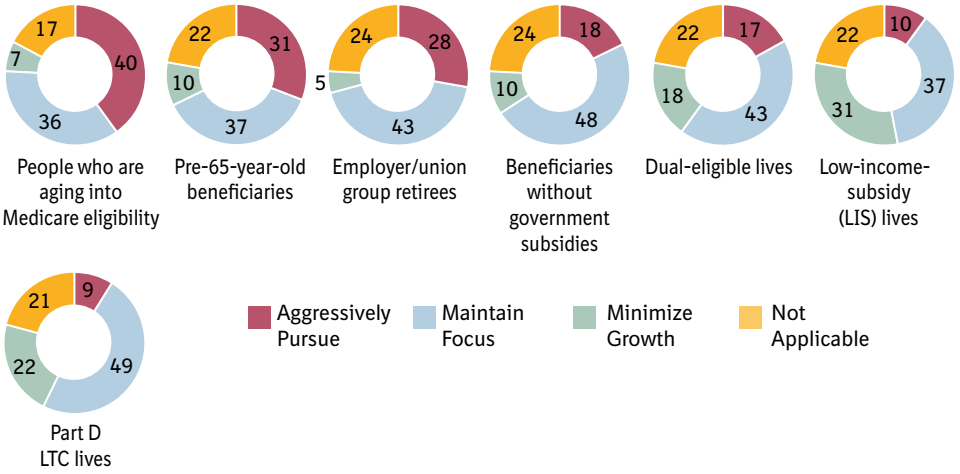


Figure 3: What is your most likely strategy for marketing Medicare PDP offerings to the following groups?



they did so because the areas were not profitable, while 39% says there were too few enrollees.

The patient populations being targeted by MA-PDs and PDPs are similar. Both are aggressively pursuing persons who are aging into Medicare eligibility, followed by pre-65-year-old beneficiaries, and employer/union group retirees.

Less attention is being paid towards dual eligibles (eligible for coverage under both Medicare and Medicaid), low-income subsidy (LIS) lives, and Part D long-term care beneficiaries, which represent less profitable sectors or as Jack Hoadley, PhD, indicates, represent sectors that typically use more drugs.

Glenda Owens, RPh, MHA, is not surprised by the tendency of plans to gravitate towards members who are healthier and with higher incomes. "Low-income subsidy claims often present the possibility of errors and are not always reimbursed by CMS," she says. "Plans are just not receiving return on investment from government subsidies."

Cost Sharing

Many of the respondents have taken action in 2010 to increase cost sharing in their PDP and MA-PD plans. For all Part D plans, the biggest changes are increases in copayment and coinsurance amounts and in premiums. More than half of PDPs (54%) have increased

Figure 6: What changes to your Part D benefit designs did you implement in 2010 to MA-PD plans?

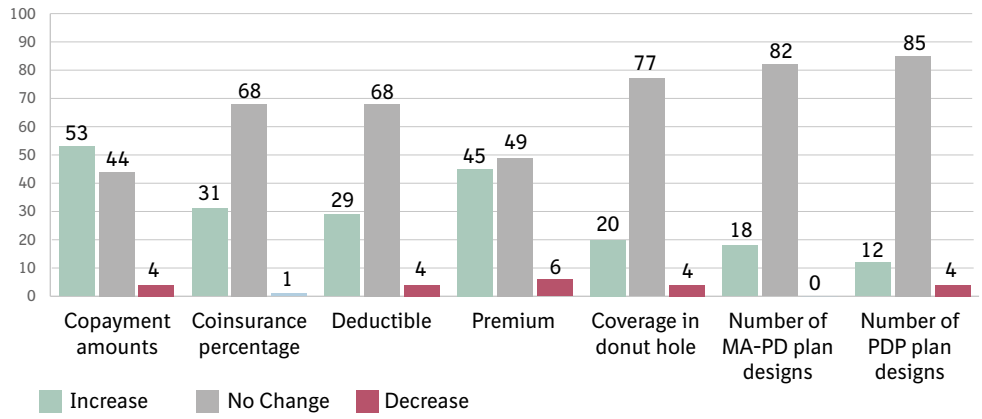
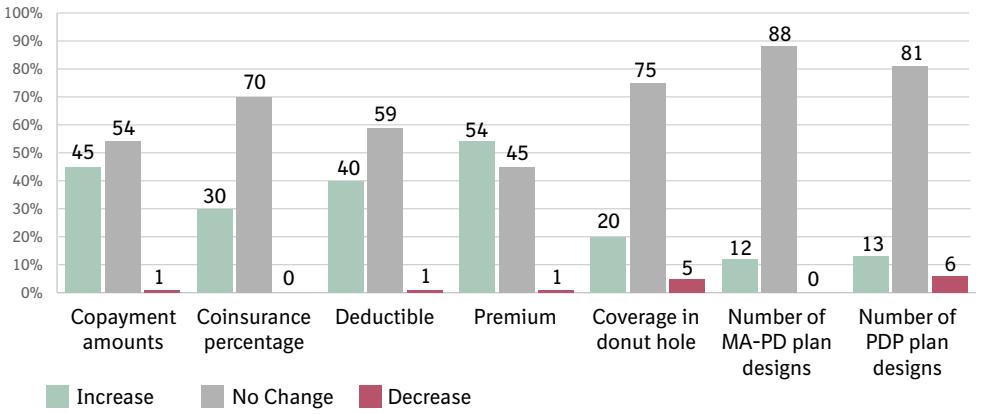


Figure 5: Did you implement any of the following changes in 2010 to your PDP plans?



In 2010, 54% of PDPs plan to increase premiums

premiums, while 45% of MA-PDs have. Just 45% of PDPs have increased copayments compared with 53% of MA-PDs. PDPs (40%) are more likely to raise the deductible than are MA-PDs (29%). Increases in coinsurance percentages are the same for both types of plans, at 31%.

"If a plan already uses coinsurance," says Maria Lopes, MD, "the cost share doesn't have too much room to grow or health care coverage will become unaffordable for many people."

Owens adds that the responses indicate strategies to compensate for reduced revenue under Medicare and health care reform.

The weighted average premium paid by beneficiaries for stand-alone Part D coverage increased by 35% over three years, from $25.93 in 2006 to $35.09 in 2009. Between 2008 and 2009, the average PDP enrollee paid 17% more in premiums–the largest one-year premium increase to date. CMS calculates that on average, MA-PD premiums before rebates are about $11 per month lower than those for PDPs.[8]

In 2010, 60% of PDPs plan to charge a deductible. More than half of PDPs with a deductible expect to charge the standard $310 amount. Use of a deductible is considerably higher than in previous years. In 2009, 45% charged a deductible and in 2006, just 42% of PDPs did.[1]

Reaching the Donut Hole

Less than one-third of beneficiaries in both PDPs (29%) and MA-PD plans (31%) reached the coverage gap in 2009,

37%

of plans cover most generics in the donut hole coverage gap.

according to survey responses.

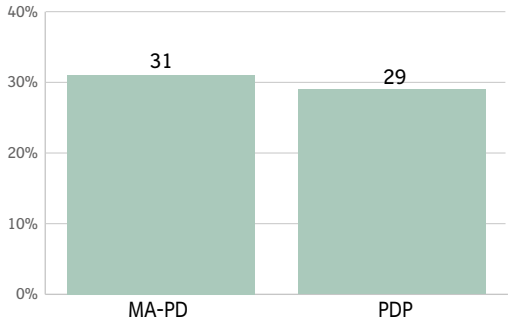
The number of beneficiaries who reached the coverage gap in 2007 is estimated at 3.4 million, or 14% of all non-LIS beneficiaries.[9] "There was a slight downward shift from 2007 to 2008 that could reflect some learning behavior by beneficiaries who reached the gap in 2007," says Hoadley. "Some patients may have found ways to reduce their spending, such as using more generics, eliminating unneeded drugs, or finding a pharmacy with lower prices. In some drug classes, such as osteoporosis, there have been significant generic introductions. Still, the downward trend is small; it remains to be seen whether the decline was a one-time blip."

The greatest proportions of beneficiaries that reach the coverage gap do so in September (26%) and October (21%).

Coverage in the Gap

More than one-third (37%) of plans cover most generics in the donut hole gap, 26% cover all tier 1 drugs, and 17% cover generics and a few branded drugs. Keith Perry calls the coverage of generics in the gap a cost-effective strategy for assisting beneficiaries with some drug costs.

Figure 7: What proportion of plan members reached the donut hole coverage gap?



Eighty percent of all PDPs do not plan to offer any gap coverage in 2010, up from 75% in 2009 but down from 85% in 2006.[1] Among the 20% of PDPs offering gap coverage in 2010, nearly all will limit such coverage to generic drugs, with no gap coverage for brand-name drugs. About 2% of PDPs will cover a "few" brand-name drugs (less than 10% percent of brands on formulary) in the coverage gap in 2010.[1]

The percentage of PDPs covering all generic drugs in the gap fell by more than half from 2008 to 2009, with more plans covering only selected generics in the gap.[8] Gap coverage for brand-name drugs is even less common in 2009; only 2% of all MA-PD plans offer relatively generous coverage of brands in the gap, while only three PDPs cover a "few" brands in the gap.[8]

The scene will greatly change once health care reform measures kick in and the coverage gap is largely phased out.

Medication Adherence in the Gap

Medication adherence by beneficiaries after they reach the coverage gap is believed to drop off once beneficiaries

Figure 8: What is the average date for Medicare Part D members to reach the donut hole?

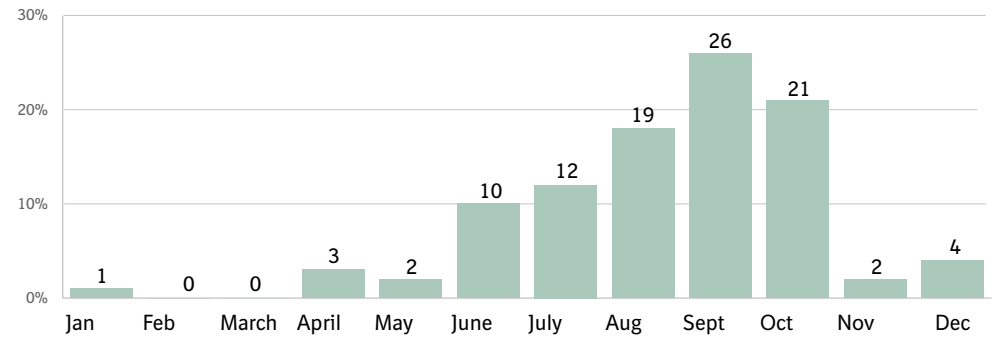
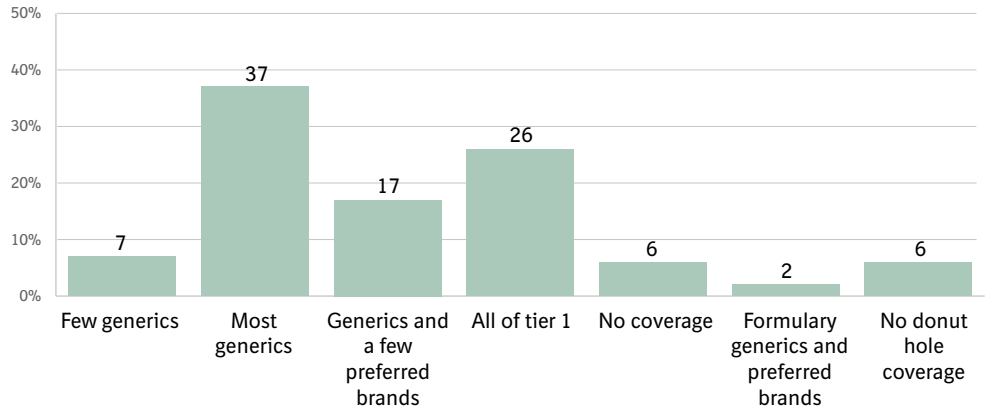


Figure 9: What coverage do you offer in the donut hole?



must pay OOP for most of their medications, according to 71% of plan respondents. The other result of reaching the gap is that more members switch from branded drugs to covered generics, according to 60% of respondents.

Perry suspects that if beneficiaries turn to generics when they find themselves in the gap, they may continue on generics once they pass through the donut hole. He also says that adherence will then improve, a concerned that may be more relevant for MA-PDs than for PDPs. “PDPs are not as concerned about medical and long-term cost offset while MA-PDs have a greater focus on these costs because they also provide the medical benefit,” Perry says. “Better adherence and lower costs may provide an opportunity for more plans to cover generics in the coverage gap,” he adds.

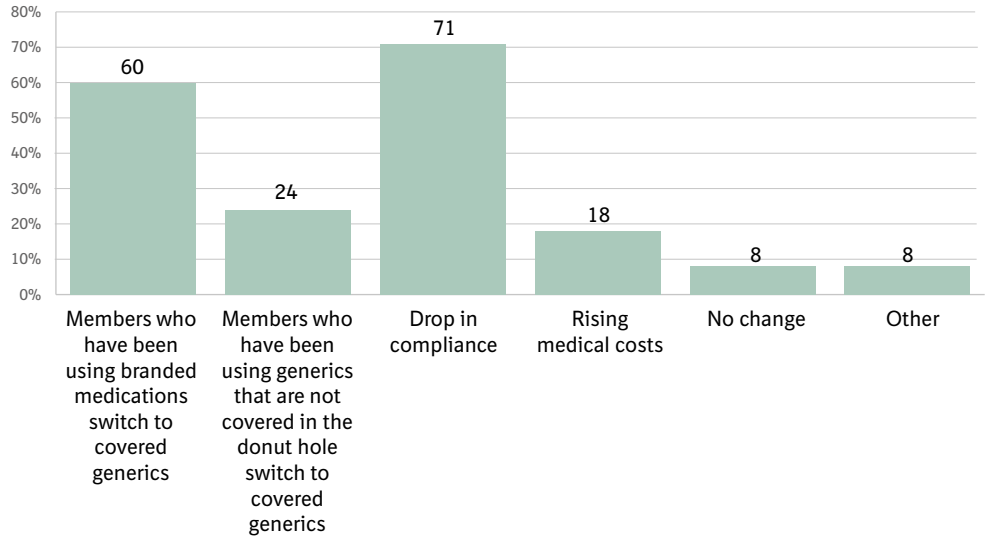
Tamara Howerton, RPh, says that the finding that 71% of respondents are concerned over a falloff in medication adherence seems high, which she attributes in part to poor tracking of members’ refill behavior. “The Part D plan may think a member has stopped taking a drug when in reality, the patient may have paid in cash or have secondary insurance,” she explains. "Beneficiaries are also using retail discount programs, which may not be reflected in the pharmacy benefit and give a misleading impression concerning adherence."

Medco looked at the impact the Medicare Part D coverage gap was having on beneficiaries’ drug utilization and adherence rates, particularly for statin

71%

of plans say that medication adherence drops off once members reach the coverage gap.

Figure 10: How does reaching the donut hole affect members?



15%

of Part D enrollees stopped therapy after reaching the coverage gap.

drugs, in a 2009 study. The pharmacy benefit manager (PBM) found that Medicare Part D beneficiaries who were prescribed cholesterol-lowering statins were nearly twice as likely to stop taking their medications when they reached the coverage gap than while they were in the initial phase of the benefit when the cost of the medication is fully covered.[10]

Medicare Part D beneficiaries with no coverage in the donut hole on average reduced their medication use by 14% or about 0.7 prescriptions per month compared with beneficiaries for whom both brand name and generic drugs were covered.[11]

A Kaiser Family Foundation report on the impact of the coverage gap reveals that 15% of Part D enrollees who reached the donut hole stopped their drug therapy for that condition; 5% switched to another medication in the same class; and 1% reduced the number of drugs they were taking in the class.[9]

A study published in *Circulation* explored the incremental cost-effectiveness of providing full coverage for aspirin, beta-blockers, angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, and statins (combination pharmacotherapy) to persons enrolled in the Medicare Part D program following an acute myocardial infarction.[12] The result was greater functional life expectancy (0.35 quality-adjusted life-year) and fewer resources expended ($2,500 in coronary heart disease-related medical costs) compared with beneficiaries who did not receive full coverage of medication costs.

Benefit Design

The most common benefit design for both PDP and MA-PD plans are three and four tiers–for MA-PDs, 33% and 37%, respectively, and for PDPs, 23% and 27%, respectively. One-third of PDPs have a separate tier for high-cost generics, while 27% of MA-PDs do. The responses are aligned with research coauthored by Hoadley, which concludes that the most common formulary structure is four tiers: generic drugs; preferred drugs and non-preferred drugs, which may also include some higher priced generics; and a specialty tier for high-cost drugs.[13]

A 4-tiered formulary is used most often by 37% of MA-PDs and 27% of PDPs.

Figure 12: Do you have a separate tier for high-cost generics?

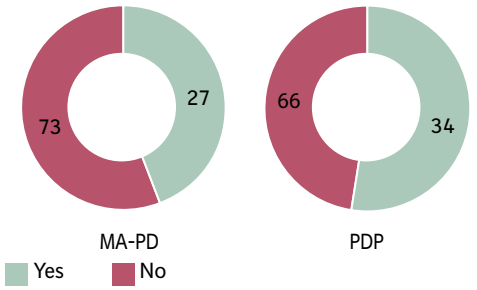
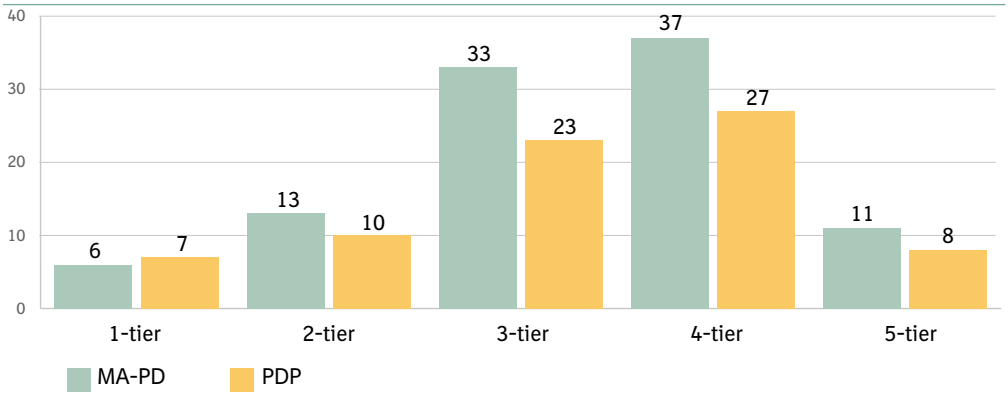


Figure 11: If tiered, what type of structure is used most often in your organization's prescription benefit plan design(s)?



The number of MA-PD plans that have a specialty tier increased from 39% in 2008 to 45% in 2010. Owens says that she can't imagine a MA-PD without a specialty tier to accommodate high-cost biologics. CMS reports that in 2009, 87% of PDPs and 98% of MA-PDs used a specialty tier.[14]

Coinsurance vs. Copayments

Although CMS allows plans to charge 33% coinsurance for drugs on the specialty tier if offset by a lower deductible,[14] none of the respondents hit that level. MA-PDs charge an average of 27% for coinsurance, with PDPs averaging 24%.

In 2009, more than half of all Part D enrollees were subject to a 33% coinsurance for specialty drugs, increasing considerably over 2006. Fifty-six percent of MA-PDs charged 33% coinsurance as did 57% of PDPs in 2009, up from 48% and 50%, respectively, over 2008.[14]

The placement of a drug on specialty tier can have a dramatic impact on patient cost-sharing.[14] For example, monthly cost sharing for two drugs used to treat HIV/AIDS is typically $228 and $285, nearly 10 times higher than if the drugs were on a preferred tier.

Cost sharing structures make a difference in OOP expenses for non-LIS beneficiaries during the initial coverage period. Once a beneficiary enters the coverage gap ($2,700 in 2009; $2,830 in 2010) and pays 100% of drug costs and then reaches the catastrophic coverage threshold ($4,350 in 2009; $4,550 in 2010), in which most beneficiaries pay only 5% of drug costs, the OOP costs are similar. However, variations in negotiated drug prices affect these beneficiaries during all three phases of the benefit.[15]

Respondents indicate that two-thirds of MA-PDs do not charge a deductible, while nearly two-thirds of PDPs charge the standard deductible of $310. Lopes says that MA-PDs, which promote better care coordination and disease management, may not be charging a deductible as a way to entice members and convert them from PDPs.

"Because MA-PD plans cover both medical and pharmacy costs, it makes

45%
of MA-PD plans have a specialty tier.

Figure 13: What proportion of all your Medicare Part D lives has a high-cost "specialty" tier (ie, products with an expected monthly cost of $600 or more)?

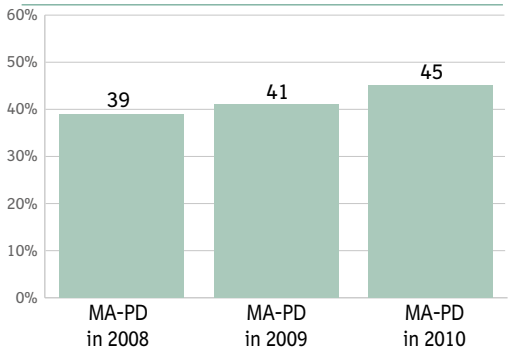


Figure 14: Does the high-cost specialty tier require cost sharing? If so, what is it?

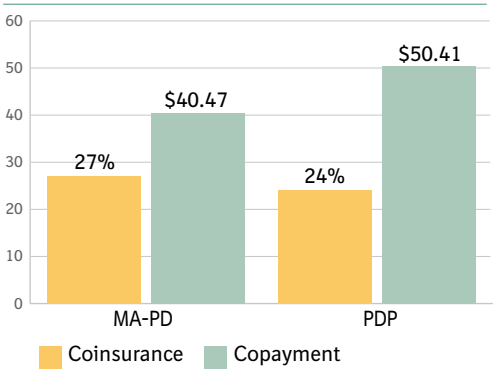
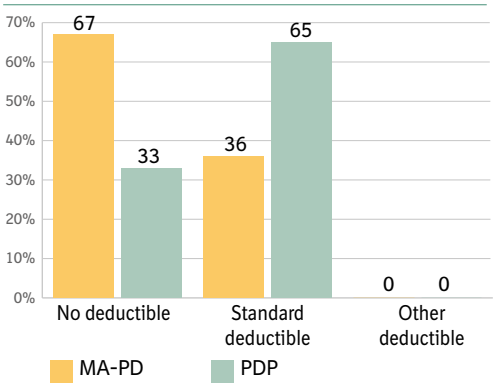


Figure 15: Do you have a deductible for your Medicare Part D plans?



33%
of Part D beneficiaries use mail service.

sense that they are doing the opposite of the PDPs by providing greater access to medications, which can reduce other medical expenditures, such as hospitalizations and physician services," Stefanacci adds.

In 2010, 60% of PDPs are charging a deductible. More than half of the PDPs with a deductible charge the standard $310 amount. Use of a deductible is considerably higher than in previous years, when 45% of PDPs charged a deductible in 2009 and 42% did so in 2006. The largest increase comes from plans adding deductibles that are less than the standard amount.[1]

Mail Service

Only one-third of total Part D beneficiaries use mail-order services.

Allowing for a 90-day fill at a retail pharmacy with reduced copayments similar to what is available through mail service–typically three months of drugs for two months' worth of copayments–is a tool used by 61% of MA-PDs and 64% of PDPs.

Any retail pharmacy must be allowed to fill a 90-day prescription under the same terms and conditions as a mail order pharmacy so long as that retail pharmacy agrees to accept the network mail order pharmacy rate for that 90-day prescription, according to CMS. Beginning in 2010, plans must provide notice to enrolled persons when prescriptions are transferred from retail to mail service pharmacies, and patients must give consent.[16]

Vogenberg is concerned that 90-day mail prescriptions may result in medication waste in cases where older adults switch

Figure 16: What percentage of Medicare Part D prescriptions is dispensed via mail-order service?

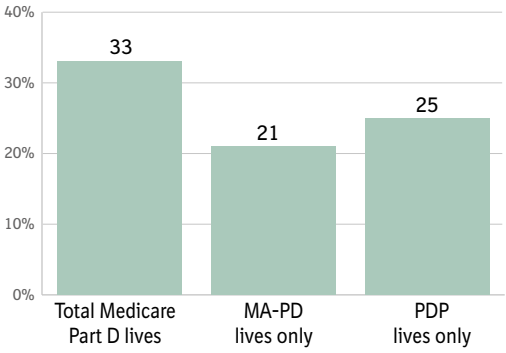


Figure 17: Do you have 90-day fill at retail program?

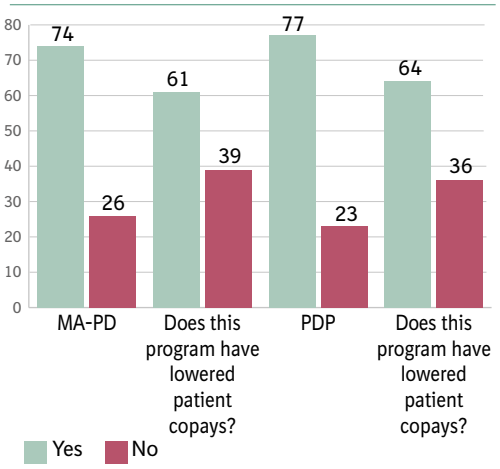
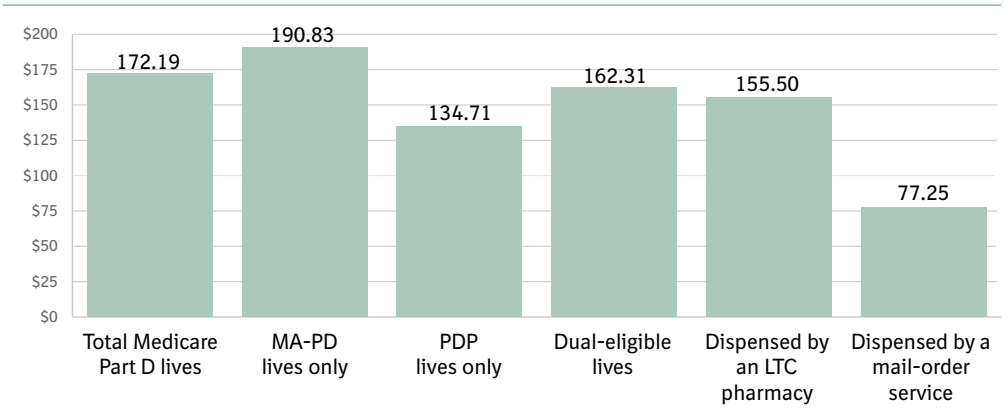


Figure 18: What are the current PMPM medication costs for your organization?



from one medication to another, but could be effective for chronically ill members once they are stabilized on a particular drug. He also suggests that many older adults are more comfortable purchasing prescriptions at a retail pharmacy where they can consult with a pharmacist.

While survey responses indicate a pmpm average medication cost of $172, CMS's estimate is higher at $220.[1] In addition, the pmpm medication costs for MA-PDs ($191) exceeds that for PDPs ($135), while CMS finds MA-PD pmpm expenditures lower–$160 vs. $250.[17]

Diabetes Leads in Drug Spend

MA-PDs and PDPs agree on the same top five therapeutic categories in terms of drug spend: diabetes, hyperlipidemia, hypertension, cancer, and depression.

Stefanacci, meanwhile, is surprised by the high ranking of drug spend for hyperlipidemia and depression as many of these medications are available as generics, but explains that perhaps their use has increased, pushing up the categories' total drug spend. Medications for rheumatoid arthritis were ranked ninth for MA-PDs and seventh for PDPs: the medications are costly but are not as highly utilized.

For CMS, cardiovascular drugs lead in drug spend, followed by psychotherapeutic drugs, unclassified drug products, gastrointestinal drugs, and hypoglycemics.[17]

Managing Utilization

Part D plans rank generic substitution as the most effective utilization management technique (77%). Next are prior authorization (58%), formulary alignment (48%), and step therapy (46%)–all of which target costs rather than outcomes. The least effective techniques are limiting prescribing to a specialist (11%), and dose optimization and plan member deductible (both 15%).

Hoadley notes there has been a steady increase in the use of utilization management from 2007 to the present, from 18% to 28% for all Part D plans.[8] With the higher cost of drugs and more utilization, he says, the increase should be expected. The use of prior authorization by PDPs nearly doubled from 8% to 15% for PDPs, and from 8% to 14% for MA-PDs. Nearly half of respondents also indicate that they have increased the number of drugs requiring prior authorization, while 45% have not made any changes.

45%
of MA-PD plans have a specialty tier.

Table 1: In the table below, please indicate the top FIVE therapeutic categories, by total drug spend, for each of the following Part D populations.

MA-PD Rank	Answer Options	PDP Rank
1	Diabetes	1
2	Hyperlipidemia	2
3	Hypertension	3
4	Cancer (oncology) orals	5
5	Depression	4
6	Gastrointestinal disorders	5
7	COPD	9
8	Alzheimer's disease	5
8	Asthma	8
8	Cancer (oncology) infused biotech	4
9	Pain	6
9	Rheumatoid arthritis/psoriasis (anti –TNF biologics)	7
10	Other psychiatric conditions (anxiety, ADHD, etc.)	10

Most effective utilization management tools are generic substitution and prior authorization.

Table 2: Which of the following utilization management techniques are the most effective in helping your organization contain pharmacy costs?

	Not as Effective	Rather Effective	Most Effective	Rank on 5 point scale
Generic substitution	6.3%	16.8%	76.8%	4.4
Prior authorization	7.7%	34.1%	58.2%	4.0
Formulary alignment	5.4%	46.2%	48.4%	3.9
Quantity limits	7.6%	46.7%	45.7%	3.8
Step therapy	7.7%	46.2%	46.2%	3.8
Therapeutic interchange	21.2%	45.9%	32.9%	3.2
Dosage limits	16.5%	62.6%	20.9%	3.1
Member co-pay/coinsurance	21.1%	56.7%	22.2%	3.0
Patient care management	22.7%	55.7%	21.6%	3.0
Dose optimization	25.6%	59.3%	15.1%	2.8
Length of therapy	30.7%	53.4%	15.9%	2.7
Member deductible	39.5%	45.3%	15.1%	2.5
Restricted pharmacy network	45.9%	32.9%	21.2%	2.5
Prescribing restricted to specialist	43.5%	45.9%	10.6%	2.3

Overall in Medicare Part D, use of quantity limits grew from 12% in 2007 to 18% in 2009 for PDPs with similar findings for MA-PDs.[8]

Prior Authorization and Step Therapy

For contract year 2010, CMS requires Part D plans to summit utilization management criteria corresponding to the use of prior authorization and step therapy. Any new 2010 or modified 2009 UM criteria will be required to be clearly marked so that CMS can focus its review on those changes identified.[16] Plan sponsors must follow existing CMS guidance regarding utilization management and coverage parameters.

Although more than half of Part D plans agree that prior authorization is an effective utilization management tool, it is required on only 13% of all drugs on the Part D formulary for MA-PDs and 14% of all drugs for PDPs. This corresponds with the use of step therapy, which covers 12% of drugs under MA-PD plans and 15% under PDPs, and with the percentages of Part D prescriptions dispensed requiring step therapy of 12% and 15%, respectively. The same percentages are aligned with the percentage of Part D adjudicated claims that require prior authorization of 12% and 15%, respectively.

The appeal rate for prescriptions

Figure 19: Approximately what percentage of all drugs on the Part D formulary requires prior authorization?

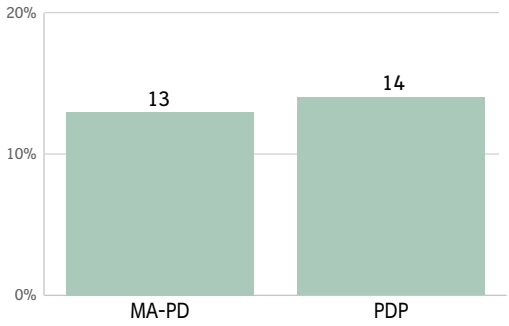


Figure 20: Approximately what percentage of Medicare Part D adjudicated claims requires prior authorization?

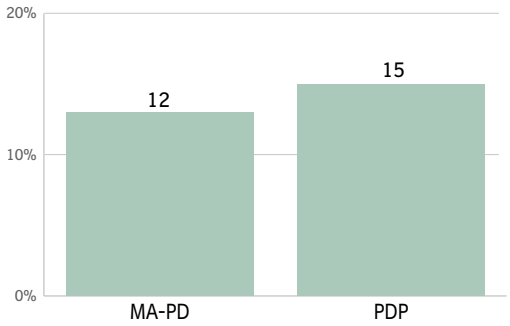
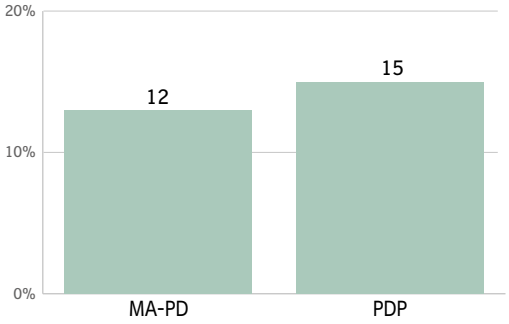


Figure 21: Approximately what percentage of all drugs on your Part D formulary requires step therapy?



requiring prior authorization is low: 10% for MA-PDs and 11% for PDPs; MA-PDs approve half of the appeals, while PDPs approve 45%. Stefanacci estimates that for every 200 prescriptions requiring prior authorization, 13% are denied and 10% of the 200 prescription decisions are appealed. Vogenberg is concerned that too many successful appeals could be a budget buster.

The majority of Part D plans, 71% of MA-PDs and 65% of PDPs, waive step therapy for patients already on existing therapy. Lopes says it makes sense to do so if the existing medication proves effective. "We like to think that if a patient is stabilized on a drug, the plan will support the physician in keeping the patient on that drug," Hoadley adds.

OTC Drug Coverage

Only 29% of MA-PDs and 37% of PDPs cover over-the-counter (OTC) products in

Figure 22: Approximately what percentage of dispensed Part D prescriptions require step therapy?

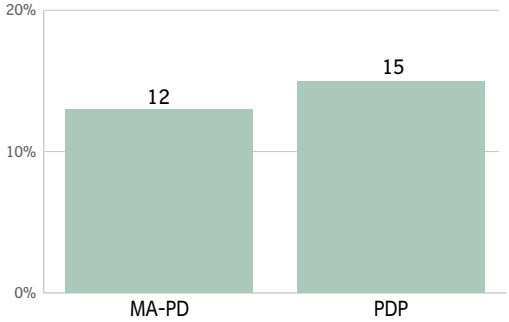
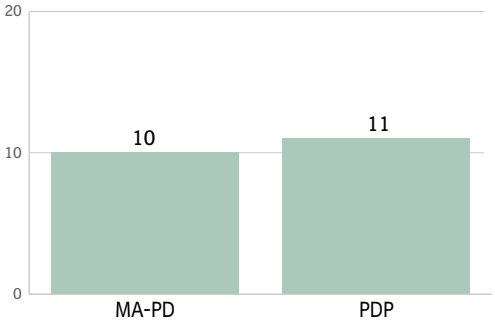


Figure 23: For your plans' Medicare Part D beneficiaries, approximately what percentage of prescriptions that requires prior authorization are appealed?



step therapy. OTC medications, such cold and pain remedies, may not be covered by Part D plans except as extra benefits provided by enhanced Part D plans, according to a 2008 CMS ruling. When a prescription drug is newly converted to OTC status, Part D plans must exclude the new OTC product from Part D coverage; however, plans are allowed to continue to cover supplies of the prescription version while these last.[18]

Beginning in 2011, health care savings

Figure 24: What is your appeal approval rate?

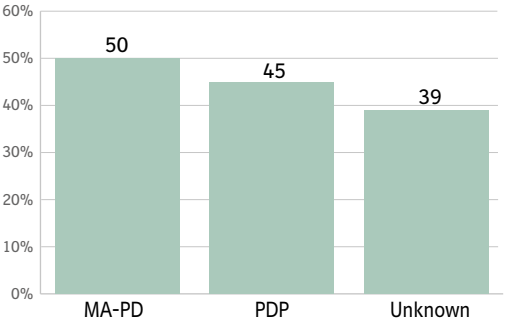
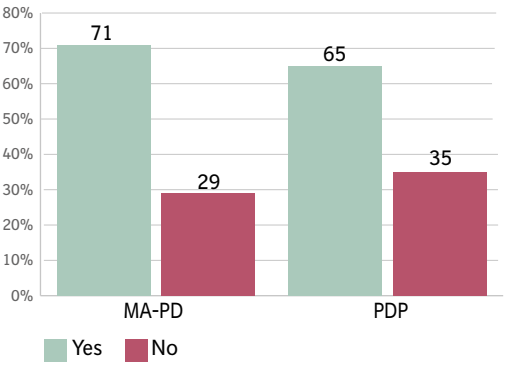


Figure 25: Do your Part D plans waive step therapy for patients on existing therapy?



Most Part D plans waive step therapy for patients already taking a medication.

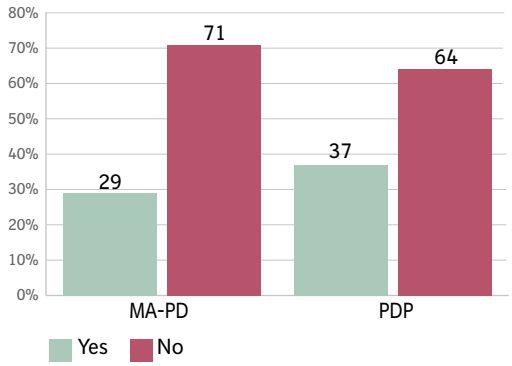
26%

of Part D members meet the eligibility criteria for MTM enrollment.

and reimbursement accounts will cover OTC drugs only if participants have a written prescription by a health care provider.

Although the Medicare Prescription Improvement and Modernization Act of 2003 does not allow Medicare plans to include OTCs as part of their prescription drug benefit or supplemental coverage, CMS will allow Medicare plans the option to provide this alternative as part of their administrative cost structure. These drugs must be furnished at no cost to the beneficiary (costs are to be included in the administrative portion of the bid and reflected in premiums), and the plan must assume full risk for OTC utilization. Plans may provide OTCs as part of drug utilization management programs (ie, step therapy). In addition, all OTC drugs must satisfy CMS formulary review.[18]

Figure 26: Do your Part D plans cover OTC products in step therapy?



Medication Therapy Management

Part D plans are using a variety of strategies for minimizing problems associated with polypharmacy: 80% rely on MTM, 76% screen for drug-drug interactions at point-of-sale, 61% are utilizing e-prescribing or electronic medical records (EMRs), and 53% share patients' medication histories with all physicians involved in a member's care.

Vogenberg questions how broadly respondents defined MTM when answering the question on polypharmacy, noting that MTM encompasses e-prescribing, drug-drug interaction reviews, and polypharmacy reports to both physicians and members. Among the most common MTM interventions are medication review, drug interaction screening, and prescriber consultation.

Just over a quarter (26%) of Part D plan members meet the eligibility criteria for MTM enrollment. Percentages reported by eligible beneficiaries participating in MTM during 2006, 2007, and 2008 were 10%, 13.1%, and 12.9%, respectively. As the requirements for eligibility are loosened for 2010, CMS expects more participants to enroll in MTM programs as a result.[19]

The changes in MTM eligibility requirements for 2010 are[20]:

Figure 27: What strategies is your organization using to minimize unnecessary or hazardous polypharmacy situations for Medicare Part D plan members?

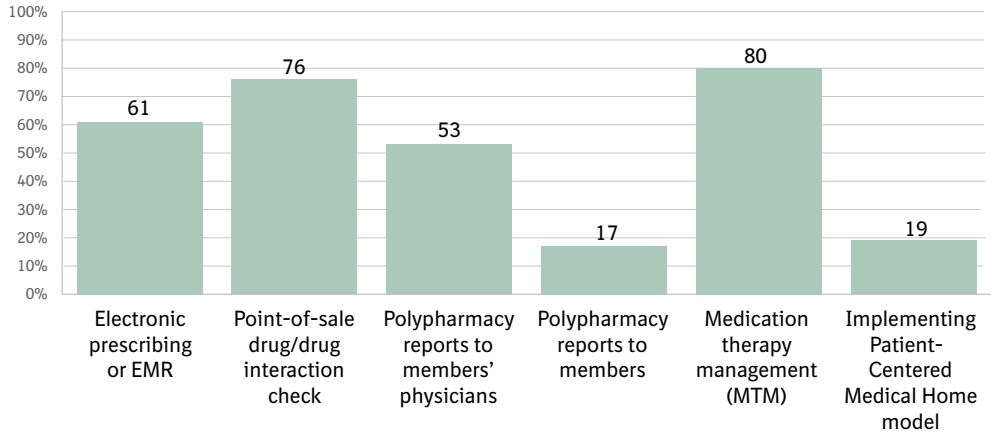


Table 3: What percentage of your Medicare Part D members meets the eligibility criteria for enrollment in your Part D MTM?

	Response Average
Percent of our organization's Part D members:	26.2%

1. Plan sponsors cannot require more than three chronic diseases for patients and must target at least four of seven core chronic diseases–hypertension, heart failure, diabetes, dyslipidemia, respiratory disease, bone disease (arthritis), and/or mental health problems.
2. Patients must be taking a minimum of eight Part D-covered drugs; and
3. Patients are likely to incur annual costs for covered Part D drugs that exceed $3,000.

In addition, new Medicare requirements prescribe a minimum level of MTM services provided by plans, including: an annual comprehensive medication review, interactive person-to-person consultation, individualized written summary of interactive consultation, and quarterly targeted medication reviews, along with the measurement and reporting of outcomes of these interventions by providers.

Although just a little more than half of Part D plans (55%) are currently offering personal consultations with members, this will change in 2010 because new rules mandate an interactive person-to-person consultation. Respondent plans have been aggressive in sending out member letters (84%), provider letters (76%), and calling members (64%).

While 87% of respondents go outside of their organizations to secure a specialty pharmacy provider, only 22% seek a PBM to provide the services; the other 65% outsource the services to a specialty pharmacy.

Perry finds it surprising that less than one-quarter of plans rely on PBMs even though many PBMs own a specialty pharmacy.

A large majority of plans (88%) use the same specialty pharmacy for both Medicare and non-Medicare business–a strategy that leverages volume and cost and avoids confusion in the provider network, says Lopes.

When respondents rank the importance of a variety of services delivered by specialty pharmacy, they find those of high value to be: cost savings (70%); adherence programs (69%); special handling and distribution (68%), and utilization management (64%). The least important services are therapeutic

88%

of plans use the same specialty pharmacy provider for both Medicare and non-Medicare business.

Figure 28: What MTM services does your plan currently offer?

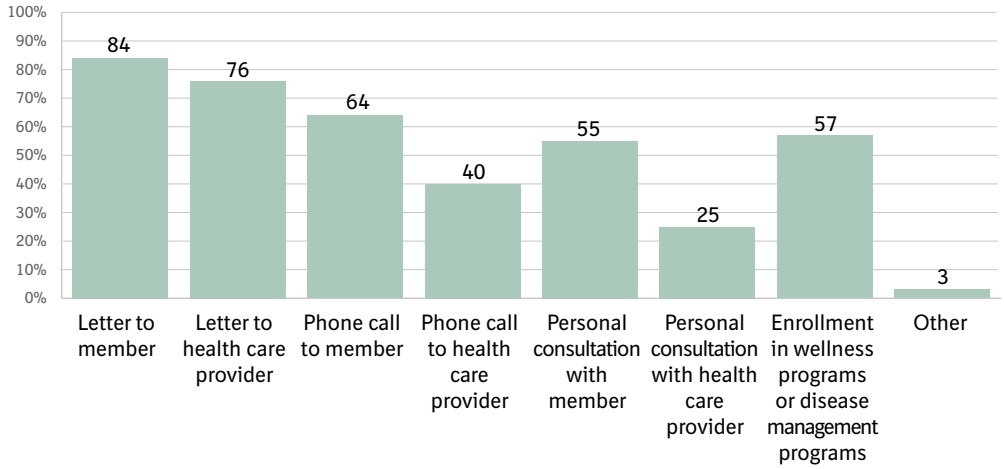
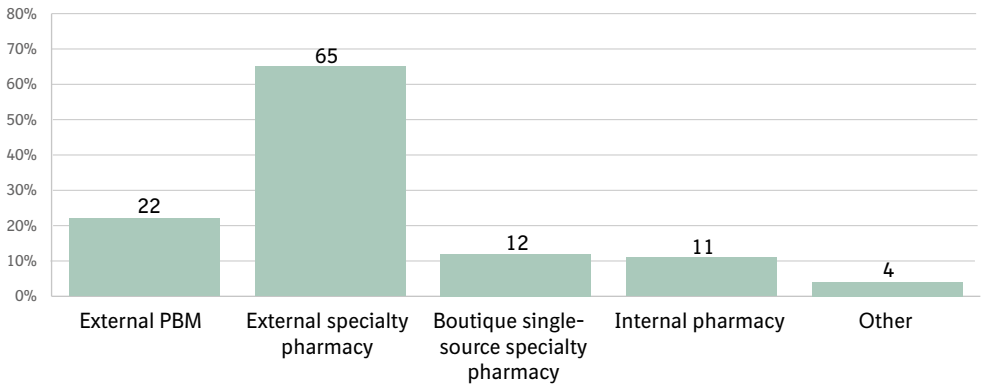


Figure 29: Which of the following best describes the type of specialty pharmacy provider your plan is currently using?

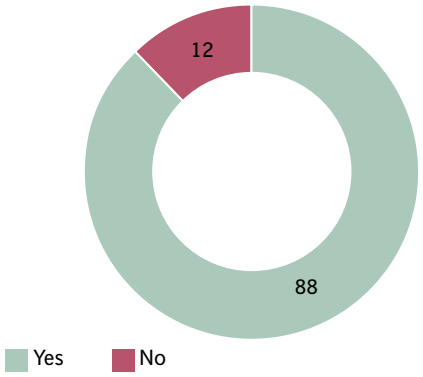


Specialty drugs accounted for 14.2% of all pharmacy spending in 2009.

substitution programs (35%), and formulary development (43%).

Specialty drugs accounted for 14.2% of all pharmacy spending during 2009, up from 12.8% in 2008 and 11.4% in 2007.[21]

Figure 30: Is this specialty pharmacy one that your organization uses for non-Medicare lines of business?



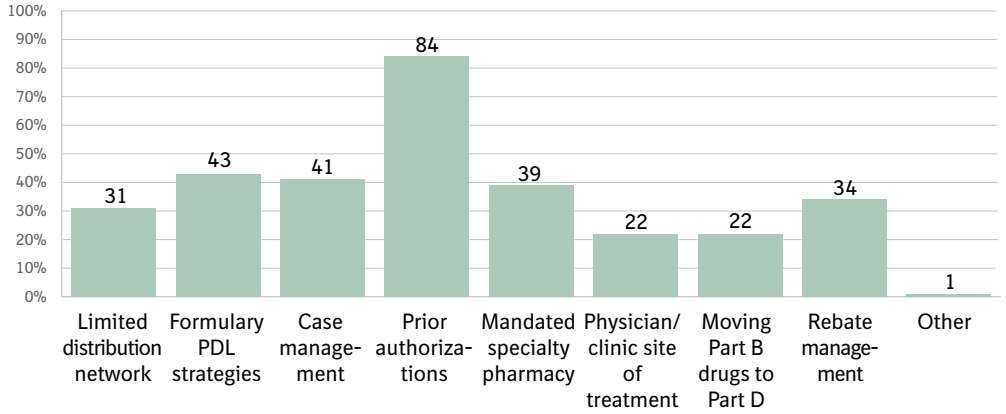
Specialty drug spending increased 19.5%, from per member per year of $92.97 in 2008 to $111.10 in 2009.[22] Not surprisingly, given the limited supply of generic specialty alternatives, trends in spending for specialty drugs were market-driven. Approximately 60% of cost growth is due to increases in cost/unit of specialty drugs and another 29% due to higher utilization.[22]

Medication adherence across all evaluated specialty and nonspecialty therapy classes increased or remained constant from 2008 to 2009 compared with flat or negative trends seen from 2007 to 2008.[19] Most adherence rates are at or above 80% medication possession ratio (MPR)– the rate generally considered optimal from a population perspective.

Table 4: Please rank the importance of all the applicable services the plan receives from the specialty pharmacy company for your Medicare Part D members.

	Low Value	Neutral	High Value	Ranking on 5 point scale
Special handling and distribution	6.4%	25.6%	67.9%	3.9
Cost savings	4.1%	26.0%	69.9%	3.8
Compliance/persistency/adherence programs	8.1%	23.0%	68.9%	3.7
Dosing limits/controls	2.7%	37.3%	60.0%	3.6
Utilization management	8.2%	27.4%	64.4%	3.5
Quantity limits/controls	9.5%	27.0%	63.5%	3.5
Case management/disease management	11.4%	30.0%	58.6%	3.2
Identification/selection of preferred brands	20.3%	28.1%	51.6%	2.7
Formulary development	27.0%	30.2%	42.9%	2.4
Therapeutic substitution programs	20.0%	45.0%	35.0%	2.3

Figure 31: What strategies are being implemented by your organization to manage Part B and Part D coverage for injectable or self-injectable drugs?



A 2006 study explored strategies used by health plans, including improving adherence to therapy, identifying and selecting preferred brands, utilization management, and providing care management. The study authors concluded that current management techniques for specialty pharmaceuticals often represent a stop-gap approach for controlling rising drug costs. They maintain that cost and care management methods will evolve as further research identifies the true clinical and economic value of various specialty pharmaceuticals.[23]

When respondents are asked which strategies they use to manage Part B and Part D office- or self-injectables, prior authorization rises to the top with an 84% response. Lagging behind are formulary preferred drug list strategies (43%), case management (41%), and mandated specialty pharmacy providers (39%).

Hoadley suggests that perhaps health plans do not find that prior authorization is sufficient, which is why they also are opting for other solutions.

Pay-for-performance

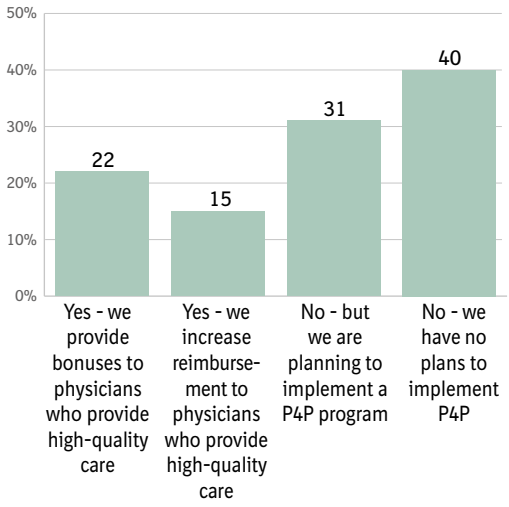
When health plans are asked if their organizations offer financial incentives to physicians for providing high-quality care, 37% answer affirmatively and another 32% say they are planning to implement pay-for-performance (P4P); 40% say they have no plans to implement P4P. Of those that do provide financial incentives, 94% provide them for chronic care management for diabetes and 81% for managing cardiovascular diseases. Nearly 60% incentivize physicians for care management of asthma, while 50% focus on chronic obstructive pulmonary disease (COPD) management. One-quarter incentiviize providers to implement a patient-centered medical home (PCMH)–a percentage that Paul Grundy, MD, global director of Healthcare Transformation for IBM, and president, Patient-Centered Primary Care Collaborative, sees as a positive sign.

While P4P has been touted as a way to address some of the problems with current reimbursement systems, its effects are unclear and there are still major problems with measuring quality and cost at the individual physician or practice level. To create more accountability, such payments could be linked to how well a practice can demonstrate that it is a fully functional PCMH. Practices could continue to receive payment based on fee-for-service, as well as reimbursement for various existing or future P4P programs.[24]

84%
of plans use prior authorization to manage injectables.

Plans are most likely to offer financial incentives for diabetes care management.

Figure 32: Does your organization offer financial incentives to physicians to provide high-quality care (eg, pay-for-performance)?



The Center for Medicare and Medicaid Innovation (CMI), established by the health care reform legislation, is expected to promote adoption of new provider payment systems. CMI has received $10 billion in funding through 2019.

The CMI is charged with testing innovative payment and service-delivery models designed to reduce Medicare and Medicaid expenditures, while preserving or enhancing quality of care. Through pilot programs, CMI could align Medicare payment with private initiatives, creating a more consistent incentive structure for participating providers.[25]

Edwina Rogers, executive director, Patient-Centered Primary Care Coalition, says that quality care incentives for providers should serve as a permanent fixture in the PCMH.

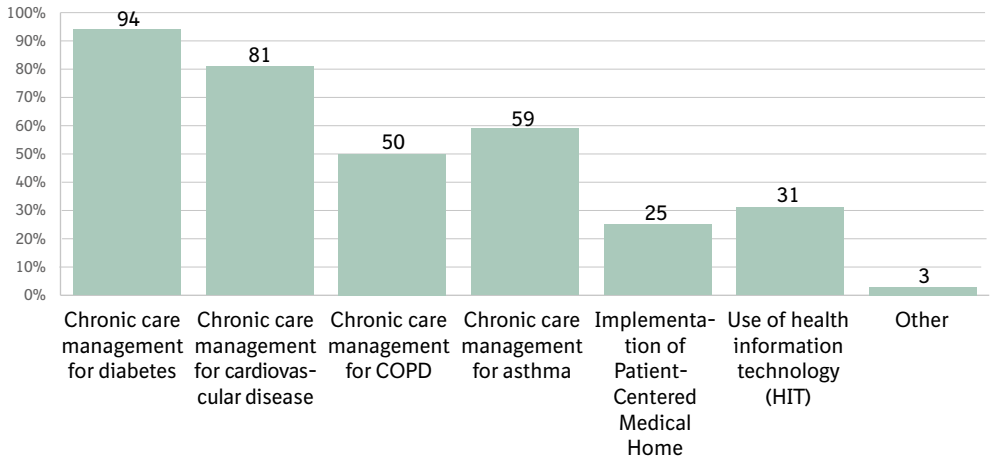
Value-based Insurance Design

More than one-third (37%) of respondents say they waive or reduce copayments or provide other financial incentives to chronically ill patients to improve medication adherence, a strategy that is a central part of value-based insurance design (VBID). At the heart of VBID is getting the most out of every dollar spent on health care. Thus, the more clinically beneficial the service for a patient, the lower that patient's cost sharing should be.[26]

Medicare Part D plans can implement VBID by reducing or eliminating cost sharing for specific drugs as long as a plan's formulary continues to meet CMS' formulary guidelines, rules on actuarial equivalence, and other applicable Part D standards. Allowing differences in benefit design for beneficiaries within the same plan may require legislative or regulatory changes.[27]

The study by the Center for Value-Based Insurance Design at the University of Michigan proposes five options for implementing VBID in the Part D

Figure 33: For which of the following areas do you offer financial incentives?



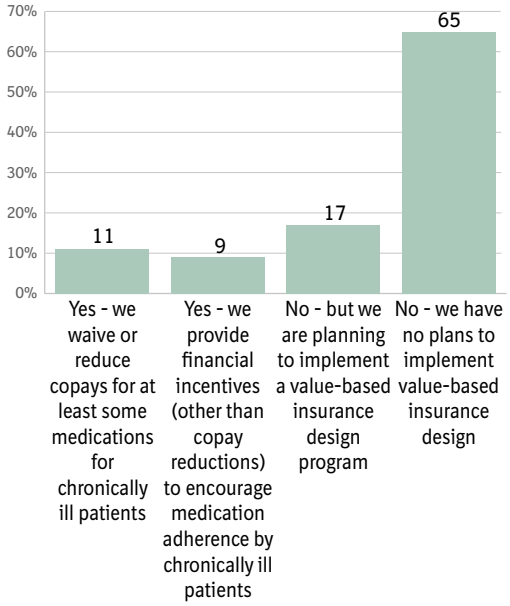
program.[27] These options include a reduction in cost sharing for 1) specific drugs or drug classes; 2) enrollees with chronic conditions; 3) enrollees participating in MTM; and 4) chronic condition special needs plans. The fifth option recommends exempting specific drugs or drug classes from 100% cost sharing in the coverage gap. Part D currently requires that plans provide a uniform benefit to all enrollees, thus ruling out options 2 and 4.

Implementing E-prescribing

Although goals of transparency and privacy are sometimes in conflict, health plans are held accountable for achieving both. When respondents are asked what information should be accessible to providers via HIT and e-prescribing, they indicate support for a variety of functions: notification of possible drug interactions (91%), treatment alternatives (85%), guidelines for therapy selection (83%), notification of drug side effects (77%), and practice standards (74%).

The number of e-prescribers was close to 156,000 at the end of 2009, having more than doubled from around 74,000 at the end of 2008, according to SureScripts, operator of the country's largest electronic prescribing network.[28]

Figure 34: Does your organization offer financial incentives to members to encourage adherence to chronic care medications?



In 2008, 41.5% of office-based physicians reported using any EMR (all electronic or partially electronic medical record system), up from 34.8% in 2007 in the National Ambulatory Medical Care Survey conducted by the National Center for Health Statistics. This proportion increased further to 43.9%, according to preliminary estimates from the 2009 survey.[29]

The Health Information Technology for Economic and Clinical Health (HITECH) Act, included in the American Recovery and Reinvestment Act of 2009, will provide incentives to health care professionals for "meaningful use" of an EMR,[30] which should stimulate further adoption.

Nearly three-fourths of plans use health claims data and analyses to track spending for various health conditions, while 61% rely on the information to monitor actuarial trend and product development and pricing. As expected, the two initiatives at the top of the list support plans' interest in saving money. Other respondents indicate use of claims data to track outcomes (44%) and treatment options (42%), and monitor program effectiveness (41%).

Lopes is concerned about the difficulty in tracking outcomes and evaluating effectiveness. The challenge, she says, is coordinating pharmacy and medical claims data to enable plans to evaluate overall health care costs.

Plans overwhelmingly agree (combining "strongly agree" and "agree" responses), that widespread adoption of HIT will improve patient outcomes (77%), improve accountability (76%), and

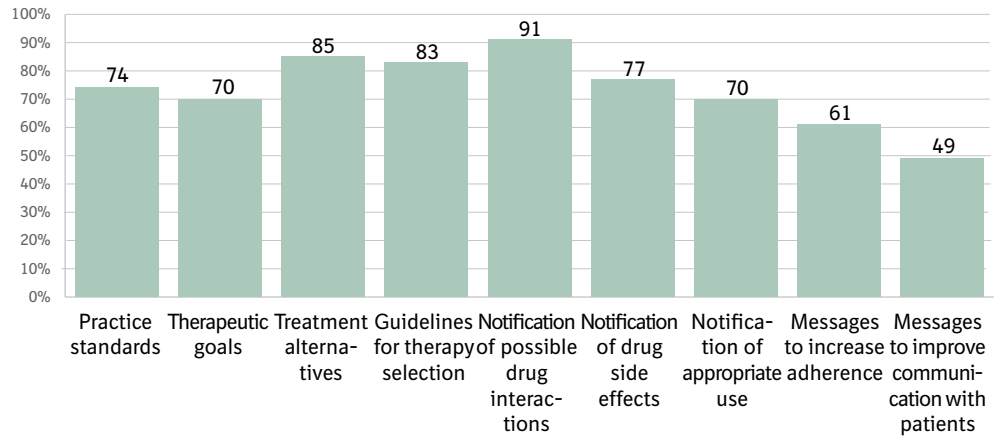
37%

of respondents waive or reduce copays for chronically ill patients.

77%

of plans agree that widespread implementation of HIT will improve patient outcomes.

Figure 35: In your opinion, what information should be accessible to providers through health information technology (HIT) and electronic prescribing systems?



standardize provider performance (66%).

Owens reinforces the need for technology at point-of-service and recommends that physicians get on board. Plans seem to be heading in that direction, with 50.6% of plans agreeing or strongly agreeing that HIT will provide point-of-care, interactive guidelines that recommend an acceptable course of treatment to PCPs and to specialists (38.5%).

Conclusions

Enactment of PPACA will bring many changes to Part D coverage and present new challenges to Part D plans. Phasing out of the donut hole coverage gap by 2020 will have the largest impact on beneficiaries with high drug costs. The elimination of the coverage gap will also affect health plans that will have to modify their Part D benefit designs.

In addition, health care reform legislation eliminates the tax deduction on Retiree Drug Subsidy (RDS) payments for employers, which could lead employers to drop coverage for retirees and increase the size of the individual market; reduces physician reimbursement; mandates that plan sponsors expand their formularies in 2011; provides for incentives in 2012 to plans that achieve quality goals; and reduces the Part D premium subsidy for high-income beneficiaries.

Figure 36: How does your plan analyze and use health-claims data you receive?

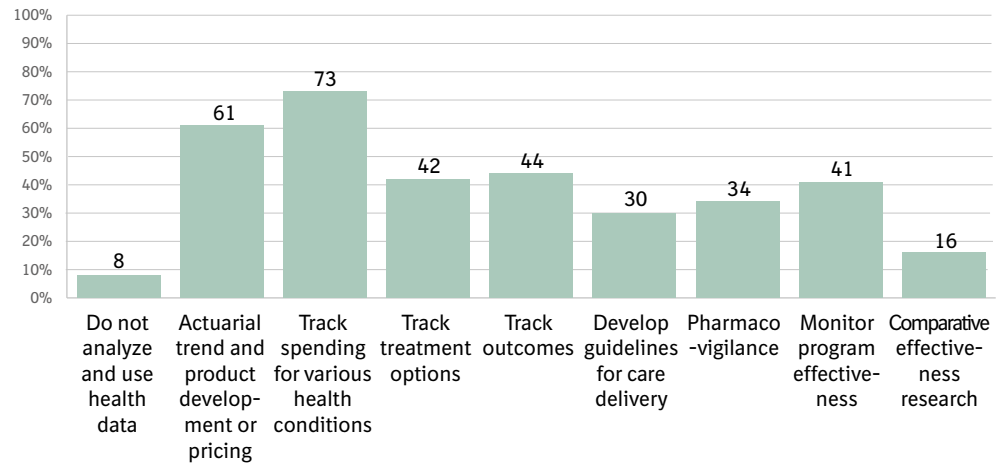


Table 5: Please state your opinion on the following health information technology topics:

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree	Ranking on 5 point scale
Widespread adoption of HIT will standardize provider performance	1.0%	3.1%	29.9%	57.7%	8.2%	3.7
Widespread adoption of HIT will improve patient outcomes	0.0%	3.1%	19.8%	64.6%	12.5%	3.9
Widespread adoption of HIT will improve accountability	0.0%	3.1%	20.8%	61.5%	14.6%	3.9
Point-of-care interactive guidelines that recommend a course of treatment will be readily accepted by PCPs	1.0%	22.7%	25.8%	45.4%	5.2%	3.3
Point-of-care interactive guidelines that recommend a course of treatment will be readily accepted by specialists	6.3%	20.8%	34.4%	35.4%	3.1%	3.1
HIT data should be used for non-traditional medical research	1.0%	11.5%	52.1%	33.3%	2.1%	3.3

New CMS mandates also will have an impact on Part D plans. The regulations: require plans to summit utilization management criteria corresponding to the use of prior authorization and step therapy; ease requirements for MTM program eligibility; prescribe new guidelines for delivery of MTM services; and promote adoption of new provider payment systems.

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Patient-Centered Medical Home Helps Fill Gap in Primary Care

Patient-Centered Medical Home Helps Fill Gap in Primary Care

As the concept of a Patient-Centered Medical Home (PCMH) evolves and a three-year medical home demonstration project sponsored by the Centers for Medicare and Medicaid Services gets underway, the PCMH is poised to assume a larger role. Clinical pharmacists and pharmacy directors affiliated with health plans provided their views on the value of medical homes, and on implementation strategies.

In addition to the medical and pharmacy benefit experts who reviewed the Medicare Part D survey research, other thought leaders also offer their perspectives on the medical home:

- Paul Grundy, MD, global director of Healthcare Transformation, IBM, Armonk, NY; president, Patient-Centered Primary Care Collaborative
- Derek van Amerongen, MD, chief medical officer, Humana of Ohio, Cincinnati
- Bruce Sherman, MD, director, health and productivity initiatives, Employer Health Coalition of Ohio, Canton; consulting corporate medical director, Whirlpool
- Edwina Rogers, executive director, Patient-Centered Primary Care Collaborative, Washington, DC

Maria Lopes, MD, former chief medical officer, Group Health, Inc, New York City, calls the PCMH a future accountable care organization (ACO), in which the entire infrastructure is centered around primary care physicians (PCPs). In an ACO, a group of providers are held responsible for the quality and cost of health care for a population of Medicare beneficiaries, and have an opportunity to share in cost savings that are the result of quality gains.

"Both models are about coordinated care led by PCPs, dependent on access to data and decision-support tools, such as electronic medical records," Lopes says. "To be successful, primary care practices need to be willing to re-engineer the delivery of care across multiple settings and leverage technology to become more efficient. Outcomes will only be as good as a practice's ability to access clinically meaningful and impactful tools."

Glenda Owens, RPh, MHA, formerly vice president, pharmacy services, Arcadian Health Plan in Oakland, CA, describes integrated delivery systems, such as Kaiser Permanente and Geisinger Health Plan, as "poster children for a PCMH," which provides for PCPs at the point-of-care and a holistic approach to managing care.

All in all, Richard Stefanacci, DO, Center for Aging Research, Education & Support (CARES), University of the Sciences, and NewCourtland LIFE Program medical director, Philadelphia, PA, is optimistic that the PCMH is addressing preventive care, using longitudinal data, and relying on PCPs, which he says should lead to better outcomes through increased medication adherence, a decrease in the use of specialists, and reduction in hospitalizations.

54%

say the most important feature of a PCMH is an emphasis on preventive care.

In 2007, four specialty medical societies–the American College of Physicians, the American Academy of Pediatrics, the American Academy of Family Physicians, and the American Osteopathic Association–together developed the "Joint Principles of the Patient-Centered Medical Home."[1] Among the principles:

- Each patient has an ongoing relationship with a personal physician.
- A personal physician-led team is responsible for patients' ongoing care.
- The approach of the model is holistic.
- Care is coordinated and/or integrated across all elements of the health care system with the assistance of patient registries and health information technology.
- Quality and safety define the medical home.
- Access to care is emphasized.
- Payment for providers is aligned with value-added services provided in the medical home.
- 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 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.
- Support for payment rates for PCPs of no less than 100% of Medicare payment rates in 2013 and in 2014 for providing services under Medicaid.

Research Results

PCMH Features

The most important features of a PCMH are: an emphasis on continuous, preventive care (54%), use of evidence-based medicine and guidelines (47%), primary care physicians as coordinators of care (46%), and e-prescribing (44%). Respondents do not feel as strongly about tracking of referrals (22%), and the use of registries and patient tracking (12%).

Paul Grundy, MD, supports the use of patient tracking to fill in information gaps, such as missed screenings or non-adherence to medication regimens. He would like to see more support for the medical home concept overall.

Derek van Amerongen, MD, suggests that all of the features are critical elements of a medical home and hold equal importance in achieving outcomes. He points to the low interest in the use of registries and patient tracking despite these being part of the medical home criteria. Bruce Sherman, MD, adds that greater interest in and use of electronic medical records (EMRs) may account for the lower interest in registries and tracking.

Expectations for PCMHs

The top response (combining "strongly agree" and "agree") is that more health information technology (HIT) support is needed to support PCMHs (71%), while many agree that the model will improve patient records (70%), patient outcomes (66%), and adherence to therapy (62%) but will raise short-term costs (51%).

Grundy points out that one area of

Table 6: Which features of the Patient-Centered Medical Home (PCMH) model of primary care delivery are most important to your organization?

	Least Important	Important	Most Important	Rank on a 5 point scale
Emphasis on continuous, preventive care	1.1%	45.3%	53.7%	4.1
Use of evidence-based medicine and guidelines	4.3%	48.4%	47.3%	3.9
Members have a primary care physician (PCP) to coordinate care	1.1%	52.6%	46.3%	3.9
Coordination/collaboration with health plan in team approach	3.3%	56.0%	40.7%	3.7
Electronic medical records (EMR)	5.3%	53.2%	41.5%	3.7
E-prescribing	8.6%	47.3%	44.1%	3.7
PCP engages patient in self-management	5.3%	53.2%	41.5%	3.7
Emphasis on continuous improvement	7.6%	55.4%	37.0%	3.6
Tracking of tests	6.4%	59.6%	34.0%	3.6
Better longitudinal patient data	9.7%	63.4%	26.9%	3.3
Performance reporting	9.7%	64.5%	25.8%	3.3
Coordination/collaboration with plan vendors (DM) in team approach	14.4%	58.9%	26.7%	3.2
Patient access to own health information	13.0%	62.0%	25.0%	3.2
Tracking of referrals	24.7%	53.8%	21.5%	2.9
Use of registries and patient tracking	20.9%	67.0%	12.1%	2.8

Table 7: Please indicate your degree of agreement/disagreement with the following statements concerning PCMH:

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree	Rank on a 5 point scale
We will have to improve our HIT to support PCMHs	0.0%	1.1%	27.7%	59.6%	11.7%	4.0
PCMHs will improve patient records	0.0%	2.2%	28.0%	64.5%	5.4%	3.9
PCMHs will raise short-term costs	1.1%	3.2%	45.3%	44.2%	6.3%	3.7
PCMHs will improve member satisfaction	0.0%	2.1%	37.9%	50.5%	9.5%	3.7
PCMHs can improve adherence to therapy	0.0%	2.1%	35.8%	57.9%	4.2%	3.7
PCMHs will improve patient outcomes	0.0%	1.1%	32.6%	57.9%	8.4%	3.7
PCMHs will lower visits to specialist providers	0.0%	5.3%	36.8%	52.6%	5.3%	3.6
PCMHs will improve PCP satisfaction	0.0%	3.2%	45.3%	45.3%	6.3%	3.6
PCMHs will lower hospitalization rates	0.0%	2.1%	42.1%	52.6%	3.2%	3.6
PCMHs may drive adverse selection in the short term	1.1%	6.4%	56.4%	35.1%	1.1%	3.5
PCMHs will be mandated for Medicare members by 2015	0.0%	8.6%	61.3%	26.9%	3.2%	3.5
PCMHs move providers away from a fee-for-service reimbursement model	0.0%	8.5%	51.1%	36.2%	4.3%	3.5
PCMHs provide the highest quality health care	0.0%	4.2%	53.7%	36.8%	5.3%	3.4
PCMHs will improve specialist provider satisfaction	0.0%	10.5%	48.4%	33.7%	7.4%	3.4
PCMHs will lower number of diagnostic tests	1.1%	8.5%	47.9%	37.2%	5.3%	3.4
PCMHs will lower the number of prescriptions per patient	0.0%	12.6%	49.5%	32.6%	5.3%	3.4
PCMHs will replace medical therapy management programs	1.1%	16.0%	47.9%	30.9%	4.3%	3.3
It will be easy to realign reimbursement to give the appropriate incentives to PCMH PCPs	2.1%	16.0%	45.7%	31.9%	4.3%	3.3
PCPs who create medical homes will receive more reimbursement without sufficient reductions in utilization or specialist reimbursement	0.0%	10.6%	60.6%	27.7%	1.1%	3.3
PCMHs will raise long-term costs	2.1%	27.7%	51.1%	18.1%	1.1%	3.0

51%
of plans are concerned that PCMHs could increase short-term costs.

misunderstanding is that the PCMH will reduce the number of patient prescriptions per month (38%). "Hopefully, the medical home will drive medication adherence," he says.

Edwina Rogers notes that most respondents are positive about the future of the medical home. She is confident that Medicare's new Advanced Primary Care demonstration project will spur the development of medical homes. The demonstration is open to states that certify they have secured sufficient participation by PCPs and private payers, have established effective primary care models, and have integrated public health services that emphasize wellness and prevention. In addition, health care reform legislation mandates a pilot program to test the independent PCMH model.

Owens suggests that greater understanding among stakeholders is needed as illustrated by the "in-the-middle, skeptical" responses.

Van Amerongen adds there is still a learning curve in implementing a medical home.

PCMH and Primary Care

In keeping with the consensus that improved HIT is needed to support the medical home, 83% suggest that HIT exchanges between plans and providers is leading the way for plans to support providers in adopting the PCMH model. Three-fourths support shared HIT, including formulary information for providers, and 63% endorse shared HIT that includes provider guidelines.

"HIT helps strengthen the relationship between provider and patient by providing access to information at the point-of-care," Tamara Howerton, RPh, says.

In practice, HIT plays a critical role in the adoption of the medical home model: nearly 50% of health plans say they have developed HIT to help access formularies and practice guidelines, while 45% have developed health information infrastructures and exchanges. Grundy says he is not surprised that only 29% of plans are working with other plans in their region to integrate HIT for the provider network. "It is much more difficult when you have to coordinate efforts. While

Figure 37: In general, how do you think health plans can best support primary care physicians who are offering PCMH?

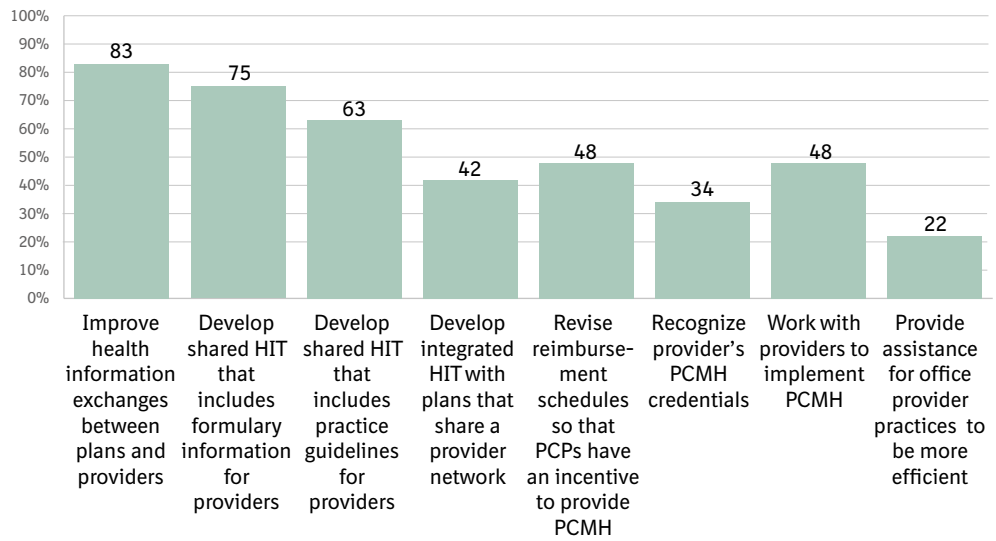
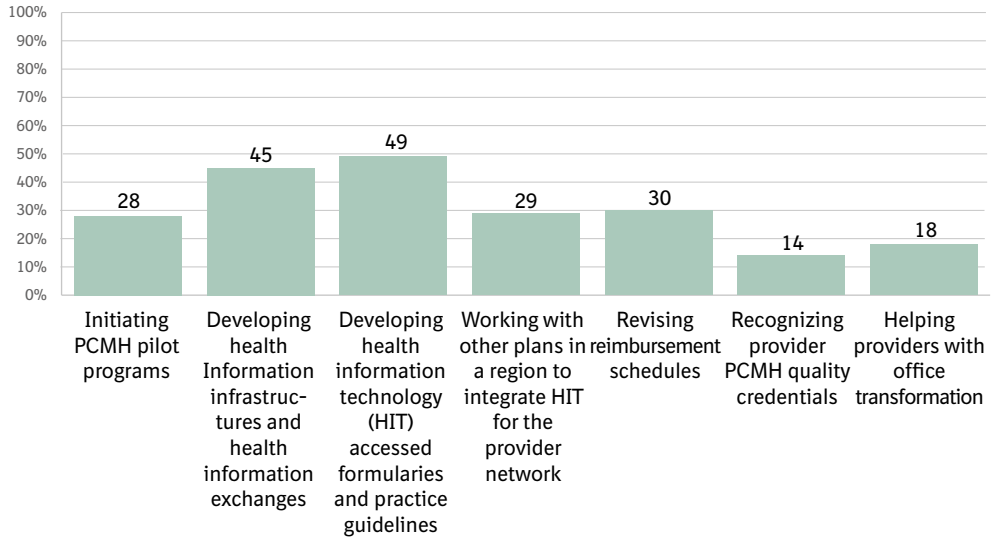


Figure 38: How is your organization supporting providers who are adopting the PCMH model?



28%

of plans say they are starting PCMH pilot programs.

plans are developing and investing in technology, they often forget that others are playing in the sandbox." Although only 28% of respondents say they are initiating PCMH pilot programs, Grundy points out that the majority of national insurers are sponsoring them.

Sherman notes that only 14% say they recognize provider PCMH quality credentials, a percentage lower than he expected; however, he anticipated that only a small number would help providers with office transformation. "That's not the responsibility of a plan," he says, although he considers health plans to be an important market driver for the PCMH concept.

"Plans can help providers be successful by identifying patients, mining data, realigning incentives, engaging patients, and supporting the adoption of HIT," Lopes adds. "If creating a medical home doesn't lead to change in clinical practice, the outcomes will not be affected and it will not be worthwhile."

Adopting the PCMH

Despite some skepticism about the medical home, most plans indicate efforts to implement one or express interest in doing so: those who have implemented one throughout the system (16%); have implemented a medical home with providers who support the model (12%); are piloting one (19%); consider the PCMH a part of the accountable care organization initiative (18%); or not yet directly involved but are pumping up their HIT to support a PCMH (28%).

Lopes is optimistic. "The medical home is an experiment right now but a lot of opportunity exists, for improvement in health outcomes," she says.

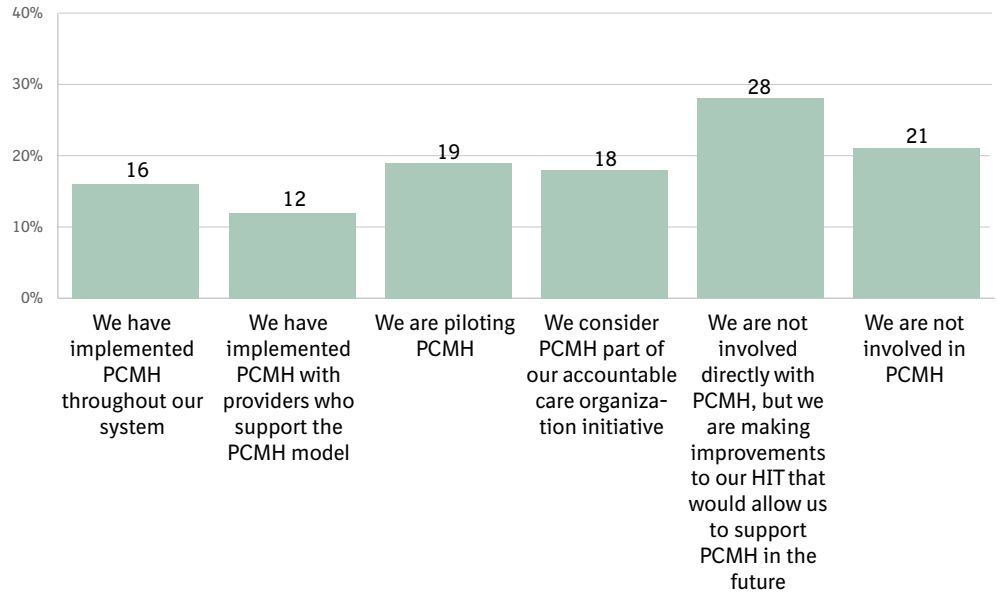
A total of 40% of plans have implemented a PCMH, are waiting for the results of a pilot, or will be initiating a medical home program or pilot in 2010. Almost half plan to either start a pilot (8%), begin implementation in 2010 (2%) or begin implementation at a future, unspecified date (38%). However, 11% each will only roll out a PCMH when they are heartened by the result of others' pilots or mandated to do so by payers.

Sherman agrees with Lopes that lack of data may be slowing the adoption of the medical home but that lessons learned from available data should help to

11%

of plans will not start a PCMH until required to do so by payers.

Figure 39: Has your organization adopted PCMH?



improve the effectiveness of future PCMH program implementation.

More than three-fourths (77%) of plans will target PCPs in their initial medical home efforts, while only 13% will focus on obstetricians/gynecologists (ob/gyns). Targeting multispecialty group practices and medical specialists garner 28% and 26%, respectively.

"There isn't much interest in ob/gyns in the medical home setting because they ultimately are not responsible for the entire patient," Rogers says. "While specialists may not be recognized as primary providers, they are seen as assuming an important role." Sherman is surprised by the high number who will target specialists and says he expected 100% of respondents would target PCPs–the core of the PCMH concept.

Grundy describes the leadership role of PCPs: "They are like football quarterbacks with specialists comprising the rest of the team," he says, referring to

Figure 40: When will your organization begin rolling out PCMH to your providers?

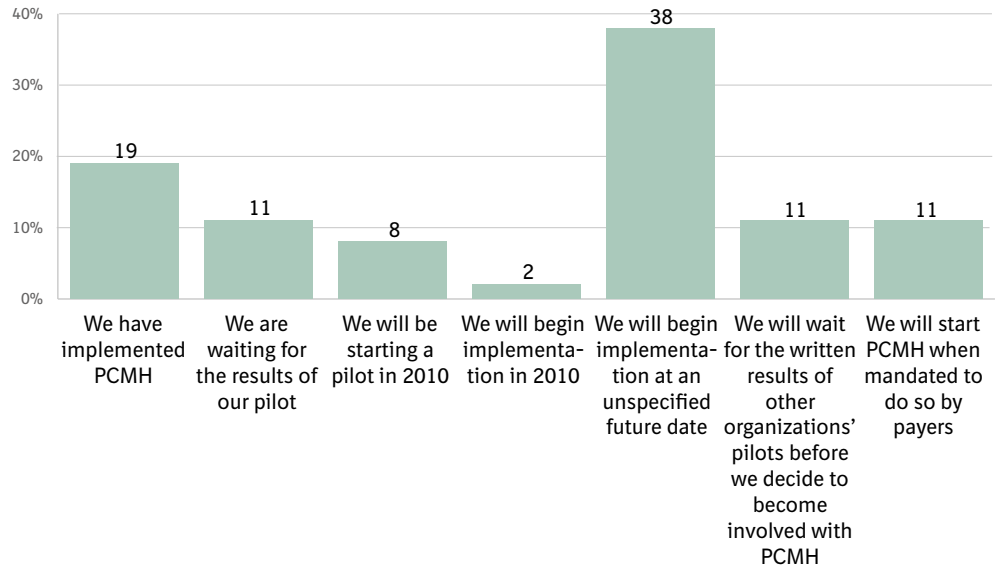
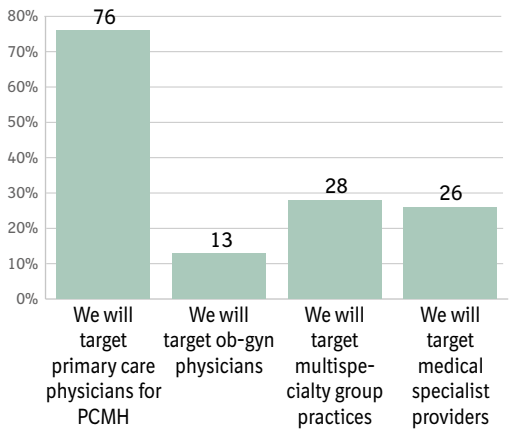


Figure 41: Which medical specialties will you target for your initial PCMH efforts?



the role of PCPs in coordinating care.

Supporting PCMH Providers

Almost half of respondents say they use internal standards as a guide for recognizing PCMH providers, while 43% rely on PCMH qualifications set by the National Committee for Quality Assurance (NCQA). About one-fifth note that they have no set standards.

Howerton sees internal standards developed by plans as the best way to recognize PCMH providers and does not feel that PCMH providers need to be accredited. "They are already held to higher standards," she says.

Van Amerongen strongly advocates for NCQA certification and standards rather than developing internal guidelines. "You can't just make up your own standards," he says. Rogers condones internal standards if they are transparent.

According to the Joint Principles of the Patient-Centered Medical Home, the payment structure should be based on the following framework[1]:

- It should reflect the value of physician and non-physician staff patient- centered care management work that falls outside of the face-to-face visit.
- It should pay for services associated with coordination of care both within a given practice and between consultants, ancillary providers, and community resources.
- It should support adoption and use of health information technology for quality improvement.
- It should support provision of enhanced communication access such as secure e-mail and telephone consultation.
- It should recognize the value of physician work associated with remote monitoring of clinical data using technology.
- It should allow for separate fee-for-service payments for face-to-face visits. (Payments for care management services that fall outside of the face-to-face visit, as described

The PCP role in a medical home is likened to that of a football quarterback.

Figure 42: How do you (or how will you) recognize PCMH providers?

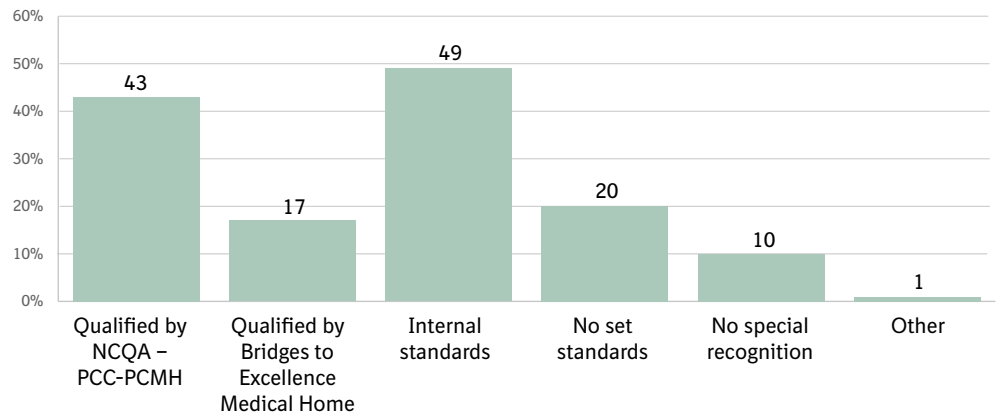
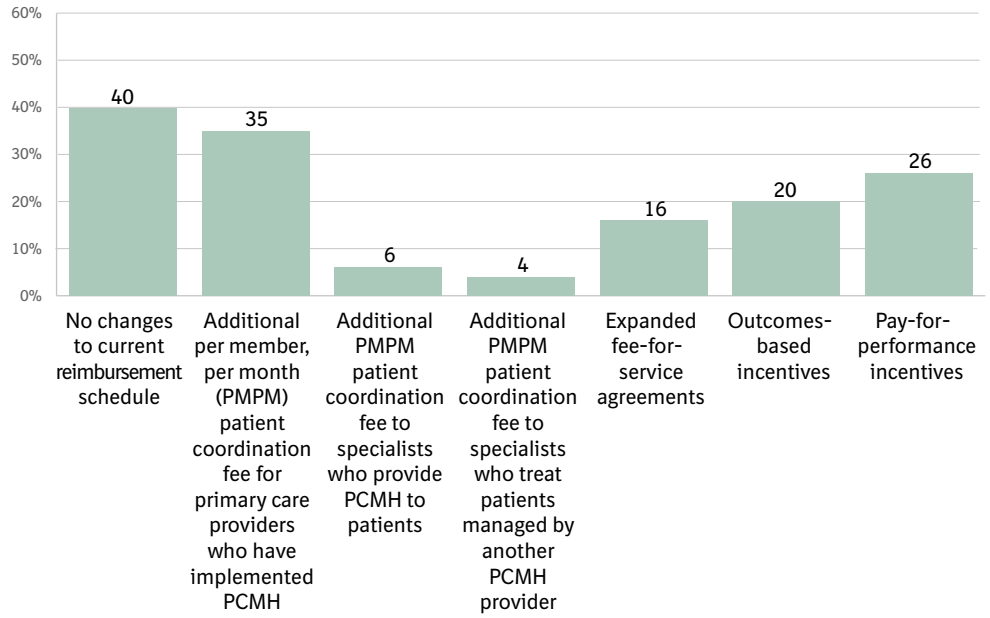


Figure 43: How will your organization reimburse PCMH providers?



40%

of plans anticipate no changes in reimbursing PCMH providers.

above, should not result in a reduction in payments for face-to-face visits).

- It should recognize case mix differences in the patient population being treated within the practice.
- It should allow physicians to share in savings from reduced hospitalizations associated with physician-guided care management in the office setting.
- It should allow for additional payments for achieving measurable and continuous quality improvement.

Despite these stated principles, 40% of survey respondents say they will not make any changes to their current reimbursement schedule for PCMH providers, while 35% plan to add an additional per member per month (pmpm) patient coordination fee for PCPs. About one-fourth intends to use pay-for-performance incentives. Few have plans to reward specialists for their role in the PCMH.

Grundy does not think that a 40% acceptance of current reimbursement schedules is sustainable under the PCMH. "Incentives for performance and pmpm are needed to drive change," he says.

Rogers agrees. "Why are so many plans sitting on the sidelines and not making any changes?" she asks. She is seeing a combination of pay-for-performance (P4P) and a monthly coordination fee as payment models.

Although the responses do not endorse any single reimbursement model, Sherman emphasizes the need to reimburse providers for additional responsibilities and for more efficient delivery of care.

Medication Therapy Management

Respondents are split on whether the medical home will provide medication therapy management (MTM) services.

The Patient-Centered Primary Care Collaborative (PCPCC) makes a strong case for the incorporation of MTM into the medical home concept: "Medication

management is needed because it has been shown to facilitate the efficiency and effectiveness of the PCMH team in improving patient clinical outcomes and reducing morbidity and mortality, while lowering total health care costs."[2] The PCPCC also finds that MTM is essential when multiple providers/prescribers are involved in caring for patients with complex medical conditions.

Stefanacci favors providing MTM services through the medical home.

PCPCC lists the key components of implementing MTM in a medical home[2]:

- assess the patient's medication experience;
- identify drug therapy problems in appropriateness, effectiveness, safety and compliance with medication regimen;
- establish personalized goals of therapy;
- resolve drug therapy problems;
- personalize interventions;
- follow-up on effectiveness and safety; and
- determine actual patient outcomes.

Rogers acknowledges that MTM in the medical home setting has only recently been explored and that well documented studies are not yet available. PCPCC plans to roll out a new guide on implementing MTM within the medical home.

Nevertheless, Howerton and Randy Vogenberg, PhD, remain somewhat skeptical about the ability of physicians to deliver MTM services without the involvement of other health care professionals, notably pharmacists.

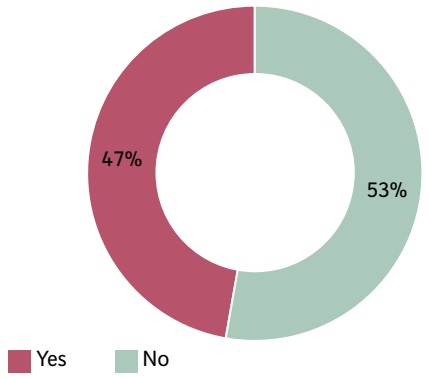
Indeed, pharmacists have been touted as having an integral function in the medical home, as described in an article in *Health Affairs*: "Pharmacists can play important roles in optimizing therapeutic outcomes and promoting safe, cost-effective medication use for patients in medical homes. They are well-trained health professionals, yet they are often underused. As a clinical expert working in an interdisciplinary primary care team, a pharmacist can assess whether medication use by patients at home is contributing to medication-related problems or failure to achieve desirable outcomes."[3]

More than half (57%) of plans expect MTM reimbursement to stay at the same rate as what former MTM providers were receiving or at the provider contracted rate; however, 29% say the reimbursement should be incorporated into the patient coordination fee.

Perry sees lack of change as indicative of plans that may embrace MTM but are not willing to spend any extra dollars on it. Hoadley adds that payers will also have to resolve how much control for MTM they can appropriately provide to the primary care team.

More than one-quarter (29%) say they will implement PCMH for members using a credentialed provider or that members may select their providers knowing which ones are in the medical home model. A similar proportion (26%) allows members to opt into the

Figure 44: If a patient has a PCMH, will the PCMH provide medication therapy management services for that patient?



Plans are split on whether the medical home will provide MTM services.

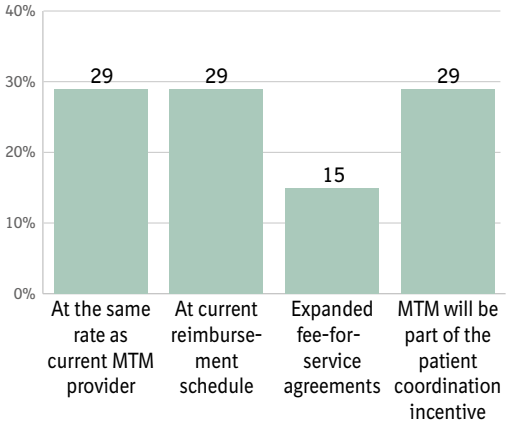
Multi-stakeholder support of the medical home is crucial to its success.

PCMH, and 17% permit an opt-out. One fifth of respondents will only implement the medical home for members when the payer requires it.

The range of answers suggests some indecisiveness on the part of respondents. Owens notes there is not just one way to implement a medical home and is encouraged that so many plans seem to have given the concept some serious thought.

Grundy adds that multi-stakeholder support of the medical home is crucial to its success.

Figure 45: If PCMH will provide MTM services, how will they be reimbursed for this?



PCMH Leadership

More than half of respondents (54%) look to CMS as the leader in developing the medical home model, while 42% rely on quality organizations such as NCQA and the Agency for Healthcare Research and Quality. "CMS will play a significant role in defining reimbursement, outcomes, performance standards, and guidelines," Lopes says.

While most plans surveyed look to CMS to set the stage for the medical home, most of the thought leaders believe that CMS is moving too slowly. "CMS is interested but it is just now starting pilots," van Amerongen says. "We can't wait for CMS to create momentum."

Although Sherman concurs with van Amerongen about the slow pace at which CMS is approaching the medical home, he is confident that the agency will create incentives and set standards. "Why reinvent the wheel when CMS sets reimbursement anyway?" Howerton asks.

About a third (31%) see health plan coalitions as leading the effort. Only 14% turn to large employers, though

Figure 46: How will you implement PCMH for your patient populations?

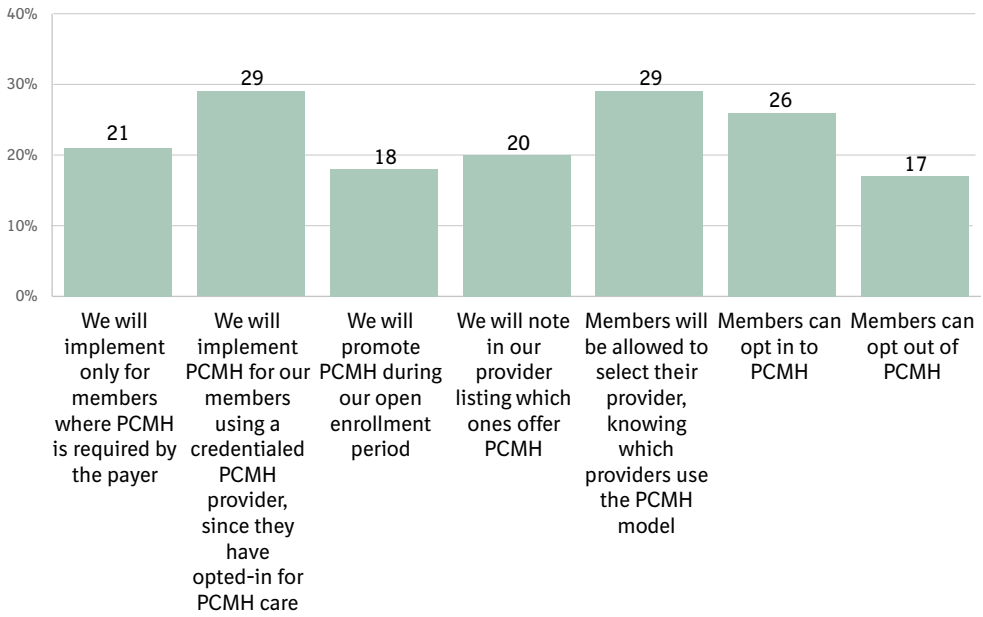
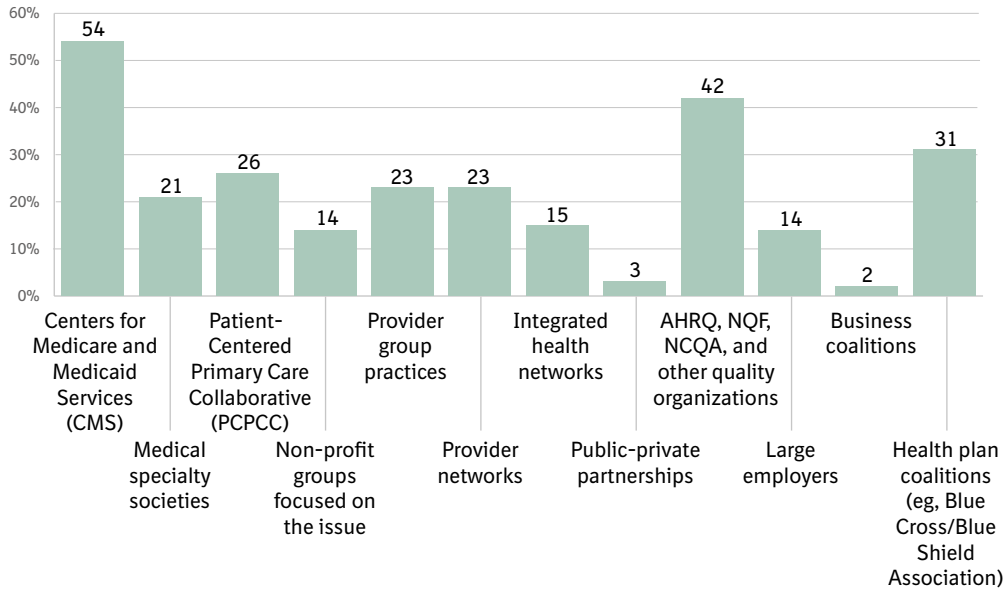


Figure 47: Whom will you look to for leadership in developing Patient-Centered Medical Homes?



54%

of plans look to CMS to lead development of the medical home.

Brooks would like to see employers play a larger role.

Rogers is optimistic that the medical home concept is gaining traction. "Four years ago, all the responses about leadership would have been zero," she says.

Conclusions

The PCMH represents a viable prototype for the delivery of quality care. Its success hinges to a large extent upon the support provided to PCPs as the foundation for health care delivery. Other key ingredients include health information technology, evidence-based care, aligned incentives, a new reimbursement structure, and continuous quality improvements. Many plans are sponsoring pilots and the concept seems to be gaining traction. Plans look to CMS, quality organizations, health plan coalitions, and employers for leadership; however, progress towards implementation has been slow.

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Emerging Issues Affecting Part D Coverage and the Medical Home

Emerging Issues Affecting Part D Coverage and the Medical Home

CER Expected to Influence Formularies, Reimbursement

"Comparative Effectiveness Research (CER) will potentially influence both future and current coverage and reimbursement levels of drugs covered by Medicare Part D plans," says John Doyle, vice president and practice leader at Quintiles Consulting, Research Triangle Park, NC. "Drugs outside of the Centers for Medicare and Medicaid Services-protected classes are at highest risk of restricted coverage or reimbursement based on CER."

CER may have an impact on Part D coverage but the effect won't be immediate, says Randy Vogenberg, PhD, principal, Institute for Integrated Healthcare (IIH), Sharon, MA. With an initial $1.1 billion in funding provided by the American Recovery and Reinvestment Act of 2009, Vogenberg says that the first studies are likely to focus on medical and surgical comparisons.

The Promise of CER

"CER studies provide an additional tool for decision-makers in determining a drug's value and where it should be placed on a formulary," says Peter Block, manager, clinical drug information and pharmacy and therapeutics process for Navitus Health Solutions, Madison, WI. "Randomized control trials (RCTs) are not typically pragmatic; they don't indicate what happens in a real-world population."[1]

Doyle agrees with Block on the limitations of RCTs. He finds that although head-to-head trials may be considered a gold standard for measuring relative differences in efficacy, the ability to conduct such trials is hindered by their protracted timelines and high costs.[2]

"Prospective observational research, such as cohort studies and registries, offer a remarkable channel to collect real-world data on treatment process and outcome, but need to be evaluated carefully to address potential bias," says Doyle. "In the end, a variety of techniques that complement each other should be deployed to investigate the comparative benefits and risks of products."[2]

Doyle favors having the biopharmaceutical industry propose a standard process for designing, implementing, and reporting an array of study designs.[2]

CER: Living up to its Reputation

The Institute of Medicine (IOM) defines CER as: "the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent,

diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels."[3]

The Pharmaceutical Research and Manufacturers of America (PhRMA) favors the use of CER as a means of comparing existing health care interventions, but adds that implementation of CER must preserve patient access to a wide array of medicines, rather than limiting choice by using the resulting data to mandate coverage or payment levels.[4] PhRMA maintains that a physician's decision on which medicine is best for a patient should be based on the full range of evidence and the physician's professional experience, rather than any mandated drug list. PhRMa adds that CER is about providing doctors and patients with the information they need to make the best medical decisions.[4]

Thus, PhRMA considers it important that any CER policy consider differences in individual patients rather than utilizing a one-size-fits-all approach for patient care, and give physicians the flexibility to tailor care for each patient.[4]

The Role of Cost-effectiveness in CER

Paul Keckley, executive director, Deloitte Center for Health Solutions, Washington, DC, supports CER studies, which he says inform and refine the strength of existing evidence.[1] "The clinical evidence should not be biased by the cost analysis. If the evidence is weak, costs need to be weighed against the estimated increase in efficacy and effectiveness," he says.

Doyle's hope is that CER appraises value holistically. "Outcomes may be measured in clinical, humanistic, and economic terms," he says, in an interview (July 26, 2010). "Drug prices are viewed more as an investment in an expected positive health event (ie, effectiveness). If drugs could be viewed as an investment portfolio by a payer under this paradigm, then the focus is on investment return, net of investment cost."

Whether CER will effect cost savings is still unclear. Doyle says that although CER could conceivably affect the cost of a drug, he believes the increase will be more than offset by savings in medical costs, such as fewer hospitalizations.

However, an analysis by Anirban Basu and Tomas J. Philipson suggests that CER may well increase spending and adversely affect patient health, particularly when treatment effects are heterogeneous across patients.[5]

Applying Studies to the Real World

Medco Health Solutions, Franklin Lakes, NJ, is putting results from its own research into clinical practice.[6] It launched an observational study to determine whether persons with a specific rate of metabolization for the anti-platelet drug clopidogrel have the same risk profiles as subjects receiving the more costly anti-platelet drug prasugrel. The study is measuring the risk of cardiovascular death, non-fatal heart attack or non-fatal stroke. Approximately 70% of a population could be considered extensive metabolizers of clopidogrel. Another 5% are poor metabolizers, and the remaining 25% are considered intermediate.

The study compares the effectiveness of prasugrel with clopidogrel using only the 70% of the population that are considered extensive metabolizers. Previous clinical trials compared the total population, without distinguishing patients by metabolism rate.

WellPoint, Indianapolis, IN, developed a standardized set of comparative effectiveness guidelines as a transparent way to quantify internal evaluations in order to make better decisions; establish drug positions on formulary; improve health outcomes; reduce cost of care; and set reimbursement policies.[7] The criteria for evaluating CER and observational studies range from study size and objectives to its bias and relevance to the WellPoint population. Doyle applauds WellPoint for taking a "pioneering step" by issuing and sharing its guidelines for CER.

The health plan measured the effectiveness of three drugs used in treating osteoporosis–alendronate, risedronate and ibandronate–and then moved the least effective agent to tier 3 on its formulary, in a study conducted in the plan's commercial population. Brian Sweet, WellPoint chief pharmacy officer, says the plan saw fewer fractures and saved $1,000 per member per year in pharmacy and medical costs.

"Such market-focused research as CER could result in active therapeutic substitution based on real-world data," Vogenberg says.

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Managing Diabetes in the Patient-Centered Medical Home

Health plans are teaming with physician practices to improve the management of diabetes by applying concepts of the patient-centered medical home (PCMH).

The "Joint Principles of the Patient-Centered Medical Home" make a strong case for managing chronic disease in a defined, systematic way. The principles emphasize coordinated care management, expanded access to primary care, a personal relationship with a primary care physician (PCP), integrated quality improvement, and an interdisciplinary team-based care delivery model.[1]

Health plans and physician practices are participating in PCMH demonstration projects and full implementation of the model. Some ventures are targeting diabetes specifically and finding that their efforts are paying off.

The Boehringer Ingelheim Medicare Part D & Patient-Centered Medical Home Report finds that survey respondents representing both Prescription Drug Plans (PDPs) and Medicare Advantage-Prescription Drug plans (MA-PDs) rank diabetes as the top therapeutic category by total drug spend for their Part D patient populations.

The Centers for Disease Control and Prevention estimates that there were 17.4 million Americans with diagnosed diabetes in 2007.[2]

Milliman, Inc, projects that by 2011, 21.9 million Americans will have type 2 diabetes, increasing to 32.2 million by 2031. As prevalence increases, the portion of national health care expenditures allocated to treat persons with type 2 diabetes is expected to grow from 10% in 2011 to 15% by 2031. Health care costs for people with type 2 diabetes are projected to increase from approximately $340 billion in 2011 to $1.6 trillion in 2031 in non-deflated dollars.[3]

Predictive modeling conducted by Milliman indicates that a 50% improvement in diabetes management and control would have an immediate impact and in 20 years would reduce: diabetes-associated deaths by 48,700 or 9%; incidence of diabetes-related complications by 239,000; and annual medical costs for diabetes patients by $196.5 billion (in 2031 dollars).[3]

Putting the Value of a PCMH Into Perspective

"As a buyer of care, a company like IBM wants care that is built on a trusting, comprehensive clinician patient relationship. We want to buy care that is integrated, coordinated, and accessible and uses the right tools. This is known as a PCMH level of care," says Paul Grundy, MD, MPH, IBM's global director of Healthcare Transformation and president, Patient-Centered Primary Care Collaborative.

"We now have seen hundreds of pilots, in which this level of care has delivered effective treatment of chronic conditions, such as diabetes, heart failure and asthma. Treatment of chronic disease is rather straightforward and relatively easy with PCMH level of care because there is a system in place with the right tools. On the other hand, when care is delivered as it most often is today–uncoordinated, disintegrated, and

episodic–failures in quality of treatment of these chronic conditions are well documented. The lack of coordination at the point of care results in services such as standalone disease management programs, which have created expensive, fragmented responses to the primary problem, along with unsustainable costs and poor quality."

Grundy is optimistic that such a redesign of care delivery–the PCMH–is moving forward. "Studies show that when a patient has a physician who cares about him or her and uses the tools to practice comprehensive care focused on patient needs, the patient will receive appropriate care at an affordable price," he adds. "Let's call that a patient-centered medical home. Let's build and deliver it."

Gus Manocchia, MD, vice president and chief medical officer, Blue Cross & Blue Shield of Rhode Island (BCBSRI), headquartered in Providence, concurs with Grundy. "We have long recognized the value of primary care providers (PCPs) and how they can have a significant impact in transforming the medical health care delivery system to provide more effective and efficient care to our members," he says. "Data show that in areas where there is more of a primary care infrastructure rather than an emphasis on specialty care, the quality of care is better and costs are lower, which ultimately makes health care more affordable."

BCBSRI Partners With Primary Care Group

In May 2010, BCBSRI agreed to develop a comprehensive medical home with the Rhode Island Primary Care Physicians Corporation, which has 162 physicians and 300,000 patients, including about 75,000 of whom are members of BCBSRI. "The PCMH will provide enhanced coordination to empower patients to make informed decisions and receive detailed action plans on how to better improve their health," Manocchia says. "The patient will have a 'quarterback' to coordinate care between the PCMH and specialty and hospital providers, as needed. Patients will become more involved in improving their health through the development of a 'care plan' outlining detailed steps on how to achieve improved health outcomes. They also will have their medications better managed, including drugs prescribed by multiple physicians, to avoid potential harmful interactions."

Before embarking on its own PCMH initiative, BCBSRI participated in a two-year multi-payer demonstration project called Rhode Island Chronic Care Sustainability Initiative (CSI-RI). Similar to the CSI-RI program, BCBSRI will reimburse practices for hiring a nurse care manager (NCM). Unlike the CSI-RI program that reimburses pmpm for all patients, the BCBSRI model ties pmpm payment directly to members requiring management of complex conditions.

Manocchia says that the medical home pmpm will compensate physicians for providing care management services, such as phone calls and efforts to coordinate care, and provide outcomes-based reimbursement as performance incentives. The heath plan also will fund training and project management to compensate for productivity costs incurred in developing the medical home; offer direct funding for a physician champion and training; and sponsor a pay-for-performance (P4P) program based on the outcomes of all of the BCBSRI patients in those PCMH practices.

Managing diabetes and other chronic conditions is an ideal focus for the PCMH, and one that BCBSRI has chosen in targeting members with comorbidities requiring complex treatment regimens. PCMHs will be responsible for actively managing these patients, as well as for completing the NCQA recognition process. As an NCQA requirement, practices must select three conditions of focus. Based on the prevalence of diabetes in practices in Rhode Island, all the CSI pilot practices selected diabetes as one of their conditions. Practices must report on select clinical measures, such as glycated hemoglobin (A1c) levels and promotion of diabetic retinopathy screenings. Manocchia says that in some cases, nurse care managers have become certified diabetes educators and certified cardiovascular disease educators, which complement the NCM role nicely.

Each practice participating in CSI is evaluating improvements in diabetes management and feeding information into an aggregated pool of data. The sites have developed evidence-based protocols for diabetes management and utilize a number of third party-developed patient education materials on diabetes. CSI uses a clinical measure related to A1c control (defined as less than 7%, but soon to change to less than 8%, as per national standards); blood pressure control defined as less than 130/80 mmHg; LDL control defined as less than 100 mg/dL; and documented retinal eye exam as optional measures.

Manocchia emphasizes that developing a PCMH takes patience. “A successful implementation is one in which the practice and the insurer are working together to meet the goals and objectives that will ultimately benefit the patient. Both the practice and payer must understand and accept that the concept of transforming to a patient-centered medical home will not happen as quickly as one might like, and it will require dedicated resources on the part of the practice, as well as infrastructure support from the health plan to ensure success,” he says.

Manocchia is optimistic about the benefits of the medical home. “It will improve the quality of care, while also addressing efficiency and costs. Through added coordination, BCBSRI expects to see decreases in unnecessary emergency department and inpatient stays, while providing proactive, rather than reactive, care for complex medical conditions,” he concludes.

Humana Leverages Medical home Experience

In November 2009, Humana and the JSA Medical Group launched a PCMH for Humana Medicare Advantage members in 17 JSA physician practices in the Tampa Bay area in Florida. Then in February 2010, the insurer joined forces with CAC-Florida Medical Centers in Dade County to further the practices’ emphasis on providing health care services "under one roof" orchestrated by a primary care physician.

Chris Corbin, program manager, physician strategies for Humana, says that diabetes consistently ranks as one of the three top conditions in its regional markets. Clinical laboratory values regularly measured include A1c, LDL, and blood pressure, and frequency of retinal and foot exams.

"The medical home is conducive to chronic disease management because chronic disease requires ongoing and regular patient interaction, management, evaluation, and testing," Corbin says. "Having a medical home for patients reduces fragmentation of care that may occur if different physicians are managing the care. Instead, a primary care physician or medical home serves as the home base or care coordinator to ensure there is a comprehensive view of the services and care provided, such as follow-up, test results, and referral reports. Additionally, the PCMH recognition program requires adoption of evidence-based medicine guidelines that helps support consistent management of patients with certain clinical conditions."

The Florida projects represent only two of Humana's medical homes. The first PCMH, initiated in 2008, was a one-year pilot with two practices that are members of the WellStar Physicians Group in Atlanta. The pilot produced the following outcomes: the number of patients with diabetes who had A1c levels less than 7% increased from 38% to 49%, and those with LDL lower than 100 mg/dL grew from 50% to 57%.

Humana also partnered with Metropolitan Health Networks (Metcare of Florida) in West Palm Beach, Florida, in an ongoing pilot with their Medicare Advantage (MA) capitated group. Average LDL cholesterol levels dropped by 1.8%, and patients with levels below 100 mg/dL (a target level) rose from 53% to 57%. Ninety-four percent of diabetes patients had an A1c level of less than 9%. Others programs include a pilot with TriHealth Physician Practices and Queen City Physicians for both commercial and Medicare Advantage members in Cincinnati and a multi-payer PCMH program with 16 family and internal medicine practices in Colorado and Ohio. In the Cincinnati pilot, 72% of patients with diabetes had foot exams, up from 57%.

"We are committed to the value of medical homes, which enhance the patient/physician relationship, influence chronic care management, and produce improved outcomes," Corbin says. He adds that the medical homes have had an impact on physician behavior–many had been reactive but are now proactive. Medical homes also promote patient education and self-management; find gaps in care and, in turn, facilitate physician visits; and emphasize the importance of achieving NCQA recognition through the adoption of the organization's standards.

Humana's medical home projects also emphasize evidence-based guidelines providing consistency in managing patients; team-based care coordination; enhanced access to care; health information technology (HIT) and information sharing; and patient outreach and engagement. "We anticipate a cost trend reduction due to enhanced access to higher quality care and a reduction in a duplication of services and in emergency department visits," Corbin says.

The medical home model has enabled Humana to step beyond the traditional patient management team (physician, nurse, medical assistant, and case manager) and in some pilot practices, has added nursing staff, incorporated nurses into various practice locations; assigned "patient navigators" to assist patients in getting referrals to specialists and to ensure coordination of care; and hired a clinical pharmacist to assist and educate patients to improve overall care management.

Corbin is a strong supporter of using HIT in the medical home to manage care for all of its patients. "In terms of managing individual patients with specific chronic conditions, HIT is useful to longitudinally track, monitor, and evaluate the management of patients over time and provides the resources and opportunity for more thorough evaluation of information, such as medication adherence, monitoring of laboratory values, and other diagnostics," he says. "In managing populations of patients with specific clinical conditions, HIT is also important in identifying care opportunities, such as delays or absences of preventive care, vaccinations, or tests, which enable practices to be more proactive in reaching out to patients to schedule follow-up appointments and close gaps in care."

Humana provides an additional per member per month care coordination payment to its fee-for-service reimbursement for physicians participating in these programs in recognition of their patient-centered medical home status.

To develop a medical home, Corbin explains that health plans and physicians need an adequate number of members to help financially support their efforts. Physicians also need to fully understand the commitment of seeking and completing the NCQA recognition process in addition to their regular workload.

States Join the Medical Home Action

From a state perspective, Pennsylvania is coordinating the largest state pilot program in the United States called the Chronic Care Initiative, involving more than one million patients, 800 physicians, and 16 insurers across seven regions. The state is contributing $3.4 million to run the program, while insurers are providing $30 million over three years as provider incentives.[4]

Within the initiative, one medical home project, including In 22 physicians' practices in southwestern Pennsylvania and 7,500 diabetes patients, indicates that those with high blood glucose levels dropped from 29% to 24% after nine months in the program.[4]

"The medical home allows primary care physicians to do what attracted them to primary care in the first place–focus on patient relationships in a collaborative approach," Corbin concludes.

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ACOs: Coordinating Care, Improving Outcomes

Accountable care organizations (ACOs) offer an alternative approach to the more familiar patient-centered medical home (PCMH) concept to promote and reward the delivery of quality patient care.

A National Public Radio story on its "All Things Considered" program described the ACO approach this way: "An ACO is a bit like a building contractor. The contractor gets together with some other contractors–plumbers, electricians, roofers–and they agree to repair your house for a set amount of money.[1]

Although both PCMHs and ACOs incorporate many of the same principles–coordinated, holistic care; aligned payment systems among all providers; improved access to care; application of health information technology (HIT); and quality incentives–Paul Keckley, executive director, Deloitte Center for Health Solutions in Washington, DC, points out the primary ways they differ:

- ACOs target both chronic and acute problems, while PCMHs address mostly chronic care delivery.
- ACOs incorporate a variety of providers including multispecialists, primary care physicians (PCPs), and hospitals to provide evidence-based care using a coordinated model, while the medical home emphasizes an ongoing relationship between a patient and a personal PCP.
- The return on investment from an ACO is more immediate than the long-term results accrued from a medical home.
- ACOs are accountable for 100% of the quality, cost, and overall care of Medicare beneficiaries who are assigned to them.

Two Collaboratives Promote ACOs

The Premier health care alliance, a performance improvement organization, launched two ACO collaboratives in May 2010. The ACO Implementation Collaborative involves 1.4 million patients, more than 5,000 physicians, and 19 health systems, including more than 70 hospitals, in 15 states. It targets health systems with existing payer partnerships and physician networks. The ACO Readiness Collaborative includes 45 health systems that are still developing the capabilities to support an ACO. The collaboratives parallel the development of two similar partnerships established by the American Medical Group Association in April 2010.

"The ACO needs to deliver primary care and coordinate with other providers as patients move across the delivery system," says Wes Champion, senior vice president of Premier Consulting Solutions, Premier, Charlotte, NC.

Champion anticipates that both its alliance and the new collaboratives will:

- Speed up implementation.
- Provide expert input needed to build key ACO operating activities, such as health homes and bundled payment models.
- Evaluate population health information infrastructure and tools, including electronic health records (EHRs) and health information exchanges that enable community-wide care coordination.

- Facilitate early ACO contracts with the Centers for Medicare and Medicaid Services (CMS) and other payers.
- Create shared toolkits, best practices, and contracting models to facilitate the goals of accountable care.
- Develop standard performance metrics to manage population health and identify improvement opportunities.
- Create a gap analysis and a roadmap to help health systems currently not ready to launch an ACO effectively transition to the necessary business model when they're prepared to do so.

The Premier alliance also foresees short- and long-term cost savings resulting from more efficient care, better care coordination, improved outcomes, and less waste.

Champion says that the ACO collaboratives' first steps will rely on the alliance's proven experience to establish goals and a mission; define consistent measures of success; use standardized data sets to meaningfully compare results across participants; commit to open sharing of performance data; develop analyses based on the data so that the collaborative can set performance targets, identify opportunities for improvement, and establish areas of focus; share best practices; evaluate ongoing performance improvement; and connect providers within a community.

The Provider Payment Structure

Structuring provider payment is an element of the ACO that has not yet be clearly defined. The new Center for Medicare and Medicaid Innovation (CMI) should give the discussion some momentum. A result of enactment of the Patient Protection and Affordable Care Act (PPACA), CMI is responsible for testing innovative payment and service-delivery models designed to reduce Medicare and Medicaid expenditures, while preserving or enhancing quality of care. Through pilot programs, CMI could align Medicare payment with private initiatives and create a more consistent incentive structure for participating providers.[2]

One of the proposed structures is the Shared Savings Program, outlined under Section 3022 of PPACA. The health care reform legislation requires Secretary of Health and Human Services (HHS) Kathleen Sebelius to establish a Shared Savings Program by January 1, 2012, in which authorized providers contract with HHS to manage and coordinate care for Medicare fee-for-service beneficiaries for three years through an ACO. On top of receiving fee-for-service payments, ACOs can earn additional payments if the organizations meet quality performance standards and achieve savings.

Some of the issues still to be decided are the appropriate allocation of savings to each ACO participant, how shared savings will be calculated, what standards will determine "quality" performance, and incentive alignment in the collaborative organization.

"Today, doctors and hospitals are paid for every service they provide. The more they do, the more they are paid, regardless of the outcomes that patients experience," Champion says. "In addition, care is fragmented and providers don't always 'talk' to one another, leading to duplication of services and insufficient data, hindering

support decision-making." He points out that this disconnected health care "production" model creates perverse incentives that directly lead to serious problems, including unsustainable spending, inefficiency, waste, poor care coordination, and sub-optimal outcomes.

Champion applauds ACOs as a way to transform health care to address these concerns simultaneously: "In an ACO, providers will no longer be rewarded for the volume of care provided to those that are sick; instead, they will be paid based on their ability to keep people healthy," he says.

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Plans Face Challenges in Managing Atrial Fibrillation

Atrial fibrillation (AF) is the most common sustained arrhythmia and it affects 2.3 million persons in the United States.[1] The most devastating complication of AF is stroke, which is 5 times more likely to occur in persons with atrial fibrillation than in the general population.[2] The condition is of concern to Part D plans because of its growing prevalence among seniors, high drug costs of treating comorbidities, and need for alternative treatments.

Incidence of atrial fibrillation increases with age and is present in 9% of persons older than 80 years of age; more than 80% of AF patients are age 65 years and older.[1] US treatment costs were estimated at $7 billion in 2006, with 4% going for drugs.[3] These costs are expected to rise given that the number of adults with AF is projected to increase 25% between 2010 and 2020.[1] In addition to the aging of the US population, the survival rates for underlying conditions closely associated with AF, such as hypertension, coronary heart disease, and heart failure, are also increasing, growing the risk population and leading some to term AF "an emerging epidemic."[4]

Wu et al found that the excess annual direct cost per AF patient was $12, 349, with AF patients approximately 5 times as costly as non-AF persons ($15,553 versus $3,204, respectively).[5] Kim et al report that by 199 days into the coverage year, most AF patients (59.9%) had spent $2,250 on prescription drugs, putting them into the "donut hole" of Medicare Part D coverage, and by 257 days 21.2% had reached the coverage gap exit threshold of $5,100. AF-related medications accounted for 15% of total prescription drug costs; the remainder was due to treatment of comorbidities.[6]

The treatment of AF involves three major therapeutic strategies. Beta-blockers, calcium channel antagonists or digoxin are used to control heart rate to minimize symptoms. Anti-arrhythmic agents, such as flecainide, sotalol or amiodarone, are used to maintain normal sinus rhythm. The final important strategy utilizes anticoagulants to prevent stroke.[7] In AF, the atria beat so quickly that there is no effective atrial contraction. As a result, blood becomes stagnant in the atria and can result in blood clots (thrombi), which can break off and go to the brain (embolus), causing a stroke or transient ischemic attack (TIA).

In patients at low risk for stroke, or for those with contraindications to oral coagulants, aspirin is the preferred agent to prevent stroke.[7] However, in patients with high blood pressure, diabetes, heart failure, a prior stroke or TIA, or who are age 75 years or older, warfarin is the preferred therapy to prevent stroke.[7] Warfarin has been proven effective in multiple large studies. Lakshminarayan et al reported that as warfarin use more than doubled over a 10-year period, incidence of both ischemic and hemorrhagic stroke declined.[8] While warfarin use reduces risk of stroke by almost 70%,[9] patients often dislike taking it. Because it "thins the blood," patients bruise and bleed much easier. Warfarin use also affects diet; patients need to avoid vitamin K containing foods, such as green leafy vegetables.[10] Warfarin interacts with multiple other medications, which can adversely affect warfarin international normalized ratio (INR) levels.[11] Finally, and most important, warfarin levels need to be maintained at a specific INR, which means that patients need to have their blood levels checked on a regular basis[12]

(at least every 4 weeks).[7] The total cost of warfarin treatment is high, driven by monitoring costs, health care professional time, missed work, cost of travel, and cost of the drug. One study reported missed work costs alone exceeded $2,000 annually per patient.[5] Go et al reported that only 55% in an eligible patient population use warfarin.[13] While genetic testing for the ability to metabolize warfarin offers promise, it is still in the early stages and expensive.[14] These cost and management issues have spurred pharmaceutical companies to look for safer and more effective alternatives.

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