Healthcare Reform and Future Directions for Co-Pay Foundations

A Discussion Paper for the Strategic Advisory Committee to the Patient Access Network Foundation

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INTRODUCTION

The health care reform debate that dominated the news a year ago has largely focused on providing access to insurance coverage for the uninsured. The plight of the underinsured, generally defined as persons with health insurance but who cannot afford their out-of-pocket medical expenses, has been for the most part overlooked. The underinsured population—estimated at 25 million and growing in 2007—is roughly half the size of the 50 million uninsured population, but is a faster growing segment.

Because these 25 million are not economically disadvantaged enough to qualify for Medicaid, they are usually ineligible for most other safety net assistance programs offered by government agencies, pharmaceutical manufacturer patient assistance programs, and non-profits. As a result, this group is at risk for suboptimal medical care, lack of continuity and coordination of care across time, and care compliance problems, for the most part attributable to unaffordable co-payment obligations. All of these problems are associated with suboptimal outcomes, and are a gateway to exacerbated illness, disability, and financial ruin. To help address this unmet need, co-pay assistance foundations, sometimes referred to as “cost-sharing assistance programs,” were established to provide financial assistance to patients diagnosed with medical conditions with high therapeutic costs, such as cancers, and chronic and rare diseases.

A broad array of organizations exist that provide cash assistance and other supportive services to facilitate patient access to care, ranging from disease-specific to more encompassing foundations that support a broad category of medical conditions. Within the context of healthcare reform, this paper looks out to the anticipated needs for such foundations during and after the implementation of the sweeping reform law.

HEALTHCARE REFORM AND THE NEW LANDSCAPE

The enactment in March 2010 of the Patient Protection and Affordable Care Act (ACA), as amended by the Health Care and Education Reconciliation Act of 2010, promises to change fundamentally the regulation, pricing and availability of health insurance – and thereby access to health care – in the U.S. The sweeping reform provisions enacted in the ACA will have significant impacts on public and private payers, providers, manufacturers and, most importantly, patients. Likewise, these changes will impact all forms of patient assistance, including co-pay assistance foundations. This paper examines the major provisions of the ACA, timeline of essential provisions, gaps in the reform law, and the current dynamics marking the phased implementation of healthcare reform, and anticipates the ongoing need for assistance with out-of-pocket healthcare expenses.

Healthcare Reform Objectives

Often referred to as the “triple aim” of reform, the overarching goals of the ACA can be categorized into three buckets:
The total impact of the reform law’s changes to the healthcare system will not be fully realized for several years. Many provisions, including some of the most significant from an insurance regulatory and coverage expansion standpoint, do not take effect until 2014.

A key success factor in obtaining congressional and public support of the ACA was the inclusion of several provisions designed to maximize insurance options and minimize existing barriers for individuals, particularly the sickest patient populations. Several provisions are aimed at achieving these goals.

**Pre-existing Condition Insurance Plans (PCIPs):** Now—End of 2013

Prior to eventual passage, the House and Senate debated multiple versions of health reform legislation, many of which contained a provision for a publicly owned and operated insurance plan—the “public option”—which would have extended coverage to uninsured Americans through a government-run program similar to Medicare and Medicaid but without any age or income restrictions. The public plan option was removed from the final bill, forcing policymakers to establish other programs to ensure access to coverage for the nation’s 50.7 million uninsured. Congress created two provisions to address the uninsured: pre-existing condition insurance plans (PCIPs)—also referred to as “high-risk pools”—and state-based health insurance exchange plans (HIEPs).
The ACA mandated the availability of state-based PCIPs by October 1, 2010, to provide an insurance option for individuals without health insurance; primarily those denied private health insurance coverage because of a pre-existing condition. Persons who have been uninsured for 6 months or longer are eligible to apply for these plans.

The ACA allocated $5 billion to run the PCIPs until January 1, 2014, at which point the state-based HIEPs will begin offering coverage. States had the option of applying for federal funds to support their PCIPs or allow the U.S. Department of Health and Human Services (HHS) to develop and operate PCIPs within their state. Twenty-three states opted for the federal operated plan and 27 opted for state-operated PCIPs.⁵

The PCIP provision is important from a patient perspective as individuals without employer-sponsored health insurance who fail to qualify for public programs (e.g., Medicare and Medicaid) will need to buy private insurance after full implementation of ACA. Individuals with any type of chronic or acute condition that could be categorized as a pre-existing condition today face challenges in finding any insurance options, much less an affordable option. The PCIPs serve as a stopgap measure until the full implementation of ACA, which includes the prohibition on the preexisting conditions by all health plans, and access to those plans on a community-rated basis through the HIEPs.

Overall participation in the first few months of the new federally-subsidized PCIP availability was well below expected, with just over 8,000 enrollees in November, 2010.⁶ ⁷ Enrollment appears to be dictated by monthly premiums, which in 2010 ranged from $115 to $1,735, depending on the enrollee’s age and state of residence; most fell between $140 and $900. In response to the lower than expected enrollment numbers for 2010, HHS announced additional plan options⁸ at reduced premium levels for 2011.⁹

Availability of the federally subsidized PCIPs is a temporary fix to ensure previously uninsurable Americans have the option to obtain affordable coverage before the permanent state-run HIEPs become available. Upon the creation of the HIEPs, individuals will be able to purchase comprehensive insurance, although the affordability of such insurance will not be tested until 2014.

**State Health Insurance Exchange Plans (HIEPs)⁵: 2014 and Beyond**

State-run HIEPs will provide an opportunity for several groups of previously uninsured Americans to buy health insurance. The ACA requires each state to establish a health insurance exchange for individuals and another for small employers; states have the option to operate a single exchange for both individuals and small employers. States can establish their own exchanges or pool with other states to establish regional exchanges. States may also defer to the federal government to establish an exchange for them. The exchanges must be in place by 2014, when all U.S. citizens and legal residents will be required to maintain minimum essential health insurance coverage through the individual insurance market, insurance exchanges, public programs, or employers—or face a penalty.

The exchanges will provide a new regulated marketplace in which eligible Americans without access to employer coverage that meets certain affordability and coverage standards can purchase insurance—a federally determined essential benefits package. In general, individuals whose employer offers health insurance will be ineligible to opt into the exchanges. However, Americans with employer coverage who spend more than 9.5% of their income on premiums, or those with a plan that covers less than 60%, on average, of their medical costs are eligible to purchase coverage through the exchange.

This provision aligns with the employer requirement which also takes effect in 2014.¹² Employer requirements ensure that employers do not drop out of the health insurance arena and encourage employees to purchase an HIEP.
HIEPs will offer four benefit categories in addition to a separate catastrophic-only plan.

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| Bronze  | • Minimal coverage requirement; Plan provides essential health benefits, including hospital care, mental health and substance abuse services, noncustodial skilled nursing services, prescription drugs, preventive care, and maternity iv  
  • Covers 60% of benefit costs  
  • Out of pocket maximum is equal to annual health savings account (HSA) levels |
| Silver  | • Same options as Bronze, but covers 70% of costs |
| Gold    | • Same options as Bronze, but covers 80% of costs |
| Platinum| • Same options as Bronze, but covers 90% of costs |
| Catastrophic | • Available only those under 30, or those exempt from the individual mandate  
  • Provides catastrophic coverage only for the coverage level set at HSA level  
  • Preventative care and three primary care visits are exempted from the deductible  
  • This option is only available in the individual market |

An additional component to the creation of the state-run exchanges is the required inclusion of Medicaid and State Children’s Health Insurance Program (SCHIP) enrollment options as HIEPs within each exchange system. The exchanges themselves will likely require considerable infrastructure investment from individual states to ensure a seamless, high-technology enrollment option for exchanges. The combination of Medicaid, SCHIP and exchange enrollment will improve access, provide transparency and also increase overall portability of health insurance.

In addition to the option to purchase insurance, a premium subsidy will be offered to certain individuals and families who do not qualify for Medicaid, but face financial hardship as determined by the federal government. xv The federal government will provide refundable premium credits to eligible individuals and families with incomes between 133 – 400% of the federal poverty level. Premium credits will be tied to the second lowest cost silver plan within the state and subsidies are on a sliding scale based on actual income level. It should be kept in mind, a “tax credit” is not cash in hand, and so it remains to be seen how powerful this incentive will be in moving the working poor into HIEPs voluntarily.

Another consideration around the topic of the new exchanges is the impact on high-deductible health plans. Currently, high deductible health plans (HDHPs) offer consumers very low premium costs in exchange for a high annual deductible, often as high as $5,000 per year. HDHPs can offer individuals who are generally healthy a low cost option. A provision in the ACA sets individual deductible maximums at $2,000 annually and families at $4,000, consistent with today’s maximum levels for Health Savings Accounts, which are coupled with HDHPs. It is unclear if organizations that offer HDHPs will revise their offerings, or if HDHP models will disappear in 2014 when the provision takes effect.
Medicaid Expansion

The creation of both the PCIPs and the HIEPs will provide health insurance to a large segment of the uninsured population in the US. In order to provide additional coverage options, the ACA mandated a significant expansion of the Medicaid program. Beginning in January 1, 2014, for those individuals and families who are non-Medicare eligible with incomes up to 133% of the FPL ($29,725 for a family of 4 in 2011) will be Medicaid eligible.

All newly eligible individuals will be guaranteed a benefit package that meets the essential health benefits (yet to be fully defined by HHS) available through the exchanges. The ACA also requires states to maintain current income eligibility levels for children in the SCHIP programs until 2019 and extends funding through 2015.

To enable the expansion of the Medicaid program, the ACA outlines federal funding allocated to assist states in insuring newly eligible individuals and families. Federal funding for the additional coverage will be distributed to states on a sliding scale, beginning at 100% in 2014 and declining to 90% beginning in 2020 and subsequent years. States were given the option to expand Medicaid eligibility beginning April 1, 2010; however, there is no additional federal funding available until January 1, 2014. To enable this expansion and address the chronic shortage of Medicaid providers in the U.S., states are required to increase Medicaid reimbursement for primary care services provided by primary care physicians to 100% of Medicare rates, in order to incent physician participation and utilization of services. States will receive 100% of funding to cover this increase in payment rates.
Changes to Cost-Sharing for Medicare Part D Drug Coverage

Since the implementation of Medicare Part D program in 2006 and until January 1, 2011, beneficiaries on numerous and/or high cost therapies faced a coverage gap (the “donut hole”) during which they were required to pay all prescription drug costs until they hit the catastrophic dollar limit, or the calendar year ended. The donut hole existed for a variety of reasons, most importantly because (1) it would lower the overall price tag of the prescription drug benefit, and (2) the gap would ensure both the government and beneficiaries had “skin in the game” to ensure appropriate utilization of drugs.

The coverage gap is a challenging hurdle for many Medicare beneficiaries to meet, and is thus a source of many patients in need of PAN’s services. In 2009, an estimated 3.4 million beneficiaries entered the coverage gap, while only 15% spent enough of their own income to hit the catastrophic limit and regain drug coverage.xvi Historically, 42% of PAN’s patients have needed assistance in the “donut hole.”

As the President and Congress turned their legislative efforts towards comprehensive healthcare reform, the closure of the coverage gap was a top priority for patient advocate groups. After significant lobbying efforts and stakeholder negotiation, the end-result is that by 2020 the coverage gap will be narrowed, but not completely closed for beneficiaries.xvii This narrowing occurs on a phased-in basis, beginning in the current year, with a drug benefits illustrated in the following graphic.

Medicare 2011 Standard Benefit – Post Healthcare Reform

With the passage of ACA, the federal government provided beneficiaries a one-time, $250 rebate check upon hitting the coverage gap. Beginning in the current year, when beneficiaries hit the coverage gap, pharmaceutical manufacturer(s) are now required to pay 50% of the cost of branded drugs while the beneficiary is in the coverage gap, with the beneficiary paying the remaining 50%.
Beginning with this year and going forward in annual increments, the coverage gap cost-sharing levels for the beneficiary are reduced until 2020, where beneficiary cost-sharing comes to rest at a fixed 25%, thus synchronizing cost sharing levels of coverage in the gap with those before hitting the gap. The final versions of the drug benefit, one for branded and one for generic drugs, are illustrated in the next two graphics.

**Medicare 2020 Standard Benefit – Post Healthcare Reform (Brand Drugs)**

- Coverage gap ends and catastrophic coverage begins
- 25% Paid by Plan
- 75% Paid by Plan
- 50% Paid by Manufacturer
- 5% cost sharing through catastrophic coverage
- Beneficiary pays 25% in Rx spending on brand drugs (100% counts toward catastrophic coverage)
- Beneficiary pays 25% co-insurance
- Beneficiary pays deductible

Initial coverage limit

Exact methods for achieving this goal will be borne out by regulatory decisions in the coming years

Catastrophic Coverage
Insurer & Medicare pay 95% of costs

2020
Changes to the coverage gap are positive for Medicare beneficiaries and drug manufacturers, despite their increased burden associated with their own cost-sharing for branded drugs. Increased cost-sharing has been demonstrated to reduce compliance with all drug regiments, and with reductions in this burden, patients are more likely to continue on all treatment regimens through the coverage gap, thus improving overall health outcomes. While positive for beneficiaries and manufactures, these changes will significantly change the composition of PAN’s historic assistance.

**Broader Health Insurance Market Reform**

The broader health insurance reforms included in the ACA are an effort to maximize insurance access for all beneficiaries, regardless of age or health condition. Prior to enactment of the ACA, the government had little reign over how health insurance companies provided coverage for individuals, particularly those with chronic or acute, high cost diseases. There are several provisions within the ACA which institute sweeping restrictions on private health plans.

As of September 23, 2010, health plans were precluded from implementing pre-existing exclusions for pediatric patients. Beginning in January 1, 2014, this pre-existing condition exclusion will be extended to include all adults. For many years, those individuals seeking to buy insurance coverage were unable to find affordable coverage if they had a chronic condition that could be interpreted by a health plan as a preexisting condition. The prohibition against these types of exclusions is a significant win for individuals facing a chronic condition.
In addition to the prohibition of pre-existing conditions exclusions, another significant safeguard for individuals is the prohibition on “rescission,” or the business practice of health plans dropping coverage for individuals or families based on a newly acquired disease or previously undisclosed pre-existing conditions. This provision, which went into effect this year, seeks to ensure continuous coverage for individuals despite health status.

There are three additional provisions included in the ACA which are significant to individuals. First, dependent coverage under health plans has now been extended to adult children up to the age of 26. This significant provision is aimed at improving access for young adults who may not be in a position to purchase insurance or work for an employer that offers insurance. Second, insurers are no longer allowed to place lifetime maximums for insurance coverage. Finally, beginning in 2014, annual maximums will no longer be permissible.

Theoretically and upon its full implementation, the ACA will result in significant coverage and delivery system reforms aimed at reducing cost growth; provide consumers with financial protection; and improve the quality of health care. Establishment of state-based HIEPs and the introduction of new insurance market rules and consumer protections, combined with enhanced oversight of insurance industry practices, lays a foundation for progress toward increasing the functioning and competitiveness of U.S. health insurance markets while improving the continuity and quality of health care in the U.S. However, implementation of the reform law promises to be met with many challenges.

Healthcare Reform’s Misses and Turbulent Implementation

When fully implemented, the Congressional Budget Office (CBO) estimates the ACA will result in coverage for some 32 million of the nation’s 50 million non-elderly uninsured. But the transition to expanded coverage and more consumer protections has been—and likely will continue to be—met with challenges for many patients, primarily because the reform law doesn't dampen increasing costs or the practice of cost-shifting between the employer's and individual's portion of costs. Moreover, the changing political landscape resulting from the 2010 federal congressional and state gubernatorial elections and the federal court rulings challenging the constitutionality of the ACA has perpetuated the years-long and fractious debate of the health reform law and portends a rocky implementation of the law.

The balance of this section highlights areas of exposure either unresolved or created as a result of the reform law.

Increasing Out-of-Pocket Costs for Privately Insured

According to myriad employer and benefits consultant surveys, in 2011 Americans who have health insurance through large, employer-sponsored health plans are paying more for coverage, with higher shares of increasing premiums and higher out-of-pocket maximums. Hewitt Associates reports that health care cost increases will be the highest levels in the last five years due to rising medical claim costs, the aging population and the changing healthcare reform landscape. In addition to projecting an average premium increase of 10% in 2011 over 2010, Hewitt’s research estimates employee out-of-pocket costs will increase to $2,177 in 2011 from $1,934 in 2010. Hewitt also reports that employers were able to mitigate costs in this difficult economy by cost shifting, negotiating costs with health plans and increasing their efforts to promote preventive care.
Mercer’s 2011 health benefits researchxxiv is consistent with Hewitt Associates’ survey findings, and further determined that while much of the cost growth is due to increased utilization of health care services, the passage of healthcare reform added between 1 and 2% to the cost increase in 2011.

**Medicaid Program Cost-Reduction Efforts Result in Higher Spend-downs**

States revenues are down significantly as a result of job and revenue losses stemming from the ongoing recession, and as a result many state officials are grappling with difficult decisions on budget cuts and reductions in services. According to the Center for Budget Priorities, states face estimated shortfalls of about $125 billion for state fiscal year 2012xxv, which begins on July 1 in most states, and which coincides with the end of the fiscal relief appropriated by the American Recovery and Investment Act of 2009 (ARRA).

Amid the looming loss of the enhanced federal matching funds provided by the ARRA and the heated debate between Republican governors and the Obama Administration, states are evaluating their authority to implement cost-reducing measures in their Medicaid programs while they pursue forgiveness of the maintenance of effort requirements of reform law. One such cost-saving mechanism Medicaid programs have begun to employ is increasing spend-down amounts, which work like an insurance deductible, for individuals with incomes exceeding thresholds for regular Medicaid eligibility under state medically needy programs. Historically, PAN’s total level of Medicaid spend-down assistance has been at 1-2% of its population; however, in recent months PAN has seen an increase in the number of patients requesting assistance through the spend-down period and at considerably higher amounts. North Carolina, for example, has modified its requirements from monthly spend-down amounts in the low hundreds to a quarterly amount near and, in some cases, exceeding $1,000. Such changes will put access to medical services out of reach for much of this patient population.

**Increased Medicare Advantage Co-insurance Creates Access Barriers**

The ACA includes a provision for parity payment for Medicare beneficiaries in original Medicare and Medicare Advantage resulting in a phased reduction in payments to Medicare Advantage plans starting in 2012. According to a recent survey of pharmacy and medical directors in Xcenda’s Managed Care Network (MCN)xxvi, Medicare Advantage plans have responded to the impending changes by modifying their benefit design and requiring 20% co-insurance on many services, including drug therapies. This structural change has resulted in increased beneficiary out-of-pocket responsibilities and a benefit restructuring that closely resembles Medicare Part B co-insurance requirements. Moreover, the Medicare supplemental policies available to Part B beneficiaries are not available to Medicare Advantage beneficiaries and, as such, many Medicare Advantage beneficiaries are growing the ranks of the underinsured.

Collectively, these dynamics result in a coverage landscape that makes co-pay foundations even more vital in the post-healthcare reform environment.
CONCLUSION

The ACA seeks to provide virtually all Americans with basic coverage and protections against medical and financial catastrophe, but the health reform law is not designed to fix all of health care’s problems, nor alleviate all negative economic impacts of illness on the nation’s patients.

The most likely net effects of the ACA will be the elimination of most of the uninsured and catastrophically exposed, while simultaneously exposing others to new premium costs and cost-sharing schemes and creating a wider, if less deeply rooted swath of the underinsured. In short, more Americans will have health coverage AND more and generally larger co-payments. This paradigm shift will likely result in a transfer of patients from manufacturer-sponsored patient assistance programs for the uninsured to commercial co-pay programs and foundations for the federally uninsured. As such, the ACA represents opportunities for PAN and other co-pay assistance foundations to include increased capacity to capture some of this shift while navigating the changing composition of the historic underinsured.

Reprising the healthcare reform provisions outlined in this paper, following is a summary of the essential net impacts—both short and long-term—of the ACA in the context of the underinsured and the ongoing need for co-pay foundations such as PAN.

| 1. | Upon its full implementation, the ACA will bring most of the chronically uninsured into the current public and private health insurance system but does not eliminate, and will likely exacerbate, the number of underinsured. |
| 2. | The temporary PCIP offers some uninsured patients the opportunity to gain coverage before the expansion in 2014; however, the high risk pool insurance premiums may still be cost-prohibitive for patients thereby leaving them uninsured. |
| 3. | The ACA will expand the size of the Medicaid population and, potentially, the number of underinsured through increased spend-downs and cost-sharing obligations. |
| 4. | The ACA will subsidize and limit out-of-pocket exposure for many of the newly insured; however, the HIEPs themselves will still expose patients to significant costs. Moreover, those ineligible for subsidies will bear the full burden of their plans’ cost-sharing obligations. |
| 5. | Continuity of care will be an important and challenging consideration as patients undoubtedly will cross between HIEPs and Medicaid, creating a need/opportunity for assistance in the transition. |
| 6. | The ACA will reduce, in a multi-year phased approach, drug cost-sharing for Medicare Part D beneficiaries, but the beneficiary responsibility across all the coverage corridors at 25% up to the catastrophic coverage threshold means that many will continue to be unable to meet their cost-sharing obligations. |
| 7. | The ACA makes no changes to Medicare Part B cost-sharing requirements, thereby continuing to expose Medicare beneficiaries to costly co-pays for medical services and physician-administered drug treatments. |
| 8. | Changes to the Medicare Advantage reimbursement scheme have resulted in plans’ shift to co-insurance for physician-administered drug therapies, resulting in a new underinsured segment of the Medicare population. |

In this white paper, we use “ACA” to refer collectively to both the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010.


Of the new options created for 2011, two options will include separate medical and drug deductibles. The standard plan option will have a $2,000 medical deductible, a $500 drug deductible, and a premium that is roughly 20 percent less than the 2010 premium. The extended plan will have lower medical and drug deductibles and premiums slightly higher than 2010 levels. The third option has the same deductible and similar coinsurance as the 2010 plan but with a premium that is 16 percent less than the 2010 premium.


Large employers that either do not offer health insurance to their employees or offer health insurance at high cost to employees or of poor quality are required to make payments. For employers with 50 or more full-time employees who do not offer health insurance, the ACA will require a payment of $2,000 per full-time employee, if an employee becomes eligible for a premium subsidy through the exchanges.

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Section 1101

Section 2712

Section 2714


