WHITE PAPER

Feeling Some 'Side Effects' from Health Reform

September 2014

TABLE OF CONTENTS

Executive Summary **3**

Side Effects **4**

Exchange vs. ESI **4**

Benefit Design **5**

Higher Costs **6**

Uncomfortable Precedents **7**

Be Prepared **7**

Action Plan **8**

About inVentiv Health **9**

About Breakaway Policy Strategies **9**

About Chandler Chicco Companies **9**

References **10**

EXECUTIVE SUMMARY

Consumers are getting health coverage through the new state exchanges, but higher cost sharing could discourage patients from filling prescriptions of new and necessary medications.

More than eight million Americans have now purchased health insurance through state health exchanges. The Affordable Care Act (ACA) has begun delivering benefits and new insurance protections to a large swath of the population, including many people who had no previous coverage. But stakeholders across the healthcare landscape, from patients to policymakers, have started to contemplate what the real costs of these benefits will be.

The protections include an end to coverage exclusions for pre-existing conditions and a cap on the overall amount that insurers may charge a patient in any given year. Along with such safeguards, however, comes significant challenges — call them the "side effects" of extending health insurance coverage. In order to hold down the cost of premiums on the ACA exchanges and comply with ACA regulatory requirements, insurance carriers have implemented novel cost-sharing arrangements, discussed in a 50-state analysis below, that could place some medicines out of reach for many patients. In addition, patient access to specialists most likely to understand and prescribe certain treatments may be circumscribed, causing challenges both for people who are sick and for biopharmaceutical companies.

These challenges will likely become more pronounced over the next decade if the number of Americans enrolled in exchanges more than triples, as some experts predict. At the same time, new benefit designs such as higher cost sharing and tighter formulary controls could migrate to private exchanges and across the broader commercial health insurance market, affecting ever larger numbers of American patients.

Given these developments, it is not too soon for biopharma companies, patients and disease advocacy groups to strengthen partnerships and start advocating for policies that will improve patients' access to needed treatments. At the same time, drug companies will need to develop and implement more robust communications programs aimed at safeguarding patient access to needed treatments.

The following article compares various aspects of ACA exchanges with employer-sponsored plans. Our aim is to more closely examine benefit design and cost-sharing features that already are having an impact on patients nationwide and may have a greater impact in the future should ACA features migrate into the private market. In addition, we discuss the importance of biopharmaceutical and advocacy groups and patients stepping up to make sure their voices are included, especially in formulary decisions.

Side Effects

In the final weeks before enrollment closed, there was a surge in the number of Americans signing up for health insurance through state health exchanges. Some media commentators concluded at the time that the ACA had crossed a critical threshold of public support. Yet the data snapshots[1] released by the Obama administration in April provided little information on many practical matters at the heart of the rollout, including details about the health plans where most people will get coverage.

For example, we know that premiums for many health plans available through the exchanges are moderately priced compared to the cost of individual insurance coverage before the ACA. For millions of people, premium subsidies have made coverage affordable.[2,3] In addition, there's a guaranteed set of benefits, such as coverage for preventive care. Importantly, there are no exclusions from coverage for pre-existing conditions. In other words, the ACA has begun delivering on much of what it promised.

However, this information tells us little about the cost-sharing tradeoffs adopted by health plans to guarantee these benefits — the tradeoffs we have characterized as "side effects." Government reports alone do not provide a full picture. The tradeoffs, consisting of higher deductibles, copays, restrictive drug formularies and other cost-sharing mechanisms, have profound implications for patients relying on the exchanges for health coverage and for biopharma companies whose products offer the best hope of positive medical outcomes.

Breakaway Policy Strategies, a healthcare research and policy firm backed by inVentiv Health, has filled in some of the gaps. Our research, conducted with support from the Robert Wood Johnson Foundation (RWJF), provides a baseline understanding of cost sharing and other aspects of benefit plan design that are emerging in exchange plans in all 50 states and the District of Columbia.[4] By plotting the data against corresponding measures in employer-sponsored insurance (ESI) plans, we have provided the first comprehensive framework for helping consumers, policymakers and other stakeholders compare and assess these tradeoff costs.

Conducted with support from the Robert Wood Johnson Foundation, Breakaway Policy Strategies has provided the first comprehensive framework for helping consumers & policymakers assess the trade-off costs associated with the Affordable Care Act.

Exchange vs. ESI

In this article, we make some comparisons between the premiums and cost sharing requirements of exchange plans and ESI plans. Many of the new exchange plan enrollees previously were uninsured or were insured through the individual market, which looked fundamentally different from the ACA exchanges. This means there cannot be an "apples to apples" comparison between the ACA exchange and ESI markets. Nevertheless, the ESI figures are relevant because there is likely to be more crossover between the two markets in coming years, and because ACA benefit design and cost-sharing features could migrate into the ESI market.

The Breakaway data, augmented with testimony from pharmaceutical clients at our sister agency, Chandler Chicco Companies, reveal some troubling clouds on the horizon. The evidence suggests that the vast majority of individuals receiving coverage through the new exchanges will find higher cost sharing (copayments, coinsurance and deductibles) for prescription medications than those under most ESI plans.

Recently, there have been signs that patients and consumer groups are pushing back against insurers regarding cost sharing and other restrictions. They fear that these restrictions will impede access to needed drugs, as well as other healthcare products and services. Drug companies share their concerns, particularly with regard to formulary changes and higher deductibles.

It will be in the interest of pharmaceutical companies to formulate a response that is both proactive and reactive. As many commentators have observed, biopharmaceutical companies will have to expend more effort and resources to demonstrate the clinical value of their products to payers. In addition, companies must start to re-imagine or reinvent their messaging to communicate the value to other key stakeholders. One priority is to make more effective use of their health economics and outcomes research (HEOR) in order to counter the critics, explain the value of the products and clarify the risks or pitfalls connected to benefit restrictions. These key messages should be woven throughout communications to all stakeholders, including policymakers, managed markets, advocacy groups and patients.

Benefit Design

To help illuminate health coverage designs under ACA's exchanges nationwide, Breakaway compiled a dataset called HIX Compare. It contains information on premiums and cost-sharing requirements (deductibles, copays and coinsurance) for 7,027 Silver ACA plans available nationwide. Silver plans are the second-lowest cost offerings among the ACA's four tiers, and also the most popular, based on current enrollment trends.[1] As the premiums vary by age, we focused on data for just two groups: 27-year-olds (who are at the low end of the price scale) and 50-year-olds at the upper end.

In the younger cohort, the U.S. average for 2014 monthly premiums on state exchanges was $265. This is significantly less than the $491 national average for ESI premiums in a 2013 nationwide survey by the Kaiser Family Foundation. Virginia's exchange had the highest median monthly premium for 27-year-olds on a silver plan: $1,858. Minnesota, at $126, was the lowest. Premiums for 50-year-olds, unsurprisingly, were much closer to the $491 ESI monthly average. The U.S. median for silver ACA plan premiums in the 50-year-old bracket was $435. Virginia and Minnesota again were the bookends: $3,168 and $215, respectively.

As noted, the ACA has succeeded in offering affordable insurance rates to many people, but what are the overall costs to patients? To help answer the question, Breakaway examined cost sharing including deductibles, copays and coinsurance for primary care physician (PCP) and specialist visits, inpatient hospital stays and prescription drugs.

Before looking at individual deductibles under the ACA exchange plans, it's important to understand a basic distinction. In many plans, consumers have to meet a separate Rx deductible or a combined deductible toward which medical and prescription drug expenses accumulate. This is required before the individuals can obtain a desired medication for the price of the copay or coinsurance alone.

In the employer-based market where most Americans now get insurance coverage, plan members are not generally required to meet a deductible before Rx coverage begins. The deductibles on the exchanges are also relatively high compared with ESI deductibles. As a result, even with subsidies that are available to low-income individuals, some members will have trouble managing out-of-pocket costs before receiving coverage on the exchange.

HIGHER COSTS

So how do the costs stack up? If we look only at exchange plans that separate the medical and Rx deductibles, the median medical deductible is $2,500 — about twice as much as on the ESI market. The Rx deductible in these same exchange plans ranges as high as $2,500, with a median of $400.

Our research shows that 49 percent of Silver plans on the exchanges require the deductible to be met before cost sharing assistance kicks in on preferred brands. For non-preferred brands and specialty drugs, the ratio is much higher: 61 percent and 64 percent of Silver plans require the deductible to be met, respectively.

Copays show a similar trend. Like deductibles and other cost sharing features, they are generally higher in the ACA Silver plans than in employer-sponsored coverage. Across all exchange markets, the median copay to see a primary care physician is $30 — and as high as $50 in Florida and Georgia — versus just $23 under the average employer-sponsored plan. The cost of specialist visits in exchange plans reveal a steeper disparity: $75 to see the doctor in Florida and Georgia, $55 for the U.S. overall and $35 in the ESI market.

Coinsurance for inpatient hospital stays — which averages 18 percent in employer-sponsored plans — runs about 30 percent in exchange plans in Florida, Maryland and Virginia. And while median copays for generic prescription drugs are comparable on the exchanges and in ESI plans (typically $10, but double that in California and some other states), preferred and non-preferred branded drugs often cost patients on exchanges double what employees under an ESI plan would pay. In Georgia and Texas, that would be a median of $100 copays for branded drugs, versus $52 under an ESI plan. (It is important to note that many consumers will be eligible for cost sharing reductions (CSRs), which will lessen the economic burden to some extent.)

Uncomfortable Precedents

An Rx deductible may sound foreign to individuals who are currently on employer-sponsored plans. But they may find an unwelcome surprise down the road as some of the tactics designed to help payers control costs under ACA migrate to commercial and ESI plans. And while exchange plans with aggressive cost-sharing strategies serve a relatively small number of consumers today, the number of individuals enrolled in such plans is expected to triple to 25 million people over the next few years.[5]

The insurers who designed the benefits to help hold down premium costs on the exchanges also manage most of the country's employer-sponsored plans, as well as Medicaid programs and individual insurance markets outside the exchanges. In the past, we have seen instances where plan designs aimed at federal programs spill over to the broader insurance market. For example, prior to the 2005 launch of Medicare Part D, it was rare to see separate specialty drug tiers with higher cost sharing. Now, specialty tiers are common in the commercial insurance and ESI markets.

The growth and migration of the benefit designs already seen in the ACA's state exchanges are a source of concern; the trend could present a tremendous challenge for biopharma companies that supply new treatments, for patients who go off the drugs because they can't afford them and for the healthcare system at large. After all, pharmaceutical companies make a forceful case that medication adherence is often an effective and relatively inexpensive strategy for patient care, compared with inpatient treatment for diabetes, heart disease, early-stage renal illness or other chronic conditions. Biopharma companies need to begin clearly making this case to regulators overseeing the design of ACA benefits.

The growth and migration of the benefit designs already seen in the ACA's state exchanges could present a tremendous challenge for biopharma companies that supply new treatments.

Be Prepared

Among restrictive policies that may have an impact on patient wellbeing, formulary status is an immediate and constant threat. Last December, for example, Express Scripts and Caremark, which handle pharmacy benefits for more than 200 million Americans, announced that they would remove nearly 50 brands from their formularies starting in January 2014. Early research suggests that formulary designs in ACA exchanges are even more restrictive than in the employer-based insurance market.

Recent Chandler Chicco client experiences give us a sense of how the process is starting to play out. The first signal may look like a *fait accompli*. Insurers send a letter to all healthcare providers regarding a specific therapeutic category. It says there is now only one drug that's preferred and prescribers will need prior authorization for any other drug that was previously approved. In fact, ACA rules describe avenues for physicians and patients to respond, and biopharma companies can help make sure there is a game plan in place.

While developments like this may seem impossible to thwart, it would be a mistake for healthcare stakeholders to retreat into their shells. Health reform is dynamic and sensitive to external inputs — especially the voices of patients. Unlike essential health benefits, which have force of law under the ACA, the insurance benefit designs on the early exchanges are not written in stone. If specific benefit innovations prove unacceptable to many plan members, political activism could redraw the roadmap. Patient organizations and pharmaceutical companies may also be able to slow the migration of these benefit designs by doubling down on strategic communications that highlight patient needs and incorporate HEOR data.

The onus is on brand managers to preempt action by payers and pharmacy benefit managers and to educate patients.

Action Plan

The onus is on brand managers — working in concert with government affairs and managed markets — to preempt action by payers and pharmacy benefit managers and to educate patients. In addition to messaging that leverages HEOR data, there are five steps that should be carried out in tandem before the first volley arrives from an exchange:

1. Identify products that are potential targets for cost sharing, including new and specialty medicines. It goes without saying that the more expensive or the less unique a drug is seen to be, the more important the messaging.
2. Reach out to patient groups and high-profile patient bloggers to create a dialogue around patient perspectives, wants and needs.
3. Arm these organizations with materials that help show the medicine's value — and not just in terms of effect measured against a placebo. Where possible, include comparative data and show cost savings that will be realized by avoiding medical interventions and/or hospital admissions.
4. Where ACA safeguards are insufficient, product suppliers should consider advocating for additional state or federal policy interventions. Work with your stakeholders to develop the messaging and closely coordinate communications to all stakeholders, especially around value and pricing.
5. Assume that external and internal communications are transparent to payers seeking chinks in the defense of a drug's value proposition. Make sure these internal and external communications are identical.

The ACA has begun to deliver on its promise of improving access to medical care for millions of patients, regardless of their health status or economic class. However, the real impact will not be known until we see how benefit designs affect patients' access to medicines and other health products and services.

It would be naïve to assume that a transformation of the healthcare system as complicated as the ACA, with so many stakeholders, would be a law that everyone endorses. The exchanges have shown their hands. Our research illuminates the tradeoffs patients must make to realize moderate premiums under the ACA. Now is the moment for patients and providers to realize the full impact of how benefits are being designed and make sure their voices are heard.

About inVentiv Health

inVentiv Health, Inc. is a life science knowledge and services company purpose-built for the new healthcare marketplace. inVentiv has created a new model by converging a vast range of essential services to fully align with our clients' development and commercialization goals. With more than 12,000 employees supporting clients in 70 countries, our global scale and broad expertise make us an attractive strategic partner for companies seeking to get medicines to patients in a complex operating, regulatory and reimbursement environment. inVentiv Health's clients include more than 550 life sciences companies, including all 20 of the largest biopharmaceutical companies in the world. inVentiv Health, Inc. is privately owned by inVentiv Group Holdings, Inc., an organization sponsored by affiliates of Thomas H. Lee Partners, L.P., Liberty Lane Partners and members of the inVentiv management team. inVentiv Health transforms promising ideas into commercial reality for the financial success of our clients and the delivery of better treatments to patients worldwide. For more information, visit www.inVentivHealth.com.

About Breakaway Policy Strategies

Breakaway, a joint venture with inVentiv Health, is a health policy firm that provides research, analysis, practical advice, and strategic solutions to help a wide range of health care stakeholders navigate the transformative changes taking place in today's health care market. Breakaway offers health strategy and research for the real world.

About Chandler Chicco Companies

Chandler Chicco Companies (CCC) is a global health communications group that helps launch brands and build the reputations of companies working to improve human health. With an integrated approach to communications, CCC agencies offer best-in-class capabilities spanning public relations, digital and social media, medical and scientific education, and analytics and measurement. CCC creates communications that drive corporate value, enhance brand perception, and deliver on the bottom line. CCC agencies include: Allidura Consumer, Biosector 2, Chamberlain Healthcare PR, Chandler Chicco Agency and SharedVoice PR.

CCC is part of inVentiv Health, Inc. with companies based in New York, Los Angeles, Washington, London, Paris, Shanghai and Frankfurt, as well as global health care network operations in 40 markets. For more information, visit www.chandlerchiccocompanies.com or contact Heather Gartman, managing director of Chandler Chicco Companies in Washington, DC (hgartman@chandlerchiccocompanies.com).

REFERENCES

1. Department of Health and Human Services (2014, May 1). *Health Insurance Marketplace: Summary Enrollment Report for the Initial Annual Open Enrollment Period*. Retrieved from ASPE Office of Health Policy: http://aspe.hhs.gov/health/reports/2014/MarketPlaceEnrollment/Apr2014/ib_2014Apr_enrollment.pdf

2. Levitt, L., Claxton, G., & Damico, A. (2014, March 27). *How Much Financial Assistance Are People Receiving Under the Affordable Care Act?* Retrieved from The Kaiser Family Foundation: http://kff.org/health-reform/issue-brief/how-much-financial-assistance-are-people-receiving-under-the-affordable-care-act/

3. Burke, A., Misra, A., & Sheingold, S. (2014, June 18). *Premium Affordability, Competition and Choice in the Health Insurance Marketplace.* Retrieved from ASPE Research Brief: http://aspe.hhs.gov/health/reports/2014/Premiums/2014MktPlacePremBrf.pdf

4. Breakaway Policy Strategies (2014). *Health Insurance Exchange (HIX) Compare Dataset.* Retrieved from Robert Wood Johnson Foundation: http://www.rwjf.org/en/research-publications/find-rwjf-research/2014/03/breakaway-policy-dataset.html.

5. Elmendorf, D. (2014, April). *Updated Estimates of the Effects of the Insurance Coverage Provisions of the Affordable Care Act*. Retrieved from Congress of the United States Congressional Budget Office: http://www.cbo.gov/sites/default/files/cbofiles/attachments/45231-ACA_Estimates.pdf